Tobacco Harm Reduction 2010

a yearbook of recent research and analysis

Carl V. Phillips & Paul L. Bergen

editors

A production of TobaccoHarmReduction.org

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Dedicated to everyone whose lives converged at 8215-215 or 51540-223.

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We thank all of the authors who contributed new material or cooperated with the reprinting of their previous publications. We express particular appreciation for Catherine Nissen who worked alongside us during the crunch to get this formatted, proofread, and finalized, and thank Karyn Heavner for also contributing to this effort. Various former employees and students in our research group also contributed to some of what is represented here. In particular, most everything in the book written by current or former members of our research group – Phillips, Bergen, Nissen, Heavner, Heffernan, et al. – benefited substantially from input by some combination of others on that list, other former students and employees who worked with us when we were at the University of Alberta, and Brad Rodu (who we also thank for helping review some of the final product).

The costs of producing and distributing this book were, thanks to modern technology, basically just the time spent by the authors and editors. The trivial out-of-pocket costs came out of the pockets of the editors, who thus served as publisher. The time we spent creating and editing this book was volunteered (or, equivalently, cross-subsidized by severance pay and other sources of income).

Readers concerned with "conflict of interest" should understand that almost all research and analysis about THR is created by entities with strong worldly goals (i.e., biases), including individuals who believe that promoting THR will improve the world, companies interested in selling THR products, companies and individuals interested in discouraging THR so they can sell abstinence aids, organizations and individuals with libertarian or anti-drug-war missions, organizations with a mission of eliminating smoking, and organizations with a goal of eliminating all tobacco/nicotine use, including THR. Moreover, research is costly and must be paid for by someone that is interested and has money; for THR that means that basically all research is paid for by someone on this list of biased entities. The contents of this book are no exception. In addition to the aforementioned motives, all of the independent authors presumably hope to benefit from writing and publishing their work via some combination of getting consulting business or grants, selling their books, impressing their friends, or otherwise securing enhanced reputational capital from getting their work read.

We make these observations about biases and worldly goals in order to (a) ridicule those who engage in television-news level simplification, paying attention to particular sources of funding as if they are really the major conflict of interest, often to the point of ignoring the analysis itself and (b) provide a generic conflict of interest statement for all the authors in lieu of the usual useless statements (we have not gone so far as to excise such statements from the reprints, but we have excluded them from all original contributions). We will add only the observation that, to

our knowledge, all analysis and writing in the book was controlled entirely by the named authors and the organizations they explicitly represent, not by any hidden funders. Those who prefer to only read the title, sources of funding, and conclusions of a paper before making up their minds will, alas, be forced to actually assess the analyses themselves.

Finally, we want to thank those who have contributed to modernizing scientific and scholarly publishing, including the Creative Commons system, journals that use it, and authors that choose them, as well as public domain publishing, intelligent blog writers, etc. We were pleased to discover that every journal article that we wanted to reprint happened to be in a Creative Commons journal, and so we thank BioMed Central and especially Ernie Drucker and his *Harm Reduction Journal* for adopting that model and thereby encouraging publication in the true sense of the word. New ways of publishing are tearing down the old gatekeeping, which in our field has degenerated into little more than an annoying obstacle to the exchange of useful information. Scientific and scholarly exchanges require a web of trust to progress, but in our field today, there are many who cynically take advantage of that trust, hiding behind black-box analyses, anonymity, and pseudo-objectivity while they let political goals control the distribution of scientific information. As a partial step to finding a path back to a trustworthy system, we openly tie our personal and organizational reputations to the representativeness and basic honesty (though not, of course, perfect accuracy) of the work we have collected here.

Carl V. Phillips and Paul L. Bergen
Edmonton, Canada
April 2010

Chapter 1

Introduction

Carl V. Phillips & Paul L. Bergen

This yearbook collects and summarizes recent research and analysis about tobacco harm reduction (THR) and provides a snapshot about current thinking in an area where the conventional wisdom is changing from year to year. The work is part of the efforts by the TobaccoHarmReduction.org research and education group to bring comprehensiveness, organization, and clear analysis to discussions of THR. As a yearbook, this volume includes works that were written or published during roughly the last year, 2009 and early 2010, though there are a few entries from a bit earlier. This introduction includes no overview or background about the topic itself, since that is provided in several of the chapters (and can be found at the TobaccoHarmReduction.org website). Instead it focuses on highlighting the value of the book and the individual chapters.

The collected volume may seem to be an antiquated medium, but the situation in the field makes a book like this (ideally, an annual series) a valuable contribution. Yes, a page of hyperlinks can substitute for all but very historical collections, so no book is required. But the reading-list approach has proven to have several disadvantages. For whatever reasons – most obviously, that no one has it as a primary responsibility to optimize the list and keep it up – those lists that have been compiled about THR have been rather disappointing. Moreover, like most webpages, such lists are typically interpreted as being current, though they tend to become frozen in time without acknowledging this. However, a collection that is explicitly and intentionally fixed in time has advantages. Readers will have no doubt about when the content of this book was current, and so the limits are made clear while its historical value is preserved. Moreover, creating a book rather than just a list means that the collected material is easy to access even if URLs change, the collection has book-like invariance, and there is an opportunity to provide some overarching analysis.

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The historical value may become evident after only a few years, due to what might politely be called "short memories". The political actors who have come to dominate discourse and scientific claims related to tobacco have a habit of rewriting history. Like the neo-Malthusians who have somehow gotten away with predicting the imminent fall of civilization – selling new books that make the claim every five years for the last four decades – anti-tobacco activists repeatedly promise that if society just does what they demand then smoking will disappear. When their new favorite regulations are put in place, however, and smoking prevalence merely continues to slowly creep down, they conveniently forget they ever promised anything (e.g., starting now you can watch as they conveniently forget, after the result fails to materialize, their prediction that eliminating smoking from Hollywood movies – which they have largely succeeded at – will reduce smoking initiation by 10% or more).

Many of the same activists predict specific dire outcomes if THR is promoted or implemented at an institutional or grassroots level. The fashionable predictions about exactly what dire consequences will ensue change over time without explanation or acknowledgment – the diseases change, but the dire prophecy remains the same. A hypothetical THR yearbook from five years ago would have included numerous references to the claim that smokeless tobacco causes a substantial risk for oral cancer. But since for more than a decade the weight of the evidence has contradicted this claim, the anti-THR activists have quietly forgotten that this was once their main line of attack on THR. It would have been nice if they had informed the public, who still largely believe the old misinformation, but that admission might have made it more difficult for them to simply move on to making the different, but equally vehement (and equally unsupported), claims that are alluded to in this volume.

At the same time, it is easy to forget our own past predictions. Some of us who were advocating for THR six or seven years ago predicted that the major institutions that published anti-THR propaganda and otherwise opposed THR would, within a few years, quietly drop their opposition, pretend that they supported it all along, and give each other awards for inventing THR. We did not, at the time, recognize the consolidation of influence by anti-tobacco extremism: By then, anti-tobacco institutions had already stopped being about public health. They had adopted a Drug War mentality, dedicated to eliminating tobacco use from the world regardless of how much damage such efforts would cause for health, welfare, human rights, and the integrity of science.[1] Instead of promoting THR and taking credit for it, the extremists dramatically

[1] I.e., they adopted the most extreme possible anti-tobacco position, which has led to the adoption of the descriptor *extremists* to contrast with anti-tobacco or anti-smoking *activists* or *advocates* who do not necessarily favor the unconditional elimination of all tobacco/nicotine use regardless of the costs. This offers an important clarification that can dramatically aid readers' understanding of the current situation. Among its contributions, the term emphasizes the contrast between public health goals and anti-tobacco extremist goals; points out that, given the range

increased their attacks on it, delaying its widespread implementation by perhaps a decade, and thus prevented millions of smokers from learning that they might have prevented an early death by switching to a low-risk alternative.

However, it is interesting that, going back to our earlier predictions, some anti-tobacco activists seem to be laying the groundwork for saying "we always supported THR" (see, e.g., the "Strategic Dialogue" project that appears in the Dillard chapter). Unfortunately, this does not represent any relenting in anti-THR efforts, since what they call THR is practically no different from the usual prohibitionist agenda. Instead, this tactic seems to be some combination of wanting to be able to later claim they were not on the wrong side of history (as some of us predicted) and an effort to co-opt actual THR advocacy (which we cannot claim to have predicted).

It should be clear from the preceding analysis and much of what we have written in this book that we are supporters of promoting THR and encouraging individuals to adopt it in the absence of institutional promotion. That said, we expect that any open-minded observer who is familiar with our work (on this topic and beyond) will see that we are fierce in our defense of good science and legitimate methodology. As such, we would not omit important anti-THR writings from this book. But, honestly, we did not find any research that seriously called THR into question or any analysis that brought up defensible arguments against it. As noted in Nissen's chapter in this volume, it turns out that in order to respond to anti-THR arguments, it is necessary to construct them from scratch or extract them from ill-explained anti-THR statements, because THR opponents cannot or will not justify their claims. Perhaps some legitimate anti-THR analysis will be written during the next year and we will be able to put it in another book (we have already identified one recent article by non-activists that tries to analyze the moral bases for opposing THR), or perhaps we will simply publish some prominent anti-THR statements without filtering.

We personally invited a large number of anti-THR individuals and organizations to contribute original chapters to this book, offering various assurances about how they and their work would not be treated unfairly or ambushed. Several replied that they would write something, but none did. (We hereby extend the invitation and request submissions for Tobacco Harm Reduction 2011 from anyone working in the field. We promise that any on-topic submission will either be included in the volume or, if it is excluded, we will include a note that it was submitted, explain our reason for not including it, and include a link to it if the authors post it elsewhere.)

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of possible anti-smoking approaches, there is something strange about the near-uniformity of extremism among governments and powerful NGOs; and might reduce the temptation to use the more colorful popular terms for that faction, replacing condemnation with useful description.

An additional advantage of the edited book format is to work around some of the failures of the peer-reviewed journal system in the health sciences. As many readers are probably aware, that system is terribly broken. One of us (CVP) has written about this at some length, but it is easy to summarize the main problems. The politics, lack of available time, and lack of training in critical analysis are well known. Less well known is the ultimate fatal flaw and dirty secret of peer review: Reviewers almost never have access to either the data or the statistical methods used to analyze it, let alone critical information regarding data collection, data cleaning, choices about exclusions, etc.; they see only the same summary and black box that readers eventually see in the journal. Many non-experts think that the peer review system somehow vouches for the accuracy of the data and validity of how it was analyzed, but it does not. Since they cannot assess whether the conclusions follow from the data, most reviewers simply assess whether they like the conclusions. Moreover, unlike other fields of major social importance, health-related journals generally restrict contributions to formats that discourage serious analyses, almost exclusively publishing empirical findings, offering no forum for the thoughtful reasoning required to translate such findings into worldly recommendations. As a result, non-thoughtful brief "conclusions" are frequently tacked onto reports of empirical results, though the ostensible conclusions seldom actually follow from the reported results. Thus, publication in peer-reviewed health science journals does little to validate study results, and virtually nothing to validate other conclusions, while many important analyses are never allowed to appear in such journals.

For politicized issues the situation is worse than average, and worse still for tobacco specifically, presumably because of anti-tobacco extremists' financial and political power. Anyone who follows the literature will be aware that most any claim that is anti-tobacco or anti-THR, no matter how absurd, can get published in one of the many journals that supports anti-tobacco activism (to cite just a few examples that we have written about, see "third hand smoke", the misleading anti-smokeless-tobacco propaganda coming from University of Minnesota toxicologists, and claims that second-hand smoke causes half of all fatal heart attacks). The "conclusions" of such studies are quite often blatant statements of political goals that make normative claims without any normative analysis, and are only tangentially related to the actual study findings.

What is not so obvious, since the crime and cover-up are simultaneous, is the effectiveness of censoring analyses that question the anti-tobacco extremist and anti-THR orthodoxy. It is nearly impossible to get analyses whose results support the case for THR, let alone those that study ways to promote THR, into most public health or medical journals (the notable exception being *Harm Reduction Journal*, whose articles are represented in these pages). To cite just one example of the apparent exercise of anti-THR political pressure, one of the studies included in this volume was accepted for publication by a journal and in the final production stage when the

journal's editor suddenly announced that it was rejected, refusing to offer any explanation for the complete reversal. Some supposedly-scientific journals have publicly indicated that they would not publish anything about THR because they oppose it politically. Quite a few journals have – explicitly or secretly via their editorial decisions – decided to never publish authors who have worked with the tobacco industry or received funding from it; this effectively censors THR research since it is basically impossible to do more than token research without engaging with companies who make the THR products.[2]

At other journals, the review process offers little more than ignorance and censorship. We have a collection, just from submissions by our research group, of dozens of reviews that are either (a) completely clueless about the science (e.g., the Geertsema study published in this volume was most recently rejected from a public health journal with no criticism of the methods or value of the study, but with the comment, "Are you not familiar with the literature about smokeless tobacco and oral cancers?") or (b) are attempts by anti-tobacco extremists to just censor heterodox research. Most examples of the latter "peer reviews" find no flaws in the methods or analysis, but still declare that the paper should absolutely not be accepted for publication, sometimes basically arguing that no one should even be studying the topic and therefore the journals should help hide the fact that anyone is doing so, or sometimes declaring, in effect, that since the authors do not conform to the reviewer's political opinion about what people should believe or do, the results of their studies should never be allowed to become part of the scientific record, no matter the legitimacy or value of the study. Our experience suggests that editors seldom have the combination of scientific integrity and analytic skills that would allow them to reject even the most transparent of such political demands. Someday we will publish a collection of the comments we have received from referees and editors.

An additional frustration for those who wish to exchange thoughtful analysis about THR is that the few journals that break with the censorship and publish an occasional pro-THR commentary or analysis seem to believe that these are best coming from people who are not focused on researching and promoting THR. This may be anti-THR bias leaking through, though perhaps this is due to the notion – long discredited in studies of the history and philosophy of science, but still apparently taught in most health science programs – that research should and can somehow be "objective", and thus someone with a dedication to a topic should not be the one to analyze it. It is something akin to the American news media's notion that one person's opinion is as good as

[2] The journals that have explicitly forbidden publications from those associated with the tobacco industry seem to have overlooked what their declarations say about their self-perceived ability to review submissions. Typically such journals justify the rule based on the claim that tobacco companies and those who work with them sometimes distort the science. In so doing they implicitly admit that they – the journal editors and reviewers – are not capable of recognizing flaws in the science that might be present in submissions, and so they simply have to impose blanket censorship.

another's, resulting in lay people rather than experts being interviewed about technical topics. As a result of this, the strongest pro-THR commentaries and non-empirical analyses – the ones written by those most dedicated to making the case, and with the most expertise to back their claims – have not been collected anywhere that is likely to be widely read.

In sum, with this book, we hope to (a) create an informative reading list, (b) create a record of contemporary views and discourse, and (c) add to what can be published on this topic in a serious academic-style forum by bypassing the journals which, with one exception, do a very bad job of covering this topic. The rest of this introduction is a brief summary of the contents, offered as a guideline for readers. For many chapters we wrote more in-depth or specific assessments which appear at the beginning of the chapters.

Overviews

Those who are not already familiar with the basic science and politics of THR will want to start by reading the chapter by Phillips, Heavner & Bergen. As a yearbook, this collection is not intended as a primer. However, we had the opportunity to pre-print a preliminary version of a forthcoming book chapter that is a primer overview for people with little knowledge of THR. The chapter describes the basic scientific facts and provides (in our obviously biased opinion) the most complete brief summary of the socio-political side of THR. Since this is basically the version that circulated as a working paper more than a year ago, it reflects the changing state of the science – e.g., the coverage of electronic cigarettes and other new products is minimal and the latest important studies, like some of those that appear in this volume and the European population study by Heavner et al., are not included.

An overview of the published science can be found in the chapter by Rodu, a reprint of his submission to the U.S. FDA. Other overviews can be found in the O'Reilly and Dillard chapters, government filings from tobacco companies, and in the Norwegian report by Lund. The reader may find interesting the differences – in terms of the strength of factual claims, emphasis on different goals, etc. – among these overviews, and our chapter notes offer some comments on this.

Quantitative studies

We included several recent studies that provide specific empirical or quantitative analytic results that are relevant to THR.

The recent review and meta-analysis by Lee & Hamling is probably the most scientifically useful summary of evidence related to THR (specifically, about the cancer risk from smokeless tobacco) ever published, and the most ambitious apolitical gathering of THR-related literature ever

conducted. We include only the abstract of that study and a link to where it is free online, because of its length and technicality. We include the entirety of their related analysis, which has been comparatively overlooked, that demonstrates why their review is more accurate and honest than an earlier review that was published as part of an anti-smokeless-tobacco and anti-THR broadside. We strongly recommend it to any reader who is interested in how to identify scientific honesty.

The study by Rodu & Phillips bends our definition of the period covered by this yearbook a bit, but we include it to call greater attention to its implications for the progress of THR. That study demonstrated – contrary to the frequent claim that only Swedes are interested in switching products – that THR has been successful in the United States despite efforts to keep people from learning about it. (The chapters on e-cigarettes, described below, show even greater movement toward THR by Americans since the time that the Rodu article was published.) The later article by Phillips is also (in our obviously biased opinion) a critical step in the debunking of anti-THR claims, pointing out that, compared to immediately promoting existing low-risk alternatives to smoking, it is not actually possible to achieve better public health outcomes by waiting for better options. We republish it here also to highlight a misstatement in the original version (since the erratum by the author that is published at the journal is likely to be generally overlooked), which does not really change the basic message, but since the error is embarrassingly prominent, correction is demanded by scientific integrity.

We include a study by Geertsema et al. that was not previously published because the author in charge has simply run out of patience with the aforementioned censorship by health journals in spite of this being a unique and innovative study. Many studies demonstrate the public's limited interest in THR or lack of realization that THR is even possible (many are cited in the introduction of that chapter), but almost none have attempted to discover what, exactly, are the barriers to interest or understanding. This survey was designed with the assumption we would find the usual results and set out to explore *why*, a question that has been ignored in almost all other studies. We also include a preliminary version of a Heavner et al. study about e-cigarettes to help bolster that under-represented topic. Both of these were previously published as working papers.

<u>Government filings</u>

We include several government filings because they contain useful content – particularly a good overview of the science (Rodu) and specific analysis about e-cigarettes (Nitzkin) – and by their nature represent a contemporary record of how different thinkers choose to contribute scientific analysis to the political arena. Our own comment is intended to be provocative, pushing the

cutting-edge of thinking about the future, while Rodu's is tightly matter-of-fact, and Nitzkin's has elements of a legal pleading.

The other two government submissions are particularly interesting, coming from tobacco companies who seek to promote THR. These entries, written by O'Reilly on behalf of British American Tobacco (BAT) and Dillard on behalf of Altria (Philip Morris USA and U.S. Smokeless Tobacco Company), provide interesting insight into the contemporary positions of the companies and represent important historical events. (Note: CVP has consulted for both of these companies on matters of science related to THR, but had no involvement in these documents or the companies' policy statements more generally.) Both documents present analyses of THR and express suggestions about future action. Given that these are public documents from big companies with legal departments, it is, of course, necessary to read between the lines some to extract details about each company's exact views and positions (and to note the differences between the two). It is particularly worth noting that they are very conservative in their claims compared to what is written by independent analysts. The common rhetoric that tobacco companies misrepresent the evidence is true in discussions of THR only if interpreted to mean that the companies' claims understate the case they are trying to make to such a degree that it could be considered misleading – that they under-interpret the evidence that supports their positions and concede some claims made by anti-THR activists that are not actually supported by the science.

Inclusion of these chapters in the book is also intended to call attention to the fact that, like it or not, THR is substantially dependent on the tobacco industry as an engine of innovation (a point we make in our aforementioned comment to FDA). Pharmaceutical companies might or might not develop and produce low-risk nicotine products that are targeted at long-term use. E-cigarette companies are unlikely to contribute much research, product innovation, or quality control until they have some intellectual property protection and brand equity, which requires market consolidation through one means or another. But appealing low-risk tobacco products are already available from tobacco companies and they are likely to continue to bring more low- and perhaps medium-risk substitutes for cigarettes to market.

Original analyses

While this is primarily a collection of writings previously published in other forums, we invited dozens of people to submit new or not-elsewhere-published contributions. We assume the limited response represents a lack of existing analyses that were waiting for a forum (which is disappointing) and doubts about the utility of creating anything new (which is understandable – we hope that anyone who was unsure about whether the project would really come together will see more value in submitting something for next year).

The new analyses we received were all from authors who will be presenting that work at the harm reduction meetings in Liverpool where we will debut this book. As a result of these chapters being based on talks, they are abbreviated, and we refer those who are interested to past and future works on the topics by those authors. Bergen & Heffernan present a preliminary version of graphical tools to help overcome public misunderstanding (natural and manufactured) about how dramatic the benefits of THR are. The Payne chapter is an updated version of a widely circulated commentary about the state of THR regulation in Europe and hope for what can be done to improve it.

The other chapters that are included would probably be inaccurately described as "commentary" in health science journals, though anyone who reads beyond such journals will recognize them as scholarly analysis. Snowdon's entry is a compelling summary of the history of anti-THR activism, adapted from his fascinating book on the history of anti-smoking efforts. He points out that opposition to THR is as old as THR, and attributes it to the inevitable "mission creep" and "idealism" experienced by activists (which might, perhaps, be considered polite synonyms for egocentrism, extremism, and hubris). Snowdon's analysis tends to suggest that current anti-THR activism appears new and different not because it is qualitatively different, but because the growing appreciation for and success of THR has generated a commensurate increase in quantity of anti-THR activism.

Peele presents a historical analysis of the concept of addiction, focusing on the American government's conceptualization, and how it originally excluded smoking but then was redefined. He points out how most definitions were political more than scientific, and were inconsistently applied in the case of nicotine. His analysis indirectly points out how the common claim that THR is bad because it does nothing to reduce "addiction" is meaningless without reference to what exactly the historically plastic term means. Clear definitions are needed to assess whether THR products really are "addictive" (more likely for more inclusive definitions) and whether being such is inherently damning (less so for more inclusive definitions).

The chapter by Nissen et al., adopted from a 2009 presentation and subsequent working paper, analyzes the ethical validity of the main anti-THR arguments. Though normative statements abound in discussions of THR, there is an almost total absence of discussion about the ethical bases for those claims. This glaring omission is only recently starting to be addressed. Several other chapters (the first overview chapter, the Phillips reprint, and others) include some such analysis, and we hope that far more will exist in time for a 2011 yearbook.

Electronic cigarettes

The contributions relating to electronic cigarettes (aka e-cigarettes, e-cigs, personal vaporizers), collected in the latter chapters, warrant particular explanation here. The biggest changes in the world of THR over the past year or two related to the continued growth in the popularity of e-cigarettes and their impressive effectiveness as a method for quitting smoking. It is difficult to fully capture that phenomenon here because evidence can mostly be found in online forums and other discussions of fandom; no sales figures or similar formal reporting is available, and the major organizations (governments, etc.) that might have monitored this progress have staked out positions opposing the products, and thus are unlikely to collect data on their success.

As a result, we do not have all the contributions on this topic that we might like. We created a brief overview for this volume to help fill the gap (Bergen & Heffernan), included a widely-read informal report about a gathering of e-cigarette aficionados (Godshall), and presented an early limited analysis of e-cigarette users (Heavner et al.). The latter, a survey by an e-cigarette merchant analyzed by our research group, was, to our knowledge, the only published analysis of consumer behavior research on the topic (the version that appears here was released as a working paper at TobaccoHarmReduction.org in late 2009 and a more complete version that includes the qualitative data collected, is forthcoming).

The politics surrounding e-cigarettes is represented by Nitzkin's chapter, comments written on behalf of the American Association of Public Health Physicians. That organization has embraced THR, presenting strong support for the role e-cigarettes could play in improving public health. Nitzkin's writings, along with some of the others, refer to several actual and potential threats to e-cigarettes (everything from bans to the standard anti-THR propaganda) whose proliferation in the past year rivaled the proliferation of the product itself and its success in helping smokers quit.

Note on formatting

For chapters that are reprints of works that were previously published in a particular format, we have kept the original layout and formatting (shrinking the pages slightly in a few cases to maintain adequate margins), adding a chapter title page and notes. We believe that this approach, instead of reformatting the text, is best for giving due credit to the original publication and better preserves the historical record. For original chapters, notes, and other material that we typeset specifically for this book, we faced a challenge: We expect many readers to download the book and read it on their computer screens, others to print it or to transfer it to e-reading devices, and others to buy copies of the bound version, and the optimal layout is different for each of these. To facilitate reading of the digital version, we chose formatting that makes it much easier to read while scrolling through on a computer screen (particularly line breaks between paragraphs and ragged rather than justified right margins). After some discussion about how books are

“supposed” to look and whether adhering to such rules offers any substantive advantage, we decided to not create a different layout for printing, keeping the pages the same across versions even though the format is not standard for printed books.

Chapter 2

Tobacco – the greatest untapped potential for harm reduction

Carl V. Phillips, Karyn K. Heavner & Paul L. Bergen

This is an early version of chapter that will appear in the forthcoming *Harm Reduction, 2nd Edition*, Katie Witkiewitz et al., editors, pre-printed with permission; this version was originally circulated in late 2008, and so reflects then-current knowledge and views (however, some references and terminology have been updated). For the final version of this chapter, please see the Witkiewitz book (expected publication in late 2010).

1. Rationale for tobacco harm reduction

Nicotine - the benefits, popularity, and unfortunate delivery method

Nicotine is one of the most popular drugs in the world. It is most commonly acquired by smoking tobacco, though there are many alternative delivery methods. In addition to its purely recreational attraction as a mild stimulant that simultaneously has calming effects, many consumers find nicotine useful for improving productivity, combating anxiety, and aiding mental focus. Many people who suffer from clinical and subclinical levels of depression, attention deficit disorders, schizophrenia, and other conditions find relief in smoking, presumably mostly or entirely due to the nicotine delivery. Some of these benefits are similar to those from one of the other most popular drugs, caffeine, though many people (apparently as much as one-third of the population) find the benefits from nicotine to be particularly appealing. Given the substantial

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benefits, it is not surprising that once nicotine consumption (in the form of tobacco use) becomes established in a population, it has never been reduced to below about one-fifth of all adults, despite massive campaigns to convince consumers to stop, draconian taxes, restrictions on usage, and social vilification.

The benefits and desirability of nicotine consumption are not widely recognized, a rather odd situation given how many people experience them. This lack of awareness appears largely due to anti-tobacco activists' success in establishing the notion that people only use nicotine because they are "addicted". Closer examination reveals that this claim is made without actually explaining what "addicted" means, other than the question-begging, "so beneficial that someone chooses to not give it up, despite the costs". Indeed, some commentators have suggested that calling nicotine addictive dilutes the concept so much as to render it meaningless (e.g., Atrens 2001). However, for present purposes the existence or absence of addiction, and whether it is well-defined, is not important. Equally unimportant are debates about whether there are "inveterate" smokers who could never be persuaded to quit no matter what the incentives. Instead, it is sufficient to observe that many people continue to use nicotine, despite the high financial and health costs of the most common delivery method, as well as the existence of every anti-smoking measure that is considered practical and effective. The number of smokers in the world continues to increase, and despite much rhetoric to the contrary there is no evidence that suggests that all nicotine users will eventually quit entirely.

Though nicotine itself is fairly benign (and so is similar to caffeine consumption in this respect as well), most users choose an extremely hazardous method for delivering it. Few realize that inhaling smoke from burning plant matter, and not the desired chemical being delivered, is the cause of almost all the health problems. While exact numbers are much more elusive than is often implied, it is safe to conclude that at least one-third of long-term regular smokers living in communities with Western-level life expectancies will suffer major disease or a substantially hastened death due to their habit of inhaling smoke. Most everyone with access to education or mass media understands that smoking is extremely hazardous. Indeed, there is a bias toward overestimating its hazards (perhaps because of the habit of activists of exaggerating the risk, a strange behavior given how high the risk is in reality).

Yet many people choose to smoke nevertheless, largely to get nicotine, and the number of smokers continues to grow, dramatically and in most places in the world. The trumpeted reductions in the prevalence of smoking in some Western populations are largely offset by population growth, such that the total number of smokers stays about the same. Meanwhile in the majority of the world's populations, both smoking prevalence and population increases are increasing, dramatically increasing the number of smokers. We can expect that prevalence will

eventually drop in populations as people become educated about the risks; historical evidence suggests that such education reduces consumption prevalence by about half, usually down to the 20%-30% range. But there is no evidence that nicotine use will drop below that range, no matter what policies are implemented, and predictions to the contrary appear to be based on little more than wishful thinking. Thus, separating nicotine delivery from smoke inhalation has the potential to be one of the greatest improvements in human welfare and public health.

Failure to understand that smoke causes the damage

The way in which the "smoking is deadly" message is typically presented results in people thinking that nicotine use, exposure to the tobacco plant itself, or chemicals added to cigarettes by manufacturers cause most or all of the health risk (see Geertsema et al., in this volume). Anti-smoking messages almost never emphasize that the danger is breathing concentrated smoke (Phillips & Heavner 2009). Instead, most of the communication about the dangers of smoking (sadly including most of the ostensibly scientific literature) misrepresents the relevant exposure as being tobacco or nicotine rather than smoking.

Tobacco, of course, is a plant, not an exposure. Exposure to it can take any number of forms, including smoking, non-combustion oral use, and occupational exposures, which have radically different health implications. Nicotine itself is also often conflated with smoking in ways that imply that it causes most or all of the health risks. There is ample evidence that these messages prevent people from learning that the risks from smoking cigarettes come from inhaling the concentrated smoke from burning plant matter. Smoke inhalation exposes the lungs, and thereby the bloodstream and rest of the body, to a huge number of particles (the "tar" that is often identified as part of what is harmful about smoking) and gasses. The salient factors are neither that the particular plant matter being smoked is tobacco leaves (possibly of some small consequence, but not definitively so, and clearly of minor importance), nor that nicotine is being consumed. As discussed below, the misleading communication often begins with claims by trusted anti-tobacco advocates, who are either lying or pretending to have expertise that they lack. However, most appear to be well-meaning people unknowingly perpetuating myths by blindly repeating the ostensibly authoritative claims. Clinicians, health educators, and other health professionals are barely less ignorant than laypeople on these points and are substantially responsible for perpetuating the misinformation. Whatever the explanation, the failure to understand this difference and act on its practical implications dooms countless smokers to premature disease and death.

The potential of tobacco harm reduction

The combination of highly-desired consumption and a needlessly dangerous technology creates an obvious potential for harm reduction. Discussions of the potential of reducing harm by substituting Western smokeless tobacco products (ST) for cigarettes trace back more than three decades, and the potential is now universally known to anyone with expertise in the area. However, understanding outside of the community of experts, as well as policy changes, have severely lagged this understanding.

Almost all efforts to reduce the harm from smoking have focused on eliminating nicotine use, rather than the harm from nicotine use. This represents an anomaly in public health practice, since it is generally accepted that we are better off making common beneficial activities safer rather than assuming we can reduce or eliminate them. For example, we encourage seatbelts and other transportation safety improvements, but do not even bother to encourage reducing travel. Even for hazardous behaviors that are not generally socially accepted, if eliminating the behavior is clearly impractical then risk reduction is encouraged. For example, we discourage all injection of recreational drugs, but we also try to provide clean needles for those who continue to use them. In cases like illicit drug use, large segments of the public and government may object to harm reduction on puritanical grounds (often mislabeled as "moral" grounds), but public health practitioners almost universally accept it. Yet many public health actors join those for whom purity is more important than protecting people from disease, and actively fight against reducing harm for tobacco consumers.

This contrast is especially odd given that the only substantial difference between harm reduction for smokers (hereafter, "tobacco harm reduction" or THR) and others engaged in risky behaviors is the magnitude of the potential benefits: First, the risks from smoking are greater than those from almost any other voluntary exposure, and when multiplied by the number of smokers totals up to a far greater public health impact than any other voluntary exposure. Second, and even more important, is that the potential reduction in risk for each individual dwarfs the reductions available from seatbelts or needle exchanges. Some sources of nicotine have been shown to be about 99% less harmful than smoking, and others probably have similar low risks. The implications of this can hardly be overstated: Switching from smoking to a low-risk source of nicotine is so close to being as healthy as quitting that it is hardly worth worrying about the difference.

Despite the widespread misperception about the risks from tobacco or nicotine, anyone with a basic knowledge of environmental health, or who notices that about half the health burden from smoking involves lung disease, would predict that getting nicotine without inhaling smoke causes less harm than smoking. There is ample evidence to confirm this hypothesis for one class of nicotine products, modern Western oral smokeless products. ST use includes snuff dipping

(holding shredded tobacco, sometimes loose and sometimes in a teabag-like sachet, between the gum and lip or cheek) and tobacco chewing. (For pictures and more information about the products see: Ballin 2007 or Rodu & Godshall 2006, both available free online.) Some newer products include powdered tobacco in hard lozenges or dissolvable strips.

Traditional ST products have been sufficiently popular in Sweden and the United States to provide substantial epidemiologic evidence about their effects. (Epidemiology is the science of quantitatively analyzing the occurrence of diseases in humans, usually with a focus of identifying their causes.) Epidemiology studies are possible because many people have used ST products for decades, and so we can observe whether they have a greater risk of disease or death than non-users. The evidence shows that the risk for any life-threatening disease from ST use is so low that it cannot be reliably measured or even definitively established. This does not mean that ST is completely harmless, since the limits of the science mean that we can never rule out small health risks. Based on best estimates of the magnitude of these small risks, it is estimated that the overall risk is about 1%, or perhaps 2%, of that from smoking. Most of that risk is based on the assumption that the mild stimulant effects of nicotine cause some small risk of cardiovascular disease.

Pharmaceutical nicotine products are produced by removing nicotine from tobacco and attaching it to an alternative substrate. Widely available pharmaceutical nicotine products include nicotine gum, patches, lozenges, and inhalers. (For more information about these products see: Royal College of Physicians 2007, available free online.) Pharmaceutical nicotine products are sometimes called “nicotine replacement therapy” in the context of using them as a short-term clinical intervention to wean people off of nicotine entirely, though this label tends to distract from their potential for long-term, self-administered, non-clinical use, and thus is best avoided when discussing THR. These products probably pose the same low risks that have been demonstrated for ST, since they are fairly similar in terms of being smokeless nicotine delivery systems

The oft-repeated claim that pharmaceutical nicotine products cause even less disease risk than ST is not actually supported by the scientific evidence. ST contains chemicals other than nicotine that are potentially harmful, but there is no evidence that doses acquired by users of popular Western ST products cause actual human disease. ST also contains chemicals that are potentially beneficial and pharmaceutical products involve exposures other than nicotine intake, so without evidence it is not possible to conclude that the risks from pharmaceutical nicotine are even lower than the low risks from ST. There have been few studies of long-term pharmaceutical nicotine users, so that evidence does not currently exist. Whatever we eventually learn about the risk from pharmaceutical nicotine, it seems very likely that the risk is low, and since the risk from ST

is clearly very low, it seems safe to conclude that they offer practically the same health benefits as substitutes for smoking.

Novel products containing either tobacco or pharmaceutical nicotine further expand THR options. The emerging products include electronic cigarettes, devices that mimic cigarettes but where users inhale heated pharmaceutical nicotine or tobacco rather than smoke. Because these products re-introduce airway involvement and inhaled chemicals other than just nicotine, we should probably hesitate to assume that the risks are as low as those of ST use. However, for products where the non-nicotine inhaled chemicals have been shown to be benign in other contexts, it seems likely that the products offer reductions in risk for smokers similar to those from other non-combustion source of nicotine. Many smokers cite the appeal of social, ritual, and time-and-motion aspects of smoking rather than pure nicotine delivery, and imitation cigarettes might satisfy those aspects, increasing their appeal.

The evolution of the use of more common ST products is discussed in detail below. For context, most discussions of THR have focused on moist snuff, particularly the form contained in teabag-like sachets because it can be used discretely and without chewing or spitting. Such products are often referred to using the Swedish word for snuff, *snus*.

It is often claimed that the snuff from Sweden, which is manufactured using different processes than some other ST products, particularly chewing tobacco and American moist snuff, is less harmful than those other products. While it is plausible that there is some small risk difference because the Swedish-style product has somewhat lower levels of a few chemicals (called tobacco specific nitrosamines or TSNAs) that are suspected (though not definitively established) to be human carcinogens in sufficient doses, this situation is similar to the claims about pharmaceutical products: There is no evidence of differences in actual human health effects, there is very little room for difference given that all the risks are immeasurably low, and the greatest health risk seems to be the mild stimulant effect of nicotine which is similar across products. Moreover, the levels of TSNAs in modern products are quite low compared to historical levels, and the epidemiology does not show that any currently popular form of Western ST causes cancer. Nevertheless, manufacturers and marketers seem to have concluded that marketing new ST products as snus outside of Sweden, and claiming that they are substantially different from existing products, is a good response to the misinformed beliefs about the risks from ST. Since people are more likely to accept a “new and improved” claim than being informed that they were badly mistaken in their previous beliefs, this strategy might prove useful for THR, even though it might tend to perpetuate scientific illiteracy.

As discussed below, several demographic groups have adopted ST use, demonstrating the viability of switching as a THR strategy. Men and, to a lesser extent, women in Sweden have largely switched from smoking to snus use, (Rodu, Stegmayr, et al. 2002; Rodu, Stegmayr, et al. 2003; Stegmayr, Eliasson, Rodu 2005) as have Norwegian men (Kraft 1997; IARC 2007; Wiium, Aarø, Hetland 2008; Directorate of Health and Social Affairs 2007) and some men in the U.S. have also shown a willingness to switch (Rodu & Phillips 2008). There is some concern that the cultural specificity of ST use to Scandinavia and particular subpopulations in North America limit its potential. But manufacturers are making concerted efforts to expand ST-based THR to other populations, and THR advocates have generally focused on ST as the most promising alternative to smoking. Some of that focus by industry and advocates appears to be shifting toward a broader variety of THR products.

2. Scientific basis and historical evidence for tobacco harm reduction

Scientific evidence of the low risk from smokeless tobacco

The potential of THR, at least in the form of substituting ST for cigarettes, is demonstrated by ample epidemiologic evidence. The popularity of ST in Sweden, and to a lesser extent in the U.S., Norway and Canada for many decades, resulted in hundreds of studies that have looked at the relationship between ST use and numerous diseases.

Perhaps more important, though usually overlooked, is the evidence from unreported results and descriptive epidemiology about the average disease risk in a population. Because public health studies typically collect data on all uses of tobacco, not just smoking, there have probably been thousands of other studies of disease risks that collected information on ST use. An unfortunate unscientific practice in public health research known as “publication bias”, the tendency to publish only those results from a study that are “interesting” or conform to the political bias of the day. In this case, that means that studies of diseases that have data on ST use that find no association will likely not even mention the ST data because it is not interesting, and those that find the “wrong” association (i.e., a chance finding that people who use ST have a lower risk for a particular disease) are likely to not publish it because their result would be viewed as wrong (Phillips 2004). Thus the absence of hundreds of reports that show a positive association between ST use and disease strongly suggests there are hundreds of studies that found there was no such association.

In addition, ST use among Swedish men is so common that any substantial health risk from it would appear in the descriptive epidemiology (i.e., basic population health statistics) for that

population (Rodu 2004). However, Swedish men have among the lowest levels of all diseases that are sometimes thought to be caused by ST use.

Unfortunately, a non-expert who attempted a casual assessment of the evidence would likely be misled. In addition to not recognizing the important points above, a non-expert looking at the headlines or the anti-THR publications would find what appeared to be evidence that ST causes substantial disease risk. For example, in contrast with the ample evidence that the popular Western ST products do not cause a measurable risk for oral cancer, there is some evidence that dry snuff products that once were popular in parts of the U.S. caused a measurable risk for oral cancer (Rodu & Cole 2002), but these products are no longer commonly used. In addition, tobacco-containing oral products that are popular in parts of Asia and Africa may cause substantial risk of oral cancer, though the epidemiology is of such low quality it is difficult to draw clear conclusions. These observations about non-Western products and older dry snuff are used as the basis for recent anti-THR activists' claims that ST causes oral cancer (IARC 2007; Boffetta, et al. 2008). These authors assume (probably quite accurately) that readers will not understand the difference and so believe that the claims are relevant to the modern Western ST products being proposed for THR.

The increasing interest in THR seems to have generated a spate of recent publications by anti-THR activists that purport to show harm from ST use, but still fail to present convincing evidence that ST causes any life-threatening disease. Many of these studies have been demonstrated to misrepresent the data and otherwise overstate the risks of ST (Heavner, Heffernan, et al. 2008; Rodu & Heavner 2009; Phillips 2007a). Furthermore, even if all of these exaggerated claims were accurate, the risk from ST use would still be a small fraction of that from smoking. But the anti-THR authors make sure never to mention the comparative risk and assume (probably quite accurately) that readers will not understand the difference between a large risk and a small risk, let alone learn of the dubious nature of their analysis.

It is biologically plausible that ST can cause acute cardiovascular events. It is a mild stimulant that temporarily increases blood pressure, and most such mild stimulants are believed to trigger incipient strokes and heart attacks. It is plausible that ST may occasionally cause cancer based on some of its chemical content, though the risk must be low or it would be detectable in the epidemiology. Some individual epidemiologic studies, considered in isolation, suggest risks for stroke, myocardial infarction, oral cancer, esophageal cancer, and pancreatic cancer. However, the evidence taken as a whole does not support these claims. (It is inevitable that when there are several epidemiologic studies, some of them will show higher results and some lower. It is sometimes effective propaganda to identify the most extreme study result and pretend that it represents the overall evidence, but proper science calls for considering all the evidence.) Thus,

it is not possible to definitively conclude based on the current scientific literature that ST kills anyone. Given the biologic plausibility of risks and the impossibility of distinguishing zero risk from low risk, however, it seems safe to assume there are some small risks and some people die from using ST. We are aware of no one (not THR advocates, manufacturers, nor anyone else) who claims that that ST or any other THR product causes no risk of disease or death.

How much less harmful is smokeless tobacco?

It is tempting to just focus on the very low best point estimate of the risk, but the potential for THR is perhaps best illustrated by the worst-case scenario. Based on the epidemiology, it is completely implausible that, compared to smoking, ST causes 10% as much risk for serious disease or death. Indeed, only the most extreme interpretation of the evidence can get this figure as high as 5% (Phillips, Rabiu, Rodu 2006). Even this pessimistic case represents a huge potential reduction in risk. The claim that ST is at least 90% less harmful is commonly repeated (e.g., Levy, et al. 2004; Royal College of Physicians 2008; Savitz, et al. 2006). Although this figure is conservative to the point of being misleading, even a 90% reduction represents a huge potential for THR – much greater than the benefits of most harm reduction measures, to say nothing of other public health interventions.

Calculating a best estimate of the risk reduction, rather than a worst-case ceiling, depends largely on what estimate of risk for cardiovascular disease is chosen. Despite the anti-ST rhetoric that emphasizes cancer risk, the maximum plausible cancer risk adds to only a fraction of 1% of the risk from smoking. Plausible estimates put the total mortality risk in the range of 1% or 2% of that from smoking (Phillips, Rabiu, Rodu 2006). ST has not been linked to serious non-life-threatening diseases, unless such conditions as transient blood pressure increases are included in a broad definition of disease. ST sometimes causes superficial sore spots or lesions in the mouth, which some might consider a disease, though they are not life threatening or particularly harmful.

Misleading claim that ST causes cancer

There are widespread claims that ST causes substantial cancer risk, but this is an unfortunate red herring in terms of assessing its suitability for THR. Importantly, for non-smokers in Western populations, oral cancer is very rare (DHHS 2000). Thus, even if this risk were to be increased by, say, 50%, it would represent very low total risk. This usually comes as a complete surprise to non-experts – including most clinicians, public health officials, and educators who incorrectly believe they are knowledgeable. More importantly, despite most non-experts' belief that the scientific evidence shows a substantially increased risk of oral cancer among ST users, the evidence shows that even a 50% increased risk is not plausible. The risk is actually so small as to be undetectable (RCP 2007; Rodu & Jansson 2004; Rodu & Cole 2002).

In the last few years, after it became clear that claims of a substantial risk for oral cancer were false, it became fashionable for anti-THR activists to claim that ST causes a substantial risk for pancreatic cancer. This claim is based on less evidence than the now-discredited claims about oral cancer were originally based on, before further evidence contradicted it, and the data has clearly been interpreted in a biased fashion to exaggerate the association (Phillips 2006; Heavner, Heffernan, et al. 2008). But even if the relative risk claims are accurate, the total absolute risk is small because the baseline risk is quite low, and so would represent extremely low risk compared to the total risk from smoking.

The benefits are clear

Disentangling the biases and misleading interpretations that litter the research is beyond the present scope, but fortunately it is not necessary. Nor is it necessary to resolve the genuine uncertainty about the exact magnitude of the actual risks of non-smoked nicotine products. There is ample evidence that the risks are very small compared to the risks from smoking, and no one with any scientific credibility claims otherwise.

While many readers might find it surprising that the reduction in risk is so great, it is not actually difficult to verify most of the reduction based on casual knowledge: About half the disease risk attributed to smoking comes from lung diseases that no one claims are caused by ST use. Most of the rest of the risk comes from cardiovascular diseases, and even the worst plausible case scenario puts the risk for these at well less than half that from smoking. Thus, even without delving into the details of other diseases, it is clear that the vast majority of risk is eliminated.

In addition, ST and other non-combustion sources of nicotine eliminate the harm that users impose on others. This includes eliminating the health risks from second-hand smoke and fires, as well as the aesthetic impact of smoke. Since it eliminates all the costs to innocent bystanders, THR is the perfect solution for anyone who believes in the rights of individuals to make their own health-affective decisions, but wants to protect other people from the negative externalities from smoking.

Toxicology as a distraction from the wealth of epidemiological evidence

Some confusion about the risks from ST has been created by activists who try to distract from the good news from the epidemiology with studies of “toxins” or “carcinogens”. As with any plant matter (dietary vegetables, etc.), tobacco contains thousands of chemicals, some of which (when removed from their context and concentrated in huge doses) have been shown to cause cancer and other toxic reactions in laboratory experiments on cells or non-human animals. A few chemicals that are believed to be harmful are found in tobacco in greater quantities than in other plants. ST users may receive higher doses of some these chemicals than smokers.

But anyone familiar with health science will recognize that since the epidemiology fails to show actual human health risk from ST, it must be that these chemicals, in the form and concentrations found in ST, do not cause measurable levels of disease, irrespective of what they might do under certain laboratory conditions. After all, if a particular chemical that entered the body due to an exposure caused disease to a substantial degree then the exposure would cause that disease to a substantial degree. Studies of chemistry or laboratory exposures are sometimes useful in helping us guess what health impact something might have when we do not have actual epidemiology, or in exploring the possible mechanisms involved in an effect that has already been determined, but using it to predict what might happen when we already know what actually does happen is obviously useless.

Other lower risk nicotine products

The epidemiology on pharmaceutical nicotine products is very limited. Data exist about the immediate effects of use, as well as effects over a several month course of use. However, this is of little value in assessing the disease implications of a lifetime of exposure by someone who uses them instead of smoking, the type of information we have for ST. It is estimated that despite being designed, tested, approved, labeled, and marketed only for short-term weaning off of cigarettes about half of all pharmaceutical nicotine users at any given time are long-term users (Hughes, et al. 2004). Many, possibly about one-third, of all users use pharmaceutical nicotine without quitting smoking, during periods of temporary abstinence (often due to restrictions on smoking) or as means to lower but not eliminate cigarette consumption (Hammond, et al. 2008).

However, for several reasons, there have not been epidemiologic studies of long-term users. This does not mean we have no useful information, since in public health science we rarely have a measure of exactly what we want to know (the exact exposure, population, etc. we are interested in) and so need to draw conclusions based on data from the most similar analog we have. In this case, the analog that has been studied is ST. Since: 1) the acute cardiovascular effects are similar because they are caused by nicotine; 2) ST does not seem to cause measurable levels of cancer and; 3) we believe that any risks caused by the non-nicotine aspects of pharmaceutical products are minor, it seems safe to estimate the health risks to be about the same (though, of course, actual epidemiology about the pharmaceutical products could discover that this is wrong). Given the lack of epidemiology, and only speculation about the effects of differences between the delivery systems, there is no basis for concluding that ST is a bit less harmful than pharmaceutical nicotine, or vice versa. However, no such conclusions are necessary to recognize that they are both much better than smoking, but probably cause a bit more risk than not using nicotine at all.

Redesigning cigarettes, smoking and smokeless

Attempts to make cigarettes less hazardous have had a mixed history. Some changes have clearly offered health improvements, while others have failed spectacularly. One particular failure to improve the health impact of cigarettes, so called "light" cigarettes, may be responsible for some of the resistance to THR (Fairchild & Colgrove 2004; U.S. House of Representatives 2004) though exactly the opposite lesson should be drawn: In that case, health improvements that were predicted but not supported by any epidemiology did not occur. The unfortunate naïve conclusion by some observers was that since this attempt failed, harm reduction is not possible, and therefore abstinence is the only worthwhile goal. However, the actual lesson is that we should favor alternatives that have been proven low-risk and practical, like ST, over purely speculative hopes like expecting that everyone will just quit using nicotine.

Minor variations on cigarettes that still consist of burning tobacco ought to be able to reduce risks somewhat (e.g., by lowering levels of carbon monoxide levels or reducing the number of atoms of heavy metals or molecules of other hypothesized-as-particularly-unhealthy components of the smoke). But given the many harmful aspects of breathing smoke, it is difficult to imagine anything more than minor improvements. If the choice is simply to implement these changes or not, obviously a bit less harmful is better, but such changes should not be seen as substitutes for a radical switch to non-combustion products.

Major product reengineering might prove more promising. Cigarette-like devices that heat the tobacco, volatizing the nicotine and some other constituents, rather than burning it and creating all the constituents of smoke seem likely to reduce the risks, though presumably some of the hazards of exposing the airway to many chemicals remain. There has been no epidemiology on these products, and to date they have been a failure in the marketplace. (For a more detailed description of one of these products see: Fagerstrom, et al. 2009.)

A presumably low-risk variation on the cigarette appears that it might be on the verge of exploding in popularity at the time of this writing [*editors' note: when reading the sections about electronic cigarettes, readers are reminded that "this writing" refers to 2008*]. These devices resemble and are handled like cigarettes, but use pharmaceutical nicotine in aerosolizable chemicals that produce an imitation of smoke that is inhaled by the user when heated (for more details see: Laugesen 2008). These have gained popularity as a smoking-like experience that does not violate indoor smoking prohibitions, for example, allowing bar patrons to "smoke".

3. Adoption of THR

Scandinavia: Population level evidence of the viability and effectiveness of THR

The viability of ST use as a smoking cessation strategy, and the predicted dramatic reduction in morbidity and mortality from nicotine use it will cause, has been demonstrated in Sweden. Snuff use in Sweden dates back almost to the introduction of tobacco in Europe and became widespread by the 19th century before declining between 1920 and 1960, when cigarettes became popular in Sweden and throughout the West. In the mid-20th century, snuff use was most common among older male farmers, fishermen and lumberjacks but subsequently it became more common among other young men (Nordgren & Ramstrom 1990; Stegmayr, Eliasson, Rodu 2005; Furberg , et al. 2006). This trend is generally attributed to social factors rather than recognition of the benefits of THR.

But the THR benefits did occur, and then became recognized. Now more men use snus than smoke, with smoking prevalence about half that of men in even the Western countries with the most aggressive abstinence promotion policies. Snus use rates have been increasing and smoking rates have been decreasing among both Swedish males and females (Stegmayr, Eliasson, Rodu 2005), and many of the snus users switched from smoking (Rodu & Stegmayr 2003). Smoking is still the most common form of tobacco use among Swedish females, though the trends are positive (Stegmayr, Eliasson, Rodu 2005). Sweden is the only population where smoking became established but dropped to substantially less than 20% of the population. As a result, Sweden has the lowest rates of tobacco related (i.e., smoking caused) mortality in Europe (Rodu & Cole 2004).

There is also a long history of snus use in Norway, where snus use is increasing and is now common among males (Kraft 1997; Wiium 2008). There is evidence of a transition from smoking to snus use among men since, like in Sweden, snus use increased as smoking prevalence decreased from the mid 1980s to 2006 (Directorate of Health and Social Affairs 2007).

United States: History of niche popularity and a promising future for THR

Outside of Scandinavia, the U.S. is the country were modern western ST products are the most popular. Like Sweden, North America has a centuries old tradition of ST use (it pre-dates European arrival in the Americas). In the U.S., ST was the most popular method of use before cigarettes became a mass-market commodity. By the mid-20th-century, usage was largely limited to niche markets, particularly among rural males, though popularity increased toward the end of the century. While less than 5% of the adult populations used ST at the beginning of the 21st century (though this represents a large and growing absolute number of users), it remains much less than the smoking prevalence of over 20% (CDC 2008; SAMHSA 2006).

Importantly, the U.S. has had among the most aggressive anti-smoking campaigns, including education, legal restrictions, high taxes, and other measures, which probably contribute to smoking rates being a bit lower than elsewhere in the West. But despite this, nicotine use, mostly in the form of smoking, remains popular, illustrating the importance of THR. There is evidence of American men switching to ST as a method for quitting smoking (Rodu & Phillips 2008), and THR is increasingly being discussed in the scientific literature, and is gaining acceptance in the medical community (Nitzkin & Rodu 2008).

The U.S., long home to the biggest ST manufacturer and the biggest market, has recently been flooded by new ST product lines from several manufacturers. These are typically marketed as "snus", and often with low-key THR messages. This includes the two major cigarette makers introducing snus products marketed under their flagship cigarette brands. Increased public awareness of the availability of ST products likely occurred as a result of popular press coverage of the introductions of new products (e.g., Landler, Martin 2007). Widespread adoption of THR in the U.S. would likely be followed by implementation of THR policies in other countries. Unfortunately, as discussed below, there is a concerted effort to keep Americans (and others) from learning about the benefits of THR.

Hurdles to THR elsewhere

Unfortunately, outside of Scandinavia and the United States, there has been little tendency toward THR. Smokeless products that include tobacco have a long history elsewhere, particularly in South Asia and parts of Africa, but the trend is toward increased smoking, perhaps replacing those products.

Anti-THR efforts are directly responsible for the lack of success in non-Scandinavian Europe. Due to some unfortunate history, the European Union (EU) actually bans snus-style ST products. (Sweden demanded and received an exception to this rule when it joined the E.U. and Norway is not a member of the EU) However, smoking is legal and quite popular. At the beginning of the 21st century, more than 30% of adults in most EU countries smoked (Statistical Office of the European Communities 2008). This bizarre combination of banning low-risk forms of tobacco while allowing the high-risk form is possibly the most costly anti-public-health regulation that exists in the world today. Though there is a growing constituency that favors eliminating the ban (e.g., Royal College of Physicians 2008), the conventional wisdom is that a removal of the ban is, at best, several years off.

Similarly, New Zealand and Australia ban ST (though, again, cigarettes remain legal and popular). There is some limited interest in changing this, though no specific signs of progress

(Gartner, et al. 2007; Laugesen 2007). However, since these governments are much smaller and thus more responsive than the EU's, the situation could change much more rapidly.

Canada, like the U.S., has a history of ST use in small niche markets, particularly in the rural west. In 2007, Canada's major cigarette company began test marketing a snus product under its flagship brand, explicitly marketing it as a reduced harm alternative to cigarettes, an approach that had not been previously used in North America. (ST products were already widely available in Canada, but not marketed in this way.) There was evidence that smokers in the test market area were quite interested in trying low risk nicotine products (Geertsema, et al. 2010; Heavner, Phillips, Rosenberg 2008). It appeared that Canada might emerge as a leader in THR. However, an anti-THR crusade seems to have ended this hope. For example, when the research group that includes the authors of this paper started promoting THR locally, the local tobacco control groups shifted most of their emphasis to being anti-ST rather than anti-smoking (including the anti-tobacco unit of the provincial government and even groups that were explicitly anti-*smoking* and not anti-tobacco); apparently they were more worried about THR than about smoking. Canada lacks free speech protections, and various restrictions on free speech have made it almost impossible to educate smokers about the availability of the low-risk option. In addition, Canadians hear only anti-harm-reduction messages from the supposed authorities and they have a tendency to defer to authority. Thus they are particularly unlikely to learn about THR, and so despite demand and supply, there is little hope of THR happening in Canada until after it has succeeded in the U.S. and trickles over the border.

In the non-Western world the barrier to THR is more lack of interest than anti-public-health actions by governments or activists. Attempts to introduce ST products in Japan and South Africa have been largely unsuccessful, apparently largely due to the difficulty of marketing a product line unlike anything used locally, though perhaps also due to some poor choices in design and marketing strategy. However, the persistent belief that there were no risk differences among tobacco products resulted in government requiring the same warnings as are on cigarette packets be on to snus packaging, and regulations forbade communication to potential consumers about harm reduction (University of Stellenbosch Business School 2006).

The emergence of guerrilla-marketed electronic cigarettes might render some of the barriers to ST use moot. Before snus is decriminalized in Europe or becomes popular elsewhere in the world, non-smoked cigarette-like devices might occupy much of its niche. These devices emerged in China, a population that for cultural reasons is unlikely to adopt ST. They are used locally (it is not know exactly how much, but presumably they have made only tiny inroads into the massive Chinese cigarette market) and exported to the West. It is possible that regulators will declare these new products to be pharmaceuticals and thus subject to regulations that would drive

them out of the market, or otherwise restrict their availability. Bans have already been implemented in some jurisdictions (Turkey, Finland), though the usual easy access to the much riskier products, cigarettes, remains unchallenged.

4. The politics of THR

The above is intended to describe the potential for and reality of THR with minimal reference to the politics and disinformation that surrounds the issue (though the dominance of politics and misinformation makes complete separation difficult). To fully understand THR requires answering the question, "why does such a promising public health intervention have such strong opposition, and why do so few people even know about it?"

The first thing that is necessary to understand is that many people and organizations in the anti-tobacco industry are not actually pro-health, but are merely anti-tobacco. (Given the huge budgets that come mostly from the public coffers and taxes paid by smokers, careerism, and institutionalization of anti-tobacco organizations, calling them an "industry" is the most polite accurate description. Others have proposed "racket".) Once this fact is recognized it becomes clear that the apparent paradox – that many in the "public health community" are opposed to improving public health by reducing the harm from a popular behavior – is based on the incorrect premise that the anti-tobacco industry is all part of the public health community.

Part of the explanation for this is that the "public health community" in North America and parts of Europe evolved partially from various "purity"-based (and largely paternalistic and puritanical) social movements directed at modifying people's behaviors. While there was often a strong overlap between purifying behavior and improving people's health, particularly many decades ago, health concerns have often served as a stalking horse for attempts to purify people's minds and bodies, not improve their welfare or even health. To see the most salient example of this, one only needs to notice that much of the anti-smoking (and other anti-tobacco, anti-nicotine, and anti-drug) rhetoric focuses on product use being dirty or somehow sinful, rather than it being biologically unhealthy. Purity movements often condemn any dependence (chemical or otherwise) as a moral failing or even a disease, regardless of actual health effects. This explains why addiction itself is sometimes misconstrued as a disease, often without any attempt to defend the claim, or even define what addiction means. From such a perspective, the argument against smoking has little to do with the diseases it causes, so merely eliminating those diseases is not a substitute purifying the world of tobacco. Moreover, smokers are not treated as welfare-maximizing consumers whose lives could be improved by offering a safer way to do what they are doing, but rather as impure sinners who need to be cleansed of nicotine, not aided.

Many anti-smoking activists are generally anti-nicotine and anti-drug. However, many others have close ties to the pharmaceutical nicotine industry or support balanced and rational policies in other areas of drug use, so puritanism alone can only provide a limited explanation. (One could, perhaps, extend the reach of the puritan explanation: Clean, fancy, modern pharmaceutical products seem less dirty than actual plant matter. Or perhaps that the politics of self-identity of many activists requires them to treat the most destitute members of our society, such as illicit drug users, as innocent victims, but smokers get no such deference.)

A second explanation for the disconnect between anti-tobacco and pro-health is a hatred of tobacco companies. This is a particularly costly attitude since the industry is currently far ahead of the public health community and pharmaceutical industry in assessing and promoting THR. If public health advocates were to support industry efforts rather than fight them, we would be years closer to widespread adoption of THR, saving countless lives in the process.

Animosity toward the industry is often attributed to past corporate behavior, but this clearly is either not the full explanation or is based on gross irrationality: The oft-cited bad behaviors were primarily committed by cigarette companies decades ago, and yet anti-tobacco-company bias makes no exceptions for companies that make ST and not cigarettes, or companies that did not even exist at the time of the worst offenses. Indeed, it obviously makes little sense to try to punish, or even to despise, an abstract entity whose shareholders, leaders, and employees have almost completely turned over since it committed most of the acts that are considered to warrant punishment. A partial explanation for the irrationality might be the general anti-big-corporation bias of some political activists, though since some targeted companies are not large, and since the bias does not generally extend to pharmaceutical companies, this explanation also falls short.

Probably the most convincing explanation for the anti-tobacco-industry bias is that it provides some relief from the cognitive dissonance that results from "knowing" you are doing everything right but observing that you are failing. It appears that most anti-tobacco activists genuinely believe, despite all evidence to the contrary, that the actions they are advocating will eliminate the demand for tobacco and that the world will eventually be free of nicotine use. When the reality of persistent tobacco use contradicts their hypotheses, they tend to seek a *deus ex machina* rather than revising their hypotheses as scientists would.

The cognitive dissonance results from obviously erroneous beliefs. When someone has an unshakable belief that smoking has no benefits, then rational cost-benefit analysis cannot explain the choice to smoke. If one assumes everyone wants to maximize their longevity at whatever cost, then it is difficult to explain how education about the risks from smoking does not cause

everyone to quit. If it is assumed that higher taxes will only result in decreased consumption, it might be difficult to recognize that smuggling and more efficient smoking are obvious rational responses. Most importantly, the assumptions that every smoker really wants to quit, and various tools make quitting easy, mean that it cannot be the case that 1/5th of the population chooses to keep smoking. Though the rational response to these observations would be to revise the assumptions, if the assumptions have become religion rather than scientific hypothesis, it is easy to see the temptation to blame one's failure on (usually unspecified) evil acts of some opponents. The tobacco industry is the usual target, though non-industry advocates of THR and any researchers whose analyses point out errors in the anti-tobacco conventional wisdom are also targets of this frustrated fury (Enstrom 2007, Phillips 2007b, Siegel 2007).

Puritanical anti-smoking activists are likely disturbed by the reasonable expectation that when people learn that there are low-risk ways to consume nicotine and tobacco, then the incentive for purification will be tremendously diminished. Similarly, activists with an anti-corporate bias realize that tobacco companies will thrive if they can switch to low-risk products that consumers will have less reason to quit using. THR probably guarantees that the goals of driving tobacco companies out of business and eliminating self-administration of nicotine will never be realized. Perhaps even more frustrating to them, the health costs of smoking will be eliminated, but not due to the success of the anti-tobacco industry, but rather in spite of the actions to which the activists devoted their careers. Thus, it is not difficult to understand why this generates hostility toward THR efforts. Of course, none of these outcomes are bad from the perspective of public health, let alone overall human welfare.

The profound disconnect between the anti-tobacco industry and actual promotion of public health goals is so difficult for many observers to understand that they grant the anti-tobacco activists the benefit of every doubt. This makes it easy for the activists to obscure their real motives with disinformation.

Misinformation and disinformation

The great potential for THR has been discussed for decades, has been clear beyond a doubt for at least one decade, and is now universally known by anyone with real expertise in tobacco science or policy. This makes the near-universal lack of knowledge about the potential for THR beyond a small community of experts especially remarkable. The ignorance extends beyond the lay public to include most clinicians, health policy makers, and even many health researchers. What is worse, most of them are very confident in their false beliefs. Surveys show that the vast majority of the public thinks that ST is at least as harmful as smoking (Geertsema, et al. 2010; Health Canada 2006; Broome County 2006; ITPC 2004; O'Connor, et al. 2005; Smith, Curbow, Stillman 2007) and the limited data on health professionals shows almost as much ignorance

(Prokhorov, et al. 2002). Those of us who educate about THR can confirm these results based on experience. The typical conversation (with lay people, professors of public health, or others) follows the pattern "really, it is not as bad?", "no, not even close," "what about mouth cancer?" The last question is typical of even those who should know that even a high relative risk for oral cancer would result in a trivial absolute risk compared to smoking. The assertion that ST does not cause lung disease so could not possibly be as bad as smoking is usually followed by a surprised expression, then tentative acceptance of this obvious fact. Similar ignorance exists about the risks from pharmaceutical nicotine products, with many people believing that they are at least as hazardous as smoking and many smokers thinking that they will increase their risk or become "addicted" to these products, even when using those them for short periods while trying to quit.

To fully appreciate the magnitude and importance of this ignorance, it is necessary to remind ourselves that this is not a matter of some rare and obscure behavior – smoking is often considered the most important issue in public health. Nor is there any genuine scientific doubt on the huge differences in risks. Failure to understand that alternative sources of nicotine are orders of magnitude less harmful than smoking is akin to believing that wearing a seatbelt is more dangerous than not, or that common vaccines are more dangerous than they are beneficial. Granted a few people actually believe the former of these, and many lay people believe the latter, but these are generally seen as cases of unforgivable ignorance, and a health professional making such a claim would be guilty of malpractice. But a comparably absurd – and possibly even more deadly – misunderstanding exists for THR, and clinicians and opinion leaders are guilty of actively perpetuating it.

Part of the confusion stems from the aforementioned conflation of smoking, tobacco, and nicotine, which is sometimes used innocently (though still quite inaccurately) as a shorthand. Some of the confusion stems from the tendency of most people to think of a health exposure as merely good or bad, without understanding the immense differences in magnitude among the harmful exposures. But ultimately, such a major and important error can only exist with the complacency of the subject matter experts. In this case, there is not merely complacency but complicity, an active campaign to mislead.

Several studies (e.g., Phillips, Wang, Guenzel 2005; Phillips, Bergen, Guenzel 2006; Boehm 2005) have documented the claims made by the anti-tobacco industry that are designed to convince non-experts (including clinicians and policy makers) that ST is roughly as hazardous as smoking. Even a casual observation of "educational" materials about ST and other alternative sources of nicotine reveals that anti-tobacco (or anti-nicotine or anti-drug) activists are intent on obscuring the known differences in risk and the fundamental difference between smoking and

non-combustion exposures. The claims range from out-and-out lies about the risks from ST, to conflation of all types of tobacco, to trying to take advantage of scientific ignorance with impressive sounding, but ultimately meaningless, technical claims. The latter tactics include a wide variety of claims based on toxicology, such as pointing out that ST contains various chemicals that (under particular laboratory circumstances and in very high concentrations) are "carcinogens" or "toxins." This takes advantage of the widespread public fear of "chemicals," the lack of understanding that thousands of chemicals can be found in all plants, that low dose exposures do not have the same effects as high doses, and that epidemiology trumps toxicology. Experts in other areas of harm reduction might find a familiar the anti-tobacco tactics and "reefer madness"-style campaigns; compare, e.g., the attempts to convince teenagers that using condoms is a bad idea. All represent triumphs of puritanical politics (at least temporarily) over overwhelming scientific evidence.

What pass for scientific studies are often little better than the broadsides that are aimed at laypeople. The dominance of the anti-tobacco industry in scientific research and publication in the field, as well as the inherent weaknesses of health science research (Phillips 2003; 2004; 2007a; 2008), mean that almost any study can be construed to show that tobacco or nicotine use is unhealthy, and most any report that draws that conclusion will be published no matter how low the quality or absurd the conclusions.

To cite one recent example, a study by a major anti-tobacco organization (and, sadly, not actually pro-health, at least in this arena), the American Cancer Society (ACS), found that switching from smoking to ST is extremely beneficial (Henley, et al. 2007). This article, based on the same large cohort study that produces some of the most often quoted statistics about the effects of smoking, provided some of the best evidence for the value of THR ever produced (Phillips 2007a). But the ACS chose to completely obscure this finding by glaringly avoiding comparing the health outcomes of those who switched from cigarettes to ST to those who continued to smoke. Instead, they only compared those who switched to those who quit using nicotine entirely, claiming (incorrectly, it turns out) that their results showed that switching was worse than quitting entirely. The ACS then tried to convince the popular press that this showed that THR was a bad idea (ACS 2007) and their propaganda was so effective that some press reports actually told smokers that it was better to continue to smoke than to switch to ST (e.g., Spangler, 2007). ACS made no attempt to correct this misconception.

Another recent study by anti-tobacco activists (Hecht, et al. 2007) found that the concentration of a few particular chemicals that are suspected to cause cancer (though there is no actual human data to support this) in the urine of ST users is greater than in the urine of smokers. This study, obviously far too limited and technical to be useful to the public, was nevertheless touted to the

popular press as showing that ST use was harmful, even though it actually provided absolutely no information about health outcomes. Again, the propaganda was effective, and the press were misled into reporting that the study showed that ST was more harmful than smoking (e.g., American Association for Cancer Research 2007; Bakalar 2007; Fox news 2007; Tasker 2007).

Particularly of interest is that these two examples are part of a large number of quasi-scientific reports about the health effects of ST use that have recently been published, after decades in which there was relatively little interest in the topic. The increased interest, and the efforts to overstate the risks from ST, coincide with the growing acceptance of THR and the real possibility that ST might be actively promoted as a tool of helping smokers reduce their risks. What is equally interesting is that there are often clear discrepancies between what researchers or organizations report in their scientific papers and how they then report those findings (or allow others to inappropriately extrapolate from those findings). In both of the above examples, the most misleading claims were found only in press releases and other communication to the public and not the original journal articles.

More telling is that since several researchers started to document the inaccurate claims made about THR by anti-tobacco organizations, many of those organizations have changed the explicit false claims so that they are literally true but equally misleading. One common example is: instead of saying that ST is not safer than smoking they now say it is "not a safe alternative", a claim that communicates the same message to the reader, but is actually vacuous since nothing is "safe". Such careful re-crafting makes it especially clear that the authors are aware of the truth, and do not want to be caught making clearly false claims, but are still intent on misleading the public.

Efforts to prevent people from learning about THR are clear violations of the most fundamental tenet of modern health ethics, that individuals have a right to be given information so that they can make autonomous decisions about their own health. The paternalism and puritanism that dominate nicotine and tobacco policy result in both deadly consequences and a fundamental violation of people's rights. What is often called *mis*information about the potential for THR should be recognized for what it is: *dis*information, a concerted effort to mislead people. Because of misplaced trust, this disinformation campaign has been hugely successful. Since information is the key to reducing the needless harm from using a deadly delivery system for a beneficial and relatively innocuous drug, the disinformation as been very effective at killing people. Fortunately, this may finally be starting to change.

5. The future of THR

Despite the obstacles of widespread ignorance of critical facts and active opposition by the rich and powerful anti-tobacco industry, widespread adoption of THR seems inevitable. Good ideas do not remain secret forever and many smokers are interested in low risk alternatives to cigarettes. The real question is how many more people will die from smoking before they learn about the alternatives.

Some pro-THR advocates have focused on trying to convince the anti-tobacco industry to endorse THR. Since the popular belief persists that anti-tobacco activists are honest and pro-health, many other organizations and policy makers take their cues from them. Thus it is very frustrating to try to educate the public, health care providers, and policy makers in the face of their anti-THR campaigns. However, since there has been little doubt about the potential value of THR for over a decade, but during that time anti-tobacco activists have only become more hardened in their opposition to THR, it is difficult to be optimistic about this approach. While converting the purity activists is not promising, many respected organizations that are genuinely pro-health and not beholden to the anti-tobacco forces have come out in favor of THR, providing adequate political cover for those who require such endorsement before supporting THR. Britain's Royal College of Physicians (2008) recently issued a report that actively supported THR, and the American Association of Public Health Physicians also recently endorsed THR (Nitzkin & Rodu 2008). The European Commission's Scientific Committee on Emerging and Newly Identified Health Risks (2007) reported on the benefits of THR, and thus the harm caused by the EU ban, though someone who read only the political documents surrounding the actual scientific report, and not the report itself, might not have noticed that this was the message.

The clear scientific consensus on the benefits of THR, coupled with some organizational endorsement, will likely lead to increased uptake of THR. The combination of freedom of speech, easy legal access to products, and an extremely compelling message make it inevitable that educated people will eventually get the message and lead the way for others. Each smoker who learns about the potential of THR can adopt it themselves (no policy action or social infrastructure is needed). Moreover, each person who is educated about THR will ratchet the progress of THR, since it is unlikely that those who spread disinformation will be able to cause someone to unlearn the truth.

With the most promising ST products banned in the EU and elsewhere, adoption is difficult for consumers and education is also severely hindered. In countries without adequate education or free speech, information dissemination may be very slow, despite the availability of products. The U.S. is probably the best near-term hope for promoting THR. The litigious climate

surrounding corporate actions has made major manufacturers nervous about exercising their free speech rights in the U.S. but smaller companies and some individuals are trying to educate the public about THR.

Legal restrictions like the EU ban on ST will stifle the adoption of THR. However it is possible that when the ban is lifted it will be sufficiently dramatic that there will be a highly teachable moment that causes education about THR to vault ahead of U.S. levels. More subtle restrictions in less open societies, like Canada's restrictions on free speech or the almost complete dominance of unscientific anti-THR messages in less educated populations, might actually delay uptake of THR longer than bans, assuming the bans are eventually lifted. In societies that are even more closed or where there is very limited education – a substantial majority of the world's population, with a majority of its smokers – there is probably little hope for major inroads until THR is established in the West. The possible exception to this pessimism is that if corporations with major marketing clout (be they cigarette companies marketing snus, or otherwise) might actually be able to promote THR in unexpected places where there is no ST tradition. While such efforts are extremely costly, at least one major company has proven willing to accept the necessary losses to try to build knowledge of THR in new population, and they might eventually find a government that is willing to help rather than hinder their efforts.

An alternative scenario for the uptake of THR is an adoption of electronic cigarettes. These products currently have lower consumer awareness than ST. However, this is the type of product that can explode into popularity in a community if it becomes stylish. Indeed, the origination of such products in China makes that country a dark-horse hope for advancing THR. With hundreds of millions of smokers, a free-wheeling marketplace, an increasingly educated population, and free speech in the marketplace (though obviously not in many other arenas), China could emerge as the leading market for THR if the government does not interfere.

Adoption of THR seems likely to be a critical mass or tipping phenomenon (Schelling 1978), since each adopter is likely to increase the rate of knowledge dissemination and recruitment. The question then becomes, is there a way to push the positive but slow progress toward critical mass? Assuming that government and major health organizations remain part of the problem rather than the solution, marketing by ST manufacturers, targeted and localized enough to produce local critical mass, may be the most promising alternative. It is possible that before ST use reaches critical mass, electronic cigarettes or other devices could become comparable contributors to THR. Such devices could provide the impetus for a lot of switching, followed by education about the advantages of switching.

It might seem surprising to describe switching leading, rather than lagging, education about reduced harm, but this is actually not an unusual pattern for behavior change. A current impetus for using smoke-free products is time-and-place restrictions, serving an obvious consumer demand that has nothing to do with the user's health risks. Indeed, there is little evidence that smokers who try alternative products are usually aware of the much lower health risk. However, knowledge often follows behavior. It is often difficult for people to internalize the message that their actions are needlessly harmful, even smokers who intellectually know the risks (i.e., people resist cognitive dissonance), but we become interested in learning once our actions have changed (i.e., people are curious about and become invested in rationalizing the actions they have chosen).

The irony here is the subtext of time and place restrictions. Such laws and regulations are almost always justified as ways to protect nonsmokers from the risks from an involuntary exposure (notwithstanding that the risks from second-hand smoke exposure have been grossly exaggerated and the bans increasingly include places where being there is highly voluntary). This is the only way to sell the restrictions to the public in societies that respect individual liberty. However, most anti-tobacco activists have other goals and clearly, often quite openly, argue that an intentional "benefit" of the restrictions is that they make smokers so miserable that they are more likely to quit (c.f., claims about the expected reduction in risks among smokers thanks to the bans, as well as advocating forbidding not just smoking but also ST use on airplanes, prisons, and other confined venues). But misery is the mother of invention, and so the restrictions cause invention of products and innovative consumption patterns for the long-term, low-risk use of tobacco that these same activists want to eliminate.

Were it actually that nicotine use was just the result of unwanted addiction and smokers really preferred to quit entirely, they might thank the regulators for making smoking less appealing. As it is, smokers are being driven to the economically rational choice of obeying the regulations with minimal cost to themselves, and so are driven to the rational decision to reduce their health risks. Having inadvertently reduced their risk, they will soon learn they have done so, and will probably help educate others. Harm reduction is always about maximizing welfare, usually by facilitating rational individual decisions. It should come as no surprise that smokers are rational actors who want to lower their costs without eliminating their benefits. When they are finally given the opportunity to do so, it will likely be the greatest public health triumph of our generation.

References

American Association for Cancer Research. Smokeless tobacco more effective than cigarettes for delivering dangerous carcinogens into the body, researchers say (Press release). August 9, 2007a (Available at: http://www.aacr.org/home/public--media/news/news-archives-2007.aspx?d=808).

American Cancer Society. Spit tobacco no substitute for quitting smoking. February 23, 2007. (Available at: http://www.cancer.org/docroot/NWS/content/NWS _1_1x_Spit_Tobacco_ No_ Substitute_for_Quitting_Smoking.asp)

Atrens DM. Nicotine as an addictive substance: A critical examination of the basic concepts and empirical evidence. J Drug Issues 2001 31(2):325-394.

Bakalar N. Hazards: Smokeless tobacco on par With cigarettes. New York Times. August 21, 2007.

Ballin S. 2007. "Smokefree" tobacco and nicotine products: Reducing the risks of tobacco related disease. (Available at: http://www.tobaccoatacrossroads.com/ 2007report/071128_ Ballin%20Report_final.pdf).

Boehm KF. Request for Correction of Erroneous Information Under the Data Quality Act. December 12, 2005. (Available at: http://aspe.hhs.gov/infoQuality/request&response/26a.shtml)

Boffetta P, Hecht S, Gray N, Gupta P, Straif K. Smokeless tobacco and cancer. Lancet Oncol. 2008 Jul;9(7):667-75.

Broome County Health Department. Community tobacco survey of adult residents of Broome County, New York: Opinions, behaviors, and perceptions related to tobacco use, the dangers of tobacco, tobacco cessation, tobacco advertising, and exposure to secondhand smoke, 2006 (Available at: http://www.gobroomecounty.com/hd/pdfs/200702BroomeTobaccoSurvey.pdf).

Centers for Disease Control and Prevention (CDC). Prevalence of selected risk behaviors and chronic diseases–Behavioral Risk Factor Surveillance System (BRFSS), 39 steps communities, United States, 2005. MMWR Surveill Summ. 2008;57(11):1-20.

Centers for Disease Control and Prevention (CDC). Tobacco use among adults – United States, 2005. MMWR 2006; 55(42);1145-1148.

Council of the European Communities. Council Directive 92/41/EEC of 15 May 1992 amending Directive 89/622/EEC on the approximation of the laws, regulations and administrative provisions of the Member States concerning the labelling of tobacco products **(**31992L0041) Official Journal L 158 , 11/06/1992 P. 0030 – 0033(Available at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31992L0041:EN:HTML).

Directorate of Health and Social Affairs. Norwegian Tobacco Statistics 1973-2006. 2007. (Available at: http://www.shdir.no/tobakk/english/facts_and_figures/new_report__ statistics _on_tobacco_use_in_norway_1973_2006_80838).

Enstrom JE. Defending legitimate epidemiologic research: combating Lysenko pseudoscience. Epidemiol Perspect Innov. 2007 Oct 10;4:11.

Fagerström KO, Hughes JR, Rasmussen T, Callas PW. Randomised trial investigating effect of a novel nicotine delivery device (Eclipse) and a nicotine oral inhaler on smoking behaviour, nicotine and carbon monoxide exposure, and motivation to quit. Tob Control. 2000;9(3):327-33.

Fairchild A, Colgrove J. Out of the ashes: the life, death, and rebirth of the "safer" cigarette in the United States. Am J Public Health. 2004;94(2):192-204.

Fox news. Study: Smokeless tobacco more carcinogenic than cigarettes. August 10, 2007 (Available at: http://www.foxnews.com/story/0,2933,292838,00.html).

Furberg H, Lichtenstein P, Pedersen NL, Bulik C, Sullivan PF. Cigarettes and oral snuff use in Sweden: Prevalence and transitions. Addiction. 2006 Oct;101(10):1509-15.

Gartner CE, Hall WD, Vos T, Bertram MY, Wallace AL, Lim SS. Assessment of Swedish snus for tobacco harm reduction: an epidemiological modelling study. Lancet. 2007;369(9578):2010-4.

Geertsema K, Phillips CV, Heavner K. Survey of university student smokers' perceptions of risks from tobacco products and barriers to harm reduction. A version is published in this volume. 2010.

Hammond D, Reid JL, Driezen P, Cummings KM, Borland R, Fong GT, McNeill A. Smokers' use of nicotine replacement therapy for reasons other than stopping smoking: findings from the ITC Four Country Survey. Addiction. 2008;103(10):1696-703.

Health Canada. Consumers' Awareness and Perceptions of Potential "Harm Reduced" Products, Toronto, Ontario, 2006. (Executive summary available at: http://www.hc-sc.gc.ca/hl-vs/tobac-tabac/research-recherche/por-rop/other-autre_harm-mefaits-eng.php).

Heavner K, Heffernan C, Phillips CV, Rodu B. Methodologic and Ethical Failures in Epidemiologic Research, as Illustrated by Research Relating to Tobacco Harm Reduction (THR). Am J Epidemiol 2008;167(Suppl):S115.

Heavner K, Hu J, Phillips CV. Smokeless Tobacco Availability and Promotion in Edmonton: Exploring the Barriers to and the Opportunities for Tobacco Harm Reduction. In peer review.

Heavner K, Phillips CV, Rosenberg Z. Survey of Smokers' Interest in and Barriers to Tobacco Harm Reduction. Poster presentation at the 18th International Harm Reduction Association Conference, Barcelona Spain, May 2008.

Heavner K, Rosenberg Z, Tenorio F, Phillips CV. Retailers' knowledge of tobacco harm reduction following the introduction of a new brand of smokeless tobacco. In peer review.

Hecht SS, Carmella SG, Murphy SE, Riley WT, Le C, Luo X, Mooney M, Hatsukami DK. Similar exposure to a tobacco-specific carcinogen in smokeless tobacco users and cigarette smokers. Cancer Epidemiol Biomarkers Prev. 2007;16(8):1567-72.

Henley SJ, Connell CJ, Richter P, Husten C, Pechacek T, Calle EE, Thun MJ. Tobacco-related disease mortality among men who switched from cigarettes to spit tobacco. Tob Control. 2007;16(1):22-8.

Henley SJ, Thun MJ, Connell C, Calle EE: Two large prospective studies of mortality among men who use snuff or chewing tobacco (United States). Cancer Causes Control 2005, 16:347-358.

Hughes JR, Pillitteri JL, Callas PW, Callahan R, Kenny M. Misuse of and dependence on over-the-counter nicotine gum in a volunteer sample. Nicotine Tob Res. 2004;6(1):79-84.

International Agency for Research on Cancer (IARC). IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, vol 89. Smokeless Tobacco and Some Tobacco-specific N-nitrosamines. Lyon, France: IARC, 2007.

ITPC Adult Tobacco Survey Highlight Report, 2004, (Available at: http://www.in.gov/itpc/files/ research _250.pdf, Last accessed July 17, 2007)

Kraft P, Svendsen T. Tobacco use among young adults in Norway, 1973-95: has the decrease levelled out? Tob Control. 1997;6(1):27-32.

Landler M. Martin A. Swedish Smokeless Tobacco Aims at U.S. Market. New York Times October 3, 2007.

Laugesen M. Safety report on the Ruyan e-cigarette cartridge and inhaled aerosol. Health New Zealand. 21 October 2008. (Available at: http://healthnz.co.nz/RuyanCartridgeReport21-Oct-08.pdf).

Laugesen M. Snuffing out cigarette sales and the smoking deaths epidemic. N Z Med J. 2007 Jun 15;120(1256):U2587.

Levy DT, Mumford EA, Cummings KM, Gilpin EA, Giovino G, Hyland A, Sweanor D, Warner KE. The relative risks of a low-nitrosamine smokeless tobacco product compared with smoking cigarettes: estimates of a panel of experts. Cancer Epidemiol Biomarkers Prev 2004, 13**:**2035-2042.

Nitzkin JL and Rodu B. The case for harm reduction for control of tobacco-related illness and death. AAPHP Resolution and White Paper. October 26, 2008. (Available at: http://www.aaphp.org/special/joelstobac/20081026HarmReductionResolutionAsPassedl.pdf).

Nordgren P, Ramström L. Moist snuff in Sweden–tradition and evolution. Br J Addict. 1990 Sep;85(9):1107-12.

O'Connor RJ, Hyland A, Giovino GA, Fong GT, Cummings KM. Smoker awareness of and beliefs about supposedly less-harmful tobacco products. American Journal of Preventive Medicine, 2005;29, 85-90.

Phillips CV. American Cancer Society / U.S. Centers for Disease Control study confirms the value of tobacco harm reduction: Switching from smoking to smokeless tobacco is almost as good as quitting entirely. 2007a. (Available at: http://www.tobaccoharmreduction.org/papers/phillips-henleycomments-mar07.htm).

Phillips CV. Warning: Anti-tobacco activism may be hazardous to epidemiologic science. Epidemiol Perspect Innov. 2007b Oct 22;4:13.

Phillips CV. An example of "publication bias in situ": Alguacil and Silverman's (2004) study of smokeless tobacco and pancreatic cancer. Working Paper. May 2006. (Available at: http://tobaccoharmreduction.org/papers/phillips-pbis-pancreaticcancer-may06.pdf).

Phillips CV. Commentary: Lack of scientific influences on epidemiology. Int J Epidemiol. 2008 Feb;37(1):59-64

Phillips CV. Publication bias in situ. BMC Med Res Methodol. 2004 Aug 5;4:20.

Phillips CV. Quantifying and reporting uncertainty from systematic errors. Epidemiology. 2003;14(4):459-66.

Phillips, CV, Bergen P, Guenzel B. (2006). Persistent misleading health advice about smokeless tobacco on the Web. 11th World Congress on Internet in Medicine, October 13-20, 2006, Toronto, Ontario, Canada.

Phillips CV, Heavner KK. Smokeless Tobacco: the Epidemiology and Politics of Harm. Biomarkers. 2009; 14(S1): 79-84.

Phillips CV, Rabiu D, Rodu B. Calculating the comparative mortality risk from smokeless tobacco versus smoking. American Journal of Epidemiology 2006;163:S189.

Phillips CV, Wang C, Guenzel B. You might as well smoke; the misleading and harmful public message about smokeless tobacco. BMC Public Health 2005;5:31.

Prokhorov AV, Wetter DW, Padgett D, de Moor C, Le T, Kitzman H. Spit tobacco prevention and cessation counseling: statewide survey of health care professionals and educators. Substance Use & Misuse 2002;37:171-197.

Rodu B, Cole P. The burden of mortality from smoking: comparing Sweden with other countries in the European Union. Eur J Epidemiol. 2004;19(2):129-31.

Rodu B**,** Cole P. Smokeless tobacco use and cancer of the upper respiratory tract. Oral Surgery 2002; 93: 511-515.

Rodu B, Godshall WT. Tobacco harm reduction: an alternative cessation strategy for inveterate smokers. Harm Reduct J. 2006;3:37.

Rodu B, Heavner KK. Errors and Omissions in the Study of Snuff Use and Hypertension, Letter to the Editor. J Internal Medicine; 2009.

Rodu B, Jansson C. Smokeless tobacco and oral cancer: a review of the risks and determinants. Crit Rev Oral Biol Med. 2004;15(5):252-63.

Rodu B, Phillips CV. Switching to smokeless tobacco as a smoking cessation method: evidence from the 2000 National Health Interview Survey. Harm Reduct J. 2008 May 23;5:18.

Rodu B, Stegmayr B, Nasic S, Cole P, Asplund K. Evolving patterns of tobacco use in northern Sweden. J Intern Med 2003; 253: 660–665.

Rodu B, Stegmayr B, Nasic S, Asplund K. Impact of smokeless tobacco use on smoking in northern Sweden. J Intern Med 2002; 252: 398–404.

Royal College of Physicians. Ending tobacco smoking in Britain: radical strategies for prevention and harm reduction in nicotine addiction. A report by the Tobacco Advisory Group of the Royal College of Physicians. London: RCP, 2008.

Royal College of Physicians. Harm reduction in nicotine addiction: helping people who can't quit. A report by the Tobacco Advisory Group of the Royal College of Physicians. London: RCP, 2007 (Available at: http://www.rcplondon.ac.uk/pubs/contents/bbc2aedc-87f7-4117-9ada-d7cdb21d9291.pdf)

Savitz DA, Meyer RE, Tanzer JM, Mirvish SS, Lewin F. Public health implications of smokeless tobacco use as a harm reduction strategy. Am J Public Health. 2006;96(11):1934-9.

Schelling TC. Micromotives and macrobehavior. New York: W.W. Norton & Company. 1978.

Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR). Health Effects of Smokeless Tobacco Products. 2007 (Available at: http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_009.pdf)

Siegel M. Is the tobacco control movement misrepresenting the acute cardiovascular health effects of secondhand smoke exposure? An analysis of the scientific evidence and commentary on the implications for tobacco control and public health practice. Epidemiol Perspect Innov. 2007 Oct 10;4:12.

Smith SY, Curbow B, Stillman FA. Harm perception of nicotine products in college freshmen. Nicotine &Tobacco Research 2007;9:977–982.

Spangler JG. Smokeless doesn't mean harmless: those switching from smoking to chewing tobacco could be increasing their health risks. February 28, 2007. ABC News: Cancer Resource Center. (Available at: http://abcnews.go.com/Health/CancerPreventionAndTreatment/ Story?id =2911815&page=1)

Statistical Office of the European Communities. Health status indicators from the national Health Interview Surveys (HIS), 1999-2003. (Accessed November 5, 2008) (Available at: http://epp.eurostat.ec.europa.eu).

Stegmayr B, Eliasson M, Rodu B. The decline of smoking in northern Sweden. Scand J Public Health. 2005;33(4):321-4.

Substance Abuse and Mental Health Services Administration (SAMHSA). (2006). Results from the 2005 National Survey on Drug Use and Health: National Findings (Office of Applied Studies, NSDUH Series H-30, DHHS Publication No. SMA 06-4194). Rockville, MD.

Tasker F. Quick study | Smokeless tobacco. Miami Herald. Aug. 21, 2007.

U.S. Department of Health and Human Services. (USDHHS) Oral Health in America: A Report of the Surgeon General. Rockville, MD: U.S. Department of Health and Human Services, National Institute of Dental and Craniofacial Research, National Institutes of Health, 2000.

U.S. House of Representatives , "The Lessons of "Light" and "Low Tar" Cigarettes: Without Effective Regulation, "Reduced Risk" Tobacco Products Threaten the Public Health" (February 17, 2004). Tobacco Control. Reports on Industry Activity from Outside UCSF. Paper USREP. (Available at: http://repositories.cdlib.org/tc/reports/USREP).

University of Stellenbosch Business School: Is responsible product stewardship possible within the context of harm reduction? Workshop Report May 2006. (Available at: http://www.bat.com/group/sites/uk__3mnfen.nsf/vwPagesWebLive/DO725M6L/$FILE/medMD 725MPQ.pdf?openelement).

Wiium N, Aarø LE, Hetland J. Subjective attractiveness and perceived trendiness in smoking and snus use: a study among young Norwegians. Health Educ Res. 2008 Oct 8. Epub ahead of print.

Chapter 3

Still Fiddling Whilst Cigarettes Burn?

Adrian Payne

Adapted from an article of the same name in World Tobacco, May 2008, revised and reprinted with permission of World Tobacco, Tobacco Journal International (successor to World Tobacco).

Although Nero, fifth and last Emperor of the Julio-Claudian dynasty, is often castigated for fiddling whilst Rome burnt, evidence suggests he was out of town when it happened and, besides that, at the time the fiddle had not even been invented. No such alibis are available for any modern-day European politicians who fail to recognise the current pressure building for the present European (EU) ban on Swedish-style moist snuff (snus), a particular type of oral smokeless tobacco, to be replaced by a more rational regulatory approach – one that would allow snus to be legally available in the twenty six EU countries other than Sweden, which has an exemption from the ban.

Official figures estimate that more than 500,000 people die every year in the EU as a direct or indirect consequence of smoking (European Commission 2010). Quit rates are slowing, public smoking bans have had little or no impact on smoking prevalence, and some believe that the actual number of smokers might go up rather than down in the years to come. But according to one recent study (Rodu & Cole 2009), almost 300,000 deaths in the EU would be avoided if smoking rates were as low as in Sweden, which is attributed in large part by many observers to the Swedish preference for snus instead of cigarettes. Snus is hardly a new invention; it's been used in its homeland for over two hundred years. No one, least of all tobacco companies, is saying snus is harmless, but a growing body of persuasive evidence proves that, like oral smokeless tobacco in general, snus is vastly less harmful than cigarettes. A review of all the

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estimated risks of smokeless tobacco show the total risk to health to be about 1% or 2% that of smoking (Phillips et al. 2006) and a recently published analysis that looked at all the epidemiological evidence on smokeless tobacco use and cancer found very little evidence that the use of this type of tobacco is associated with any cancer (Lee & Hamling 2009 - an excerpt appears in this volume). Yet, incredibly, the overwhelming majority of EU smokers continue to be denied access to snus, which, apart from being massively safer than cigarettes, might also be a more effective and cheaper way of self-regulating their smoking behaviour, including quitting, than pharmaceutical nicotine. With this potential in mind, it's pertinent that a very recent study in New Zealand found that both snus and a new pharmaceutical nicotine product (developed by a small company that is now a wholly owned subsidiary of a US tobacco company) were superior to nicotine gum in reducing urges to smoke and also caused fewer side effects (Caldwell et al. 2010). As the use of snus does not involve any spitting, it is also arguably much more consumer friendly than other forms of smokeless tobacco such as chewing tobacco.

But there have been some instances over the past few years where members of the European Parliament (MEPs) have indicated a positive interest in snus. Examples are its consideration by the 'MEPs Against Cancer' campaign group, and the backing of an amendment in the EU Parliament calling on the EU Commission to "investigate the health risks associated with the consumption of snus and its impact on the consumption of cigarettes" as part of its policy on workplace smoking bans (EU Resolution 2007). Furthermore, the final version of the SCENIHR (2008) report on smokeless tobacco was much more positive than the preliminary version where snus is concerned although curiously this was not reflected in the executive summary. However, the signs coming from the EU executive remain distinctly negative in that the relatively recently appointed new EU Health Commissioner has so far not deviated from the line of her predecessor: the ban on snus should be maintained. This hard-line stance is well illustrated by a press report (Helsingin Sanomat 2008) of the Commissioner apparently reprimanding Finland's Minister of European and Migration Affairs, for having imported into Finland ten boxes of snus that she bought for "friends and acquaintances" during a stop-over in Sweden on her way home from an official visit to Brussels. It is an open secret that, despite the product being banned from sale, many Finns choose to use snus rather than smoke cigarettes. Clearly this is all too much for the Finnish authorities, who now propose banning the personal importation of snus other than 30 small packets of 1gram each, or in other words, around 2 days' supply for an average snus user. Since the end result of this proposed restriction may well be a rebound rise in cigarette smoking, it is hard to imagine a more paradoxical approach to reducing the public health impact of smoking. The fact remains that considerable public health gains might be achieved by doing just the opposite, not only in Finland, but in the EU as a whole. So what are the barriers to a change in the current political stance on the EU ban, and how might they be overcome?

In the first place, there is the natural caution of governments to avoid possibly making things worse or being perceived to do so. Particularly evident when it comes to tobacco, any proposal that might be seen as deviating from the current orthodoxy of abstinence risks drawing fire from powerful anti-tobacco lobby groups and organisations, including some affiliated with the pharmaceutical industry. Harm reduction is an accepted public health policy in other areas such as illicit drugs, sex and alcohol. So why the difference when it comes to tobacco? An important clue can be found in what one MEP once said to me when he and I were discussing harm reduction and the role snus might play: *"Yes it makes sense, but it's the T-word*". Somehow the highly-charged judgemental attitude toward tobacco issues has to give way to a more pragmatic way of thinking. As the renowned thinker, Edward de Bono (2000), comments in one of his more recent books, "You can analyse the past but you have to design the future". This necessitates open and frank discussion among all stakeholders if any progress is to be made: the "tobacco wars" of the past need to be consigned to the intellectual dustbin.

The current climate in which the tobacco industry clearly needs to build credibility just to get a wider discussion going on issues like snus is an obvious hindrance to this. However, whilst there is no quick fix to the low opinion of the tobacco industry in some people's minds, it is not just some of the tobacco companies that are presently arguing for a regulatory solution that would allow the snus ban to be lifted. Some public health groups are thinking along the same lines, although for their part they would prefer to see the ban replaced by an all embracing regulatory framework covering all nicotine-containing products rather than just oral smokeless tobacco. Such a change in the regulatory landscape might incentivise mainstream tobacco companies to derive an increasing share of their profits from much less harmful products than cigarettes, surely a potential win-win-win situation for public health, the industry, and last but not least, the consumer.

Progress is further hindered because, at first glance, the ban is almost certainly seen by some as indicating that all forms of oral smokeless tobacco, not just snus, are currently illegal in the EU apart from in Sweden. Hence, even the mere suggestion of reversing an apparent 'across the board' ban might be seen as representing a sea-change in tobacco policy, with much frantic pacing in the corridors of power as a result. But closer examination of the definition of 'tobacco for oral use' in the relevant EU Directive (2001/37/EC) reveals that the ban applies to all products for oral use, *except* those intended to be smoked or chewed (emphasis added). Consequently – some might say bizarrely – many oral tobacco products, certain of them undoubtedly more harmful than snus, are legally on sale in the EU because they fall into the "chewing" category, whereas snus does not (it is held under the lip instead). Arguably, such a ban on "tobacco for oral use" is almost like banning "all alcohol for oral use" *except* alcohol intended to be swallowed. If the logic employed in the case of tobacco were applied to such a ban on

"alcohol for oral use" any attempt to reverse such a ban might be met with huge resistance. After all, alcohol, like tobacco, is labelled a Group 1 human carcinogen by the International Agency for Research on Cancer. But, a similarly convoluted definition as that used for "tobacco for oral use" might mean that beer, wine and whisky would be legal whilst mouthwashes that contained alcohol would not. Yet it's self-evident that the adverse public health impact of alcohol use comes primarily from excessive drinking rather than frequent gargling.

Granted, there are concerns that snus might be attractive to new users, and pharmaceutical nicotine is safer still. But there is evidence, at least from Sweden, that first using snus seems to lessen the likelihood of subsequent use of cigarettes (Ramstrom & Foulds 2003). That does not mean to deny that the public health message should remain that avoiding the use of any form of tobacco is the safest option. The issue of "dual use" (i.e. a consumer using both snus and cigarettes), possibly leading to greater cigarette consumption has also been raised, although more so of late in the US where snus and many other smokeless products are legal and moderately popular. Detractors claim that smokers might use snus in situations where smoking is not permitted and thus not be motivated to quit smoking entirely. But it's hard to take this claim seriously when the same might be said for pharmaceutical nicotine products, which are increasingly being marketed for temporary abstinence. Snus also offers the possibility for smokers to switch tobacco formats when children are around, and so not expose them to environmental tobacco smoke either in the home or in the car, without necessarily having to resort to a pharmaceutical nicotine product which for reasons of price and lack of availability may not be readily to hand.

Adding to the confusion is that the Swedish government itself has at times seemed ambivalent on the issue of snus. The government supports snus sales and tobacco harm reduction and in an article published in European Voice in April 2009, Sweden's trade minister Ewa Björling said *"How would the people of France react if the European Union wanted to prohibit them from selling wine in other member states on health grounds? Or their wonderful cheese, which contain the Listeria monocytogene bacteria, a well-known health risk?"* In their response to the EU Green Paper Consultation on Public Smoking, the Swedish Ministry of Health and Social Affairs drew attention to the need to take account of the Swedish experience with the use of snus as an alternative to cigarettes. However, the recent huge tax hikes on snus in Sweden created some ambiguity in the message, although the reason was primarily for raising revenue.

Also it can't have escaped the notice of Swedish and other European politicians that some of the most strident opposition to snus comes from home grown Swedish anti-tobacco activists. But many such activists acknowledge that snus is much safer than cigarettes (in contrast to many of their counterparts in other countries), and their abstinence-only agenda has not stopped the rise in

'snussing' in Sweden as opposed to smoking. Nevertheless, such opposition, and the moralistic way in which it is sometimes elaborated, does raise the stakes somewhat for politicians from other countries – not just in the EU – to show interest in the Swedish experience and challenge the effectiveness of orthodox tobacco control policies that effectively exclude harm reduction as an option.

Another barrier to change is the lack of consumer information. The overwhelming desire by governments worldwide to signal that all tobacco use is bad overrides the provision of accurate information to the consumer on the relative risks of different tobacco products, which vary by as much as 100-fold. One can understand that with no widespread access to either the product or information there is hardly a consumer groundswell in the EU countries for a change in the law on snus. Ironically, one of the mainstays of the current EU Consumer Policy Strategy is "Putting consumers in the driving seat" on the grounds that this "benefits citizens and boosts competition significantly" (Commission of the European Communities 2007). It's difficult to see how the ban on snus is compatible with either of these aspirations. If it is, one can only assume that there is only one type of car for the consumer to choose from and that the "tobacco road" only leads in one direction: towards cigarettes. Perhaps I am being too critical here; there are rumours that the EU Commission might be more flexible in relation to the current two-year period in which they regularly review the Directive, especially as regards evaluation of tobacco products that may have the potential to reduce harm.

None of the barriers described above are insurmountable; almost all revolve around better awareness, a more objective assessment of the facts, multi-stakeholder engagement and, at the end of the day, political will. Although it may not always attract the audience it deserves, the ideological battle over the snus ban continues to rage in the public health arena. But there does appear to be a glimmer of light at the end of the gladiatorial tunnel. Firstly, evidence is now emerging from Norway (a non EU country) that the increasing use of snus over the past two decades has resulted in a substantial decline in smoking in Norwegian men, paralleling the picture in Sweden. A report on this phenomenon by Dr Karl Erik Lund (2009 – excerpts reprinted in this volume) of the Norwegian Institute for Alcohol and Drug Research has led to a sea-change in the attitude of the Norwegian Directorate of Health towards snus as a quit-smoking aid. This government body reportedly now accepts and recommends that, if medicinal NRT products are unsuccessful in helping individuals to quit, then a recommendation can be made that snus is tried instead. Secondly, the United Kingdom Department of Health (2010) has recently announced a strategy for England to halve the number of smokers from 21 to 10 percent of the population by 2020. A bold aspiration, but it's questionable just how this can be achieved on the basis of similar tobacco control measures that have to all intents and purposes been an abject failure in countries such as Canada (quit rates stalling) and Ireland (smoking prevalence

increasing). What is arguably much more interesting is that almost hidden away in the pronouncement of this new strategy are the words, *" Although always encouraging smokers to break their nicotine dependence entirely, we will support smokers to: cut down their levels of smoking before completely quitting; manage their nicotine addiction, using a safer alternative product, when they are unable to smoke; dramatically reduce their health harms, and the harms to those around them, by using a safer alternative to smoking"*. On the assumption that "safer alternatives to smoking" might include smokeless tobacco, it would seem that harm reduction, at least in theory, has become an integral part of UK Department of Health tobacco control policy. Coupled with the Citizens Council of the UK National Institute Health and Clinical Excellence (2010) voting overwhelmingly in favour of the use of harm reduction as a way to reduce the dangers of smoking, this suggests that opinions may have at long last started to change for the benefit of EU cigarette smokers who are currently denied any other choice but "quit or die".

Nero may or may not have involved himself in more mundane issues when Rome was burning, but he supervised its rebuilding with fire precautions. At the time, this was a major public health advance. Today, building perhaps on recent events in Norway and the UK, MEPs have the opportunity to push for a more rational framework for tobacco regulation that would empower EU tobacco consumers outside of Sweden to choose snus as a less harmful alternative to cigarettes.[1] In view of the life-saving potential of such an initiative, this could yield public health benefits of even greater proportions. Rome certainly wasn't built (or even rebuilt) in a day, and it may take time for attitudes to change, but surely it would be a telling lesson in history if MEPs continue to give tobacco harm reduction the proverbial "thumbs down" by not overturning in some way the self-defeating ban on snus.

References

Caldwell B, Burgess C and Crane. Randomized crossover trial of the acceptability of snus, nicotine gum, and Zonnic therapy for smoking reduction in heavy smokers. J. Nicotine and Tobacco Research 12, 179-183, 2010

Citizens Council of the UK National Institute Health and Clinical Excellence. Smoking and Harm Reduction with invitation to comment, 2010. Available at: http://www.nice.org.uk/getinvolved/patientandpublicinvolvement/opportunitiestogetinvolved/citizenscouncil/reports/Citi

[1] And reduce the chance of further burning Rome (or London): While discarded snus cannot start fires, figures for the United Kingdom (Department of Communities and Local Government 2007) show that smokers' materials were the most frequent cause of accidental dwelling fire deaths, accounting for over a third of all such deaths. Yet another reason for politicians not to fiddle.

zensCouncilReportSmokingAndHarmReductionWithInvitationToComment.jsp?domedia=1&mid=756786C0-19B9-E0B5-D4CCB836FFC94B72

Commission of the European Communities : Communication from the Comission to the Council, The European Parliament and the European Economicand Social Committee. EU Policy Strategy 2007-2003 ; Empowering consumers, enhancimg their welfare, effectively protecting them. Brussels 13.03.07 COM (2007) 99 Final. Available at : http://ec.europa.eu/consumers/overview/cons_policy/doc/EN_99.pdf

De Bono, E. New Thinking for the New Millennium. Penguin Books ISBN 0-140-28776-0, 2000.

Department of Communities and Local Government: Fire Statistics, United Kingdom 2007. Available at: http://www.communities.gov.uk/publications/corporate/statistics/firestatisticsuk2007

Directive 2001/37/EC of the European Parliament and of the Council of 5th June 2001 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products. Available at: http:/ /eur-lex.europa.eu/pri/en/oj/dat/2001/l_194/l_19420010718en00260034.pdf

European Commission; Health & Consumer Protection Directorate-General. http://ec.europa.eu/health/ ph_determinants/life_style/Tobacco/ smoking_prevention_tobacco_en.htm. Accessed April 2010.

EU Resolution. Tobacco smoke: policy options at EU Committee on the Environment, Public Health and Food Safety PE 388.595 European Parliament resolution of 24 October 2007 on the Green Paper 'Towards a Europe free from tobacco smoke: policy options at EU level' (2007/2105(INI)). Available at: http://www.europarl.europa.eu/sides /getDoc.do?pubRef=-//EP//NONSGML+TA+P6-TA-2007-0471+0+DOC+WORD+V0//EN

Helsingin Sanomat International Edition – Foreign 11.12.2008: Health Commissioner reprimands Astrid Thors for snus liberation campaign . Available at: http://www.hs.fi/english/article/Health+Commissioner+reprimands+Astrid+Thors+for+isnusi+liberation+campaign/1135241921421

Lee, P. and Hamling, J. Systematic review of the relation between smokeless tobacco and cancer in Europe and North America. BMC Medicine 7, 36, 2009. Available at: http://www.biomedcentral.com/1741-7015/7/36

Lund KE. A tobacco-free society or tobacco harm reduction? Which objective is best for the remaining smokers in Scandinavia? SIRUS Report No. 6/2009, Norwegian Institute for Alcohol and Drug Research Oslo 2009. Available at: http://www.sirus.no/files/ pub/ 484/sirusrap.6.09.eng.pdf

Phillips CV, Rabiu D, Rodu B: Calculating the comparative mortality risk from smokeless tobacco versus smoking. Am J Epidemiol 2006, 163:S189. Available at http:/ /tobaccoharmreduction.org/ papers/ phillips-comparativerisk-poster-jun 06.ppt

Ramstrom L, Foulds J. Role of snus in initiation and cessation of tobacco smoking in Sweden. Tobacco Control 12: 349-359, 2003

Rodu, B. and Cole, P. Lung Cancer Mortality: comparing Sweden with other countries in the European Union. Scandinavian Journal of Public Health, 37: 481-486, 2009

SCENIHR. European Commission; Health & Consumer Protection Directorate General. Scientific Committee on Emerging and Newly Identified Health Risks. Health Effects of Smokeless Tobacco Products. 2008. Available at: http://ec.europa.eu/health/ph_risk/ risk_en.htm

United Kingdom Department of Health. A Smokefree Future: A comprehensive tobacco control strategy for England, 2010 Available at http://www.dh.gov.uk/dr_consum_dh/groups/ dh_digitalassets/@dh/@en/@ps/documents/digitalasset/dh_111748.pdf

Chapter 4

Switching to smokeless tobacco as a smoking cessation method: Evidence from the 2000 National Health Interview Survey

Brad Rodu & Carl V. Phillips

Reprinted from Harm Reduction Journal.

Editors' Note: This article falls slightly outside of the time range covered by this yearbook, but since there was no Tobacco Harm Reduction 2009 and the article is important to THR, it is included.

A common argument made against THR has been that smokers are not interested in switching to low-risk alternatives. The explosion of popularity and fanatic devotion to e-cigarettes since the time this article was published is sufficient evidence this is not true. But at the time of publication, it was commonly claimed that the only population of smokers that had ever experienced substantial switching to low-risk alternatives was Swedish men, and thus no one else wanted to engage in THR. Never mind that this is not actually an argument against trying to encourage THR. Moreover, given the effectiveness of anti-THR propaganda at convincing people that they might as well smoke, this is logically analogous to concluding that someone does not want money because he does not dig up the treasure that is buried in his back yard, but that he is completely unaware of. Nevertheless, anti-THR activists pretend to believe that this is a valid argument, and naive non-experts are often persuaded by it.

This article demonstrated that there had actually been a substantial interest in THR among American men. Some of them, it seems, figured out there was treasure in the yard despite the efforts to keep them from learning of it. Rodu stumbled across the U.S. government data from 2000 and observed that it showed that switching to smokeless tobacco had been a fairly popular and apparently extremely effective way to quit smoking. Unfortunately, as noted in the article, the next iteration of the same survey, in 2005, mysteriously dropped the question about switching to smokeless tobacco, though it had become even more relevant by then. Rodu (2010) recently observed that despite the proven scientific value of the question, and the

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professed interest of the government in data about THR, the latest version of the survey also glaringly omits the question. Clearly the U.S. government, which is almost completely captured by the anti-tobacco extremist faction in these matters, wants to avoid admitting how many of its citizens have saved themselves with THR.

<u>References</u>

Rodu, Brad (2010). The Federal Government Wants Population-Level Evidence But Refuses to Collect It. Tobacco Truth blog. http://rodutobaccotruth.blogspot.com/2010/03/federal-government-wants-population.html

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Switching to smokeless tobacco as a smoking cessation method: evidence from the 2000 National Health Interview Survey

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Abstract

Background: Although smokeless tobacco (ST) use has played a major role in the low smoking prevalence among Swedish men, there is little information at the population level about ST as a smoking cessation aid in the U.S.

Methods: We used the 2000 National Health Interview Survey to derive population estimates for the number of smokers who had tried twelve methods in their most recent quit attempt, and for the numbers and proportions who were former or current smokers at the time of the survey.

Results: An estimated 359,000 men switched to smokeless tobacco in their most recent quit attempt. This method had the highest proportion of successes among those attempting it (73%), representing 261,000 successful quitters (switchers). In comparison, the nicotine patch was used by an estimated 2.9 million men in their most recent quit attempt, and almost one million (35%) were former smokers at the time of the survey. Of the 964,000 men using nicotine gum, about 323,000 (34%) became former smokers. Of the 98,000 men who used the nicotine inhaler, 27,000 quit successfully (28%). None of the estimated 14,000 men who tried the nicotine nasal spray became former smokers.

Forty-two percent of switchers also reported quitting smoking all at once, which was higher than among former smokers who used medications (8–19%). Although 40% of switchers quit smoking less than 5 years before the survey, 21% quit over 20 years earlier. Forty-six percent of switchers were current ST users at the time of the survey.

Conclusion: Switching to ST compares very favorably with pharmaceutical nicotine as a quit-smoking aid among American men, despite the fact that few smokers know that the switch provides almost all of the health benefits of complete tobacco abstinence. The results of this study show that tobacco harm reduction is a viable cessation option for American smokers.

Background

For the past half century men in Sweden have had among the lowest rates of smoking – and the lowest rates of smoking-related illnesses – in the developed world [1]. Several recent studies have shown that the high prevalence of smokeless tobacco (ST) use among Swedish men has played a substantial role in the remarkably low smoking prevalence, mainly in two ways. First, the popularity of ST

among Swedish men suppresses smoking initiation [2-4]. More importantly, substituting ST facilitates risk reduction by allowing smokers to become smoke-free without abstaining from tobacco and nicotine altogether [3-6], but complete abstinence is still achievable [4,7]. There is now evidence that ST use has started to become popular among Swedish women as well, with similar effects on smoking rates [4,8]. Tobacco harm reduction, which actively encourages inveterate smokers to switch to safer sources of nicotine including ST, is increasingly seen as a promising public health intervention [9-11].

Like Sweden, the U.S. is one of the few Western countries with measurable ST use. According to the National Health Interview Survey (NHIS), the prevalence of ST use among men in the U.S. was 4.5% in the year 2000 [12]. However, in contrast to Sweden, there are only anecdotal reports of ST use for smoking cessation in the U.S [13]. In fact, few resources provide information about cessation at the population level, especially with respect to ST use.

One recent article briefly mentioned that the 2000 NHIS collected information on ST use as a quit-smoking method [14]. However, the information in that article was very selective (1.2% of male former smokers age 36–47 years had switched to snuff or chewing tobacco in order to quit smoking), and it provided little perspective on how switching to ST compared with other cessation methods.

In fact, the 2000 NHIS collected information on 12 methods used by smokers in their most recent quit attempt and who subsequently either quit smoking successfully (former smokers at the time of the survey) or had failed to quit (current smokers). This study uses that survey to estimate the number of male smokers in the U.S. that used various cessation methods.

Methods

We obtained the 2000 NHIS Adult Sample and Cancer Control Module data files from the Inter-University Consortium for Political and Social Research [15]. Our study focused mainly on men, because in 2000 the prevalence of ST use among women was too low (0.3%)[12] to provide reliable information. However, we generated point estimates of switching to ST among women for comparison.

Subjects who had smoked ≥ 100 cigarettes in their lifetime and who smoked every day or some days were classified as current smokers, while subjects who had smoked ≥ 100 cigarettes in their lifetime and who did not currently smoke were classified as former smokers [16]. Subjects who had used chewing tobacco or snuff 20 times in their life and who used either tobacco product every day or some days were classified as current smokeless tobacco users, while subjects who had used either product 20 times in their life and who did not currently use ST were classified as former users [12]. The cancer control module also asked subjects if they had ever used chewing tobacco or snuff.

In the cancer control module, 3,622 male current smokers were asked: "Have you ever stopped smoking for one day or longer because you were trying to quit smoking?" Those answering "no" (n = 1,325, 37%) were excluded from further analysis regarding cessation attempts. The remaining 2,297 smokers were asked: "The last time you stopped smoking, which of these methods did you use?" Subjects were prompted to "mark all [of the following methods] that apply": (1) stopped all at once (cold turkey), (2) gradually decreased the number of cigarettes smoked in a day, (3) instructions in a pamphlet or book, (4) one-on-one counseling, (5) stop-smoking clinic or program, (6) nicotine patch, (7) nicotine containing gum (such as Nicorette), (8) nicotine nasal spray, (9) nicotine inhaler, (10) Zyban/Bupropion/Wellbutrin medication (abbreviated bupropion here), (11) switched to chewing tobacco or snuff (ST here), and (12) any other method. Information about methods was obtained from 2,180 (95%) of the current smokers who had ever tried to quit. In similar fashion, 3,653 former smokers were asked: "When you stopped smoking completely, which of these methods did you use?" followed by the same choices. Information about methods was obtained from 3,548 former smokers (98%).

We identified the quit methods that are endorsed in the Clinical Practice Guideline (CPG) from the Public Health Service, U.S. Department of Health and Human Services [17]. The survey asked former smokers how long ago they had quit, and we classified these subjects into four groups based on the number of years since quitting: 0–4, 5–14, 15–19 and 20+. Because subjects could select more than one method, the results reported here are not mutually exclusive.

The 2000 NHIS employed a complex design involving stratification, clustering and multistage sampling. We used SPSS statistical software with Complex Samples (Version 15.0 for Windows) to provide estimates, based on the non-institutionalized civilian population of the U.S, of the quit-smoking methods used by the 24.0 million men who had successfully quit smoking (former smokers), and by the 15.1 million men who had attempted to quit but were unsuccessful on their last attempt (current smokers).

Results

Table 1 provides the number of male survey respondents who had used various methods in their most recent quit attempt and the percentages who were former and current

Table 1: Number of male smokers who had tried various methods in their last quit attempt, and the proportions (%) who were former and current smokers at the time of the survey, NHIS 2000

Method	Survey Count^	U.S. Population Estimate^*	% Former (95% CI)	% Current (95% CI)
Stopped all at once	4,822	32,589,195	64 (63–66)	36 (34–37)
Gradually decreased cigarettes smoked	426	2,888,019	45 (40–51)	55 (49–61)
Switched to ST	43	358,668	73 (55–86)	27 (14–45)
Pamphlet/book	11	75,522	28 (9–61)	72 (39–91)
CPG Endorsed				
Nicotine patch	393	2,881,084	35 (29–40)	65 (60–71)
Bupropion	138	1,059,982	29 (21–38)	71 (62–79)
Nicotine gum	129	963,692	34 (25–44)	66 (56–75)
Clinic/program	42	310,938	50 (33–67)	50 (33–67)
One-on-one counseling	19	106,501	43 (23–64)	57 (36–77)
Nicotine inhaler	13	98,124	28 (9–61)	72 (39–91)
Nicotine nasal spray	3	14,463	0 (0–35)+	100 (65–100)+
Any other method	182	1,295,707	63 (54–71)	37 (29–46)

^ Column total exceeds the number of current and former smokers because subjects chose multiple methods.
* Population estimates are reported to the last digit to aid in re-analysis of results. They are not intended to imply a level of precision beyond what can be achieved from the survey.
+ CI is an approximation based on the unweighted survey count.
CI – confidence interval.
ST – smokeless tobacco.
CPG – Clinical Practice Guideline, Department of Health and Human Services.

smokers at the time of the survey. An estimated 33 million men reported stopping all at once in their most recent quit attempt; almost 21 million (64%) were former smokers at the time of the survey. Of the 2.9 million men who tried to gradually decrease the number of cigarettes that they smoked, 1.3 million (45%) had become former smokers. Of the 76,000 men following instructions in a pamphlet or book, 28% (21,000) became former smokers.

An estimated 359,000 men switched to ST in their most recent quit attempt, and 73% of them (261,000) were former smokers. In comparison, only 42,000 women switched to ST in their most recent quit attempt, and only 38% of them (16,000) were former smokers at the time of the survey.

Among CPG-endorsed methods, the nicotine patch was used by the largest number of men (estimate, 2.9 million) in their most recent quit attempt, and almost 1 million (35%) were former smokers at the time of the survey. An estimated 1.1 million men used bupropion, and 308,000 (29%) were former smokers. Of the 964,000 men using nicotine gum in their most recent quit attempt, about 323,000 (34%) became former smokers. A stop-smoking clinic/program was used by an estimated 311,000 men, 50% of whom (155,000) became former smokers, the highest proportion among CPG-endorsed methods. Of the estimated 107,000 men who used one-on-one counseling, 45,000 became former smokers (43%). Of the 98,000 men who used the nicotine inhaler in their most recent quit attempt, 27,000 quit successfully (28%). None of the estimated 14,000 men who used the nicotine nasal spray became former smokers. An estimated 1.3 million men used other, unspecified methods in their most recent quit attempt, and 817,000 (63%) became former smokers.

We conducted additional analyses restricted to male former smokers who had quit by using the nicotine patch, nicotine gum, bupropion or by switching to ST (hereafter referred to as switchers), in order to provide a better comparison of these methods. For clarity, we use actual survey numbers and unweighted proportions when reporting these findings. Table 2 provides more information about the use of multiple methods by former smokers who quit by using the three medications or ST. Exclusive use of a single method was more common among patch (70%) and bupropion (64%) users than among gum users or switchers (55%). Forty-two percent of switchers also reported stopping all at once, which was higher than for bupropion (8%), nicotine patch (18%) or nicotine gum (19%). Fifteen percent of switchers reported gradually decreasing the number smoked, which was somewhat higher than for bupropion (3%) or the patch (4%). Multiple medication use was more frequent in former smokers who used gum (26%) or bupropion (21%), compared with former smokers who used the patch (10%).

Table 3 shows the distribution of former smokers who used medications or switched to ST, according to the number of years since quitting. Ninety-five percent of bupropion users quit from 0 to 4 years before the survey,

Table 2: Male former smokers who used medications or switched to ST, and their distribution (%) according to other methods used.

Method	Nicotine Patch (n = 128)	Nicotine Gum (n = 42)	Bupropion (n = 39)	Switched to ST (n = 33)
Stopped all at once	18%	19%	8%	42%
Gradually decreased cigarettes smoked	4	10	3	15
Switched to ST	1	5	0	55*
Pamphlet/book	2	5	0	3
Nicotine patch	70*	19	13	3
Bupropion	4	7	64*	0
Nicotine gum	6	55*	8	6
Clinic/program	2	0	0	0
One-on-one counseling	0	0	3	0
Nicotine inhaler	2	2	0	0
Nicotine nasal spray	0	0	0	0
Any other method	1	5	10	3

* Percentage of subjects using only that method.
n – unweighted survey count.
ST – smokeless tobacco.
Note: Column percentages total over 100% because some subjects used multiple methods.

while 87% of patch users quit up to 9 years prior to the survey. Although 47% of gum users quit 0–4 years before the survey, the remainder were distributed across the other timeframes, including 20+ years. This pattern was even more evident for switchers, 21% of whom had become former smokers 20+ years prior to the survey.

Because separate sets of survey questions were devoted to smoking cessation and smokeless tobacco use, we were able to obtain information about the latter on the 33 switchers. Fifteen of them (46%) were current ST users at the time of the survey, and twelve (36%) were former users. Of the six that were classified as never users, 3 answered yes to the question about ever use of chewing tobacco or snuff.

Discussion

Anecdotal reports have shown that individual smokers have quit smoking by switching to ST [13]. However, this study provides evidence from a nationally representative survey that switching to ST is a viable, although infrequently attempted, quit smoking method for men in the U.S. Of the 261,000 men who switched to ST and became former smokers, about 120,000 (46%) were current ST users at the time of the survey, indicating that the switch may be permanent for some. On the other hand, 54% of switchers did not use any tobacco product at the time of the survey, suggesting that switching to ST is not incompatible with a goal of achieving complete nicotine and tobacco abstinence.

This study shows that switching to ST resulted in over twice the proportion of former smokers (73%) than the nicotine patch (35%), gum (34%), inhaler (28%) or nasal spray (0%). It is important to note that these percentages do not mean that switching to ST is successful 73% of the time or that using pharmaceutical products have a 30% success rate. This type of study cannot answer the question "How often does a particular method work when tried by a particular individual?" The percentages reported for various methods in our study may be substantially different from corresponding answers to this question. The main reason for the distinction is that the NHIS only collected information about the *most recent* method used. It has no information on the methods used in previous failed quit attempts, or how many times each method was tried.

Table 3: Male former smokers who used medications or switched to ST, and their distribution (%) according to the number of years since quitting.

Years Since Quitting	Nicotine Patch (n = 128)	Nicotine Gum (n = 42)	Bupropion (n = 39)	Switched to ST (n = 33)
0–4	60%	47%	95%	40%
5–9	27	14	0	12
10–14	11	17	0	18
15–19	1	17	0	9
20+	1	5	5	21

n – unweighted survey count.
ST – smokeless tobacco

Regardless of how one interprets the proportions of former and current smokers, it is particularly striking that an estimated 359,000 smokers tried to stop smoking by switching to ST – and over a quarter of a million became former smokers – especially since Americans are largely misinformed about the health risks of ST use [1,18]. For example, in 2005 a survey of 2,028 adult U.S. smokers found that only 11% correctly believed that ST products are less hazardous than cigarettes [19]. In another survey, 82% of U.S. smokers incorrectly believed that chewing tobacco is just as likely to cause cancer as smoking cigarettes [20]. These findings are in direct contrast to the general agreement among tobacco research and policy experts that ST use is far less hazardous than smoking. Although estimates are not precise, ST use likely confers only 0.1% to 10% of the risks of smoking [21-23].

It is safe to assume that rates of switching would increase substantially if smokers knew that switching to ST achieves almost all of the health benefits as quitting tobacco and nicotine altogether [1]. In 2000 the most likely beneficiaries of this knowledge would have been the 1.1 million American men who were dual users of both cigarettes and ST products. These men were already comfortable consuming nicotine from both combusted and smoke-free tobacco. With the knowledge that ST products were 100 times less hazardous than cigarettes, it is conceivable that most would have chosen exclusive use of ST, resulting in a decline of 1.2 percentage points in national adult male smoking prevalence.

Comparison of ST and pharmaceutical nicotine in a regulatory, legal and social context further suggests that the potential of ST as a cessation aid has been under-realized. Nicotine gum and the nicotine patch have been available since 1984 and 1992 respectively [24], and both achieved non-prescription status in 1996, when the manufacturer conducted a large promotional campaign in conjunction with the American Cancer Society Great American Smokeout [25]. In 1999 an estimated $200 million was spent on print and broadcast advertising for smoking cessation products [26].

In contrast to the heavy promotion and advertising of pharmaceutical nicotine products for smoking cessation in the late 1990s, the environment for ST products was quite negative. A ban on broadcast advertising of ST had been established as early as 1986 [27], so the estimated $170 million spent by manufacturers in 1999 was restricted largely to print media and other forms of advertising and promotion [28]. Not only were manufacturers effectively prohibited from offering ST products as reduced-risk options for smokers, a counter-marketing program was launched by congressional legislation in 1986, in the form of a mandatory warning on every third package of ST sold in the U.S.: "This product is not a safe alternative to cigarettes" [27]. In addition, major efforts have been made by the American tobacco control community to impede any widespread transition from cigarettes to ST [1,18]. Despite the pro-pharmaceutical and anti-ST climate, an estimated 261,000 men had used smokeless tobacco to quit smoking by the year 2000. While this number is lower than the number who had successfully used the nicotine patch (about one million), it is comparable to the number who had successfully used either nicotine gum or antidepressants, and far more than the number who were successful with other pharmaceutical nicotine products.

We expected to find evidence in later surveys that increasing awareness of the low risk profile of modern, socially acceptable ST products would have resulted in heightened popularity for this cessation method. Unfortunately, no information on switching to ST is available in subsequent NHIS surveys, because that option was removed when the Cancer Control module appeared again in the 2005 NHIS [29]. It is possible that individuals responsible for designing the module expected an increase in switching as well, and that they chose to not find out.

A major strength of this study is that it is based on the survey series that the Centers for Disease Control and Prevention (CDC) uses for national smoking prevalence estimates [16]. In fact, our findings were produced from the very same dataset (and specific survey questions) used by the American Cancer Society in a recent study of smoking cessation treatments used by American smokers [30]. Thus, we were surprised when a senior Cancer Society scientist, who was a coauthor on that study [30], stated emphatically that "There is no evidence that smokers will switch to ST products and give up smoking" [31]. Although the Cancer Society has not endorsed tobacco harm reduction, its scientists certainly know that there is unequivocal evidence from the 2000 NHIS survey that 261,000 smokers have switched to ST products in order to quit smoking.

Studies based on survey data are limited by the nature of the survey instrument and the quality of self-reported information. With respect to this survey, current and former smokers were encouraged to choose multiple methods that were not mutually exclusive, which creates some difficulty in reporting the results and may be confusing for some readers. For example, "Stopped all at once (cold turkey)" was so frequently chosen (with or without other methods) – as would be expected – that all other methods pale in direct comparison. That comparison is certainly confusing, but it may also be inappropriate, since the cold turkey response is orthogonal to the other methods. However, excluding this item would have elim-

inated information that some readers consider useful. Our goal was to present a complete picture of the data, including how frequently all of the methods were chosen.

We noted some inconsistencies among former smokers using medications and switching to ST. For example, among the 128 former smokers who used the nicotine patch, 16 reported that they quit before the patch became available. Two subjects using nicotine gum and two using bupropion had similar inconsistencies. In addition, for three subjects who switched to ST, their responses to other questions indicated no ST use. It is not possible to resolve these irregularities in a systematic manner, but they may affect the certainty of the estimates.

Conclusion

This study documents that switching to ST compares very favorably with pharmaceutical nicotine as a quit-smoking aid among American men, despite the fact that few smokers know that the switch provides almost all of the health benefits of complete tobacco abstinence. As long as American smokers are misinformed about the comparative risks of ST and cigarettes, most will not consider trying to switch, or will do so only reluctantly. A social and public health environment that honestly informs smokers about comparative risks would provide many more smokers with the opportunity to lead longer and healthier lives.

Competing interests

This study was supported by unrestricted grants from smokeless tobacco manufacturers to the University of Louisville (US Smokeless Tobacco Company and Swedish Match AB) and to the University of Alberta (USSTC). The terms of the grants assure that the grantors are unaware of this study, and thus had no scientific input or other influence with respect to its design, analysis, interpretation or preparation of the manuscript.

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Authors' contributions

Both authors made substantive contributions to all aspects of this study, and both approve the final manuscript.

References

1. Rodu B, Godshall WT: **Tobacco harm reduction: an alternative cessation strategy for inveterate smokers.** *Harm Reduction J* 2006, **3:**37 [http://www.harmreductionjournal.com/content/3/1/37]. Open access, (Accessed May 5, 2008)
2. Rodu B, Nasic S, Cole P: **Tobacco use among Swedish schoolchildren.** *Tob Control* 2005, **14:**405-408.
3. Furberg H, Bulik CM, Lerman C, Lichtenstein P, Pedersen NL, Sullivan PF: **Is Swedish snus associated with smoking initiation or smoking cessation?** *Tob Control* 2005, **14:**422-424.
4. Ramström LM, Foulds J: **Role of snus in initiation and cessation of tobacco smoking in Sweden.** *Tob Control* 2006, **15:**210-214.
5. Rodu B, Stegmayr B, Nasic S, Asplund K: **Impact of smokeless tobacco use on smoking in northern Sweden.** *J Intern Med* 2002, **252(5):**398-404.
6. Rodu B, Stegmayr B, Nasic S, Cole P, Asplund K: **Evolving patterns of tobacco use in northern Sweden.** *J Intern Med* 2003, **253(6):**660-665.
7. Furberg H, Lichtenstein P, Pedersen NL, Bulik C, Sullivan PF: **Cigarettes and oral snuff use in Sweden: prevalence and transitions.** *Addiction* 2006, **101:**1509-1515.
8. Stegmayr B, Eliasson M, Rodu B: **The decline of smoking in northern Sweden.** *Scand J Public Health* 2005, **33:**321-324.
9. Gartner CE, Hall WD, Vos T, Bertram MY, Wallace AL, Lim SS: **Assessment of Swedish snus for tobacco harm reduction: an epidemiological modeling study.** *Lancet* 2007, **369:**2010-2014.
10. Sweanor D, Alcabes P, Drucker E: **Tobacco harm reduction: how rational public policy could transform a pandemic.** *Int J Drug Policy* 2007, **18:**70-74.
11. Royal College of Physicians of London: **Harm reduction in nicotine addiction: helping people who can't quit.** *London* 2007 [http://www.rcplondon.ac.uk/pubs/brochure.aspx?e=234]. (Accessed May 5, 2008)
12. Nelson DE, Mowery P, Tomar S, Marcus S, Giovino G, Zhao L: **Trends in smokeless tobacco use among adults and adolescents in the United States.** *Am J Public Health* 2006, **96:**897-905.
13. Tilashalski K, Lozano K, Rodu B: **Modified tobacco use as a risk reduction strategy.** *J Psych Drugs* 1995, **27:**173-175.
14. Tomar SL: **Epidemiologic perspectives on smokeless tobacco marketing and population harm.** *Am J Prev Med* 2007, **33:**S387-97.
15. U.S. Department of Health and Human Services: **National Center for Health Statistics. National Health Interview Surveys, [Computer file].** Hyattsville, MD: U.S. Dept. of Health and Human Services, National Center for Health Statistics [producer], Ann Arbor, MI: Inter-university Consortium for Political and Social Research [distributor].; 2000.
16. Centers for Disease Control and Prevention: **Cigarette smoking among adults – United States, 2004.** *Morbidity and Mortality Weekly Report* 2005, **54:**1121-1124.
17. Fiore MC, Bailey WC, Cohen SJ, Dorfman SF, Goldstein MG, Gritz ER, Heyman RB, Jaen CR, Kottke TE, Lando HA, Mecklenburg RE, Mullen PD, Nett LM, Robinson L, Stitzer ML, Tommasello AC, Villejo L, Wewers ME: **Treating Tobacco Use and Dependence.** *Clinical Practice Guideline, Rockville, MD: U.S. Department of Health and Human Services. Public Health Service* 2000.
18. Phillips CV, Wang C, Guenzel B: **You might as well smoke; the misleading and harmful public health message about smokeless tobacco.** *BMC Public Health* 2005, **5:**31 [http://www.biomedcentral.com/1471-2458/5/31]. (Accessed May 5, 2008)
19. O'Connor RJ, Hyland A, Giovino G, Fong GT, Cummings KM: **Smoker awareness of and beliefs about supposedly less harmful tobacco products.** *Am J Prev Med* 2005, **29:**85-90.
20. Cummings KM: **Informing Consumers about the Relative Health Risks of Different Nicotine Delivery Products, presented at the National Conference on Tobacco or Health, New Orleans, LA.** 2001.
21. Royal College of Physicians of London: **Protecting Smokers, Saving Lives.** *London* 2002 [http://www.rcplondon.ac.uk/pubs/books/protsmokers/index.asp]. (Accessed May 5, 2008)
22. Levy DT, Mumford EA, Cummings KM, Gilpin EA, Giovino G, Hyland A, Sweanor D, Warner KE: **The relative risks of a low-nitrosamine smokeless tobacco product compared with smoking cigarettes: estimates of a panel of experts.** *Cancer Epidemiol Biomarkers Prev* 2004, **13:**2035-2042.
23. Phillips CV, Rabiu D, Rodu B: **Calculating the comparative mortality risk from smokeless tobacco versus smoking.** *Congress of Epidemiology* . June 23, 2006
24. Cummings KM, Hyland A: **Impact of nicotine replacement therapy on smoking behavior.** *Ann Rev Public Health* 2005, **26:**583-599.
25. Burton SL, Kemper KE, Baxter TA, Shiffman S, Gitchell J, Currence C: **Impact of Promotion of the Great American Smokeout and Availability of Over-the-Counter Nicotine Medications, 1996.** *Morbidity and Mortality Weekly Report* 1997, **46:**867-869.

26. Avery RJ, Kenkel DS, Lillard DR, Mathios AD: **Regulating advertisements: the case of smoking cessation products.** *National Bureau of Economic Research, Working paper no. 12001* 2006.
27. Masironi R: **WHO Strategies to curb smokeless tobacco: a global perspective.** *Smokeless Tobacco or Health: An International Perspective. U.S. Department of Health and Human Services, NIH Publication No. 93-3461* 1993:315-322.
28. U.S. Federal Trade Commission: **Smokeless tobacco report for the years 2000 and 2001.** 2003 [http://www.ftc.gov/os/2003/08/2k2k1smokeless.pdf]. (Accessed May 5, 2008)
29. **U.S. NHIS Questionnaire** 2005 [ftp://ftp.cdc.gov/pub/Health_Statistics/NCHS/Survey_Questionnaires/NHIS/2005/English/QCANCER.pdf]. (Accessed May 5, 2008)
30. Cokkinides VE, Ward E, Jemal A, Thun MJ: **Under-use of smoking-cessation treatments: results from the National Health Interview Survey, 2000.** *Am J Prev Med* 2005, **28:**119-122.
31. American Cancer Society: **Smokeless tobacco: harm reduction debatable.** *CA: Cancer J Clin* 2008, **58:**4-6 [http://caonline.amcancersoc.org/cgi/content/full/58/1/4]. (Accessed May 5, 2008)

Chapter 5

Why do anti-smoking groups oppose tobacco harm reduction? A historical perspective

Christopher Snowdon

For five centuries, opposition to tobacco use has been founded on moral or religious objections to vice as well as concerns over health. Under morality, we might include the claim that smoking was ungodly and sinful, that it was decadent and depraved, and that it was a habit suited only to "Red Indians", Jews, blacks, Turks, Spaniards, or whichever racial group was out of favour at the time (James I 1604, Proctor 1999; New York Times 1893).

Under health, we could include virtually every disease in the medical textbook. Even confining ourselves to early modern Europe, we find references to deafness, blindness, hysteria, dyspepsia, impotence, infertility, paralysis and brain damage. The evidence underpinning these fears was, for the greater part of tobacco's history, anecdotal at best, but even from the earliest days those who opposed tobacco did so on grounds that often had nothing to do with health.

From around 1700, rather by accident, the upper classes of England and France engaged in a spontaneous experiment in tobacco harm reduction. Snuff came into fashion and smoking began to die out, amongst the upper classes at least. This should have pacified tobacco's opponents for three reasons. Snuff did not fill the air with smoke, it did not carry the risk of starting a fire and it did not appear to be injurious to health. And yet it did not pacify them. Snuff was attacked as a vice – and an addictive vice at that – just as pipes had been (Clay 1854). In the United States, similar moral objections were raised against chewing tobacco (Tate 1999, p.19).

Today, the issue of health has become the dominant feature of the anti-tobacco movement, but moral and even puritanical sentiments are still in evidence. In their efforts to ban smoking outdoors, Action on Smoking and Health (2006) said such a ban was justified to prevent smokers

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from setting a bad example to others and listed smoking alongside swearing, drinking, gambling and the wearing of "scanty attire" as examples of unacceptable activities. Although smoking *al fresco* could not seriously be viewed as harmful to the health of others, it was still seen as sinful and offensive to the eye.

Similarly, Americans for Nonsmokers' Rights (2010) – in a press release titled "Electronic Cigarettes are NOT a safe alternative!" – criticised the e-cigarette specifically because it mimics the act of smoking and because it contains nicotine. Only pharmaceutical nicotine products escape criticism, partly because they are marketed as a medicinal cure for a "disease" and partly because they administer nicotine without providing pleasure. This has led to a somewhat inconsistent view of nicotine, described as being perfectly safe in pharmaceutical products but highly toxic in e-cigarettes, snus and other tobacco products. The U.S. Environmental Protection Agency (2008) describes it as "acutely toxic (Category 1) by all routes of exposure (oral, dermal and inhalation)" while the U.K. Medicine and Healthcare Products Regulatory Agency (2010) says that "nicotine, while addictive, is actually a very safe drug."

Although the amount of nicotine delivered is comparable in all cases, the drug's reputation as poison or medicine depends on how it is delivered and who is manufacturing it. Three industries are currently fighting for the nicotine market: the tobacco industry, the pharmaceutical industry and the e-cigarette industry. Each has a financial motive for denigrating alternative nicotine products. In the case of the pharmaceutical industry, this financial motive is shared by the various anti-smoking groups it directly and indirectly subsidizes.

This three-sided nicotine war is without historical precedent. Efforts to suppress alternative and/or safer tobacco products have traditionally been the preserve of the tobacco industry and the anti-smoking lobby. Initial opposition to cigarettes in the late 19th century came primarily from makers of chewing tobacco, pipe tobacco and cigars. It was from them that groups like the Anti-Cigarette League borrowed rumours of cigarettes being made in leper colonies and spiked with opium.

Attempts to bring a safer cigarette to market in the 1970s – in particular, by Liggett and Myers – were partly thwarted by rival tobacco companies closing ranks on those who, by introducing a safer alternative, would be implicating all existing brands as dangerous (Derthick 2002; Kluger 1996). In this, the tobacco companies found themselves on the same side as the anti-smoking movement, albeit for different reasons. By 1980, the consensus view amongst public health professionals was that any attempt to produce safer tobacco products would slow the quit rate. Dr Gio Gori's Less Hazardous Cigarette project, which was brought to a halt in 1978, was the last attempt to find a technological solution to a problem that many felt should be solved by behaviour modification (Gori & Bock, 1980). Thereafter, the doctrine of total abstinence took

hold. The prevailing view was that the more dangerous tobacco was (or was perceived to be), the more people would quit. It consciously withheld safer alternatives from the individual in a bid to accelerate the quit-rate in the population. Reflecting on the new doctrine, Dr Gori said: "The new policy was – smokers shouldn't be helped, smokers should be eliminated" (Otolski 1994).

At a time when governments were giving free syringes to heroin and free condoms to children, the "quit or die" approach to tobacco raised ethical questions, and was only possible by an almost evangelical faith in the smoke-free world to come. Total abstinence had previously been seen as a pipe-dream, but as the anti-smoking movement gathered pace in the 1970s, activists and governments came to believe it was possible within a generation. This was in keeping with earlier reform movements, which invariably set their eyes on prohibition sooner or later. Just as the American temperance movement set out with a message of moderation and ended with complete prohibition, so the Anti-Cigarette League of the early 20th century went from a campaign that solely targeted "coffin nails" to fighting cigars, pipes and chewing tobacco (which were the "less hazardous" alternatives of its day) (Tate 1999, pp.39-64). The Anti-Cigarette League's absolutist slogan "A Smokeless America by 1925" bears an uncanny resemblance to the Surgeon General's equally ambitious slogan of 1986: "A Smoke-Free America by 2000 AD". Both serve as reminders that bringing about total abstinence is easier said than done.

Four decades later, the "quit or die" approach survives. Its political legacy can be seen in Britain's ban on Skoal Bandits in the 1980s and Australia's recent ban on e-cigarettes. It can be seen in Finland's pledge to ban any safer tobacco product that might appear in the future. It can be seen in the ban on snus that is enforced in every EU country but Sweden. Its impact on the health of populations, however, can only be seen by comparing Sweden's significantly lower smoking rate and lung cancer rate to its EU neighbours.

In summary, modern anti-smoking activists oppose tobacco harm reduction because, like earlier reformers, they tend to be idealists. Even those who set out as pragmatists are liable to becoming more zealous once they become emerged in a worthy cause. Few activist groups of any hue avoid 'mission creep' for long. For the anti-smoking movement, the allure of prohibition – the only logical conclusion to its cause – could not be long resisted. To the anti-tobacco campaigner, the appearance of new tobacco products, even if demonstrably safer, innately feels like a step backwards. Their prohibition, on the other hand, feels perfectly natural and, since most alternative nicotine devices are niche products with relatively few users, they can be nipped in the bud with minimal resistance.

Tobacco harm reduction does not offer a Utopia, nor does it promise to rid the world of an addictive vice that some find intolerable. Nor, for that matter, does it hold the promise of

destroying the tobacco industry. This is the stated goal of the most fervent activists, who have long convinced themselves that getting rid of the industry will get rid of the problem.

The future offered by harm reduction is not as tidy or pure as the vision offered by the idealists. Convinced that a tobacco-free world is within reach, a world of reduced harm seems pitifully unambitious. History provides many examples of anti-smoking crusades built on similar beliefs collapsing under the weight of their own hubris, and no examples to the contrary. If they are aware of this inauspicious track record at all they would, I fear, reply with those famous last words: "This time it will be different."

References

Action on Smoking and Health (USA). Reasons for banning smoking in certain public outdoor places, www.ash.org, undated (circa 2006)

Americans for Nonsmokers' Rights. Electronic Cigarettes are NOT a safe alternative! http://www.no-smoke.org/learnmore.php?id=645, accessed 13 February 2010.

Clay W. O tempora! O mores! Or a word to the wise on the use of tobacco and snuff, Houlston & Stoneman, 1854.

Derthick M. 'The lawyers did it: The cigarette manufacturers' policy toward smoking and health', Legality and Community, ed. Kagan et al, Rowan & Littlefield, 2002; pp. 281-295.

Gori G, Bock FG (eds.). Banbury report: A safe cigarette?, Cold Spring Harbour Laboratory, 1980.

James I. A Counter-blaste to Tobacco 1604.

Kluger R. Ashes to Ashes, Knopf, 1996; pp. 451-60.

Medicine and Healthcare Products Regulatory Agency (MHRA). Consultation Letter MLX 364, Department of Health, 2 January 2010.

New York Times. Editorial, 15 June 1893.

Otolski G. Cigarette firms found unlikely ally in adversary. Courier-Journal, 11 August 1994, p. A1.

Proctor R. The Nazi War on Cancer, Princeton University Press, 1999.

Tate C. Cigarette Wars: The Triumph of the Little White Slaver, O.U.P., 1999.

U.S. Environmental Protection Agency. Reregistration eligibility decision for nicotine, EPA, OPP-2005-0231, March 2008, p. 11.

Chapter 6

A tobacco-free society or tobacco harm reduction? Which objective is best for the remaining smokers in Scandinavia? (excerpts)

Karl Erik Lund

Reprinted with the permission of the author from the Norwegian Institute for Alcohol and Drug Research Sirus Report no 6 (2009) (Full report at: http://hera.helsebiblioteket.no/hera/bitstream/10143/84913/1/sirusrap.6.09.eng.pdf).

Editors' Note: These excerpts are from an important new contribution to the THR discussion. Most of us involved in THR were surprised when we heard that optimistic and pro-THR reports were coming out of Norway recently, and appreciated it when an English-language version of this document was produced. (Interested readers can find the full 85 pages, including the references which do not appear in this excerpt, at the URL above.)

This is a insightful document at many levels. Though it appears intended to stay closer to the center of the debate than the positions we typically support, it is difficult for us to find many major points of disagreement. Without seeming to attack opposing positions, and yet challenging many of their flaws, Lund smoothly makes the case for THR in terms of practical arguments about how the future might look. The implication of the fact that all imagined non-THR anti-smoking measures have been implemented is particularly well-argued. This document feels very much in the style of the comprehensive reports from government or quasi-governmental organizations that reluctantly acknowledge the value of THR but then bury that information behind manufactured doubt and reaffirmation of abstinence-only-based policies; this report carries the analysis to its logical conclusions.

Probably our major point of disagreement is about the very nature of the positions in the worldly debate. Lund categorizes pro-THR actors as "pragmatists" who apparently only care about health benefits and "proponents" who think there are no downsides to THR and whose use of science is to disguise "agitation" (the third pro-THR category, industry, is really orthogonal to these). Neither of those descriptions seems to apply to us or anyone else whose support for THR goes beyond its health benefits to include welfare and human rights. On the anti-THR side are "skeptics" who oppose THR because they think we need more data. We would argue that

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this characterization demands that the author identify at least a few people or organizations who fit that "proponent" label (who dismiss science and believe there are no costs) or skeptics who actually understand the current evidence but have identified the particular additional knowledge (not vague moving targets) that stands between them and believing that educating people about THR is beneficial. We cannot identify anyone fitting either of those descriptions.

Of course, it is easy to understand the urge to frame an attempt to persuade someone in terms of "you and I are reasonable people, and I like everything you have done and am sure we have the same goals, so we just need to work out our different interpretations of the evidence and ignore all those crazy people who have stronger views in either direction." Lund's characterization of his own and the prevailing political position in the introduction (not included here) is: "I have taken a conditional supportive stance to harm reduction - but only as a supplement to the traditional measures to prevent the use of tobacco. Even though harm-reduction ideology has great support in relation to other types of risk behavior, such as the use of drugs, most authoritative health bodies in Scandinavia are still sceptical to its use in the area of tobacco. However, as the debate has developed, resistance has become weaker, and in Norway, the health authorities have recently opened up for health care personnel in individual cases to advise inveterate smokers to use low-nitrosamine smokeless tobacco (Swedish snus)." It is our impression that the strategy Lund seems to be pursuing would not have much impact on reducing resistance to THR in the Anglophone world, but perhaps it will be a successful strategy elsewhere.

Karl Erik Lund

A tobacco-free society or tobacco harm reduction?

Which objective is best for the remaining smokers in Scandinavia?

SIRUS-Report no. 6/2009
Norwegian Institute for Alcohol and Drug Research
Oslo 2009

Summary

Harm reduction means that cigarette smokers who are either unable or unwilling to stop using nicotine products are encouraged to switch to nicotine products with much lower health risk.

Harm reduction has previously been debated in various forms in the area of tobacco when filter cigarettes were introduced in the 1960s, and when so-called «light cigarettes» with reduced tar and carbon monoxide content were introduced in the 1980s. However, epidemiological research has shown that the health benefits associated with switching to such products have been small – perhaps even non-existent. The result of such previous negative experience is that the health authorities in most countries have shown very little enthusiasm for new preventive strategies that include switching to tobacco and nicotine products that are less damaging.

However, the current debate about harm reduction is different from the previous debates in that this time real risk-reducing products (snus, medicinal nicotine products and other non-medicinal nicotine products) are being discussed. There is consensus that a switch from cigarettes to such products would involve a significant reduction in risk for individual smokers. The reason for current scepticism is primarily uncertainty about what a harm reduction strategy could lead to at the population level. In addition, the established measures that the authorities in Scandinavia have introduced to reduce smoking have been very effective, and why not just intensify their use? If snus were added to the arsenal of harm-reducing products, for example, this would go against the stated aim of the authorities to achieve a totally tobacco-free society.

Some of the important areas that are discussed in this report:

- Despite the fact that measures to prevent smoking have been effective, and the proportion of smokers is decreasing in Scandinavia, the need for harm reduction measures has become greater because:

  - There is an imbalance between the motive to stop smoking that the authorities have created with campaigns, duties, restrictions etc, and the help that is offered to people who are trying to stop smoking. Nicotine replacement products are used to a small extent. The amount of assistance provided by health care personnel is moderate. In addition, the effect of nicotine replacement products and the effect of interventions provided by doctors is very limited.
  - The remaining group of smokers increasingly contains a higher proportion of people with social, mental and demographic characteristics associated with reduced ability to stop smoking.
  - For twenty years there has been a social gradient in smoking pattern in Scandinavia. The search for measures that are tailor-made for smokers with specific characteristics, for example short education, has been going on for a long time. Literature reviews have not identified measures that the authorities could implement in order make the social gradient in smoking pattern less steep.
  - In Scandinavia, nearly all the political measures recommended by WHO for reducing smoking have already been implemented. There is probably little potential for further reduction by using publically-regulated control of tobacco. Despite the fact that tobacco control measures are utilized to such a degree, the proportion of deaths due to smoking among adults is still very high.
  - Intensifying the existing measures against smoking that have been effective up to now would probably give only a moderate return (diminishing marginal returns).
  - Cigarette smoking is ideal for a harm reduction strategy, because the substance that causes addiction – nicotine – is not the cause of the health risk. People smoke because of nicotine, but die from tobacco smoke. Much less hazardous nicotine products are available.
- Harm reduction is an obvious strategy for a many other areas of risk. The reason why the debate about harm reduction in the area of tobacco has come later, is probably related to the widespread belief that it is possible to achieve a tobacco-free society.
- If the authorities in the Scandinavian countries wish to even out future social differences in health in the population, a harm reduction strategy in the field of tobacco may be appropriate.
- In order for harm reduction to be successful, consumers must receive correct information about the relative health risks of different types of nicotine products. Today, both smokers and general practitioners are misinformed.

- The ban that exists in several Scandinavian countries against «new types of tobacco and nicotine products» can function today as a barrier to effective harm reduction in the remaining segment of smokers, and should be replaced with regulations that control «new» nicotine products.
- Production of nicotine products that have higher potential for use than currently available medicinal nicotine products, and that is more effective in stopping smoking, should be stimulated.
- Harm reduction policy must be made legitimate by the authorities. It is clearly a disadvantage and a hindrance for harm reduction if the snus industry is the most visible proponents of harm reduction.

Snus as a harm-reducing alternative:

- The health authorities in Norway and Sweden – where sale of snus is allowed – provide information about the health risks associated with the use of snus, but do not inform smokers about the health benefits that can be achieved by switching from cigarettes to snus. At worst, this can mean that nicotine-addicts remain smokers with no motive to try a harm-reducing alternative.
- The cigarette industry are in the process of buying themselves into the snus industry, and wish to sell snus in addition to – and not instead of – cigarettes. They regard snus as a so-called «bridging product» that can be used in social arenas where there are smoking restrictions in order to keep smokers dependent on nicotine (nicotine maintenance policy). In addition, there are several examples from Scandinavia that the snus industry are carrying out innovative product development with a view to recruiting young people of both sexes.
- Reviews of the scientific literature show that snus is substantially less hazardous than cigarettes. The magnitude of the overall reduction in hazard has been estimated to at least 90 %.
- Much research remains to be done before we know the precise effects of snus from a public health perspective. Several issues are not possible to research, but the pattern of use of snus in Sweden and Norway suggests that availability of snus must have a positive net effect on public health. This can be an argument for withdrawing the ban on snus in the EU, but it can also be argued that the pattern of use observed in Scandinavia not necessarily will occur in other countries.
- There is little empirical data from Scandinavia to support the hypothesis that snus increases the risk of starting to smoke. There is some empirical data to support the hypothesis that snus reduces the risk of starting to smoke.

- There are no randomized controlled studies in which the effect of snus on smoking cessation has been measured. Observational data from Scandinavia are consistent in demonstrating that snus leads to an increase in the quit rate for smoking. Self-reports from Norwegian quitters indicates that the effect is greater than the effect of nicotine replacement products.
- An argument for including snus in the arsenal of harm-reducing products is that it has great potential for use in marginalized smoking populations, which include people who have high immunity for traditional preventive measures for smoking.

The structure of the report

The report starts with a discussion of what should be the overall aim of future tobacco policy in countries with an advanced tobacco epidemic: a tobacco-free society or reduction in tobacco-related diseases? Does striving towards a tobacco-free society hinder harm-reducing measures that could save lives?

In the report, the harm reduction debate is presented. The difficult climate for discussion, resulting from harm reduction being an ethical issue, is discussed. In a society where tobacco has become «our worst enemy», that everyone can be united in fighting against, it is easy to regard harm reduction as an untimely course of action, and to dismiss it by labelling it as tobacco liberalism.

I then show how harm reduction will become increasingly relevant and appropriate in Scandinavia, among other things because political measures can have attained their full effect, while levels of harm remain high. Harm reduction may also become appropriate because the group of remaining smokers in Scandinavia will consist of more and more people with the psycho-social characteristics of people who are difficult to influence just by more intensive use of the traditional preventive measures against tobacco. I argue that harm reduction will be an appropriate measure for achieving the aim of the authorities to reduce inequalities in health between different social groups.

Harm reduction may also become appropriate because there is an imbalance between the strong desire for smokers to stop smoking that the authorities have created (with campaigns, restrictions and duties), and the moderate supply and mediocre effect of the help that is offered to people who are trying to stop smoking. We also discuss how biased information about the relative health risks associated with the use of different tobacco products has created misinformed consumers who are unable to make optimal choices.

1 A tobacco-free society or harm reduction?

The aim of this report is to stimulate a debate about whether *harm reduction* should be included in the arsenal of preventive measures for smoking. If this was the case, harm reduction ideology would challenge the traditional paradigm for control of tobacco, which briefly involves eliminating all use of tobacco. In the light of the psycho-social and demographic characteristics of today's smokers, we shall pose the question of whether a tobacco-free society is a realistic and sensible aim in the short term. Is elimination of all use of tobacco – «the null vision» – particularly appropriate if the real aim is to prevent tobacco-related illness and death in the remaining group of daily smokers? Has *the best solution* (a tobacco-free society) become *our worst enemy* (reduction in tobacco-related mortality)? Instead, should the authorities accept harm reduction, such as, for example, in the area of drugs.

1.1 Definition of harm reduction

In a report published in 2008, the American Association of Public Health Physicians dealt with the application of the principle of harm reduction in the field of tobacco, and proposed the following definition of harm reduction:

«Harm reduction is taken to mean encouraging and enabling smokers to reduce their risk of tobacco-related illness and death by switching to less hazardous tobacco products. This switch could be short-term or long-term, partial or full, with the understanding that every time an alternative tobacco product is used in place of a cigarette, risk of tobacco-related illness and death is reduced» (AAPHP 2008: 2).

The Institute of Medicine in the USA dealt with harm reduction in the book «*Clearing the Smoke. Assessing the Science Base for Tobacco Harm Reduction*» from 2001, and defined the concept in the following way:

«A product is harm-reducing if it lowers total tobacco-related mortality and morbidity even though use of that product may involve continued exposure to tobacco-related toxicants» (IM 2001: 2).

To an increasing degree, tobacco research has been concerned with the effects that harm reduction could have. In the article *«Charting the Science of the Future. Where Tobacco-Control Research Must Go»*, the eminent American researcher Kenneth Warner maintains that the harm reduction debate is the most important thing that has happened during his 30 years as a tobacco researcher (Warner 2007). But before harm reduction can be included as a strategy, there are several issues that must be clarified:

«Should products less hazardous than cigarettes, including tobacco products, be promoted as alternatives to smoking for smokers who are unable, or unwilling, to quit? If, so, is it possible to target promotion so finely, thereby avoiding encouraging others to use a product, still risky, when otherwise they would have abstained entirely? What kinds of products should be considered as acceptable members of the tobacco harm reduction arsenal? For example, is it advisable to promote low-nitrosamine smokeless tobacco products (snus) as much less hazardous than cigarettes (which they certainly are)? How can the population impact that will follow from the introduction and promotion of ostensibly less hazardous products be assessed? What surveillance system could evaluate use patterns, and ultimately health consequences, when confronted with possibly a dozen or more qualitatively different types of products and the hundreds of mixed use patterns that would emerge? Indeed, short of waiting 30 years for the (possibly inadequate) epidemiological evidence, how can risk reduction potential be evaluated scientifically?

The questions are endless, with none of them leading to easy resolution. Yet, «Harm Reduction» may be an important wave of the future. Will it join prevention, cessation and protection of others as the fourth pillar of comprehensive tobacco control?» (Warner 2007: 315 – 6).

1.2 What does harm reduction involve for the area of tobacco?

In Scandinavia, the harm reduction debate began for the area of tobacco after having its counterpart in a series of other areas of risk behaviour, including drug use (handing out syringes, premises for injection of drugs, methadone projects, heroin prescribed by doctors), use of alcohol (blood alcohol limits, point

abstinence, temperance) and gambling (less aggressive gambling machines). That the area of tobacco has not been a topic for harm reduction until recently, indicates how deep-rooted the vision of a tobacco-free society is. In addition, the reduction in smoking in Scandinavia during the last decade has given many people the impression – realistic or otherwise – that use of tobacco can actually be eliminated. According to some, to debate harm reduction in the area of tobacco has turned out to be more provocative and challenging than in other areas (Sweanor 2007).

Many people also believe that harm reduction in the areas of drugs and tobacco, for example, are so different that we are talking about two different phenomena. However, it is interesting to note that several of the traditional arguments used against harm reduction in the area of drugs, can now also be used in the area of tobacco (Table 1).

Table 1. Arguments against harm reduction that can be used in the areas of drugs and tobacco

Drugs	Tobacco
Harm reduction implies that public authorities abandon the ideal of a drug-free society	Harm reduction implies that public authorities abandon the ideal of a tobacco-free society
Harm reduction measures such as premises for the injection of drugs are in conflict with the UN conventions that the Scandinavian countries have ratified, and can weaken the countries' credibility in international drug policy issues	Harm reduction measures such as use of snus are in conflict with the recommendations of WHO, and can weaken the Scandinavian countries' credibility in international tobacco policy issues
Premises for the injection of drugs and the handing out of free syringes can maintain and reinforce injection culture – the most hazardous type of heroin use in relation to overdoses	Smokers who are advised to switch to snus will maintain and perhaps increase their addiction to nicotine, which can increase the probability for starting to smoke again – the most hazardous type of nicotine use
Harm reduction in the field of drugs can weaken drug users' motivation for treatment and rehabilitation	The introduction of less harmful alternatives to smoking will mean that smokers who otherwise could have completely stopped using nicotine now continue to use a nicotine product with uncertain consequences for health
It is difficult to regard the existence of an offer that makes it possible to continue to use drugs as an incentive to stop using drugs.	It is difficult to regard the existence of an offer that makes it possible to continue to use nicotine as an incentive to stop using nicotine.

1.3 Informed consumers

Another implication of harm reduction ideology is that consumers should be able to choose to move downwards on a risk continuum, by being offered precise information about alternative nicotine products. This is far from present-day reality in e.g. Norway, where studies show that consumers have serious misconceptions about relative health risks (Øverland et al 2008). This also applies to Norwegian general practitioners in a study conducted in 2008 (Lund et. al to be published). For example, the health hazards of both snus and medicinal nicotine products compared to smoking are exaggerated. If these misconceptions are not corrected, the result may be that smokers loose a motive for choosing a less hazardous nicotine product. In several reports, the American nicotine researcher Lynn Kozlowski has claimed that correct information about the relative health hazards of different nicotine products must be regarded as a human right.

«Cigarettes kill about half of those who smoke them. It is urgent to inform smokers about options they have to reduce risk. Public health policy in this instance lacks compelling justification to override the human rights of the individual» (Kozlowski 2002).

«Public health concerns should trump individual rights only when there is clear and convincing evidence of harm to society. Lacking that evidence, individual rights should prevail» (Kozlowski 2003).

The situation with uninformed smokers (and doctors) can be the result of unfortunate but unintended biased information from the health authorities. In Canada, the researchers Carl Phillips et al. (2006) – though they do have close connections to the snus industry – have accused North American health bodies for having tacitly accepted the situation because their hatred of tobacco has prevented correct information about snus being given out.

«Certain health advocates believe it is acceptable to mislead people into making choices they would not otherwise make...Through the use of various tactics, advocates who oppose the use of Smokeless Tobacco as a harm reduction tool have managed to convince most people that the health risk from Smokeless Tobacco is several orders of magnitude greater than it really is. The primary tactic they use is making false or misleading scientific claims that suggest that all tobacco use is the same…Apparently motivated by their hatred of all things tobacco, they are trying to convince people to

not switch from an extremely unhealthy behavior to an alternative behavior that eliminates almost all of their risk» (Phillips et al 2006: 19).

In its information, health authorities typically highlight the following: 1. snus is carcinogenic (pancreas and oesophagus), 2. other diseases cannot be discounted (cardiovascular diseases, diabetes, obesity, impotence, preeclampsia), 3. snus leads to dependency, and 4. snus should not be used when giving up smoking. The Norwegian Directorate of Health e.g. says little about the great difference in relative risk between snus and cigarettes. Is the information given adequate for consumers to be able to make an informed choice? In the article «*Not safe is not enough: smokers have a right to know more than there is no safe tobacco product*», Kozlowski & Edwards (2005) addressed the issue of information in connection with harm reduction. Their criticism may also be relevant for the situation in Scandinavia.

«The 'not safe' or 'not harmless' messages don't address the reality that some tobacco products are substantially safer than others... Saying tobacco 'isn't safe' isn't incorrect, but it isn't saying enough. Going beyond the no safe tobacco message to provide better information on the nature of risks from tobacco products and nicotine delivery systems is necessary to respect individual rights to health relevant information.»

1.4 The climate for the harm reduction debate

In Scandinavia, the debate about harm reduction in the area of tobacco has had a difficult start. Up until now, neither those who have been involved in measures to prevent tobacco-related harm, nor those involved in developing tobacco policy, have invited people to deal with the principle of harm reduction in a systematic way, such as is the case, for example, in the area of drug use. The Norwegian Minister of Health has in 2008 in fact invited people to a debate about prescription of heroin by doctors.

The result of this is that harm reduction policy has not been taken up by those who have an influence in this area. To the extent that exchange of views has taken place, this has typically been initiated by the media, with subsequent exaggerated polemic coverage of for-and-against arguments. This has been disadvantageous for the debate. In addition, the five Nordic ministers of health prepared a document that effectively terminated all expectations that steering bodies could initiate a debate about harm reduction in the area of tobacco (Holm et al. 2009). Among researchers, who work systematically with testing the strength of for-and-against arguments, this type of «dogmatic bulletin» creates a certain degree of astonishment.

Articles in international scientific journals such as The Lancet, Addiction, Nicotine & Tobacco Research, Journal of Harm Reduction and Tobacco Control have contributed significant knowledge in this area. But also here, the discourse is characterized by a polarized disagreement that has rarely occurred in the tobacco research literature.

The people involved in the debate about harm reduction can be divided roughly into five general types, according to, for example, their debating style. The groups in the table are, of course, neither all-embracing nor mutually exclusive, but they provide the reader with a general overview. However, it is difficult to place the purists who, for opportunistic reasons, disguise their hatred of tobacco by using the scientific arguments of the sceptics, or the people from the industry who try to increase their credibility by camouflaging their profit motive with the scientific arguments of the pragmatists.

Table 2. Typology of people involved in the harm reduction debate in the area of tobacco

General type	Main argument	Debating style
Purists	All tobacco is dangerous and must be eliminated. To grade the health risks of different products is a dead end	Accusing people of having ulterior motives Criticism of researchers Emotional (and rational) hatred of tobacco Moralistic orientation to duty ethics Puritanism Agitation disguised as science
Sceptics	Harm-reducing products delay the elimination of tobacco use and can result in a negative net effect at the population level. Alright at the individual level	The precautionary principle Demand empirical data Scientifically orientated
Pragmatists	The characteristics of today's smokers make harm reduction timely. Working towards a tobacco-free society hampers the transition to less hazardous nicotine products that can save life	Experience from treatment Empiricists Scientifically orientated Knowledge base in favour of harm reduction
Proponents	Harm reduction has only positive aspects	Dedicated Agitation disguised as science
The snus industry	Our products are the solution to the tobacco problem	Selective information People paid to provide information / to carry out research

In order to illustrate the differences of opinion between the purists/sceptics (PS) on the one side and the pragmatists/proponents (PP) on the other side, we can allow them to take their positions in a hypothetical debate. In this debate, the PSs stress that use of snus increases the risk of cancer of the pancreas. The PPs point out that the risk of cancer of the pancreas is almost halved if cigarettes are replaced with snus. The PSs then point out that the *increase* in risk will apply to new users of snus who have no previous experience of smoking, and if we get enough new users, the effect at the population level will be negative. The PPs reply that, in total, the health risk of snus is at least 90 per cent lower than with smoking, so that there must be 90 per cent more users of snus than smokers in society in order for the net effect to be negative – and such an increase would be completely unrealistic. The PPs also point out that the pattern of use of snus shows that most users have previously been smokers – there are actually few people who begin directly with snus. The PSs reply that this will not necessarily be the case for very young people. Snus is often the first product they use. The PSs will also not exclude the possibility that young people who start to use snus are vulnerable for starting to smoke (the gateway hypothesis). The PPs take a completely different standpoint, and mean that snus probably functions as a protection against young people starting to smoke – if snus were not available, these young people would otherwise have begun to smoke (the immunization hypothesis).

2 All the measures are being fully utilized – but many people are still dying

The public measures that are used in Scandinavia to prevent use of tobacco, as in other countries, have been focussed on three areas:

i) to prevent young people from beginning to smoke *(prevention)*

ii) to motivate and to help people who are established smokers to stop smoking *(cessation)*

iii) to protect third parties from involuntary exposure to passive smoking *(protection)*

This has been an extremely successful policy. It is satisfying to confirm that Scandinavian tobacco policy has provided a model example for other countries and for international recommendations, such as WHOs Framework Convention on Tobacco Control (FCTC). Within Scandinavia, Finland and Norway in particular have set the trend. Norway has had comprehensive tobacco legislation, which, among other things, from 1975 led to a total ban on all tobacco advertising, introduced health warnings on tobacco packets and sat the age limit for buying and selling tobacco at 16 years. Further provisions were added to the legislation to protect people from passive smoking in the workplace and on public transport (1989) and places where food and drinks are served (2004), to forbid new nicotine products (1989), to introduce more (1984) and larger (2003) health warnings, and to increase the age limit to 18 years (1995). The ban against visible display of tobacco products in outlets, and colour illustrations of damage to health on packets, will be introduced in 2010. At the same time, the real price of tobacco has increased, systematic anti-addiction measures have been introduced with, for example, the establishment of the free telephone service Quit-line, general practitioners now receive a fee for counselling on stopping smoking, and campaigns have been intensified. The efforts of the authorities have contributed to speeding up the reduction in the number of smokers, but the reduction is also the result of other

factors outside the direct control of the authorities, such as the change in the symbolic aspect of smoking (Scheffels 2008, Lund 2008) and the fall in social class of the group of people who smoke, which has reduced their importance as agents for promoting smoking (Lund & Lund 2005).

One of the results of Norwegian tobacco policy has been that the proportion of smokers who are men has almost halved since the 1960s and the increase in the number of women smokers has stopped at a much lower level than the top level for men. In 1973, there were more than twice as many smokers as former smokers in the population, but this ratio was 1:1 in 2009. The reduction in the proportion of smokers and the fall in the use of tobacco have occurred in parallel with a change in attitude to tobacco in a negative direction, and an increase in knowledge about the adverse health effects of tobacco (Lund 1996). Preventive work in the field of tobacco in Norway has been used to illustrate how effective state intervention against risk behaviour can be (Elvbakken & Stenvoll 2008).

Because Norway – along with the other Nordic countries – has already introduced more or less all the elements in the internationally recommended package of measures against tobacco, it looks as though we have come as far as it is possible to come with the measures that we know about today. NGO's with support from central professional organizations have always managed to create legitimacy for introducing new measures, and politicians and public officials have worked to implement them. The questions that are asked more and more often in countries with a history of similar tobacco control policy as the Scandinavian countries are «*What do we do when the measures have attained their full effect? What is left when politicians have already used all the tools in their tool box? Is the solution to intensify use of the existing measures?*»

2.1 Intensified use of existing measures?

Because Scandinavian tobacco control policy has been successful, it can be tempting and quite easy to use more intensively the measures that have been shown to be effective. But there are practical and political problems with this. Also, it must be expected that intensified use of these measures will lead to diminishing marginal returns. Let us explain in more detail why we should have limited expectations about the effect of intensified use of the old measures.

2.1.1 Duties and taxes

In the present-day situation, where border trade and import of tobacco from abroad amounts to almost 40 per cent of total sales in Norway (Melberg 2007), it would probably be almost politically impossible to introduced anything other than inflation-adjusted changes on duties. A more realistic aim would be to maintain the level of duty at the present level (Lund 2005, Melberg 2007).

2.1.2 Restrictions on places where smoking is allowed

Further restrictions on places where smoking is allowed would also probably give little further benefit, because smoking is already regulated in so many of our most frequented places (work-places, public transport, public squares, places where food and drinks are served etc.). The medical justification for introducing smoke-free outdoor places (primarily parks, beaches, lay-bys, places where food and drinks are served outside, parking places, sports arenas, golf courses) is much weaker than the justification for restricting smoking indoors, because the concentration of tobacco smoke seldom reaches hazardous levels (with the exception of for groups of people who are especially vulnerable). It is fairly improbable that reasons such as minor discomfort, litter, unpleasant smell and the sight of people smoking can justify legislative control of smoking outside, even though some researchers have argued in favour of this (Repace 2008). Even if this type of restriction was introduced, it would probably have only a marginal effect on the normative pressure against freedom to smoke that already exists in places where people gather.

Legislative regulation of smoking in *private places*, such as in the home and in cars could be considered because of regard for children, who are particularly vulnerable to exposure to tobacco. This could have an effect on adults' smoking behaviour in places where children are present. However, studies have shown that most families already have rules to reduce smoking in the home and in cars to a minimum (Helgason & Lund 2001), and that smoking in the vicinity of children is already declining rapidly without such regulation (Lund et al. 2004).

Excluding smokers from being employees has, for example, been practised by the World Health Organisation (WHO) since 2005. This measure led both to general protests and to a heated debate in traditionally tobacco-hostile communities, such as GlobaLink (a web site for researchers, bureaucrats and activists in tobacco control). In the article «*Going too far? Exploring the limits of smoking regulations*», Simon Chapman, Australian professor in public health and former editor of the

scientific journal «Tobacco Control», claimed that supporters of the ban practised bizarre, paternalistic and unscientific arguments for null tolerance (Chapman 2008). This practice might result in social apartheid policy. No serious agents in the health field has so far recommended such rules in Scandinavia, and this will probably not happen in the near future

On the other hand, several employers have introduced a ban on smoking in working time for their employees. Some of the first organizations to do so were voluntary organizations such as Cancer Societies and Heart and Lung Associations, and some hospitals. Several municipalities have also introduced, or will introduce, such regulations for their employees. The justification is protection of both individual smokers and people around them. The profile of the workplace and economic considerations have also been used as arguments. Authorities are also planning to introduce an all-day total smoking-ban throughout working hours for both students and teachers in all schools including upper secondary schools. The idea of providing role models is one of the justifications. Research shows that smoke-free working time reduces the prevalence and the intensity of smoking among employees and pupils (Fichtenberg et al 2002, Levy et al 2003), so here there is potential for further reduction in smoking.

2.1.3 Restrictions on sale of tobacco

To raise the age limit for buying and selling tobacco above the age of consent of 18 years of age – if at all politically possible – would probably have modest effect. Today, all people under 23 years of age are required, unsolicited, to confirm their identification when they buy cigarettes. Raising the age limit, for example to 19 years of age, would probably have some but little effect on recruitment. However, studies have shown that many under-age smokers buy their own cigarettes. Improving the enforcement of the present age-limit regulations, for example by introducing licences and threatening licensees with losing their licence if they sell tobacco to under-age persons, would perhaps be more appropriate.

Reducing the number of places that sell tobacco and shortening the hours for sale of tobacco, could be another measure. Today tobacco can be bought 24 hours a day in the whole of Scandinavia. However, reduced availability has not been discussed in Norway since the idea of a state monopoly of tobacco sales outlet was rejected at the end of the 1920s (Lund 1996). This measure seemed to lie far from the political agenda, until the Norwegian Medical Association, in January 2009, recommended

restricting sale of tobacco to alcohol sales outlets. This would prevent sale of tobacco from, for example, petrol stations, snack bars and convenience stores.

2.1.4 Restrictions on marketing

All types of direct and indirect advertising, including sponsoring, have been banned for a long time in most Scandinavian countries. Since the legislation is already effective, there is little potential for further restrictions. However, research has shown that there can be benefits from measures such as making health warnings on packets visible (Hammond et al. 2007), plain packaging of tobacco products (Freeman et al. 2008) and a ban on visible display of tobacco products (Lund & Rise 2008).

2.1.5 Information

Scandinavian health authorities have conducted many different campaigns to change attitudes and to provide information. Launching new campaigns would be very costly, and would require more funding than the health authorities have at their disposal. New anti-smoking campaigns would possibly be taken notice of by a new segment of the population who have not been exposed to campaigns earlier – primarily children and young people who have «come of smoking age» since the last campaign. New campaigns would probably also reinforce smokers' motives for quitting, which most smokers already have, and could help to maintain the negative climate to tobacco in society that already exists. 90 per cent of the Norwegian population were after several years able to recall a specific anti-smoking campaign run by the Norwegian Directorate of Health (Larsen et al. 2006, Lund & Rise 2004). Therefore, we should not have high expectations that new campaigns would lead to a big increase in the level of information in the population.

2.1.6 A fee for doctors for helping patients to stop smoking

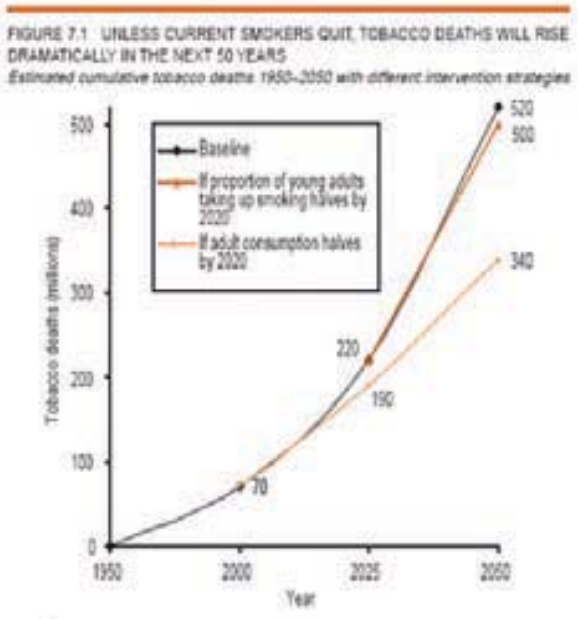
The doctor's fee in Norway is currently (in 2009) 25 Euros. This fee can be claimed twice for the same patient during one calendar year from the first consultation for individual, structured weaning from smoking, as a stage in treatment for disease, according to an approved programme. Some people would claim that the fee does not cover the actual time needed to follow up closely and adequately an attempt to stop smoking, and that this hampers intervention. The effect of assistance from health care personnel to quit smoking is discussed in Section 7.2.

2.2 A comprehensive policy, but many people are still dying

The tobacco policies of the Scandinavian countries have scored high on a European ranking scale from 2006 (Joossens and Raw 2006). With a so robust infrastructure for tobacco control, the potential for improvement is somewhat limited. It is disturbing that the questions about the limitations and inadequacies of tobacco policy are being raised in a situation in which smoking – despite the reduction in use of tobacco – is still one of the absolutely most important preventable causes of disease and premature death in Scandinavia. «*The glass remains half empty*», claims Ken Warner, describing the parallel situation in the US (Warner 2007). According to the Norwegian Institute of Public Health, 16 per cent of all deaths are attributable to smoking in Norway (Vollset et al 2006). The number of tobacco-related deaths in Norway is actually greater today than it was in 1964 when the US Surgeon General published his report on smoking and health. This is because of three factors: i) the population has increased, ii) there is a long time lag between smoking behaviour and the resulting diseases, so that the epidemic of diseases in the 1960s reflected the relatively low, but increasing use of tobacco 30 – 40 years previously, iii) the health benefits of more recent preventive measures have not yet been reaped, because of the time lag.

3 From a long-sighted to a short-sighted gain timescale in tobacco policy

The delay between the behavioural component and the disease component (the time lag) in the tobacco epidemic means that measures to prevent recruitment to smoking among young people operate with a long-term gain timescale. Perhaps the authorities in Scandinavia would achieve more by being more short-sighted when considering preventive measures. A simulation model launched by the World Bank can be interpreted in this direction. The World Bank compared the health effect of halving recruitment to smoking among young people with the effect of halving adults' consumption. The result is shown in the figure below, from the publication *Curbing the Epidemic* (World Bank 1999).

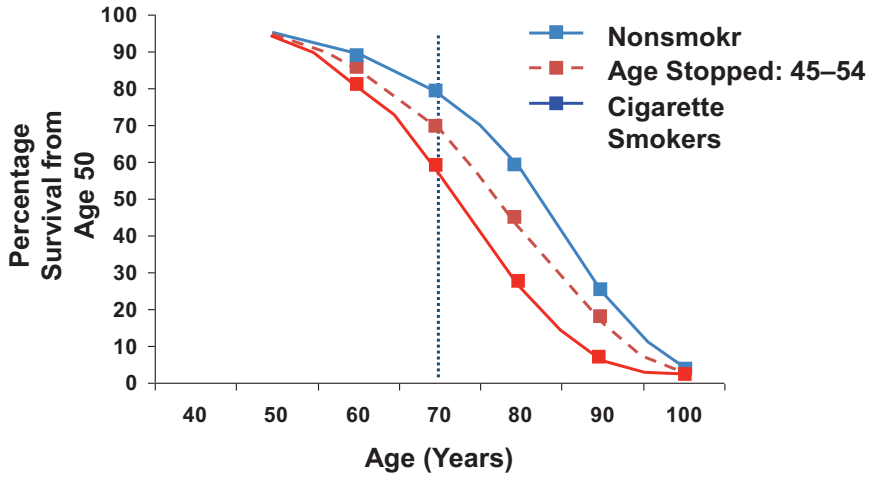


At the world level, if we succeeded in halving recruitment to smoking among young people from 2000 to 2020, the accumulated reduction in tobacco-related deaths in 2050 would be 20 million. If we succeeded in halving tobacco consumption among adults (mainly by getting adults to quit smoking), the accumulated reduction would be 180 million deaths. The basis for the estimates of the World Bank were Doll & Peto's (1995, 2004) estimates of survival after quitting smoking at different times in life (see the figure below).

Thus, with a short-sighted timescale, the gain from a reduction in recruitment is relatively modest, while a doubling of the rate of quitting would have an enormous effect. If we are to reduce tobacco-related mortality and morbidity in our lifetime, it is more important to stimulate quitting cigarettes than to prevent recruitment among young people. Harm reduction for today's smokers must also be assessed according to this perspective.

Quitting at Any Age May Increase Life Expectancy
Age Stopped Smoking: 45–54 Years Old

Results From a Study of Male Physician Smokers in the UK

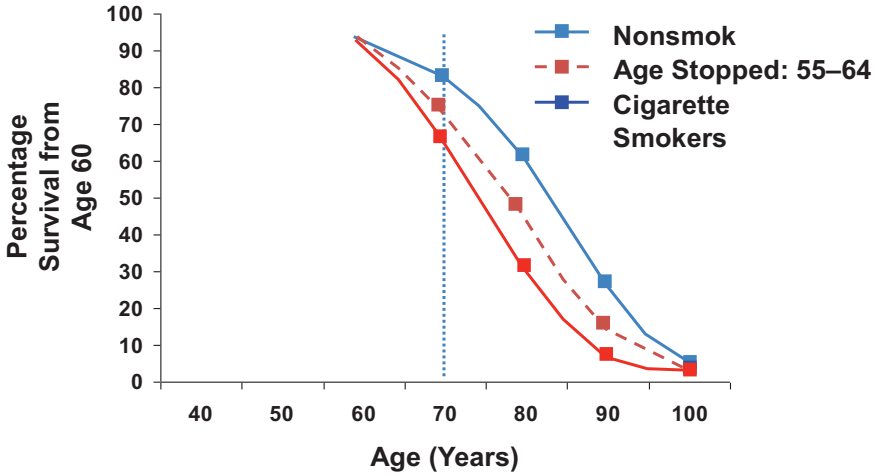


Even quitting smoking later in life can lead to longer life expectancy

1. Doll R, et al. *BMJ*. 2004;328:1519-1527.

Quitting at Any Age May Increase Life Expectancy
Age Stopped Smoking: 55–64 Years Old

Results From a Study of Male Physician Smokers in the UK



Even quitting smoking later in life can lead to longer life expectancy

1. Doll R, et al. *BMJ*. 2004;328:1519-1527.

7 Imbalance between the motive to quit created by society and assistance to quit

Scandinavian smokers now practise their behaviour in a very tobacco-hostile norm climate (Pedersen 2008). The symbolic content is negative, the habit can only be practised in restricted areas, repeated campaigns sustain pressure on cognitive information, and the price is high. In other words, «society» has created strong incentives to quit. About 75 per cent of Norwegian smokers have made repeated unsuccessful attempts to quit (Lund & Lindbak 2007), and nearly all smokers regret that they started (Fong et al. 2004). The question is whether the assistance that is offered to the remaining smokers – with their special characteristics – is adequate and effective. Research has shown that this is not the case

In the policy document from the five Nordic directors of health, referred to previously, it is stated that:

«There are evidence-based methods for smoking cessation. The most effective methods are a combination of support and medication.

(Holm et al. 2009)

However, a critical appraisal of the Cochrane reviews on effects, how long effects last, and studies of «real-world» implementation, can cause optimism to be moderated.

7.1 What effect do medicinal nicotine products have on the quit rate for smoking?

The answer depends on who you ask!

«You actually double your chance of quitting smoking if you use medicinal nicotine products».

«By using NICORETTE® you double your chance to succeed, compared to if you just trust your willpower».

The claims given above about a 100 per cent increase in effect have been made by the pharmaceutical suppliers of Nicorette and Nicotinell medicinal nicotine products.

(http://www.nicorette.no/Vare-produkter.aspx) (http://www.nicotinell.no/)

This message is communicated in advertisements, is often repeated in newspaper articles, and has probably given many people the impression that use of medicinal nicotine products is very effective for quitting smoking.

However, the impression of the effect of medicinal nicotine products has been moderated by research. In a Cochrane review from 2008 (Stead et al. 2008) the authors concluded that nicotine chewing gum increased the quit rate for smoking by 58 per cent, while nicotine patches gave a 43 per cent increase in effect compared to a placebo.

«We identified 132 trials; 111 with over 40,000 participants contributed to the primary comparison between any type of NRT and a placebo or non-NRT control group. The RR of abstinence for any form of NRT relative to control was 1.58 (95 % confidence interval [CI]: 1.50 to 1.66). The pooled RR were 1.43 (95 % CI: 1.33 to 1.53, 53 trials) for nicotine gum and 1.66 (95 % CI: 1.53 to 1.81, 41 trials) for nicotine patch». http://www.cochrane.org/reviews/en/ab000146.html

The pharmaceutical industry maintain that:

«*If you manage the first three months, the next three months are much easier. And after half a year, your chances of remaining smoke-free for the rest of your life are good!*»http://www.nicorette.no/Slutte-a-royke/Nikotinlegemidler.aspx.

Again, this statement is modified by scientific reviews. In the article *Nicotine replacement therapy for long-term smoking cessation: a meta-analysis* (Etter & Stapleton 2006), researchers focussed on the long-term effect on smoking cessation of the present NRT (nicotine replacement therapy) products. More precisely, they based their conclusions on the results of twelve studies with a total of 4 792 patients who had been followed up over a period of two to eight years after quitting smoking. After twelve months, with a mean use of NRT of 22 weeks, one out of twelve were still smoke-free, while after 4 years only one out of 19 were still abstinent. The conclusion was that the effect continued to fall by 30 per cent after the first year, and that tobacco dependence should therefore be regarded as a chronic disorder requiring repeated episodes of treatment.

«*Results after only 6 – 12 months of follow-up, as used in existing reviews and treatment guidelines, will overestimate the lifetime benefit and cost-efficacy of NRT by about 30 %. Because the long-term benefit of NRT is modest, tobacco dependence treatment might be better viewed as a chronic disorder, requiring repeated episodes of treatment*».

As mentioned in Chapter 4.2, the pharmaceutical industry has financed much tobacco addiction research. The focus has most often been on the effect of their products, compared with a placebo or no treatment. Testing takes place in randomized controlled trials in a clinical setting, most often managed by a doctor. There has been less research to measure the effect of the products in a real-world setting. However, Pierce et al. (2002) pointed out that the results obtained in randomized controlled studies of medicinal nicotine products cannot necessarily be repeated in the real world when the products are bought in a shop. Cummings & Hyland (2005) studied the effect that the availability of NRT products has had on smoking behaviour in the American population. The conclusion was remarkable:

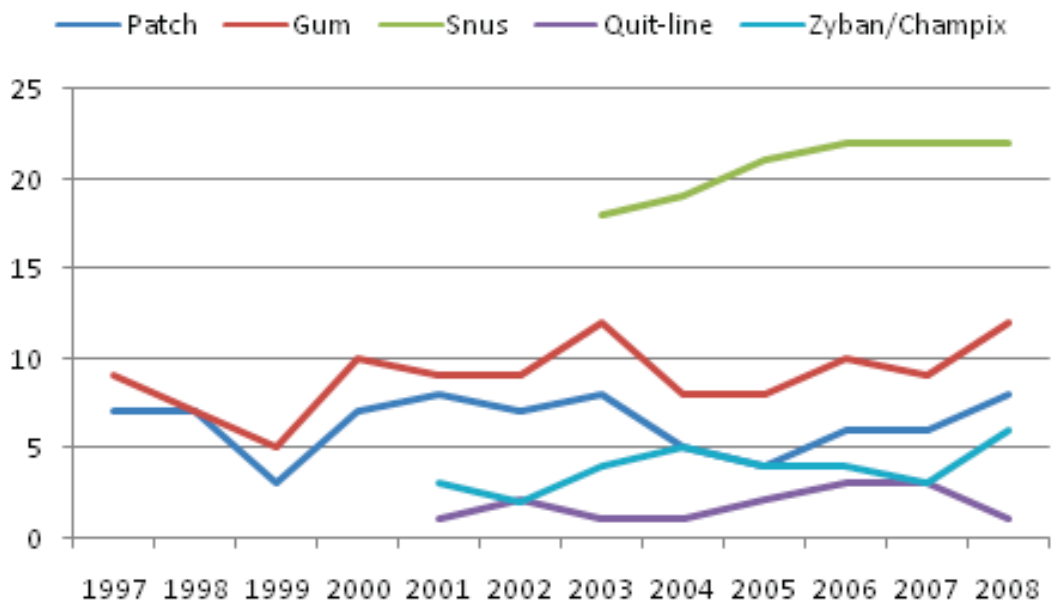
«*Accumulated evidence from controlled clinical trials has demonstrated that available forms of NRT (e.g., gum, transdermal patch, nasal spray, inhaler, and lozenge) increase quit rates compared with placebos by 50 %-100 %. However, despite the positive results from these studies, fewer than one in five smokers making a quit attempt do so with the benefit of NRT. Because not enough smokers are using NRT,* ***the availability of NRT has not had a measurable impact on influencing population trends in smoking behavior****. Among the factors contributing to the low utilization of nicotine medications are the inadequacies of the current dosage strengths and formulations of existing*

medications, smokers' perceptions of the high cost of the drugs, and concerns that many smokers have about safety and efficacy of nicotine medications».

Even with the use of medicinal nicotine products, the relapse to smoking was extremely high, and no different from the relapse to use of opiates after treatment for drug addiction (US Surgeon General 1988). Hughes et al. (2004) showed that the majority of relapses to smoking occur during the first eight days.

In Norway, just under 30 per cent of smokers attempt to stop smoking each year (Lund & Lindbak 2007). The figure[8] below shows that only a small proportion of men who have quitted (successfully and unsuccessfully) used an NRT product, even though these products increase the probability for abstinence to a certain extent[9]. According to the statistics, of the approximately 90 per cent of daily smokers who try to quit each year begin again within 6 to 12 months.

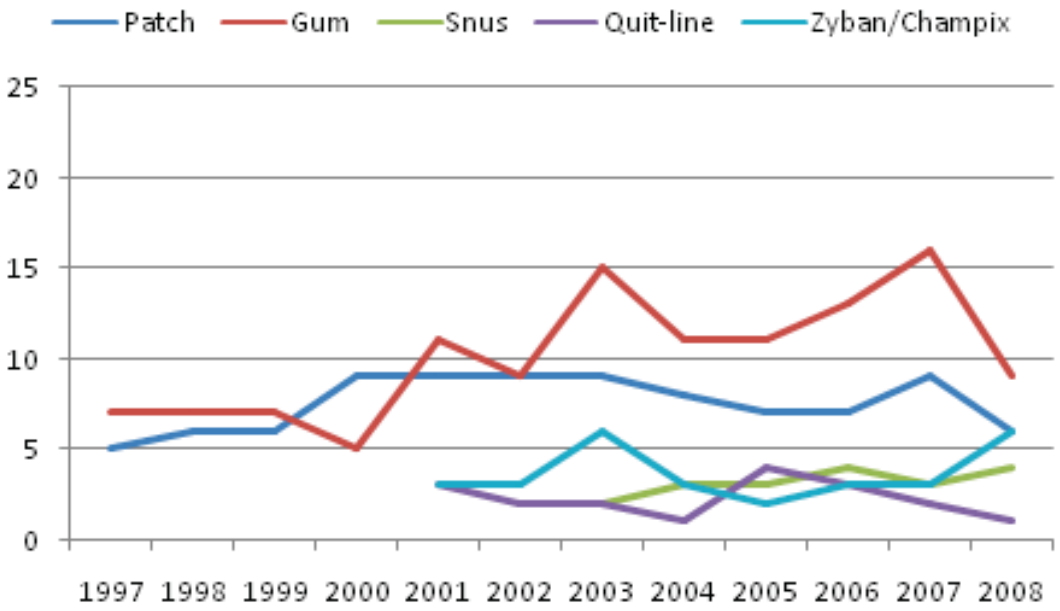
Smoking cessation aids used by Norwegian male ever-smokers 1997 – 2008. Weighted mean successful and unsuccessful quitters.



[8] The black line shows the regression line for use of snus at smoking cessation.

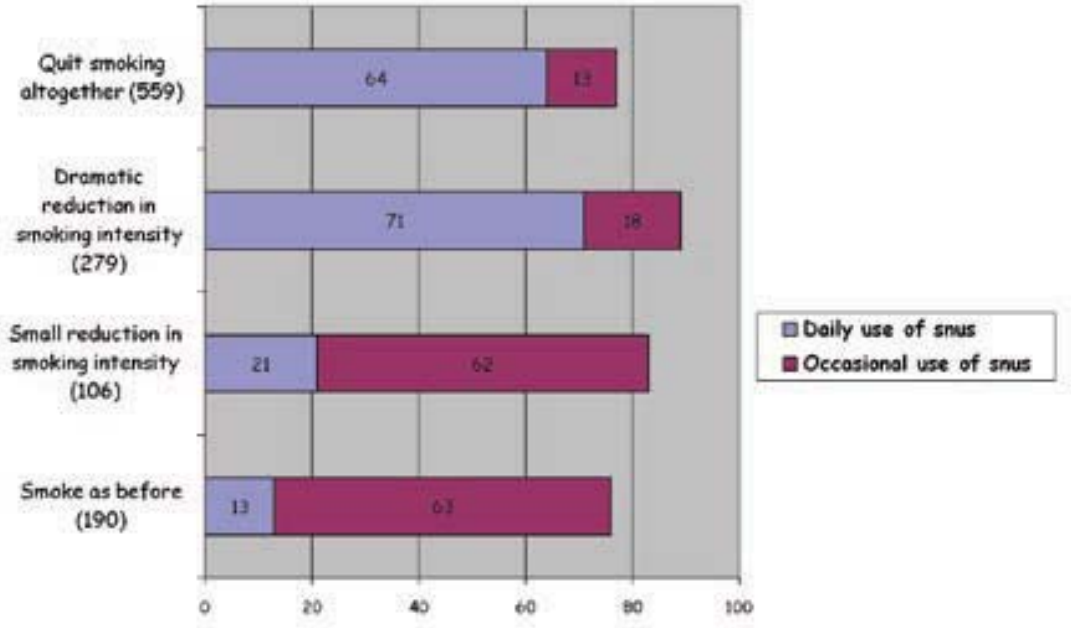
[9] As part of a PhD study, SIRUS will examine more closely the barriers that smokers give for use of NRT products at smoking cessation.

Smoking cessation aids used by Norwegian female ever-smokers 1997 – 2008. Weighted mean successful and unsuccessful quitters.



Percentage still using snus after having used snus at latest quit attempt

Men aged 20-50 years, 2007



10 Conclusions

To get people to understand the necessity for a measure that appears to involve changing the expressed aim of tobacco policy – a tobacco-free society – is a challenging task. The task is no easier when the traditional measures for reducing smoking have been successful. Why should we change direction?

However, harm reduction does not involve a *change* in direction for preventive work. Harm reduction should be regarded as an *additional component* to the measures that have already been shown to be effective. On the way to the final aim of a tobacco-free society, harm reduction could be a pragmatic and temporary measure that could clearly save many lives.

Harm reduction is appropriate because of four factors in two pairs.

The first pair of factors is the social gradient in today's smoking pattern, combined with the fact that research has not identified tailor-made measures for the lower social classes. The second pair of factors is the fact that smokers in the remaining group of smokers have additional social and psychological burdens that reduce their ability to quit, combined with the fact that the measures used and the assistance offered today have little effect. Without encouragement to use harm-reducing nicotine products, a large proportion of the remaining smokers will continue to smoke, and will thus have a 50 per cent chance of dying from a tobacco-related disease. With the status quo in the tobacco/nicotine policy that is given legitimacy by the authorities – that is a policy without an active harm-reduction strategy – use of tobacco will maintain and strengthen future social inequalities in health status.

In Scandinavia up until now there has been little willingness to discuss harm reduction in the area of tobacco. The debate has been hampered by dogmatic statements of principle (particularly about snus) that suppress exchange of opinions and reflections about the ethical implications of harm reduction. Interest for – albeit limited – empirical research that can illuminate the theme has been moderate, taking into consideration the potential that harm reduction has for improving public health. Maybe this report can stimulate less biased debate?

In Scandinavia, the tobacco problem is not substantially less serious now than it was in the 1960s. At that time, doctors did not know the extent of the hazards of smoking (Lund 2007), or that cigarettes would be the cause of so many deaths over the next 40 years. We now have knowledge about the extent of the hazards, nearly all conceivable preventive measures have been used, and we can predict future changes in smoking behaviour. In contrast to the doctors in the 1960s, we are now on the brink of a human catastrophe that *we have been warned* will occur if the reduction in smoking does not speed up. To ignore harm reduction as a future strategy in the area of tobacco can be erroneous in this situation. An uncompromising attitude to a tobacco-free society can deny many nicotine-dependent smokers the possibility to survive, which they could have had if the authorities had assumed a more pragmatic attitude to harm reduction.

10.1 Questions for further debate

Some central questions to discuss in future debates on harm reduction are:

i) Should the aim of a tobacco-free society be replaced by the aim to reduce tobacco-related morbidity?

ii) Should the ban on new nicotine products be replaced by regulations to control nicotine products?

iii) Should the Scandinavian authorities be inspired by the recommended harm-reduction policy of health agents in England and the USA, and encourage production of new harm-reducing nicotine products that can compete with cigarettes?

iv) How important is it really to consider who produces nicotine products (the pharmaceutical industry, the tobacco industry or others) when we decide which products shall be regarded as harm reducing?

v) How can we correct smokers' (and others') misconceptions about the relative health risks of use of different nicotine products?

vi) Should the level of tobacco duties and measures to prevent use of tobacco to a larger extent reflect differences in the relative health risks of the different products?

vii) Should the authorities regard harm reduction in the light of the aim to reduce social inequalities in health?

viii) How long should the authorities take a precautionary principle stance in the harm-reduction debate? How much evidence is needed to make them change this stance?

11 Prologue

About half a year before this report was published in English, an almost identical version was published in Norwegian. In Norway, the report received a lot of attention, and stimulated a continuation of the debate on harm reduction, both in the media and in professional circles. The Norwegian Directorate of Health and representatives of the Norwegian Medical Association have some new points of view that can be interpreted as more positive to harm reduction ideology. For example, a director of division in the Norwegian Directorate of Health said to the newspaper Bergens Tidende under the headline «The Norwegian Directorate of Health is willing to consider snus»:

The Norwegian Directorate of Health says yes to general practitioners, dentists and other health care personnel being able to recommend health-damaging snus to inveterate smokers. Snus is clearly less damaging to health than smoking. If patients have tried other methods without success, we mean that health care personnel can recommend that they use snus instead, says Knut-Inge Klepp, director of division in the Norwegian Directorate of Health. He stresses that before such a recommendation can be made, other nicotine replacement products, and, if appropriate, medicinal nicotine products, must have been tried. Klepp also stresses that such a recommendation must be made directly by health care personnel to the person who needs advice. He is strongly against a general recommendation.

On the web site of the Norwegian Directorate of Health, a new attitude to use of snus as a harm-reducing product is confirmed:

We know that a large proportion of people who smoke have contact with a dentist or a general practitioner, says Klepp. It is important that health care personnel take up the topic of smoking, recommend quitting, and help people who wish to quit. In the first instance they should try established methods such as nicotine chewing gum, nicotine patches or medicinal nicotine products available on prescription. If patients have tried these methods without being successful, the Norwegian Directorate of Health means that health care personnel in individual cases can consider that the patient should try snus instead.

Chapter 7

The implicit ethical claims made in anti-tobacco harm reduction rhetoric – a brief overview

Catherine M. Nissen, Carl V. Phillips & Courtney E. Heffernan

This paper is adapted from a presentation by CMN at the 2009 International Harm Reduction Association conference, Bangkok, Thailand, with additional material by CVP and CEH; while this version expands substantially on the presentation, it still retains some of the abbreviation and informal citations to philosophical thinkers and theories; a more formal version should be available from the TobaccoHarmReduction.org working paper series in 2010.

Despite an ever-growing base of evidence and support, tobacco harm reduction (THR) – more so than harm reduction in general – has had an uphill battle to gain acceptance as a public health policy. This has occurred despite the lack of any clear and fully-articulated arguments as to why promoting THR is not a good public policy. Statements made in opposition to THR are generally delivered as propaganda, meant to evoke naïve and visceral support rather than reasoned agreement, even when presented in scientific or scholarly contexts. They are typically presented with phrasing that implies an agreed ethic about how people should act and what policies should be made. But can we find any such ethical principles implicit in their arguments, or do attempts to ground anti-THR activism in ethical claims appear to just be rationalization for individual preference? It has been widely pointed out that many empirical claims, implicit and explicit, made in anti-THR statements are unsupported by evidence and often easily demonstrated to be false. What is overlooked is that the implicit ethical foundations for the prescriptive assertions are also left unsupported and, indeed, the ethical foundations are not even identified. Any insistence that something should or should not be done is implicitly invoking a claim about what

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actions and public policies are right and good. However, these implicit ethical claims appear to be little understood by those invoking them.

Only if an argument is examined and presented in its most defensible terms is it possible to assess its validity. Given that anti-THR advocates do not do this for their own claims, it falls to us who support harm reduction and want to seriously examine the arguments for and against it, to try to decipher the underlying ethical positions behind anti-THR claims. In so doing, we find that the implicit ethical bases of the claims are very difficult to justify based on any accepted notion of Western policy ethics.

This paper reports a few of the central examples from our effort to disentangle the many different implied ethical positions that underlie the arguments for and against THR, and reduces them to their objective functions in order to better discuss their credibility. Further analysis of these points can be found in a series of papers that are being collected at or will be added to http://www.tobaccoharmreduction.org/wpapers.htm.

Acts and Consequences

In reducing arguments to their underlying ethical statements, it proves useful to focus on the two primary bases of modern Western policy ethics. Consequentialist ethics focus on the worldly outcomes (or, more precisely, the expected value of predicted outcomes) of an act or policy, judging its goodness based on those. This includes the familiar concepts of welfarism and utilitarianism. Deontological ethics focus on the character of an act or policy itself, judging it based on its own properties or its motives, apart from its consequences. This includes many manifestations of familiar Western post-Enlightenment rights-based arguments, as well as more subtle points like Kantian categorical imperatives. The arguments analyzed in this paper seek to identify the implicit consequentialist and deontological arguments used against THR. What is often presented as a third orthogonal category of ethical bases, Aristotelian virtue ethics, are omitted from this brief analysis due to their subtlety (which is to say, they are very difficult to operationalize in a political street fight) and their lack of invocation in any of the language we analyzed. However, it is possible that some rudimentary notion of value ethics underlies some of the thinking of some anti-THR activists.

Arguments for THR

To provide contrast, it is worth briefly sketching the simplest ethical arguments in favor of promoting THR (these are expanded upon in the above-referenced working paper collection). From a deontological standpoint, it is the central accepted tenet of modern health ethics that people have a right to make informed choices about their own health, and thus authorities are obligated to tell them that THR is possible and to not interfere with access to low-risk nicotine

products. It has been argued that it is *per se* unethical for authorities and opinion leaders to try to mislead people regarding options that affect their own health (for specific examples relating to THR see: Kozlowski & O'Connor (2003), Kozlowski & Edwards (2005), and Phillips et al (2005)). The principle that individuals should decide what they should do (or what should be done to them) regarding their health, and that authorities have a duty to provide them with accurate information that informs such decisions, is called informed autonomy.

From a consequentialist standpoint, with better health outcomes or greater longevity as the goal, overwhelming evidence suggests that THR would reduce the total health impact of nicotine/tobacco usage by encouraging the smokers who are not going to soon quit to switch to low-risk products such as smokeless tobacco (ST) or electronic cigarettes (e-cigs) (see TobaccoHarmReduction.org, Rodu and Godshall (2006), Phillips (2009 - reprinted in this volume), and Phillips, Heavner, & Bergen (2010 - in this volume)). Moreover, when we realize that longevity or physical health alone is not actually an accepted ethical goal, and analyze the case for THR based on welfare (the overall well being of people, including physical and psychological health and everything else people value), the case for THR is even stronger: Compared to promoting abstinence (which has about the same health benefit for smokers as switching to low-risk alternatives), THR would offer a welfare advantage of minimizing the loss of benefits smokers get from their consumption, by not forcing them to quit tobacco/nicotine to achieve the longevity benefits.

Arguments against THR

The previous ethical statements in favor of THR are quite compelling to most people. Most people in our society support informed autonomy or improved health and welfare. (It is beyond the present scope to argue the bases of these ethical principles; this analysis simply starts with them and applies them to the specific case.) The question we should then ask, as advocates of THR, is if there are any equally compelling and logically valid ethical arguments against THR. This is a challenge, because the opponents to THR make lots of assertions, but make almost no attempt to present real arguments, or to justify or defend their claims. The following statements are a few of the seemingly more convincing or more common arguments that arise against THR. We have tried to give the proponents of these the best possible benefit of the doubt and tried to validate their arguments, something the anti-THR activists have not done themselves.

Argument: If we tell people about ST and other low-risk alternatives, more people will start using nicotine products that have some risk, potentially increasing total risk. Moreover, the low-risk products might be a "gateway" that causes more people to take up smoking, causing further risk still.

These arguments are grounded in a consequentialist argument based on the objective of maximizing physical health or longevity. They implicitly deny the deontological arguments that it is unethical to mislead people to manipulate their health-affecting decisions, even if it is "for their own good", and that we have a duty to treat people as more than a means to end of improving their health. Moreover, they implicitly elevate health to trumping all other goals by declaring that an increase in health risk is a sufficient objection, regardless of the effect on other contributions to welfare compared to the magnitude of the effect on health. While it would be possible to state (though not empirically defend) these claims in terms of overall welfare loss, we are not aware of anti-THR actors ever having done so.

While the "health promotion" community – the political faction that dominates the public face of public health, though not the actual promotion of public health itself – implicitly claims that maximizing physical health without regard to other human wants is a legitimate goal of social policy, almost no one (probably including themselves if they stopped to think about what they were claiming) would agree. To offer some benefit of the doubt, some commentators who invoke this objective may be implicitly appealing to a narrow definition of the phrase "harm reduction": If total physical harm from using tobacco/nicotine products has increased in the population, then *harm reduction* has not been achieved. However, at best this represents an objection to the jargon, not to the proposed policy. Moreover, this relies on ignoring the spirit in which proponents of harm reduction typically use the term, which is to refer to reducing the risks of something people want to do, so that if they choose to do it they are better off than they otherwise would be.

The most common responses to these claims are not attempts to challenge the claim that physical health outcomes trump all other social and ethical concerns, but are empirical. The claim that the extra users of low-risk products could cause an increase in total risk in spite of the benefits of reduced smoking has been thoroughly debunked (see Phillips, 2009, and the references therein). The arithmetic resulting from the extremely low risk caused by THR products makes it clear that the claim is completely implausible. The gateway claim – that THR will cause some would-be abstainers who start using low-risk products to start smoking when they would not otherwise have done so – while theoretically possible (in the sense that this is true for anything that is not precluded by physical law), has never been empirically supported. Moreover, it relies on an implausible narrative that the people who make the most rational decisions will behave

irrationally: The claim basically translates into "we predict that the people who avoided or quit smoking but adopted low-risk THR products when they learned that they were low risk, and who thus seem to be thoughtful and motivated to avoid the health effects of smoking, will forget the reason they avoided smoking in the first place and switch to it from a low-risk product."

The one part of these claims that is predictably true and empirically verified is the claim that some people who would not be tobacco/nicotine users (either would-be never-users or current smokers who would have quit) because of the health effects, but are interested in tobacco/nicotine and derive some pleasure or other benefit from it, will decide that the benefits warrant the lower cost of the low-risk options. This is simple economics: Using tobacco/nicotine has benefits (for many people) and costs; if the costs are lowered a lot and the benefits are lowered only a little bit (which is the case for many people who substitute other products for smoking), then net benefits increase and more people will get positive net benefits from using such a product. In other words, if the health risk is low enough, and the psychological benefits (pleasure, relaxation, relief from distress, etc.) are high enough, people will rationally choose to use ST or e-cigs. (This argument is presented in more detail in Phillips 2009.) Some confusion has been created by pro-THR advocates who (indefensibly) deny that increased total use is inevitable, rather than denying that this should be considered a problem. Arguments that increased use is a problem in itself, even though it will not plausibly cause an increase in total risk, are addressed below.

Argument: We will soon eliminate all self-administration of nicotine, so we do not need THR.

This is a specific case of the "more people will use nicotine if we promote THR" argument. It is based on a purely speculative prediction, since there is no evidence to suggest that current policies will bring about any further substantial reduction in nicotine use, and the results of other drug wars are sufficient evidence of the folly of increasingly prohibitionist policies. What is interesting from the perspective of ethical analysis is the sharp focus this brings to the question of legitimate goals.

When dealing with empirical reality, the goals of reducing the health impacts of tobacco use and of maximizing the welfare of users and potential users are both furthered by promoting THR. If we assume that all physical health costs will be eliminated by the incipient universal abstinence, then promoting THR would actually slightly increase total health risks since low-risk products have trivial, but non-zero, physical health risk. However, declaring that a sufficient reason to oppose educating people about THR is a clear declaration of the primacy of minor health concerns over both individual informed autonomy and welfare. This is a logically well-defined position, and seems to be quite common among anti-THR activists. However, the position runs

contrary to people's actual choices in life, as well as basically all health policy rules outside the realm of substance use.

Argument: Anything that causes more people to use nicotine in the long run is bad because we should avoid letting people be addicted.

Any argument that invokes the word "addiction" is inherently slippery, since the term is practically meaningless without a specific definition, which is seldom offered. "Addiction" is used to mean everything from "an acquired compulsion that is so intense it destroys everything else in someone's life" to "any habitual consumption pattern that some people choose but that the commentator disapproves of", and hundreds of variants in between. Moreover, it is quite often used (presumably intentionally in many cases) as a way of confusing the different definitions. The use of "addiction" in moral arguments (as opposed to a shorthand to simply describe a consumption pattern) seems intended to conflate nicotine use with hard drugs that rapidly destroy people's entire lives, or to denigrate the user.

Taken as a consequentialist argument, the argument appears to be that avoiding addiction – whatever that means – should be a goal in itself, apart from the welfare effects of the consumption associated with the addiction. There are compelling policy arguments to discourage behaviors labeled "addiction" that cause people to rapidly proceed on a path of destruction, but this is an argument against the particular behavior based on its consequences, not against addiction as a consequence. The goal of minimizing addiction is even more difficult to justify as a policy ethics goal than the goal of minimizing physical health costs, and not just because it is not well-defined. Like physical health costs, it could be argued that addiction should be considered as a negative in the overall welfare calculation, balanced against other interests, but this is not the form the anti-THR argument ever seems to take.

Some of the language surrounding arguments based on avoiding addiction seems to invoke a misunderstood notion of Kantian autonomy. Kant argued (roughly speaking) that anything that diminishes someone's autonomy to act based on their rational will (the duties defined by pure reason) diminishes the person. Anti-addiction activists may be interpreting such deontological claims as justifying their position. But Kant's notion of what threatened autonomy included all pleasures and worldly goals that we did not choose. With this clarification in mind, it becomes difficult to find an ethical argument that condemns the addiction-quality of nicotine use without also condemning most behaviors whose purpose is to fulfill personal tastes or desires. (Indeed, there is a case to be made that an addiction is somehow better than other preferences since it was self-created, rather than an accident of genetics or social pressures. In any case, anti-THR

activists are unlikely to find ethical justification in Kant, though further analysis is beyond the present scope.)

Of course, puritanical ethical codes have held sway in many governments, with undercurrents throughout Anglophone history and clear contemporary examples found in some Islamist societies. However, despite the existence of such factions, condemnation of the fulfillment of desires is almost universally condemned in serious modern Western discourse about policy ethics. Indeed, if we exclude those anti-nicotine positions that are explicitly attributed to organized religion, we are not aware of any anti-THR activist who actually defends a puritanical ethical code that condemns recreational caffeine or sexual activity alongside nicotine. Thus it is difficult to find a logically defensible anti-addiction or anti-nonautonomous-desire based ethical position, even apart from the difficulty in defining addiction.

Argument: Anything that causes more people to use tobacco/nicotine in the long run is inherently bad because the goal is vilifying or eliminating all use.

A clearer version of the more-is-worse argument is simply that the act of self-administering nicotine is bad in itself, and the goal of relevant public policy should be to discourage it, regardless of how great the benefits of use might be or how far the risks can be reduced. This claim is the anti-tobacco (or anti-nicotine) *extremist* position, and many anti-THR activists explicitly identify it as their goal. (Some naïve commentators have objected to the term "extremist", interpreting it as invective, a mistake that may be caused by the U.S. government and its allies using this term as an epithet for its enemies. But, of course, the word has an actual meaning, and the goal of eliminating all tobacco/nicotine use regardless of its benefits and of how low the costs are, and vilifying it pending its elimination, seems to be the most extreme possible position on the matter.)

In pursuit of the anti-tobacco extremist goal, keeping the health risks high (i.e., by discouraging THR so that nicotine users continue to incur the dangers of smoking) is a reasonable tactic, since lowering risks will reduce the incentive people have to avoid the consumption. But can the goal be ethically justified? It is difficult to imagine any legitimate ethical rule that singles out this consumption choice for condemnation, let alone puts the goal above all other concerns. Such line-item specifics are generally a sign that a goal does not stand up to ethical scrutiny, and that someone is trying to cloak their personal preferences in the guise of ethical rules. Moreover, the casuist analysis is fairly damning given the tactic of keeping risks high: Any ethical rule that calls for causing people to needlessly suffer, for no benefit other than trying to discourage them from doing what causes them to suffer because it is bad for them, is highly suspect.

Only occasionally do those who assert the extremist position attempt to justify it. Most often this takes the form of portraying any acceptance of tobacco/nicotine usage as a blight on society or humanity. This borders on pure circularity, begging the question of why usage is bad: If people adopt low-risk tobacco/nicotine products, then more people will be doing a bad thing, which is bad, and therefore promoting THR is bad.

When the argument is phrased in non-circular ways, it is usually the Lovejoy-esque "won't somebody think of the children" (for non-Simpsons fans, see, en.wikipedia.org/ wiki/ Helen_Lovejoy) plea about visibility of use: that if we try to improve the welfare of smokers, we will send the "wrong" message to nonusers by not wholly condemning the behavior. This is basically the same argument that is commonly offered by anti-gay-rights activists who stop short of calling for criminalization of homosexuality but oppose policies aimed at reducing discrimination, facilitating domesticity, or providing public health services. This too borders on the circular: anything that acknowledges the preferences and basic human rights of those who engage in a particular behavior (homosexuality; using tobacco/nicotine) could be interpreted as encouraging the behavior, and since the behavior is bad, encouraging it is bad.

The most logically charitable interpretation of such claims seems to be that the concerns of nonusers trump the concerns (health, welfare, right to honest information) of users, because the latter have made themselves undeserving, and that exposure to low-risk product use will hurt nonusers. While this presents the extremist position as something other than circular or anchored only in individual pique, and thus offers some logic, it fails both empirically (why would nonusers discovering the advantages of low-risk nicotine products hurt them?) and morally. The language is disturbingly similar to the excuses for discrimination against any disfavored group on the basis of race, sexuality, poverty, etc. More formally, imposing costly limitations on one group of people (by misleading them) purely to benefit another group violates most every ethical rule accepted by anyone: utilitarianism, basic civil liberties, health ethics, Kantian duty to not use people purely as means to an end, categorical imperatives about honesty, etc.

Argument: Public health advocates should never promote something that is not 100% healthy.

Often, if you ask someone who has never seriously thought about ethics or the practice of medicine or public health what the preeminent health ethic is, they will recall the Hippocratic Oath, and say "do no harm", rather than correctly identifying the principles surrounding informed autonomy. They might then go on to interpret this non-rule as forbidding any action/policy/recommendation that has any possibility of causing any harm. It should be immediately obvious that this is tantamount to a demand for complete paralysis.

No medical or public health action is 100% free of risk of something going wrong. Vaccines and surgery sometimes kill people, mammography sometimes causes cancer, and even a trip for a preventive exam exposes someone to the dangers of transport. Promoting the use of seatbelts reduces, but does not eliminate, the risk of automobile travel (and, indeed, does not reduce the relevant risk nearly as much as THR does). Moreover, automotive safety features, like any other harm reduction measures, make risky behavior less costly (i.e., less health risk), and so people engage in more of it than they otherwise would (driving more, driving faster, etc.). Indeed, in the case of auto safety features, the behavior resulting from greater safety for the occupants of the vehicle creates greater risk for pedestrians and cyclists (the children!). Thus, the "do no harm" pseudo-argument effectively condemns almost all of public health practice. Fortunately no such ethical rule is accepted in our society.

Argument: Low-risk nicotine products provide smokers a way to avoid suffering in situations where they cannot smoke, and is sometimes even promoted for this purpose, and therefore may actually increase long-run smoking prevalence.

The reason that this does not read like an argument against THR is that it really is not one. However, currently it is the claim that is probably most commonly used as an attack on THR and so needs to be included in this analysis. It should be immediately apparent that this might constitute an argument against the *availability* of smokeless nicotine products (which is roughly synonymous with low-risk nicotine products), including pharmaceutical nicotine patches, gum, etc. However, given that some kinds of smokeless nicotine products are already widely available in almost every relevant jurisdiction, and that smokers know where to find them and that they can use them in smoke-prohibited situations, this obviously does not constitute an argument against promoting THR. Indeed, it is really an argument in favor of promoting THR, since if smokers are going to use these products anyway, we should endeavor to persuade them of the benefits of switching entirely.

From an ethical standpoint, this erroneous argument is quite a telling statement about the behavior of the anti-tobacco extremist faction. Time and place restrictions on smoking are justified based on concerns about the health of bystanders who might be exposed to second-hand smoke, with the imposition on smokers declared to be an acceptable price to pay. Setting aside debates about the scientific validity of the claims, the ethical argument – about not being the involuntary victim of someone else's behavior – is easy to defend. However, since there was never a social consensus that smokers should intentionally be made unhappy, merely that making them unhappy is a reasonable price to pay to protect others, the existence of restrictions on

smoking cannot justify restricting the availability of smokeless products, let alone hiding the benefits of THR.

When anti-THR activists decry the use of low-risk smokeless products to "get around" the restrictions, they are effectively admitting that they were lying about their motives for restricting the behavior of smokers. They were not trying to protect nonsmokers from the minor effects of small doses of second-hand smoke; they were trying to hurt smokers by leaving them longing for a cigarette. So, whether the goal of that was to motivate smokers to quit or simply to punish the behavior (it is easy to find examples of anti-tobacco extremists openly expressing glee about the suffering of smokers), anything that diminishes the suffering of a smoker undermines the desires of this faction. This presents another casuist observation that seems to condemn the ethics of the extremist agenda. Moreover, the logic of the argument seems to be that punishing smokers is such an important goal that a promising public health policy for helping them should be avoided because, though promoting THR (as opposed to banning nicotine gum) does not even directly affect the attempt to punish the smokers, it might theoretically have some tangential impact on it. It seems a rather damning commentary about those who oppose THR that they actively anchor their position on the ethics and logic of this argument.

Conclusions

This attempt to find ethical arguments against promoting THR shows that finding defensible arguments is remarkably difficult. It is possible that anti-THR activists could make a better case for themselves, but if we knew how it could be done, we would have included it. The fact that they have not done so tends to suggest that they agree that it is not possible. While it is never possible to prove the universal non-existence of something, in this case an ethically valid anti-THR argument, the best evidence for the non-existence tends to be strong motivation of a lot of people to find it. Given that there is a large and well-funded industry devoted to making the case against THR, but the case has never been made, the evidence supporting the universal negative is about as strong as it can be.

The best that can be said for the arguments we have identified is that if one accepts an ethical system where physical health trumps all other contributors to welfare, and pursuit of such consequences need not be constrained by individual rights or categorical imperatives, *and* we assume – contrary to all the evidence that exists – that promoting THR would actually increase physical health risks, then there is a case against THR. Alternatively, it is always circularly the case that if a particular behavior – in this case consumption of any tobacco/nicotine product – is simply declared to be unethical, then any effort that might encourage it is also unethical. It should be obvious that allowing people in positions of influence to turn their own minority opinions into declared social ethics is a rather scary way to make social policy.

This analysis suggests that attacks on THR are not based on defensible ethics. They are presented in ways that apparently appear credible to some observers, but seem to be based on undefended ethical positions that, if accepted, would equally condemn a wide variety of other public health activities and a large portion of activities that people choose to engage in. We present this as a challenge and invitation for anti-THR activists to better defend their arguments as stemming from ethical principles that others would accept. If they continue to fail to do so in light of explicit challenges like this one, then those arguments must be judged to be not only unpersuasive, but also inherently unethical to put forward.

References

Kozlowski, L.T. and Edwards, B.Q. (2005). "Not safe" is not enough: smokers have a right to know more than there is no safe tobacco product. *Tob.Control, 14*(Suppl 2):ii3-ii7.

Kozlowski, L.T. and O'Connor, R.J. (2003). Apply federal research rules on deception to misleading health information: an example on smokeless tobacco and cigarettes. *Public Health Rep., 118*(3):187-192.

Phillips, C.V. (2009). Debunking the claim that abstinence is usually healthier for smokers than switching to a low-risk alternative, and other observations about anti-tobacco-harm-reduction arguments. *Harm Reduction Journal, 6*(29).

Phillips, C.V. (2009.) The affirmative ethical arguments for promoting a policy of tobacco harm reduction. Working paper. http://www.tobaccoharmreduction.org/wpapers/affirmative.pdf

Phillips, C.V. et al. (2010). TobaccoHarmReduction.org.

Phillips, C.V., Heavner, K., and Bergen, P. (2010 in this volume). Tobacco – the greatest untapped
potential for harm reduction. Book chapter.

Phillips, C.V., Wang, C., and Guenzel, B. (2005). You might as well smoke; the misleading and harmful public message about smokeless tobacco. *BMC Public Health, 5*(31).

Rodu, B., & Godshall, W.T. (2006). Tobacco harm reduction: an alternative cessation strategy for inveterate smokers. *Harm Reduction Journal, 3*(37).

Chapter 8

Debunking the claim that abstinence is usually healthier for smokers than switching to a low-risk alternative, and other observations about anti-tobacco-harm-reduction arguments

Carl V. Phillips

Reprinted from Harm Reduction Journal, with a correction by the author that is forthcoming in HRJ.

Editor's Note: Mistakes were made in the history of this paper. Before I (this note is written by CVP alone) first circulated a draft of this analysis I was sure that most people who thought about THR were generally aware that the average day of smoking posed a non-trivial risk compared to a lifetime of low-risk product use, and thus a fairly small number of days of smoking was fully as bad as a lifetime of low-risk product use. I quickly discovered that this came as quite a surprise to many readers, and some told me that what I thought was just a simple quantification exercise was really a breakthrough analysis that could change the way many people saw THR. The lesson there is that not everyone thinks the same and I erred in not quantifying and reporting this years ago when it first occurred to me.

In retrospect, I might have realized the value of reporting this simply because of how much mileage anti-THR activists have gotten out of the claim that we should not start promoting THR now, but rather should wait until we can offer something that is even lower risk than current products, resulting in even greater health benefits. The quantification shows that such an improvement is effectively impossible because the needless extra smoking that will occur while waiting causes far more risk than current THR products ever could. There is simply no conceivable way that waiting for even-lower-risk products or a way to induce abstinence will have greater net health benefits than immediately promoting THR based on existing low-risk products.

Of course, it is pretty clear that most anti-THR activists are not really interested in what the evidence shows, as noted in the correction to the article that appears after the reprint, and when that is combined with their political and financial control over most of the discourse it means that

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even a clear debunking of their claims probably will not stop them from continuing to make the claims. But at least THR advocates can now point out that not only is opponents' professed optimism that better options might emerge pretty clearly a rationalization to hide their real (extremist) goals, but also that their claim represents a quantitative impossibility.

On the subject of the correction, please read it for an explanation of the error that resulted in a misstatement in the abstract. I made the mistake and the many readers who read it before the article was published made the mistake of assuming that I reported the numbers correctly rather than mixing up two calculations, and so did not check my work (though I do not blame them for my error, of course). Fortunately, the mistake makes no practical difference for the worldly implications of the result, and so I hope it does not distract from the potential usefulness. Republishing the article here, with this introduction, a marked-up abstract, and the erratum should increase the chance that future readers will get the useful information in its corrected form.

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Debunking the claim that abstinence is usually healthier for smokers than switching to a low-risk alternative, and other observations about anti-tobacco-harm-reduction arguments

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Abstract

Nicotine is so desirable to many people that when they are given only the options of consuming nicotine by smoking, with its high health costs, and not consuming nicotine at all, many opt for the former. Few smokers realize that there is a third choice: non-combustion nicotine sources, such as smokeless tobacco, electronic cigarettes, or pharmaceutical nicotine, which eliminate almost all the risk while still allowing consumption of nicotine. Widespread dissemination of misleading health claims is used to prevent smokers from learning about this lifesaving option, and to discourage opinion leaders from telling smokers the truth. One common misleading claim is a risk-risk comparison that has not before been quantified: A smoker who would have eventually quit nicotine entirely, but learns the truth about low-risk alternatives, might switch to an alternative instead of quitting entirely, and thus might suffer a net increase in health risk. While this has mathematical face validity, a simple calculation of the tradeoff -- switching to lifelong low-risk nicotine use versus continuing to smoke until quitting -- shows that such net health costs are extremely unlikely and of trivial maximum magnitude. In particular, for the average smoker, smoking for just ~~one more month~~ before quitting causes greater health risk than switching to a low-risk nicotine source and never quitting it. Thus, discouraging a smoker, even one who would have quit entirely, from switching to a low-risk alternative is almost certainly more likely to kill him than it is to save him. Similarly, a strategy of waiting for better anti-smoking tools to be developed, rather than encouraging immediate tobacco harm reduction using current options, kills more smokers every month than it could possibly ever save.

Correction: "..a few more months..." see note at the end of the chapter.

Introduction

Tobacco harm reduction (THR), the substitution of low-risk nicotine products for cigarette smoking, is increasingly recognized as offering huge public health benefits. Smoking is well known to be a very hazardous activity, but the main reason why people smoke - nicotine - does not itself cause much risk when separated from inhaling smoke. Extensive epidemiology shows that the use of Western oral smokeless tobacco (ST) causes a trivial fraction of the mortality risk from smoking, and it is believed that electronic cigarettes and pharmaceutical nicotine products (gums, patches, lozenges) have similarly low risks. Many smokers will keep smoking until they die from it because, when given only the options of smoking or completely giving up nicotine, many will not give it up. But many of them probably could be persuaded to switch to a low-risk source of nicotine, and the health benefits would be almost as good as quitting entirely.

Readers interested in background on THR that is beyond the present scope, including quantifications of its potential benefits and reports of past successes, can find them in our website [1], in various overview papers (Phillips CV, Heavner K, Bergen P. Tobacco - the greatest untapped potential for harm reduction. Submitted, Available at: http://www.tobaccoharmreduction.org/wpapers/006.htm) [2,3], and in endorsements by British and American medical organizations [4,5]. Other relevant contributions to the issue include studies that allow estimates of the potential benefits (Geertsema K, Phillips CV, Heavner K. University Student Smokers' Perceptions of Risks and Barriers to Harm Reduction, Submitted, Available at: http://tobaccoharmreduction.org/wpapers/001.htm) [6,7], estimates of how much THR has already been employed in the past in the U.S. [8], and how it has largely succeeded in Sweden, where ST has substantially replaced smoking, resulting in the lowest tobacco-related disease rates in the Western world [9,10].

Stated estimates for how much less risky ST is compared to smoking vary somewhat, but the actual calculations put the reduction in the range of 99% (give or take 1%), putting the risk down in the range of everyday exposures (such as eating french fries or recreational driving), that provoke limited public health concern [6]. Even this low risk is premised on the unproven assumption that nicotine causes small but measurable cardiovascular disease risk (as do most mild stimulants such as decongestant medicines, energy drinks, and coffee), since such risks account for almost all of the remaining 1%. Perhaps just as important, even a worst-case scenario puts the risk reduction at about 95%, meaning that any scientifically plausible estimate shows THR has huge potential health benefits. There is no epidemiology for the new electronic cigarettes and very little useful epidemiology for assessing long term use of pharmaceutical nicotine products. But since most of the apparent risk from ST comes from nicotine, and the other ingredients in the non-tobacco products are believed to be quite benign, we can conclude that the risks across these product categories are functionally identical from the perspective of THR.

Because it is not necessary to distinguish among product categories for purposes of the present analysis, a collective description, *THR products*, is used. Product preferences vary and many smokers become attached to aspects of the smoking experience, including the aesthetics (flavor, smell, mouth and airway feel) and social behaviors for which no other product is a perfect substitute. The variety of THR products increases the chance that a given smoker will find one of them a sufficiently good substitute for smoking.

Harm reduction is a generally accepted public health principle that recognizes that eliminating an exposure is often not practical, welfare maximizing, or ethical, and so we should endeavor to reduce the harm from the exposure. The best example is encouraging the use of seatbelts without trying to curtail exposure to automotive transport. However, for politically controversial exposures (e.g., injection drug use, sexual activity outside of marriage, tobacco use) opponents of harm reduction often try to defend their beliefs that "just say no" (abstinence only) is the only acceptable option by observing that "lower risk does not mean no risk". But in the absence of quantification, this observation is merely a trivial vocabulary lesson, not a useful contribution to decision making. The present analysis offers a quantification that illustrates how a 99% reduction in risk is so close to zero risk that the "let's wait and see if we can do even better than current low-risk options" attitude is clearly killing more people than it could ever save. Rational decision strategies call for taking advantage of existing knowledge at some point, rather than continuing to search. If a risk is low enough, it is obviously better to accept that risk than to stick with high risk levels hoping that a way to achieve even lower risk will be discovered.

Harm reduction is particularly compelling for the use of nicotine because so many people have such a strong propensity for using it. Nicotine is a very beneficial drug for many people, providing alertness, focus, pleasure, and relief from a variety of psychological symptoms and pathologies. A substantial fraction of the population gets these benefits by smoking even though the health costs are so high, which means that demanding they quit entirely entails great welfare costs and is not likely to work.

Smoking can be described compellingly in terms of normal welfare economics, such that the consumer is maximizing his welfare by choosing among the available options (smoke or not smoke). Both choices have costs and benefits, and some consumers judge that the benefits of smoking outweigh its very high costs. However, for many such smokers, the possible reduction in benefits from switching to a less-enjoyed product would be greatly outweighed by the reduction in costs from health risks, so knowing about the benefits of switching to a THR product would be tremendously beneficial. Alternatively, it is often implicitly argued that smoking behavior does not conform to rational choice theory: Smokers do not choose smoking from among their options, but rather "addiction" (a rather slippery concept which is seldom actually defined, but is still widely invoked and accepted) or some related phenomenon prevents smokers from being able to choose to be abstinent. In that case, THR offers a health benefit that is not going to be achieved by choosing abstinence, and thereby also provides a great welfare benefit. Thus, either of these models of individual behavior leads to the same conclusion: Many people who are faced with

the dichotomous choice of smoking and abstinence will not just quit, and many of them would be better off using nicotine in a low-risk form. Therefore, whether one believes that smokers are making a rational welfare-maximizing choice or are victims of a curse, THR makes sense from the perspective of both individual welfare and public health. (Further exploration of the policy-ethics arguments surrounding promotion of THR can be found in the collection of papers at http://www.tobaccoharmreduction.org/wpapers/010.htm.)

It might seem surprising that something as promising as THR is largely unknown and unimplemented as a policy. Much of the problem is that people (smokers, health educators, policy makers) hear the messages that THR products are not safe, that "all tobacco is deadly", and "the only safe choice is to quit entirely". This convinces people that THR either is not possible at all or represents only a marginal improvement that is not worth pursuing. Still, this begs the question of why anyone would choose to deliver the message that a 99% reduction in risk is almost as bad as continuing to smoke, rather than the obviously more accurate message that it is almost as good as quitting entirely. Answering this is useful for understanding the significance of the analysis presented here.

Why analyses like this one are needed

The discourse surrounding tobacco policy and education is dominated by people who pursue the most extreme possible goal regarding tobacco: unconditional elimination of its use. Explicit statements of that goal are very common. Their goal is not to design tobacco policies that maximize human welfare or even that maximally reduce physical health costs. Any such concerns are, at best, secondary to the goal of simply reducing consumption of all forms of tobacco, and usually also reducing any long-term self-administration of nicotine that has been extracted from the tobacco (i.e., electronic cigarettes and pharmaceutical products). Thus, while getting smokers to switch to using ST represents an almost perfect success from the public health perspective (and is even more attractive from the human welfare perspective), it represents little or no progress for someone pursuing the goal of unconditionally eliminating tobacco use from the world. Presumably those who believe that eliminating tobacco is the appropriate goal would not dispute this. With this in mind, it is much easier to understand why some people reject a 99% reduction in risk as not worth pursuing: reducing risk is not the major factor in their objective function.

(This, of course, does not address the question of *why* anti-tobacco extremists are motivated to pursue this goal. Exploring possible explanations is beyond present scope (they are discussed in a bit more depth in Phillips, Heavner & Bergen (Phillips CV, Heavner K, Bergen P. Tobacco - the greatest untapped potential for harm reduction. Submitted, Available at: http://www.tobaccoharmreduction.org/wpapers/006.htm)). The list includes: the economically absurd belief that nicotine products provide no benefits and thus no one really wants to use them, usually closely tied to the paternalistic notion that the activists are better able to determine what people really want than the consumers themselves; an irrational hatred of companies who make nicotine products (often with the exception of pharmaceutical companies who many anti-tobacco activists are closely allied with); the common drug-war mentality of wanting to purify everyone and considering users to be sinners; and simple involvement of individual ego, whereby the goals becomes about winning the race and defeating the opponent, without ever admitting that their strategy may not have been optimal, rather than trying to develop humane, rational, practical policies.)

Understanding this is critical because those pursuing the extreme anti-tobacco agenda are often thought to have risk reduction as their primary objective, and take advantage of this by making dozens of health risk claims. It is, of course, people's right to hold the political opinion that we should work toward eliminating all tobacco use, regardless of how pursuing that goal would affect people's welfare and health, and it is those advocates' right to campaign for their goal. The ethical problems and public confusion result when the primary goal is eliminating tobacco, but the rhetoric mostly consists of claims about health. When such a disconnect occurs, the claims are merely rationalizations or attempts to persuade those who might not be persuaded by the true goal, rather than representing true underlying motives. When the language of science is used to rationalize rather than analyze, the probability is high that the science will degenerate into pseudo-scientific rhetoric.

None of this should come as a great surprise given the history of other abstinence-only agendas presented in the guise of public health. It has long been accepted by the public health community that harm reduction strategies for illicit drug use, from needle exchanges to education about the advantages of moderation, save many lives. Nevertheless, anti-drug warriors who support a "just say no"-only strategy frequently try to shut down programs that promote harm reduction. Their explicit argument is never "those criminals deserve to die if they do not quit using drugs, so we should not try to lower their risk"; in fact, their public argument is often based on inaccurate claims that the harm reduction strategies increase risk. Similarly, it has been known for decades that abstinence-only approaches to sex education in the West produce inferior health outcomes compared to balanced harm-

reduction-oriented education, combined with product and service provision. Activists who persist in claiming that promoting only sexual abstinence is health-improving seem to not be concerned with health so much as they are just annoyed that people are enjoying sex outside of marriage.

The politics and rhetoric of the abstinence-only approach to nicotine use have much in common with these other abstinence-only approaches, but this is not yet widely recognized. As a result, many people who are genuinely motivated by promoting personal and public health, and do not share the extreme anti-tobacco agenda, often believe the inaccurate health claims that are really rationalizations for the anti-tobacco position. Since this often is to the detriment of both public health and the scientific legitimacy of the health sciences, it is important for the public health and scientific communities to debunk these claims.

Debunking these claims is a difficult challenge. Anti-THR health claims are typically speculation or assertion, without the support of evidence or analysis, and thus actual scientists will immediately relegate them to the realm of, at best, speculative hypothesis. But it is easy to take advantage of laypeople's tendencies to accept at face value all manner of urban myths and other misconceptions, and to demand scientific proof that the claim is wrong [11]. Endeavoring to disprove a long list of assertions is far more difficult than making up those claims in the first place. Indeed, the sheer number and ever-changing nature of those claims is further evidence of attempts to rationalize a pre-determined conclusion, not an exploration of real reasons: Generally when someone shops different claims to various populations to see which changes their behavior in the preferred way, we call it marketing, not science, education, or ethical public health policy.

Methods of responding to misleading claims

But though trying to disprove unsubstantiated claims is not considered necessary in scientific thinking and is obviously an epistemic nightmare, it is necessary to advance public health policy. Advocates of THR have endeavored to debunk some of the most erroneous anti-THR claims. Some claims have been debunked by simply pointing to existing scientific literature (e.g., claims that ST use causes substantial disease risk are contradicted by decades of epidemiologic evidence to the contrary). Some claims have required new directed empirical work (e.g., the claim that promoting THR would create a "gateway" to smoking required focused empirical research and analysis to debunk). Still others are hypothetical scenarios that require an analytic approach to show they are misleading or of minor consequence.

An example of such analysis is the debunking of the claim that if we allow smokers to learn that they have low-risk alternative sources of nicotine, then many people who might have had zero risk from consuming nicotine (because they would have quit entirely or not started) will choose to consume ST or pharmaceutical nicotine and suffer some small risk. This will, the claim goes, increase total population risk. But when it is demonstrated that net social risk could not conceivably increase in this manner, anti-THR activists sometimes counter with a second assertion: Even though total population risk will decrease, there are many smokers who would have quit nicotine entirely but instead switch to a low-risk product, and they will suffer greater risks than they otherwise would, and that this constitutes an argument against THR. Debunking this requires the additional analysis presented below.

One might argue that the ethical considerations make quantifying this claim irrelevant. The leading deontological tenet of modern health ethics is the obligation to provide people with accurate information so they can make informed autonomous decisions about their own health. Thus, whatever one might think about actively promoting THR as public policy, it is *per se* unethical to mislead people in order to manipulate their health behavior, even if it is "for their own good" (Phillips CV. The affirmative ethical arguments for promoting a policy of tobacco harm reduction. Submitted, Available at: http://www.tobaccoharmreduction.org/wpapers/010.htm). In other words, preventing a smoker from learning about a low-risk alternative, even if he is about to quit entirely, is clearly unethical. Moreover, a consequentialist analysis reveals that someone who chooses to forgo nicotine because of the high cost of smoking but, upon learning of a low-risk way to consume nicotine, chooses to consume low-risk nicotine must have concluded that the net welfare benefits of consumption (the benefits of nicotine, net of the health and other costs) are positive, even though the net benefits of smoking were negative. Therefore misleading people about the option necessarily has net negative welfare impact (Phillips CV. The affirmative ethical arguments for promoting a policy of tobacco harm reduction. Submitted, Available at: http://www.tobaccoharmreduction.org/wpapers/010.htm).

Nevertheless, some observers are unconcerned with these ethical arguments. More importantly, the claim brings up an interesting analytic question that is worth answering even apart from the politics of THR: In terms of physical health risks, someone who keeps smoking is clearly worse off than someone who switches immediately, who in turn is probably slightly worse off than someone who immediately quits entirely. But how long would someone have to keep smoking before his health risks would have been lower had he just switched today and used low-risk nico-

tine for the rest of his life? Or, equivalently, how much time can pass while powerful interests vilify THR products while waiting for theoretical perfect alternatives to emerge before that delay kills as many people as using THR products ever could? For anyone who is primarily concerned about maximizing health outcomes (even apart from rights to autonomy or welfare maximization), the answer to these questions should make it clear that THR should immediately be embraced using currently available alternative products.

Analysis

It is illustrative to begin this analysis by addressing the assertion that total social (population) risk will increase if THR is embraced, explaining how that is insupportable, before continuing to the new analysis of the individual smoker who will either switch or quit.

Net effect on social risk of lowering individual risk

It is clear that lowering the risk from consuming nicotine (or, more precisely, making people aware of the fact that they have the option of lowering their own risk) should result in some people using nicotine who otherwise would not. Simple economics tells us that when the population learns that they can receive the benefits of nicotine with much lower total cost (due to almost eliminating the health risk), rational behavior causes increased consumption. This means that demands like the Society for Research on Nicotine and Tobacco's (SRNT) policy statement, " [THR] should not reduce the likelihood of eventual cessation of tobacco use" and "should not lead to increased population prevalence of tobacco [use]" [12] are tantamount to saying that any step that lowers the risk from using tobacco - whether it be creating a safer product or finding a cure for lung cancer - is unacceptable. This is critical to understand: Finding a cure for lung cancer would inevitably increase the number of people who smoke, and thus the SRNT is demanding that no such cure be pursued. More generally, insisting that a health policy or technology, even one that saves many lives, is only acceptable if it does not lead to an increase in the number of people engaging in risky activities would not only forbid THR, but would also prohibit condoms, sports safety equipment, sunscreen, lifeguards, vaccines for travelers, and trauma centers.

In fairness, those who make such statements are probably not intentionally calling for a prohibition against lowering the risks from smoking, such as by demanding that we avoid curing cancer. They are probably just ignorant of basic economics and how changing costs influence people's decisions. Though there are skilled economists involved in "tobacco control" research and advocacy, they seem to have done little to educate or influence activism or policy statements. The most vocal activists are clearly unaware of the overwhelming economic evidence about how individuals optimize consumption, or reject that evidence without any basis for doing so, and thereby reject the liberal ethics of economics-based consumer policy that follow from it. This is not merely a matter of considering individual smokers as irrational, since it even extends to assuming profit maximizing businesses do not follow their best interests - e.g., they insist that prohibiting a popular voluntary commercial choice, banning smoking areas in pubs, does not merely result in a net health improvement, but actually never hurts any merchant [13]. However, even though economic ignorance is a compelling explanation, we cannot rule out the possibility that many anti-tobacco extremists really mean what they say, and actually favor maximizing the risk from using nicotine and otherwise intentionally lowering people's welfare in order to make tobacco/nicotine use less appealing.

Empirical support for the economic prediction that lowering risk will increase consumption (either by more people consuming the good, or those who are consuming it using more, or both) can be found in Sweden. Most Swedish would-be-smokers (particularly men, but increasingly women also) use ST instead, resulting in by far the lowest consumption of smoked tobacco in the Western world. The result is the expected reduction in smoking-caused diseases, with no offsetting increase in ST-caused diseases (which is to be expected, since no detectable level of any disease has been shown to be caused by ST). But total tobacco consumption in Sweden is among the highest in Europe. Anti-tobacco extremists, therefore, consider the Swedish experience to represent a failure, consistent with their political goal of reducing tobacco use regardless of the health effects. Realizing, however, that most observers would not share that goal, they try to rationalize their position that this public health triumph is really a failure by trying to deny the public health gains.

Indeed, it should be recognized as a reassuring observation about people to see that when the health risk from a consumption choice is dramatically reduced, people rationally increase total consumption. Many readers will probably find it odd to declare it reassuring that more people would become nicotine users, but a single observation should be sufficient to eliminate all confusion: The prediction that some people who would not smoke will choose to use low-risk nicotine products is equivalent to the more politically correct statement, "some people choose to avoid smoking due to the high health costs even though they would like to get the nicotine." Few would disagree that the latter is a reassuring observation about people's rationality.

Extending this, it is plausible that lowering the health risks of consuming something could increase consumption to the point that the total social risk will increase. It must be the case that there is an improvement in total net social

benefits, since the change would result from free choice of a preferred option, and the major externalities would likely also be positive. But health risk, considered apart from other contributors to welfare, might increase. All that is necessary for an increase in health risk is that the quantity consumed goes up by enough that even with the lower risk, the total risk (i.e., quantity consumed multiplied by average individual risk per unit of consumption or, in units of people, the number of consumers multiplied by the average risk per consumer) is greater. Whether this happens in a given case is an empirical point, but for the case of smokers and some nonsmokers adopting a low-risk nicotine product, a simple analytic reality check shows that it is effectively impossible.

Given the estimate that switching to a low-risk alternative reduces a smoker's risk by 99%, if only 1% of a population switched from being continuing smokers to using THR products, then even if the entire rest of the population switched from no consumption to the low-risk products it would not result in a social risk increase. (The number of additional users necessary to make up for the risk decrease from one switcher is easily calculated as (1-x)/x, where x = the proportion of the risk from smoking caused by the THR product, so since (1-.01)/.01 = 99, then for 1 smoker who switched from smoking, there would have to be 99 non-users who took up ST to make up for it.) Even if the alternative product was 5% as harmful as continuing to smoke, which is difficult to imagine given the available evidence, if 1% of the population switched (which would represent less than 5% of all smokers in Western populations, a very modest success), the new product would have to attract 19% of the population, roughly one-quarter of all current non-users, to start using nicotine in the low-risk form to result in no net gain. This would represent total nicotine usage prevalence close to the maximum it ever reaches, even in populations not worried about health risks, which is presumably the total portion of the population that benefits from using nicotine. Thus, even a pessimistic comparative risk scenario leaves little room for an increase in social health risk.

The argument that total population risk might increase and therefore we should not inform people about THR - though arithmetically absurd and based on the unethical premise that it is acceptable to mislead people - has proven to be a remarkably persistent rationalization for anti-THR activists. It is so often repeated that the original debunking of it, an article that basically just graphs the y = (1-x)/x function and expands on the point from the previous paragraph [14], has been cited by scores of journal articles about THR (including most of the substantive overview articles on the topic) and hundreds of presentations and popular communications, presumably because the later authors believed it was necessary to respond to the claim that the article debunks. But there has not previously been a good quantitative response to the next layer of rationalization: Even though social risk will clearly be lower if THR is widely adopted, somewhere out there is a hapless smoker who would have soon won his struggle to give up nicotine to avoid all further health cost, but he becomes doomed to failure when presented with the information that he could use a low-risk alternative, resulting in a net health cost.

This claim, plausible until one actually checks the numbers, typically takes a form like THR "may undermine efforts leading to the healthiest outcome of all, namely, complete tobacco abstinence". Versions of this claim are common in statements made to the popular press by anti-THR activists and in rhetorical documents put out by anti-tobacco extremist organizations (though this particular quotation actually comes from an ostensibly scientific journal article [12]). Setting aside the inappropriate breadth of this phrasing (it is generally accepted that "healthiest" should incorporate psychological health, not just longevity, and since nicotine has substantial psychological benefits, abstinence is often not healthiest), the implicit claim is quantitative and a function of the time periods involved. Claiming that the outcome the authors personally prefer, abstinence, is healthiest (in the narrow sense of maximizing life expectancy) depends on the implicit quantitative claim that the hypothetical complete cessation of nicotine use would have begun soon enough that it would have resulted in less physical health risk than consuming a low-risk alternative. (Some might claim that such authors are merely suggesting that immediate abstinence would be the physically healthiest behavior, without reference to what might actually happen. But this defense is not convincing since the statements are made in the context of policy recommendations and other practical discussions, where obviously no one would suggest that assessing the effect of universal immediate abstinence has any practical relevance. After all, if the authors merely wanted to make a statement about what would be best, without regard to what is actually possible, then making it so that no one ever smoked in the first place would actually be best.)

Sometimes the claim is made in a form that practically concedes that eliminating tobacco use (and often any close substitute for it, like electronic cigarettes), rather than improving health, is the author's primary goal (e.g., "The major concerns of promoting a dangerous product as less harmful than another are that it may undermine efforts to achieve total tobacco-product cessation" [15]). However, such claims are typically presented in a way to imply that readers concerned with health outcomes should consider them to be health-based (in the previous example, the assertion appeared under the heading, "pub-

lic health implications of the findings from this study"). But even authors editorializing a pro-THR position, and thus presumably not basing their views on the anti-tobacco extremist position, often suggest that a "downside" [16] of having the option to switch will cause some people who would have quit entirely to suffer greater risk because they switch instead. But how many potential quitters actually fall into this "downside"? That is, how many were going to quit soon enough that switching actually represents a net increase in disease risk?

Calculation of the switch-versus-eventually-quit tradeoff

The following analysis quantifies the question about "soon enough". Note that this calculation addresses only the risk-risk tradeoff, ignoring any benefits of continuing to use nicotine rather than quitting and the welfare costs of the act of quitting. It is also limited to mortality even though non-fatal morbidity is probably not perfectly proportional to mortality risk. The latter simplification, as well as the necessarily rough input numbers, are relatively minor compared to the simplifications that exist (though are seldom acknowledged) in most population health analyses. More important, they prove to matter little, given the clear implications of the result. This analysis proves to be an excellent example of the value of a back-of-the-envelope calculation as adequate response to an unanalyzed claim: While it is often not practical to complete a precise analysis of a scientific or policy claim, it is often the case that the rough analysis that is practical is quite adequate for present needs, and is a great improvement over unquantified speculation.

For any given smoker at a particular time, who is not already doomed to die from his smoking to date, we wish to estimate how many days of continuing smoking causes as much risk of death as a future lifetime of using a low risk nicotine product. (Note: describing something as causing someone's death is shorthand for saying that it substantially hastened the death, and obviously not that ever-dying was conditional on the behavior.)

Answering the question for an individual would require determining the probability of dying from a lifetime of THR product use, starting at the present, and the probability of dying from future smoking as a function of how long the smoking continues. While it would be useful to have such a lifecycle-based model for individual decisions, it is not currently possible. An individual's risk from a lifetime of THR product use could be reasonably estimated as a function of the individual's current life expectancy, with possible refinement by inclusion of other variables. But despite the extensive research on smoking and health, there is apparently no good calculation of the risk from a short future period of smoking, based on current age, sex, etc. There is ample research about the benefits of quitting and it clearly establishes that quitting sooner is better, but it offers very limited information for calculating the marginal cost of a given additional period of smoking as a function of past smoking duration and other individual characteristics. Thus, while comparative observations are possible based on the demographics of the individual in question (e.g., a very young smoker, with a long potential period of THR product use, has more to lose from switching rather than quitting after a particular delay, and thus could afford a longer wait until quitting), there is currently no realistic way to do this calculation for individuals.

But from the public health education and policy perspective, knowing the risk-risk tradeoff on a population average basis is almost as useful, and calculating that is possible. The population average can be viewed as comparing switching-now-versus-quitting-later for all smokers acting simultaneously (which, of course, will not happen - it is just a useful unit of analysis) or, equivalently, asking the question for a random smoker we know nothing about. Public health interventions, particularly the provision of information, typically affect all or random individuals, making this the relevant level of analysis.

The key to the calculation is the observation that if we assume that smoking more never cures a disease that was caused by previous smoking, then for anyone who dies from smoking, there will be a day, D, in his smoking history such that if he had quit entirely before that day he would not have died from smoking, but as a result of smoking through that day he does die from smoking. Because we never know which day that is, and because smoking-caused disease results from an accumulation of insults, this observation may not be obvious to all readers. For those who do not find this observation intuitive, a simple proof follows.

> *Proof*: Assume that a destined-to-be-fatal disease that was caused by past smoking is never cured or delayed by future smoking. Consider someone who dies from smoking. Consider the latest day, if it exists, of smoking during his life such that had he quit entirely before that day he would not have died from smoking. Since this is the latest such day and he did die from smoking, if he smoked that day he would still have died from smoking, which defines day D. The smoker's life was finite, and thus includes a finite t days of smoking. Had he quit just before day t, either he would have still died from smoking (either from the disease that actually killed him or another disease also caused by smoking) or not. If not then day t meets the definition of D (if he had quit the day before he would not have died, and t is necessarily the latest such day). If day t is not D, then either he would have not died from smoking if he he had only smoked through day t-2, in which case day t-1 is D (if he had quit before that day

he would not have died, and this is not true for any later day). If t-1 is not D then a similar analysis can be applied to t-2, and so on. Thus, by counting down through the finite list of days, we either find some day that is D or reach day 1 without having found D, in which case quitting any time after day 1 would not have stopped the death from smoking. But by hypothesis the death was caused by smoking, so never starting (quitting before day 1) would have prevented it, and therefore day 1 is D. Therefore, D exists sometime within the days of smoking for each individual who dies (or is destined to die) from smoking.

The same logic proves that for every smoker who dies of smoking there was one particular cigarette that was the fatal point-of-no-return. The proof does not address the fact that moving toward quitting might alter which day is D by altering smoking intensity or starting and stopping. It also ignores the possibility that further smoking past D could further accelerate the death from smoking, making the subsequent analysis conservative because it ignores the possible longevity benefits of switching among those already doomed to die from their smoking.

Given that everyone who dies from smoking has a D, it is possible to estimate the increased risk of dying from smoking for the average smoker (or all smokers) from smoking one more day. For a typical Western population, we can estimate the average lifetime days of smoking for someone who dies from smoking to be about 18,000 (about 50 years). Since one of those days must be D, the average day of smoking from someone who is destined to die from smoking (averaged across all days of smoking among all such individuals) has probability 1/18,000 of being the day that doomed the smoker to die from smoking. Thus, if all current smokers who are destined to die from smoking gave up smoking tonight, some number, x, of them would be saved from dying from smoking, but if instead they gave up smoking tomorrow night, only x minus 1/18,000th of that population would be saved.

Notice one immediate observation based on this that is apparently not obvious to many smokers and people who give advice on these matters: Quitting *someday* is not sufficient - it is possible to quit too late and there is no way to know in advance which day is one day too late.

Estimates for Western populations of the fraction of current smokers whose deaths will be caused by smoking range from 1/4 to 1/2, so roughly one death from smoking is caused by each 50,000 days of smoking. The best available estimate is that the average risk of dying from THR product use is about 1% that from smoking. Following the above logic, this represents 5×10^6 days of use per death caused. Since the ratio of the risk from THR product use compared to smoking enters the calculation linearly, readers who believe the ratio is really 2% or 3% can adjust the final estimates upward by a factor of 2 or 3. (Readers who believe the ratio is much more than that should take a closer look at the scientific evidence.) Assume that the total risk from THR product use is the same whether it is a lifetime of exclusive THR product use or switching to THR products after some period of smoking. Note that this is a conservative assumption, since any smoker who is already doomed to die from smoking experiences no increase in the chance of dying from nicotine use by using a THR product. Moreover, it seems fairly likely that if THR product use causes any negative health impacts other than the minor effects of nicotine itself, then they are not exactly the same as those from smoking, and so the additive health effect of THR product use on top of smoking would probably be less than the additive effect of a longer term of THR product use.

We can estimate that if smokers who are going to eventually cause themselves to die from smoking will smoke an average of 18,000 days, then the average such current smoker has about 9,000 days of smoking ahead of him. (This is would be exactly true if we were in steady-state with respect to smoking and if smokers with fewer days of smoking ahead of them were not more likely to already be doomed. Failures of these assumptions will tend toward canceling out, and the net error seems to be within the limited precision built into the calculation.) Thus, using the conservative simplification above, if the average such smoker switches immediately, he has a $9{,}000/5\times10^6 \approx 1/600$ chance of dying from ST use. Comparing this to his extra probability of dying from smoking by waiting longer to completely quit, at 1/18,000 chance of causing death per day, shows that this is the equivalent of delaying quitting by about one month. Thus, on average, this smoker only endures greater total risk from using a THR product for the rest of his life if he were going to become abstinent in less than a month.

Note that the "all smokers" or "randomly selected individual" condition is crucial here since, for example, a particular smoker who is young and therefore has not yet smoked much can probably get away with smoking years more before being doomed, but has many more days of potential THR product use ahead of him, might not reach risk parity for several months. Conversely, there are older demographic groups, possibly identifiable, who may not yet be doomed but are much more likely than average to be close, for whom a single additional day of smoking poses greater risk than a future lifetime of THR product use.

Discussion

While it is logically possible that lowering the risk from an exposure could increase population risk, the (1-x)/x calculation shows this is not plausible for THR. The suggestion

that, despite the lower population risk, many individuals might still face greater risk is also logically possible, but the calculation presented here shows that this is not a substantial practical worry.

On average, someone who would die from smoking who is going to take more than a month to quit entirely (or will experience relapses that will have a similar health impact - probably roughly a total of one month worth of days) will have less total health risk by switching immediately, even if he never quits the alternative product. The typical pattern of even dedicated quitters, starting and stopping smoking for a year or two, will cause much more risk than switching to a low-risk alternative. Moreover, even an average smoker who was going to successfully quit after only a week or two more will suffer only a tiny net increase in physical health risk from switching now, a change so trivial compared to the net benefits of switching for smokers who will not quit for years or ever that it is clearly inconsequential.

The practical implications of this analysis do not change based on plausible variations in the input parameters, including the risk from using ST. Even if we use a completely implausible high risk from ST use, say that it causes 10% of the risk of smoking, then if an average smoker would have taken ten months to quit entirely, he would have had lower risk had he switched immediately. The break-even might be as low as about half a year - recall the conservative assumption built into the calculation. Thus, even discovering that ST use is an order of magnitude worse than the ample current evidence suggests would not fundamentally change the implications of the analysis.

Since this analysis is based entirely on mortality risk, it ignores other contributions to welfare. The reason that current smokers have not already quit, in spite of the health benefits of doing so, is that it would have resulted in substantial costs to them and, similarly, whenever a smoker chooses to switch it implies that there is a net welfare benefit (compared to either smoking or abstinence) to using the alternative product. This welfare gain from switching rather than quitting probably dwarfs the welfare implications of the mortality risk from low-risk products, though quantifying that is beyond the present scope.

Finally, it is worth noting that someone who switches from smoking to a low-risk alternative still has the option of quitting entirely, lowering his risk slightly more still. Indeed, there is reason to believe that eventually quitting alternative products is easier. This means that even the young smokers who might have been better off with several more months of smoking rather than a lifetime of THR product use stand a good chance of quitting entirely anyway (if they decide that the benefits of consumption are outweighed by the benefits of quitting), further favoring the option of switching now. Even those smokers who cannot afford another day of smoking but fortunately switch just in time (who are likely from older demographics that are the primary target for THR) could then survive long enough to quit nicotine entirely.

Many of the claims about health risk made to try to discourage the adoption of THR have been proven to be out-and-out false. This includes the "total social health risk will increase" claim. The present analysis does not relegate the "some people would be stopped from quitting entirely and thus have worse health outcomes" claim to universal falsehood - it will still inevitably be true for a very few individuals. But this is common in public health interventions, from automobile safety equipment to vaccines - the net social effects are overwhelmingly beneficial, though some people (who cannot be identified *ex ante*, and often not even *ex post*) suffer net harm rather than benefit. The analysis shows that only a tiny portion of all future quitters will be quitting soon enough that they would have higher expected risk by switching immediately. Moreover, the net increase in expected risk even for those individuals would be extremely small, and the net welfare effects would still be positive. Clearly, then, the claim does not represent a sufficient concern to override the huge net expected social benefit, to say nothing of the ethical requirement that smokers be informed about their options. The claim is thus relegated to being a distraction from rational and honest discourse on the subject, not a contribution to it.

This calculation emphasizes the cost of delaying the adoption of THR at the individual level also: Those of us who promote THR are familiar with smokers who, upon learning about THR, insist that they do not need to consider that option because they will eventually be exercising the "perfect" option of quitting anyway. But many such individuals never quit, and almost none quit in time for it to be a healthier choice. Similarly, each additional month that anti-THR activism keeps a potential switcher from learning about THR is more likely to kill him than is a lifetime of using ST or another low-risk nicotine product. To put it bluntly, anti-THR activism and disinformation do far more damage to public health than smokeless tobacco, electronic cigarettes, or other THR products ever could.

Since THR can be self-tailored and requires no clinical or government intervention, it does not matter that there may be smokers for whom no low risk product is an adequate substitute or that there is no political will to actively endorse it. THR can be adopted by individuals who do find an acceptable substitute, and likely will be widely adopted if smokers were simply given accurate information. The usual explanation for the lack of such information is that anti-tobacco extremists promulgate disinformation it and then even the opinion leaders who

are genuinely concerned about public health repeat the inaccurate claims because they have been misled. But an alternative explanation is misplaced optimism on the part of the public health leaders: That is, many may not be misled by the disinformation about THR, but may genuinely believe that most smokers will successfully quit using nicotine very soon or that a perfect new anti-smoking method, policy, or product will be developed and cause everyone to quit soon, reducing their risks more than THR would. The present analysis shows just how overly-optimistic that belief needs to be in order to justify the failure to immediately promote THR using current technology.

Whatever the explanation for it, the present analysis shows that anti-THR activism is deadly. Hiding THR from smokers, waiting for them to decide to quit entirely or waiting for a new anti-smoking magic bullet, causes the deaths of more smokers every month than a lifetime using low-risk nicotine products ever could.

Competing interests

The author is an advocate of tobacco harm reduction, and thus has worldly goals that are furthered by debunking anti-THR rationalizations. He is also interested in improving research in public health and promoting evidence-based public policy, and thus has an interest in calling attention to flawed reasoning. In particular, he has long taught his students the value of back-of-the-envelope analysis and related reasoning, and so is motivated to seek examples that demonstrate its usefulness. The author has been the target of a well-documented campaign of attacks by anti-THR activists trying to damage his career and force him to stop doing THR research [17]. While nothing in this paper is a specific response to those attacks (the worst attacks have come mostly from minor local activists and the administration of the University of Alberta School of Public Health, not the internationally-known political activists cited in this paper), anyone who takes the concept of competing interests seriously will realize that such personal experiences may motivate behavior in ways an individual is not consciously aware of. The author's research is partially supported by an unrestricted (completely hands-off) grant to the University of Alberta School of Public Health from U.S. Smokeless Tobacco Company; the funders have had no input into the design or content of this analysis, and were not aware of it until it was made available to the public. Far more importantly, this author, like almost all other health researchers, is dependent on getting future funding from someone, future positive peer reviews, etc., if he is to continue his research, which in this case creates the conflicting incentive to push the frontiers in supporting the wisdom of THR (to make the research agenda more accepted) and for minimizing confrontations with powerful interest groups (to make himself more acceptable). The author advises many organizations on tobacco harm reduction, some of which are companies that profit from selling nicotine products, and is sometimes compensated for his time. In addition, he consults for USSTC in the context of litigation, has minor financial interests in the financial health of certain nicotine product manufacturers, occasionally uses several of the products mentioned in this paper, and has friends who have no intention of ever quitting their use of nicotine.

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References

1. Phillips CV, *et al.*: **Tobaccoharmreduction.org.** 2008 [http://www.tobaccoharmreduction.org]. Edmonton: CV Phillips et al. c2006-8
2. Rodu B, Godshall WT: **Tobacco harm reduction: an alternative cessation strategy for inveterate smokers.** *Harm Reduct J* 2006, **3:**37.
3. Ballin S: **"Smokefree" tobacco and nicotine products: Reducing the risks of tobacco related disease.** 2007 [http://www.tobaccoatacrossroads.com/2007report/071128_Ballin%20Report_final.pdf].
4. Royal College of Physicians: **Harm reduction in nicotine addiction: Helping people who can't quit.** *A report by the Tobacco Advisory Group of the Royal College of Physicians* 2007 [http://www.rcplondon.ac.uk/pubs/brochure.aspx?e=234]. London: RCP
5. Nitzkin JL, Rodu B: **The case for harm reduction for control of tobacco-related illness and death.** *AAPHP Resolution and White Paper* 2008 [http://www.aaphp.org/special/joelstobac/20081026HarmReductionResolutionAsPassedl.pdf].
6. Phillips CV, Rabiu D, Rodu B: **Calculating the comparative mortality risk from smokeless tobacco versus smoking. Poster Presentation. Congress of Epidemiology conference.** *American Journal of Epidemiology* 2006, **163(11):**S189.
7. Heavner KK, Rosenberg Z, Phillips CV: **Survey of smokers' reasons for not switching to safer sources of nicotine and their willingness to do so in the future.** *Harm Reduct J* 2009, **6:**14.
8. Rodu B, Phillips CV: **Switching to smokeless tobacco as a smoking cessation method: evidence from the 2000 National Health Interview Survey.** *Harm Reduct J* 2008, **5:**18.
9. Rodu B, Stegmayr B, Nasic S, Cole P, Asplund K: **Evolving patterns of tobacco use in northern Sweden.** *J Intern Med* 2003, **253(6):**660-5.
10. Stegmayr B, Eliasson M, Rodu B: **The decline of smoking in northern Sweden.** *Scand J Public Health* 2005, **33(4):**321-4.
11. Gardner D: **Risk: The science and politics of fear.** Toronto: McClelland and Stewart; 2008.
12. Hatsukami DK, Henningfield JE, Kotlyar M: **Harm reduction approaches to reducing tobacco-related mortality.** *Annual Review of Public Health* 2004, **25:**377-95.
13. Marlow M: **Honestly, who else would fund such research, reflections of a non-smoking scholar.** *Econ Journal Watch* 2008, **5(2):**240-268.
14. Kozlowski LT, Strasser A, Giovino GA, Erickson PA, Terza JV: **Applying the risk/use equilibrium: use medicinal nicotine now for harm reduction.** *Tob Control* 2001, **10:**201-203.
15. Tomar SL: **Snuff use and smoking in U.S. men: Implications for harm reduction.** *Am J Prev Med* 2002, **23(3):**143-9.
16. Gray N: **Mixed feelings on snus.** *The Lancet* 2005, **366(9490):**966-7.
17. Libin K: **Whither the campus radical?** *National Post* 2007:A1 [http://www.tobacco.org/news/252963.html].

Correction by the author

Forthcoming as a Comment attached to Phillips (2009) "Debunking the claim that abstinence is usually healthier for smokers than switching to a low-risk alternative, and other observations about anti-tobacco-harm-reduction arguments" in Harm Reduction Journal.

It has been called to my attention that one of my conclusions does not match the calculation that is presented. In particular, the statement in the abstract, "for the average smoker, smoking for just one more month before quitting causes greater health risk than switching to a low-risk nicotine source" should read either "for a smoker *who is doomed to die from smoking* if he does not quit, smoking for just one more month…." or "for the average smoker, smoking for *just a few more months*….". The latter is probably better as the take-away message from the analysis.

The explanation is that I ran two different calculations when carrying out this analysis, one for the average smoker and one for those smokers who are doomed to die from smoking if they do not quit. The advantage of looking at the former is that it describes an identifiable characteristic; the advantage of the latter is that it distills the analysis to those smokers we are most concerned about. Obviously the average smoker is at less risk from smoking another month than the doomed-but-for-quitting smoker, since the population of non-doomed smokers dilutes the average risk (by a factor of 2, 2.5, 3, or whatever the reciprocal of one's estimate of the proportion of lifetime smokers who die from their habit). In the published version of the paper I ended up including only the calculation for the doomed smokers, but erred by describing it as applying to the average smoker.

Had I observed such a switch in an analysis that was intended to attack tobacco harm reduction (THR), or something similar in an empirical study to spin it as anti-THR, I would have characterized it as certainly misleading and probably dishonest. I hope I can avoid the latter accusation for the following reasons: (a) I am highlighting the error and voluntarily running this correction with contrition (I do not recall anti-THR activists ever doing such a thing despite the enormous flaws that have been identified in some of their articles); and (b) When I have previously cited my results, including in a press release about the article, I believe I always described the break-even point as "a few months" or something similar, the accurate result I had in my head but did not correctly put on paper (which contrasts with anti-THR activists who often make claims to the public that are far stronger than what their studies support).

Frankly, I doubt the quantitative error really matters to anyone. It should not. Is anyone really going to think "you had me sold on promoting THR when you said that smoking for only one more month is just as bad as a lifetime of a low-risk alternative, but if it is two or three months then forget it – let them keep smoking"? This makes it no less an error, but it means that it changes nothing about the practical implications of the paper.

Always the teacher and social scientist, I cannot resist drawing two interesting conclusions from this error. I wish I could say that I planted it as an Easter Egg to teach these lessons, but I might as well take advantage of it anyway.

First, this is a great reminder that the status "peer-reviewed publication" is far from sufficient to conclude that something is correct. A version of this paper that included the error was read and checked many times over many months before being published (of course, I do not blame referees or anyone else who reviewed this for my error). We can only guess how often there are comparable errors in the health science papers where it is impossible for peer reviewers, editors, or readers to check the authors' work (the 99% of papers where, unlike this one, the authors do not report enough information to assess the accuracy of the conclusions). Moreover, when confidence intervals or other error statistics are reported (which would have been completely inappropriate for something like this, but is disturbingly common in other cases where it is equally inappropriate), they are based on countless assumptions, many of which are false (e.g., the assumption the author did not switch what he was calculating in the middle of reporting his results). This illustrates how such statistics typically serve to obscure the most important sources of uncertainty, giving a false sense of accuracy to non-expert readers by pretending to quantify the potential inaccuracy.

Second, the paper was in a journal (free online) for half a year before anyone pointed it out the problem. While it may seem nice to be able to "get away with it" for that long, the broader implications are disturbing. This correction to an overly-strong pro-THR claim did not come from one of the tens-of-thousands of people whose job descriptions (self-determined or institutionally defined) include advocating against THR. (It was discovered by Peter Lee, who, while not an activist, conducts analyses that have strongly supported the case for THR and was in the process of contributing to our THR yearbook.) No one took advantage of the opportunity to catch the error and use it to undermine the analysis. Since the article is quite damning to both the ethics and quantitative health claims of anti-THR activism, why might the anti-THR activists not care to read it carefully enough to find the error? It would be too glib to suggest that none of them can do the math – it is actually pretty easy and was all laid out for the reader. The only apparent explanation that is also consistent with other evidence is that the anti-tobacco extremists have decided that getting what they want is purely a matter of exercising their immense wealth and political power (a not unreasonable expectation). It is not merely that they adopted a worldview that is something like a religion, and thus no mere scientific argument could ever change their views. (Why bother to read scientific or ethical analysis when you do not care whether you are wrong by either of these standards?) It is that they are completely uninterested in ethical or scientific analyses – whether it be criticizing mine or presenting their own – because they expect to get what they want through the exercise of pure power, and so figure it really makes no difference that the legitimate arguments are arrayed against them.

Chapter 9

Systematic review of the relation between smokeless tobacco and cancer in Europe and North America (abstract)

and

A commentary on differences between the conclusions reached by two recent reviews

Peter N. Lee & Jan Hamling

Reprinted from BMC Medicine and BMC Cancer.

Editors' Note: In this chapter, we include two (one in abbreviated form and one in its entirety) important articles by Lee and Hamling (L&H). The first is an exhaustive literature review and computation of the relationship between smokeless tobacco and all studied cancer endpoints. The results confirm, with substantially added rigor and breadth, what THR advocates have been pointing out for years (and opponents have been baselessly denying): Modern Western smokeless tobacco products have been shown to cause a risk for cancer that is too low to measure. This is probably the most important study of health outcomes related to THR for the last several years. Though it can be argued that it simply confirmed what we already knew, it did so with a completeness that no honest analyst will be able to ignore. In particular, it re-confirms the point (previously emphasized by Rodu & Cole, 2002) that claims of oral cancer risk are based entirely on a few studies of archaic U.S. products that are almost never used anymore, and not the modern products that are proposed for THR. They also point out that the current fad, claiming that snus has been shown to cause pancreatic cancer, is also not based on the scientific evidence.

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At a technical level, some of us object to synthetic meta-analysis because it conflates studies of importantly different exposure-disease-population combinations and perpetuates the myth that random sampling error is the primary source of error in epidemiologic studies. It buries publication biases behind a statistical curtain. But in this case, the publication biases in the literature probably exaggerate the associations and yet still no pattern of substantial association was found. Because the article is 47 pages of technical material, somewhat out of scale for this book, and most everyone who is inclined to read all the details already has, we included only the abstract and encourage interested readers to find the rest at http://www.biomedcentral.com /content/pdf/1741-7015-7-36.pdf.

A somewhat overlooked but equally important companion paper is included in its entirety. This analysis compares the L&H empirical analysis to a meta-analysis published by an anti-THR activist group of Paolo Boffetta, Stephen Hecht, et al. (2008). The latter was inherently a joke, given that it was published as a small half-page aside (contrasting with the 47 pages that a serious analysis required) in a politicized anti-THR article. Unfortunately, the low-quality of critical review in the health sciences means that they could get away with claiming high risks where L&H found none. Demonstrating that L&H's analysis is the better and more honest of the two is critical because if pseudo-scientific claims are simply allowed to co-exist with the real evidence, living in competing monologues, well-meaning but non-expert observers will have a difficult time recognizing which is which. The price of honest science is direct confrontation.

Forensic epidemiology is challenging since health science authors almost never actually explain their methods, and the present case was much worse than average. When the paper was originally published, several of us figured out and highlighted some of the biases that Boffetta et al., presumably intentionally, built into their analysis. But none of us wrote anything nearly so complete and thorough as the disassembly by L&H, who were able to identify the flaws and contrast them with their honest analysis. For anyone who is inclined to blindly believe health science claims, particularly those by political activists, just because they are "peer reviewed" in a "good" journal, this article should be enlightening.

An aside for completeness is a feature of the Boffetta-Hecht article that escapes L&H's critique because they only looked at the analyses that combine all studies: Boffetta et al. created a gerrymandered division into American and Scandinavian studies, rather than dividing studies by exposure – currently-used products vs. archaic dry snuff – as any first-year epidemiology student should know to do, given that it has long been known that the results of studies of the former are quite homogeneous, regardless of continent, while the latter are comparative outliers. Those of us involved in product liability litigation about smokeless tobacco (as CVP has been, as a witness for the defense) noted that the Boffetta-Hecht paper seems to serve little purpose other than as a go-to document for such litigation (and, incidentally, Hecht is employed as a witness for plaintiffs but failed to disclose that in his article and continues to fail to disclose it in his anti-smokeless-tobacco publications to this day). It might be that such attempts to denigrate traditional American products are no longer terribly important for THR, and mostly just affect litigation, since Swedish-style and novel products have become more widely promoted for THR even in the U.S. But for a while this baseless claim, "Swedish snus is low-risk but U.S. products are not", was used as a rear-guard tactic by anti-THR activists who wanted to discourage adoption of THR by Americans.

Currently the favorite claim seems to be about pancreatic cancer, which L&H thoroughly debunk here. It is educational to highlight the source of the blatant bias. The claim by anti-THR activists, by Boffetta et al. and elsewhere, is largely based on two studies. To simplify, there are two ways to look at the data in these studies, call them Method 1 and Method 2 – arguably one approach is better than the other, but a case could be made for using either one of them (see

the article for details). If you look at Study A using Method 1, it shows an elevated risk for pancreatic cancer, but if you use Method 2 it actually shows a protective effect (that is, smokeless tobacco users have lower risk). Study B, on the other hand, shows exactly the opposite pattern, with an elevated risk if you use Method 2 and a protective effect with Method 1. As you might have guessed, the anti-THR activists used Method 1 to analyze Study A and Method 2 to analyze Study B and conveniently forgot about the other results. This blatant example of "publication bias in situ" (Phillips, 2004) is basically the same as playing a game to completion and then inventing a set of rules so that your team wins, and then after the second game, which you would have lost according to your rules, you change the rules so that you win that one too.

References

Boffetta P, Hecht S, Gray N, Gupta P & Straif K. Smokeless tobacco and cancer. Lancet Oncology 2008; 9(7): 667-675.

Phillips CV. Publication bias in situ. BMC Med Res Methodol. 2004 Aug 5;4:20.

Rodu B, Cole P. Smokeless tobacco use and cancer of the upper respiratory tract. Oral Surgery 2002; 93: 511-515.

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Systematic review of the relation between smokeless tobacco and cancer in Europe and North America

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Abstract

Background: Interest is rising in smokeless tobacco as a safer alternative to smoking, but published reviews on smokeless tobacco and cancer are limited. We review North American and European studies and compare effects of smokeless tobacco and smoking.

Methods: We obtained papers from MEDLINE searches, published reviews and secondary references describing epidemiological cohort and case-control studies relating any form of cancer to smokeless tobacco use. For each study, details were abstracted on design, smokeless tobacco exposure, cancers studied, analysis methods and adjustment for smoking and other factors. For each cancer, relative risks or odds ratios with 95% confidence intervals were tabulated. Overall, and also for USA and Scandinavia separately, meta-analyses were conducted using all available estimates, smoking-adjusted estimates, or estimates for never smokers. For seven cancers, smoking-attributable deaths in US men in 2005 were compared with deaths attributable to introducing smokeless tobacco into a population of never-smoking men.

Results: Eighty-nine studies were identified; 62 US and 18 Scandinavian. Forty-six (52%) controlled for smoking. Random-effects meta-analysis estimates for most sites showed little association. Smoking-adjusted estimates were only significant for oropharyngeal cancer (1.36, CI 1.04–1.77, n = 19) and prostate cancer (1.29, 1.07–1.55, n = 4). The oropharyngeal association disappeared for estimates published since 1990 (1.00, 0.83–1.20, n = 14), for Scandinavia (0.97, 0.68–1.37, n = 7), and for alcohol-adjusted estimates (1.07, 0.84–1.37, n = 10). Any effect of current US products or Scandinavian snuff seems very limited. The prostate cancer data are inadequate for a clear conclusion.

Some meta-analyses suggest a possible effect for oesophagus, pancreas, larynx and kidney cancer, but other cancers show no effect of smokeless tobacco. Any possible effects are not evident in Scandinavia. Of 142,205 smoking-related male US cancer deaths in 2005, 104,737 are smoking-attributable. Smokeless tobacco-attributable deaths would be 1,102 (1.1%) if as many used smokeless tobacco as had smoked, and 2,081 (2.0%) if everyone used smokeless tobacco.

Conclusion: An increased risk of oropharyngeal cancer is evident most clearly for past smokeless tobacco use in the USA, but not for Scandinavian snuff. Effects of smokeless tobacco use on other cancers are not clearly demonstrated. Risk from modern products is much less than for smoking.

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The relation between smokeless tobacco and cancer in Northern Europe and North America. A commentary on differences between the conclusions reached by two recent reviews

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Abstract

Background: Smokeless tobacco is an alternative for smokers who want to quit but require nicotine. Reliable evidence on its effects is needed. Boffetta et al. and ourselves recently reviewed the evidence on cancer, based on Scandinavian and US studies. Boffetta et al. claimed a significant 60–80% increase for oropharyngeal, oesophageal and pancreatic cancer, and a non-significant 20% increase for lung cancer, data for other cancers being "too sparse". We found increases less than 15% for oesophageal, pancreatic and lung cancer, and a significant 36% increase for oropharyngeal cancer, which disappeared in recent studies. We found no association with stomach, bladder and all cancers combined, using data as extensive as that for oesophageal, pancreatic and lung cancer. We explain these differences.

Methods: For those cancers Boffetta et al. considered, we compared the methods, studies and risk estimates used in the two reviews.

Results: One major reason for the difference is our more consistent approach in choosing between study-specific never smoker and combined smoker/non-smoker estimates. Another is our use of derived as well as published estimates. We included more studies, and avoided estimates for data subsets. Boffetta et al. also included some clearly biased or not smoking-adjusted estimates. For pancreatic cancer, their review included significantly increased never smoker estimates in one study and combined smoker/non-smoker estimates in another, omitting a combined estimate in the first study and a never smoker estimate in the second showing no increase. For oesophageal cancer, never smoker results from one study showing a marked increase for squamous cell carcinoma were included, but corresponding results for adenocarcinoma and combined smoker/non-smoker results for both cell types showing no increase were excluded. For oropharyngeal cancer, Boffetta et al. included a markedly elevated estimate that was not smoking-adjusted, and overlooked the lack of association in recent studies.

Conclusion: When conducting meta-analyses, all relevant data should be used, with clear rules governing the choice between alternative estimates. A systematic meta-analysis using pre-defined procedures and all relevant data gives a lower estimate of cancer risk from smokeless tobacco (probably 1–2% of that from smoking) than does the previous review by Boffetta et al.

Background

In 2008, Boffetta et al. [1] published a short review in Lancet Oncology of the evidence relating smokeless tobacco (ST) to cancer. Included was a table summarizing smoking-adjusted relative risk (RR) estimates with 95% confidence intervals (CI) relating to cancer of the oral cavity, oesophagus, pancreas and lung in the USA and Northern Europe taken from 18 studies, together with a further table of meta-analysis results. The results of the overall (USA and Nordic countries combined) meta-analyses are summarized in Table 1, and show a statistically significant increase of 60–80% for ever smokeless tobacco use for oral, oesophageal and pancreatic cancer, and a non-significant 20% increase for lung cancer. Results for other cancers were stated to be "too sparse for a quantitative investigation."

In their review Boffetta et al. [1] give only limited information on their "search strategy and selection criteria." While they make it clear that they restricted attention to papers published up to September 2007 (including one in press at that time) they give little information on how they selected the cancers for detailed study or how they chose the estimates to be included in their meta-analyses. Thus they note that results for cancers other than those of the oral cavity, oesophagus, pancreas, and lung were "too sparse for quantitative information" without specifying the amount of data needed for analysis. Furthermore they state merely that "we included only studies restricted to non-smokers and studies that included smokers but were properly adjusted for the possible confounding effect of tobacco smoking." without giving any indication as to how they chose from alternative estimates available in a number of the papers (e.g. by sub-type of cancer, type of smoking adjustment, type of ST or timing of ST exposure). A meticulous description of the methods used should have been included, but was not.

Table 1: Comparison of our smoking-adjusted random-effects meta-analysis estimates with those of Boffetta et al.

	Boffetta et al. [1]		Lee and Hamling [2]	
Cancer	N[a]	RR (95% CI)[b]	N[a]	RR (95% CI)[b]
Oropharyngeal	13	1.8 (1.1–2.9)	19	1.36 (1.04–1.77)
- published since 1990		Not given	14	1.00 (0.83–1.20)
Oesophageal	5	1.6 (1.1–2.3)	7	1.13 (0.95–1.36)
Pancreatic	6	1.6 (1.1–2.2)	7	1.07 (0.71–1.60)
Lung	5	1.2 (0.7–1.9)	6	0.99 (0.71–1.37)
Stomach		Not given	8	1.03 (0.88–1.20)
Bladder		Not given	10	0.95 (0.71–1.29)
Overall cancer		Not given	7	0.98 (0.84–1.15)

[a] Number of individual estimates considered in meta-analysis.
[b] Smoking-adjusted estimates for any ST use.

Shortly before the review of Boffetta et al. [1] was published, we had started our own review of this evidence, a review which has recently been published in BMC Medicine [2]. We continued with our review, because our initial impression of Boffetta et al.'s was that some relevant data had been missed and that some of the RRs used in their meta-analyses seemed inappropriate. Although our review also considered effect estimates that were not adjusted for smoking, we took particular care to distinguish those that were adjusted for smoking. Our smoking-adjusted meta-analysis estimates are also shown in Table 1. As will be seen, our estimates are substantially lower for all four cancers considered by Boffetta et al. For oesophageal, pancreatic and lung cancer the estimated increases are all less than 15% and not statistically significant, while for oral cancer our estimate of a 36% increase, though statistically significant, is lower than the 80% increase estimated by Boffetta et al., and disappears when attention is restricted to studies published since 1990. Our review also considers a range of other cancers, and Table 1 also presents meta-analysis estimates for stomach, bladder and overall cancer. Each is based on at least as many RRs as are available for oesophageal, pancreatic and lung cancer, and none shows a significant excess risk in ST users.

Objectives

The objective of this article is to provide a detailed comparison of the two reviews [1,2] in order to clarify why these major differences in risk estimates have occurred. Attention is restricted to the four cancers considered by Boffetta et al. [1]

Differences between the estimates from the two reviews

Table 2 (oropharyngeal cancer [3-21]), Table 3 (oesophageal cancer [4,18,22-25]), Table 4 (pancreatic cancer [4,5,26-30]) and Table 5 (lung cancer [3-5,27,31]) summarize the estimates used in the two reviews [1,2], with comments on similarities and differences. Based on this comparison, the details of the methodology given in our review [2], and the rather brief description of their procedures presented by Boffetta et al. [1], a number of general observations can be made.

Sources of difference between the two reviews

Derivation of estimates

Whereas Boffetta et al. [1] limited themselves to using RR estimates given in the source publication, we [2] calculated an estimate using available methodology [32-35] where the required RR was not provided but could be derived from data given in the publication,. We felt this necessary so as to avoid omitting relevant studies completely or, when a study provided non-independent results from subsets of the data, presenting results only for one of the subsets.

Table 2: Comparison of individual and overall (random-effects) estimates for the two reviews – oropharyngeal cancer

	ST use[a]						
Ref	Type	Exposure	Inclusion of smokers[b]	Review[c]	Sex	Relative risk (95% CI)	Comments
[3]	ST	Current	NS	L&H	M	2.02 (0.53–7.74)	
(CPS-I)	ST	Current	NS	B	M	2.0 (0.5–7.7)	Estimates agree[d]
[3]	ST	Current	NS	L&H	M	0.90 (0.12–6.71)	
(CPS-II)	ST	Current	NS	B	M	0.9 (0.1–6.7)	Estimates agree[d]
[4]	Snuff	Ever	SNS	L&H	M	1.10 (0.50–2.41)	
	Snuff	Ever	SNS	B	M	1.1 (0.5–2.4)	Estimates agree[d]
[5]	Snuff	Ever	SNS	L&H	M	0.7 (0.5–0.9)	
	Snuff	Ever	NS	B	M	0.8 (0.4–1.7)	NS not SNS
[6]	Snuff	Ever	SNS	L&H	M	3.1 (1.5–6.6)	Too recent to be included by B
[7]	Chew	Ever	SNS	L&H	M+F	2.05 (1.48–2.83)[e]	Not included by B
[8]	Chew	Ever	SNS	L&H	M	2.00 (1.16–3.47)[e]	Not included by B
[9]	ST	Ever	SNS	L&H	M	3.63 (1.02–12.95)[e]	Not included by B
[10]	Snuff	Ever	SNS	L&H	F	2.67 (1.83–3.90)[e]	
	Snuff	Ever	NS[f]	B	F	4.2 (2.6–6.7)	Whites
	Snuff	Ever	NS[f]	B	F	1.5 (0.5–4.8)	Blacks
[11]	ST	Ever	SNS	B	M	2.3 (0.2–12.9)	Tongue cancer
	ST	Ever	SNS	B	M	11.2 (4.1–30.7)	Mouth cancer
							Not included by L&H as no valid smoking adjustment[g]
[12]	ST	Ever	NS	L&H	F	6.2 (1.9–19.8)	
	ST	Ever	NS	B	F	6.2 (1.9–19.8)	Estimates agree
[13]	Snuff	Ever	NS	L&H	M+F	0.67 (0.08–5.75)[e]	Not included by B
[14]	ST	Ever	SNS	L&H	M+F	1.04 (0.41–2.68)[e]	Not included by B
[15]	ST	Ever	SNS	L&H	M	0.96 (0.70–1.33)[e]	
	Chew	Ever	SNS	B	M	1.0 (0.7–1.4)	Chew not ST
[16]	Chew	Ever	SNS	L&H	M	1.11 (0.81–1.53)[e]	
	Chew	Ever	NS	B	M	2.3 (0.7–7.3)	NS not SNS
[17][h]	ST	Ever	SNS	L&H	M+F	1.43 (0.64–3.21)[e]	Not included by B
[18]	Snuff	Ever	SNS	L&H	M	0.98 (0.63–1.50)[e]	
	Snuff	Ever	SNS	B	M	1.4 (0.8–2.4)	Oral cancer excluding pharynx
[19]	Snuff	Ever	SNS	L&H	M+F	0.8 (0.5–1.3)	Estimate for NS also available
	Snuff	Ever	SNS	B	M+F	0.8 (0.5–1.3)	Estimates agree
[20]	ST	Ever	SNS	L&H	M	1.0 (0.4–2.3)	Not included by B
[21]	Snuff	Ever	SNS	L&H	M+F	0.7 (0.3–1.3)	Not included by B
Total				L&H		1.36 (1.04–1.77)	19 estimates
				B		1.8 (1.1–2.9)	13 estimates

[a] ST = smokeless tobacco; Chew = chewing tobacco; ever exposure includes undefined use.
[b] NS = never smokers; SNS = smokers and nonsmokers combined (with adjustment for smoking).
[c] L&H = Lee and Hamling review [2]; B = Boffetta et al. review [1].
[d] To within rounding error, as B only expressed estimates to one decimal place.
[e] Estimated from data provided.
[f] B stated that the results were for never smokers, but L&H consider the result relates to non-current smoking. L&H's estimate is for current and non-current smokers combined.
[g] Valid smoking adjustment was impossible in this study as "for users of multiple tobacco products, only the primary product was recorded".
[h] The results were cited by Gross et al. [17] based on an unpublished report by Perry et al., "Attributable oral cancer risk due to smokeless tobacco use based on a case-control study at Sinai Hospital in Detroit".

Restriction to smoking-adjusted estimates

As noted earlier, Boffetta et al. [1] stated that they "included only studies restricted to non-smokers and studies that included smokers but were properly adjusted for the possible confounding effect of tobacco smoking." Though, as is so often the situation in smoking and health literature, the term "non-smokers" was not defined, we have assumed that "lifelong non-smokers" (i.e. never smokers) was meant. What was meant by "properly adjusted" was also undefined, and in practice it appears that any smoking adjustment was accepted, as we could find no case of a published smoking-adjusted RR that was not included by Boffetta et al. This is not surprising since, as noted in our review [2], only a small proportion of studies took any account of daily consumption or duration of smoking. As a consequence, the smoking-adjusted data in Tables 2, 3, 4, 5 taken from our review are also not restricted on how the adjustment for smoking was carried out.

Studies included

We included more studies in our review [2] than did Boffetta et al [1] in theirs. Mainly these are studies [7-9,13,14,17,23,27] where the estimate required calculation, but three studies [20,21,31] appear to have been overlooked by Boffetta et al., and there is also a recent study [6] published after September 2007, the cut-off date for their literature search. There is only one study [11] included by Boffetta et al., but not by us. This study did not provide results for never smokers, and though it claimed to have presented estimates adjusted for tobacco use, this appears impossible as the authors stated that "for users of multiple tobacco products, only the primary product was recorded." A comparison of ST users with non-users of tobacco will therefore be biased by smokers being included only in the group using ST.

ST type

The majority of studies presented results only for one type of ST, usually either snuff specifically (typical for Scandinavian studies) or for overall ST use. A few studies provide separate RRs for snuff and chewing tobacco. The RRs we used in our meta-analyses [2] were based on overall ST use if possible, calculated if necessary from the separate results. We note that there were two studies [15,30] where results were available for snuff and chewing tobacco, and where Boffetta et al. [1] included only the results for chewing tobacco.

ST exposure

The great majority of the studies present only RRs for either ever use or unspecified use (which both reviews

Table 3: Comparison of individual and overall (random-effects) estimates for the two reviews – oesophageal cancer

	ST use[a]						
Ref	Type	Exposure	Inclusion of smokers[b]	Review[c]	Sex	Relative risk (95% CI)	Comments
[4]	Snuff	Ever	SNS	L&H	M	1.40 (0.61–3.24)	
	Snuff	Ever	SNS	B	M	1.4 (0.6–3.2)	Estimates agree[d]
[22]	Snuff	Ever	SNS	L&H	M	1.00 (0.79–1.27)[e]	Estimate for NS also available
	Snuff	Ever	NS	B	M	3.5 (1.6–7.6)	NS not SNS; squamous cell carcinoma not all oesophageal cancer
[23]	Chew	Ever	NS	L&H	M	1.18 (0.28–4.90)[e]	Not included by B
	Chew	Ever	NS	L&H	F	2.69 (0.92–7.87)[e]	Not included by B
[24]	ST	Ever	NS	L&H	M	1.2 (0.1–13.3)	
	ST	Ever	NS	B	M	1.2 (0.1–13.3)	Estimates agree
[18]	Snuff	Ever	SNS	L&H	M	1.2 (0.7–2.2)	
	Snuff	Ever	SNS	B	M	1.2 (0.7–2.2)	Estimates agree
[25]	Snuff	Ever	SNS	L&H	M+F	1.31 (0.89–1.92)[e]	
	Snuff	Ever	SNS	B	M+F	1.4 (0.9–2.3)	Squamous cell carcinoma not all oesophageal cancer
Total				L&H		1.13 (0.95–1.36)	7 estimates
				B		1.6 (1.1–2.3)	5 estimates

[a] ST = smokeless tobacco; ever exposure includes undefined use.
[b] NS = never smokers; SNS = smokers and nonsmokers combined (with adjustment for smoking).
[c] L&H = Lee and Hamling review [2]; B = Boffetta et al. review [1].
[d] To within rounding error, as B only expressed estimates to one decimal place.
[e] Estimated from data provided.

Table 4: Comparison of individual and overall (random-effects) estimates for the two reviews – pancreatic cancer

	ST use[a]						
Ref	Type	Exposure	Inclusion of smokers[b]	Review[c]	Sex	Relative risk (95% CI)	Comments
[26]	ST	Ever	SNS	L&H	M	1.7 (0.9–3.1)	
	ST	Ever	SNS	B	M	1.7 (0.9–3.1)	Estimates agree
[4]	Snuff	Ever	SNS	L&H	M	1.67 (1.12–2.50)	Estimates for NS also available
	Snuff	Ever	SNS	B	M	1.7 (1.1–2.5)	Estimates agree[d]
[5]	Snuff	Ever	SNS	L&H	M	0.9 (0.7–1.2)	
	Snuff	Ever	NS	B	M	2.0 (1.2–3.3)	NS not SNS
[27]	ST	Ever	SNS	L&H	M	0.29 (0.09–0.92)[e]	Not included by B
[28]	Chew	Ever	NS	L&H	M	2.82 (0.85–9.39)	Personal communication from Dr Muscat
	Chew	Ever	NS[f]	B	M	3.6 (1.0–12.8)	Estimate actually for non-current smokers
[29]	ST	Ever	NS[g]	L&H	M+F	1.1 (0.4–3.1)	
	ST	Ever	NS	B	M+F	1.4 (0.5–3.6)	Estimate biased as pipe and cigar smokers included in numerator only
[30]	ST	Ever	SNS	L&H	M+F	0.65 (0.43–0.97)[e]	Estimate for NS also available
	Chew	Ever	NS	B	M+F	0.6 (0.3–1.4)	Chew not ST; NS not SNS
Total				L&H		1.07 (0.71–1.60)	7 estimates
				B		1.6 (1.1–2.2)	6 estimates

[a] ST = smokeless tobacco; ever exposure includes undefined use.
[b] NS = never smokers; SNS = smokers and nonsmokers combined (with adjustment for smoking).
[c] L&H = Lee and Hamling review [2]; B = Boffetta et al. review [1].
[d] To within rounding error, as B only expressed estimates to one decimal place.
[e] Estimated from data provided.
[f] See comment.
[g] Never cigarette smokers, with adjustment for other tobacco use.

[1,2] have considered as essentially equivalent to ever use). Some studies present results for current and former use, and our procedure was to include the result for current use only if an estimate for ever use was not available or could not be calculated. Since they did not calculate RR estimates, Boffetta et al. [1] included current rather than ever use estimates for lung cancer for CPS-II [3]. However, otherwise the two sets of estimates agree as regards ST exposure.

Selection of results according to smoking history

There are a number of studies where RRs are available both for never smokers and for smokers and non-smokers combined, with adjustment for smoking. In the meta-analyses shown in Table 1 taken from our review [2], we have always included the smoker/non-smoker combined estimate from these studies, on the basis that they provided greater power, though our review also presents the results of meta-analyses of RRs specifically for never smokers. Boffetta et al. [1] appear not to have defined any rule here. In three such studies [5,22,30] they include results for never smokers, and in two studies [4,19] the results for smokers and non-smokers combined, without any supporting explanation.

Types of cancer

Where results are available by type of cancer, we have always included estimates for the total cancer being considered, but this is not the case for Boffetta et al [1]. Thus whereas, for Table 2, we [2] include RRs for overall oropharyngeal cancer, if available, only considering cancers of particular regions of the oropharynx if these were the only data presented, Boffetta et al. omitted relevant results for pharynx cancer in one study [18] and presented RRs separately for mouth and tongue cancer in another [11], a study in which results were also available for a number of other regions of the oropharynx. For oesophageal cancer, there are two studies [22,25] where Boffetta et al. included results only for squamous cell carcinoma, omitting those for adenocarcinoma, despite the other studies in their analysis only presenting results for overall oesophageal cancer.

Table 5: Comparison of individual and overall (random-effects) estimates for the two reviews – lung cancer

	ST use[a]						
Ref	Type	Exposure	Inclusion of smokers[b]	Review[c]	Sex	Relative risk (95% CI)	Comments
[31]	ST	Ever	NS	L&H	F	6.80 (1.60–28.5)	Not included by B
[3]	ST	Current	NS	L&H	M	1.08 (0.64–1.83)	
(CPS-I)	ST	Current	NS	B	M	1.1 (0.6–1.8)	Estimates agree[d]
[3]	ST	Ever	NS	L&H	M	1.77 (1.14–2.74)[e]	
(CPS-II)	ST	Current	NS	B	M	2.0 (1.2–3.2)	Current not ever exposure
[4]	Snuff	Ever	SNS	L&H	M	0.80 (0.61–1.05)	Estimate for NS also available
	Snuff	Ever	SNS	B	M	0.8 (0.6–1.1)	Estimates agree[d]
[5]	Snuff	Ever	SNS	L&H	M	0.7 (0.6–0.7)	
	Snuff	Ever	NS	B	M	0.8 (0.5–1.3)	NS not SNS
[27]	ST	Ever	SNS	L&H	M	0.69 (0.47–1.00)[e]	Not included by B
Total				L&H		0.99 (0.71–1.37)	6 estimates
				B		1.2 (0.7–1.9)	5 estimates[f]

[a] ST = smokeless tobacco; ever exposure includes undefined use.
[b] NS = never smokers; SNS = smokers and nonsmokers combined (with adjustment for smoking).
[c] L&H = Lee and Hamling review [2]; B = Boffetta et al. review [1].
[d] To within rounding error, as B only expressed estimates to one decimal place.
[e] Estimated from data provided.
[f] B only presented four estimates, but a combined result stated to be based on five. The random-effects estimate for the four estimates provided is 1.1 (0.7–1.6)

Unnecessary inclusion of a confounded result

In one study [29] Boffetta et al. [1] selected a RR for never cigarette smokers in which ST users who may also have smoked pipes or cigars were compared with user of no tobacco at all. We [2] preferred an estimate using those who had only used ST as the numerator, to avoid bias from pipe and cigar smoking.

Meta-analysis

Although Boffetta et al. [1] did not define their method, it appears that they used random-effects estimates as we [2] did, since for three of the cancers we calculated the overall estimate from their data under this assumption and obtained the same answer they did. We could not check this for lung cancer as they presented only four individual study RRs, but gave an overall estimate based on five.

Effect of the differences

The fact that for some studies we calculated RRs from data available, combining evidence from data subsets to make fuller use of the data, and that we applied a consistent rule for choosing between RRs for never smokers and RRs for smokers and non-smokers combined has led to differences between the RRs we include in our meta-analyses [2] and those used by Boffetta et al. [1]. Some of the differences are minor, but it is apparent that where there are substantial differences, they are always in one direction, with our systematic and arguably more complete analysis providing lower smoking-adjusted RRs than theirs.

Five particular cases deserve comment. For oesophageal cancer, Zendehdel et al. [22] reported never smoking RRs of 3.5 (95% CI 1.6–7.6) for squamous cell carcinoma, 0.2 (0.0–1.9) for adenocarcinoma, as well as smoking-adjusted RRs of 1.0 (0.8–1.4) for squamous cell carcinoma and 1.0 (0.6–1.5) for adenocarcinoma. Our smoking-adjusted RR shown in Table 3 was derived by combining the last two relative risks to give 1.00 (0.79–1.27), whereas Boffetta et al. [1] used only the first, high, estimate of 3.5 (1.6–7.6).

For pancreatic cancer, the RR selected by Boffetta et al. [1] for the study by Luo et al. [5] was that for never smokers (2.0, 1.2–3.3) and not the smoking-adjusted estimate (0.9, 0.7–1.2) we [2] used. In contrast in the Norway cohorts study [4] both reviews used the smoking-adjusted RR of 1.67 (1.12–1.50), Boffetta et al. here not selecting the lower never smoker estimate of 0.85 (0.24–3.07). Also, as noted above for the study by Alguacil and Silverman [29], Boffetta et al. selected a higher, but biased, RR of 1.4 (0.5–3.6) when we used an estimate of 1.1 (0.4–3.1).

For oropharyngeal cancer, in the study of Kabat et al. [16], Boffetta et al. chose a never smoker estimate of 2.3 (0.70–7.3) rather than the smoking-adjusted RR of 1.1 (0.81–1.53) we [2] used, while in the study of Lewin et al. [18] they chose an estimate of 1.4 (0.8–2.4) for oral cancer overlooking one of 0.7 (0.4–1.3) for pharyngeal cancer, rather than the combined oropharyngeal RR we used of 0.98 (0.63–1.50).

Exclusion of relevant studies, and in one case [11] inclusion of RRs that seem not to be smoking-adjusted, have also contributed to the difference. This is considered further below, where we comment on the four cancers in turn.

Oropharyngeal cancer (Table 2)

Based on the 13 individual estimates provided by Boffetta et al. [1], we calculate the random-effects meta-analysis estimate as 1.82 (1.14–2.90), agreeing, to one decimal place, with their figure of 1.8 (1.1–2.9). This is markedly higher than the combined estimate of 1.36 (1.04–1.77) based on the RRs we included. Eliminating the RRs from the Stockwell and Lyman study [11], which appear not to be smoking adjusted, would reduce Boffetta et al.'s estimate to 1.54 (0.99–2.38) and further, for reasons noted earlier, replacing their RR estimates from the studies by Kabat et al. [16] and Lewin et al. [18] by ours would reduce the combined estimate further, to 1.36 (0.94–1.98), making it similar to ours [2]. Adding in the extra studies we included [6-9,13,14,17,20,21] has little effect on the overall estimate.

The conclusions of Boffetta et al. [1] regarding the role of ST, as used in Western countries, on the risk of oropharyngeal cancer fail to take account of the additional evidence in our review [2] and elsewhere [36] that any excess risk essentially vanishes when attention is limited to studies that have adjusted for alcohol as well as smoking. While there may have been some effect in the past of ST as used in the USA, Boffetta et al. refrain from commenting on the fact that RR estimates have declined markedly over time. This decline is illustrated clearly in Figure 1 where the consistent (heterogeneity p = 0.34) evidence of an increase seen in case-control studies published before 1990 contrasts sharply with the consistent (heterogeneity p = 0.93) total lack of evidence of an increase in case-control studies published more recently. The prospective studies, each of which involves a long-term follow-up period starting many years ago (1959–1972, 1982–2000, 1966–2001, 1978–2004, 1973–2002 for the five studies in Figure 1 in order), give results that are heterogeneous (p = 0.004) and suggest an intermediate increase. (It should be noted that for other cancers the data are too limited to allow useful comparison between studies published before and after 1990)

Oesophageal cancer (Table 3)

Here the meta-analysis estimate we calculate based on the five RRs given by Boffetta et al. [1] is 1.57 (1.09–2.28), matching the estimate they give, of 1.6 (1.1–2.3). The difference between this estimate and ours (1.13, 0.95–1.36) is virtually wholly due to the RRs selected for the study by Zendehdel et al. [22], as replacing their estimate by ours for this study reduces their combined estimate to 1.10 (0.91–1.34), similar to our estimate of 1.13 (0.95–1.36).

We consider that there is no convincing evidence that ST increases the risk of oesophageal cancer. The results from the Zendehdel et al. study [22] suggesting an increase specifically for never smokers as regards squamous cell carcinoma clearly need confirmation by other studies before any reliable conclusion can be drawn.

Pancreatic cancer (Table 4)

Based on the data of Boffetta et al. [1], our combined estimate is 1.57 (1.09–2.25), agreeing with their 1.6 (1.1–2.2), but markedly higher than the estimate based on our data, of 1.07 (0.71–1.60). Amending, for reasons discussed above, the estimates for the studies by Luo et al. [5] and by Alguacil and Silverman [29] to the ones we used would reduce their overall figure to a non-significant 1.25 (0.83–1.88).

Our estimate of 1.07 (0.71–1.60) is somewhat lower than this due to inclusion of the low estimate we calculated from the Williams and Horm study [27]. As discussed elsewhere [37], where there is a fuller discussion of the evidence on this cancer, some objections can be made about this study. However the conclusion from our review [2], that any effect of ST on pancreatic cancer has not been clearly demonstrated, seems justified by the data whether or not results from this study are included.

Lung cancer (Table 5)

We cannot evaluate the lung cancer meta-analyses of Boffetta et al. [1] due to their only providing four of the five individual RRs they used. However, their RRs are quite similar to ours for the four studies where comparison is possible. Our analysis [2] also includes a high RR from one study [31] and a low RR from another [27] and we agree that an association has not been demonstrated.

Discussion and conclusion

We believe that our review [2] offers a more robust meta-analysis of the data than previously conducted by Boffetta et al. [1] for a number of reasons. One reason is the use of derived as well as published estimates, which adds considerably to the data available for analysis, an approach which might be improved still further by obtaining results for those studies which merely reported their findings non-quantitatively, e.g. as "no significant association."

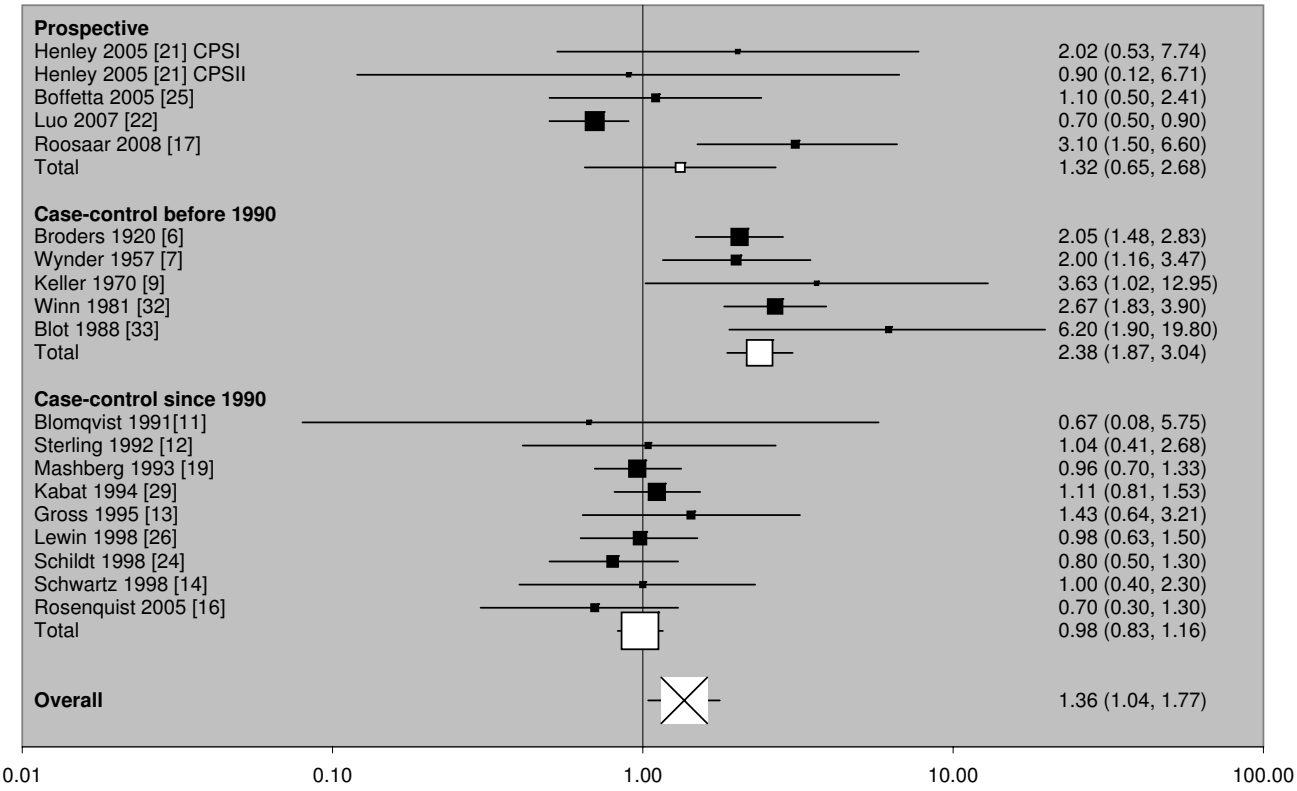

Figure 1

Variation in RR of ST-associated oropharyngeal cancer by study type and period of publication. For each of 19 studies, separated by study type and, for case-control studies, by period of publication, the individual study RR and 95% CI estimates, taken from the Lee and Hamling review [2] (see also Table 2), are shown numerically and also graphically on a logarithmic scale. In the graphical representation, the RR is indicated by a solid square, with the area of the square proportional to the weight (inverse-variance) of the estimate. Also shown are the combined estimates, derived by random-effects meta-analysis, for the three subgroups and overall. Here the sizes of the four squares corresponding to the RRs are also proportional to the weight of the estimate, though the constant of proportionality differs from that for the individual RRs.

Other reasons include ensuring that all the RRs used were in fact adjusted for smoking, and the use of a pre-defined systematic procedure to decide which estimates to include in the meta-analysis. The differences in procedures had the largest effect for pancreatic cancer and oesophageal cancer. For pancreatic cancer, significant increases for never smokers in one study [5] and for smokers and non-smokers combined in another study [4] were selected by Boffetta et al., ignoring estimates showing a lack of any increase at all for smokers and non-smokers combined in the first study [5] and for never smokers in the second [4]. For oesophageal cancer, given results for one study [22] which showed a significantly increased RR among never smokers for squamous cell carcinoma but no increase at all among never smokers for adenocarcinoma, or among smokers and non-smokers combined for either cell type, Boffetta et al. elected to include only the significant RR, despite the inherent bias from such a procedure. For oropharyngeal cancer, although Boffetta et al. recognized the lack of evidence of a relationship for studies conducted in Scandinavia, their claim of an effect for ST as used in the USA fails to recognize that this is no longer seen in more recent studies.

As a result of using a more systematic and more inclusive process we believe that our analysis [2] provides a more accurate estimate of any relationship of ST with risk of cancer. Previous claims of significant increases for oropharyngeal, oesophageal and pancreatic cancer with risk increases of 60% to 80% for each cancer [1], appear unjustified when more appropriate meta-analyses are conducted. For the oesophagus and pancreas the estimated risk increases based on smoking-adjusted data should be more like 10% and not statistically significant, while for oropharyngeal cancer we estimate the increase to be a marginally significant 36% when all the data are considered, and to be zero when attention is restricted to studies published since 1990.

Boffetta et al. [1] also claimed that the cancer risk of ST users is only "probably" lower than that of smokers. Given that, for the four cancers they consider, the RRs they estimate are substantially lower than seen for smoking (particularly for lung cancer where their estimate of a 20% increase for ST compares with an estimated increase of about 2000% for current smokers and 1000% for former smokers), it is unclear why they did not accept that the risk for ST users is definitely much lower than for cigarette smokers. This conclusion is even more evident using our more appropriate risk estimates for ST, and in our review [2] we estimate that attributable deaths from smoking-related cancers would be almost 100 times lower, if smokers instead had the risk of ST users.

While, as discussed in our review [2], the evidence we have considered has many weaknesses and, as Boffetta et al. state in their review [1], the health effects of ST products need to be better characterized, we feel it is important that appropriate inferences are drawn from the data that are available so as to put the likely cancer risks from use of ST into a proper perspective versus the risks of smoking cigarettes. This is important given that some public health authorities see a potential role for ST in tobacco harm reduction [38-40]. We also feel that this investigation underlines the advantage of a pre-defined systematic procedure for conducting meta-analyses. It is essential that all relevant data should be used, and that clear rules should be present for choosing between alternative estimates from the same study.

Abbreviations

CI: 95% confidence interval; CPS-I: American Cancer Society Cancer Prevention Study I; CPS-II: American Cancer Society Cancer Prevention Study II; RR: relative risk; ST: smokeless tobacco.

Competing interests

PNL, founder of P.N. Lee Statistics and Computing Ltd., is an independent consultant in statistics and an advisor in the fields of epidemiology and toxicology to a number of tobacco, pharmaceutical and chemical companies. JH works for P.N. Lee Statistics and Computing Ltd.

Authors' contributions

PNL conceived and planned the study and carried out the literature search. PNL and JH jointly extracted the estimates and conducted the meta-analyses. The text and tables were drafted by PNL and checked by JH. Both authors read and approved the final manuscript.

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References

1. Boffetta P, Hecht S, Gray N, Gupta P, Straif K: **Smokeless tobacco and cancer.** *Lancet Oncol* 2008, **9:**667-675.
2. Lee PN, Hamling JS: **Systematic review of the relation between smokeless tobacco and cancer in Europe and North America.** *BMC Medicine* 2009, **7:**36.
3. Henley SJ, Thun MJ, Connell C, Calle EE: **Two large prospective studies of mortality among men who use snuff or chewing tobacco (United States).** *Cancer Causes Control* 2005, **16:**347-358.
4. Boffetta P, Aagnes B, Weiderpass E, Andersen A: **Smokeless tobacco use and risk of cancer of the pancreas and other organs.** *Int J Cancer* 2005, **114:**992-995.
5. Luo J, Ye W, Zendehdel K, Adami J, Adami H-O, Boffetta P, Nyrén O: **Oral use of Swedish moist snuff (snus) and risk of cancer of the mouth, lung, and pancreas in male construction workers: a retrospective cohort study.** *Lancet* 2007, **369:**2015-2020.
6. Roosaar A, Johansson AL, Sandborgh-Englund G, Axéll T, Nyrén O: **Cancer and mortality among users and nonusers of snus.** *Int J Cancer* 2008, **123:**168-173.
7. Broders AC: **Squamous-cell epithelioma of the lip. A study of five hundred and thirty-seven cases.** *JAMA* 1920, **74:**656-664 [http://jama.ama-assn.org/content/vol74/issue10/index.dtl].
8. Wynder EL, Bross IJ: **Aetiological factors in mouth cancer: an approach to its prevention.** *Br Med J* 1957, **1(5038):**1137-1143.
9. Keller AZ: **Cellular types, survival, race, nativity, occupations, habits and associated diseases in the pathogenesis of lip cancers.** *Am J Epidemiol* 1970, **91:**486-499.
10. Winn DM, Blot WJ, Shy CM, Pickle LW, Toledo A, Fraumeni JF Jr: **Snuff dipping and oral cancer among women in the southern United States.** *N Engl J Med* 1981, **304:**745-749.
11. Stockwell HG, Lyman GH: **Impact of smoking and smokeless tobacco on the risk of cancer of the head and neck.** *Head Neck Surg* 1986, **9:**104-110.
12. Blot WJ, McLaughlin JK, Winn DM, Austin DF, Greenberg RS, Preston-Martin S, Bernstein L, Schoenberg JB, Stemhagen A, Fraumeni JF Jr: **Smoking and drinking in relation to oral and pharyngeal cancer.** *Cancer Res* 1988, **48:**3282-3287.
13. Blomqvist G, Hirsch J-M, Alberius P: **Association between development of lower lip cancer and tobacco habits.** *J Oral Maxillofac Surg* 1991, **49:**1044-1047.
14. Sterling TD, Rosenbaum WL, Weinkam JJ: **Analysis of the relationship between smokeless tobacco and cancer based on data from the national mortality followback survey.** *J Clin Epidemiol* 1992, **45(3):**223-231.
15. Mashberg A, Boffetta P, Winkelman R, Garfinkel L: **Tobacco smoking, alcohol drinking, and cancer of the oral cavity and oropharynx among U.S. veterans.** *Cancer* 1993, **72:**1369-1375.
16. Kabat GC, Chang CJ, Wynder EL: **The role of tobacco, alcohol use, and body mass index in oral and pharyngeal cancer.** *Int J Epidemiol* 1994, **23:**1137-1144.
17. Gross AJ, Lackland DT, Tu DS: **Oral cancer and smokeless tobacco: literature review and meta-analysis.** *Environ Int* 1995, **21:**381-394.
18. Lewin F, Norell SE, Johansson H, Gustavsson P, Wennerberg J, Biörklund A, Rutqvist LE: **Smoking tobacco, oral snuff, and alcohol in the etiology of squamous cell carcinoma of the head and neck: a population-based case-referent study in Sweden.** *Cancer* 1998, **82:**1367-1375.
19. Schildt E-B, Eriksson M, Hardell L, Magnuson A: **Oral snuff, smoking habits and alcohol consumption in relation to oral cancer in a Swedish case-control study.** *Int J Cancer* 1998, **77:**341-346.
20. Schwartz SM, Daling JR, Doody DR, Wipf GC, Carter JJ, Madeleine MM, Mao E-J, Fitzgibbons ED, Huang S, Beckmann AM, McDougall JK, Galloway DA: **Oral cancer risk in relation to sexual history and evidence of human papillomavirus infection.** *J Natl Cancer Inst* 1998, **90:**1626-1636.

21. Rosenquist K, Wennerberg J, Schildt E-B, Bladström A, Hansson BG, Andersson G: **Use of Swedish moist snuff, smoking and alcohol consumption in the aetiology of oral and oropharyngeal squamous cell carcinoma. A population-based case-control study in southern Sweden.** *Acta Otolaryngol* 2005, **125:**991-998.
22. Zendehdel K, Nyrén O, Luo J, Dickman PW, Boffetta P, Englund A, Ye W: **Risk of gastroesophageal cancer among smokers and users of Scandinavian moist snuff.** *Int J Cancer* 2008, **122:**1095-1099.
23. Martínez I: **Factors associated with cancer of the esophagus, mouth, and pharynx in Puerto Rico.** *J Natl Cancer Inst* 1969, **42:**1069-1094.
24. Morris Brown L, Blot WJ, Schuman SH, Smith VM, Ershow AG, Marks RD, Fraumeni JF Jr: **Environmental factors and high risk of esophageal cancer among men in coastal South Carolina.** *J Natl Cancer Inst* 1988, **80:**1620-1625.
25. Lagergren J, Bergström R, Lindgren A, Nyrén O: **The role of tobacco, snuff and alcohol use in the aetiology of cancer of the oesophagus and gastric cardia.** *Int J Cancer* 2000, **85:**340-346.
26. Zheng W, McLaughlin JK, Gridley G, Bjelke E, Schuman LM, Silverman DT, Wacholder S, Co-Chien HT, Blot WJ, Fraumeni JF Jr: **A cohort study of smoking, alcohol consumption, and dietary factors for pancreatic cancer (United States).** *Cancer Causes Control* 1993, **4:**477-482.
27. Williams RR, Horm JW: **Association of cancer sites with tobacco and alcohol consumption and socioeconomic status of patients: interview study from the Third National Cancer Survey.** *J Natl Cancer Inst* 1977, **58:**525-547.
28. Muscat JE, Stellman SD, Hoffmann D, Wynder EL: **Smoking and pancreatic cancer in men and women.** *Cancer Epidemiol Biomarkers Prev* 1997, **6:**15-19.
29. Alguacil J, Silverman DT: **Smokeless and other noncigarette tobacco use and pancreatic cancer: a case-control study based on direct interviews.** *Cancer Epidemiol Biomarkers Prev* 2004, **13:**55-58.
30. Hassan MM, Abbruzzese JL, Bondy ML, Wolff RA, Vauthey J-N, Pisters PW, Evans DB, Khan R, Lenzi R, Jiao L, Li D: **Passive smoking and the use of noncigarette tobacco products in association with risk for pancreatic cancer: a case-control study.** *Cancer* 2007, **109:**2547-2556.
31. Accortt NA, Waterbor JW, Beall C, Howard G: **Cancer incidence among a cohort of smokeless tobacco users (United States).** *Cancer Causes Control* 2005, **16:**1107-1115.
32. Breslow NE, Day NE: *The analysis of case-control studies. [Statistical methods in cancer research.] Volume 1*. Edited by: Davis W. Lyon: IARC; IARC Scientific Publication No. 32; 1980.
33. Fleiss JL, Gross AJ: **Meta-analysis in epidemiology, with special reference to studies of the association between exposure to environmental tobacco smoke and lung cancer: a critique.** *J Clin Epidemiol* 1991, **44:**127-139.
34. Greenland S, Longnecker MP: **Methods for trend estimation from summarized dose-response data, with applications to meta-analysis.** *Am J Epidemiol* 1992, **135:**1301-1309.
35. Hamling J, Lee P, Weitkunat R, Ambühl M: **Facilitating meta-analyses by deriving relative effect and precision estimates for alternative comparisons from a set of estimates presented by exposure level or disease category.** *Stat Med* 2008, **27:**954-970.
36. Weitkunat R, Sanders E, Lee PN: **Meta-analysis of the relation between European and American smokeless tobacco and oral cancer.** *BMC Public Health* 2007, **7:**334.
37. Sponsiello-Wang Z, Weitkunat R, Lee PN: **Systematic review of the relation between smokeless tobacco and cancer of the pancreas in Europe and North America.** *BMC Cancer* 2008, **8:**356-368.
38. Royal College of Physicians: *Harm reduction in nicotine addiction: helping people who can't quit* 2007 [http://www.rcplondon.ac.uk/pubs/contents/bbc2aedc-87f7-4117-9ada-d7cdb21d9291.pdf]. A report by the Tobacco Advisory Group of the Royal College of Physicians. London: RCP
39. Nitzkin JL, Rodu B: *The case for harm reduction for control of tobacco-related ilness and death* 2008 [http://www.aaphp.org/special/joelstobac/20081026HarmReductionResolutionAsPassedl.pdf]. American Association of Public Health Physicians
40. Zeller M, Hatsukami D, Backinger C, Benowitz N, Biener L, Burns D, Clark P, Connolly G, Djordjevic MV, Eissenberg T, Giovino GA, Healton C, Hecht SS, Henningfield JE, Husten C, Kobus K, Leischow S, Levy DT, Marcus S, Myers ML, Parascandola M, Ponkshe P, Shields PG, Slovic P, Sweanor D, Warner KE: **The strategic dialogue on tobacco harm reduction: A vision and blueprint for action in the United States.** *Tob Control* 2009, **18(4):**324-332.

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Chapter 10

University student smokers' perceptions of risks and barriers to harm reduction

Karen Geertsema, Carl V. Phillips & Karyn K. Heavner

Abstract

Objective: To investigate student smokers' perceptions of the health risks from smoking and barriers to switching to less harmful nicotine products. Participants: 105 University of Alberta students who smoke. Methods: Students completed a self-administered survey focusing on the health risks of different tobacco products and their willingness to use low risk products. Results: Only 31% were aware that smoke inhalation causes most of the health risks from cigarettes. Many attributed the risk to nicotine, unburned tobacco and non-tobacco ingredients. One-quarter knew that smokeless tobacco is safer than smoking and 43% expressed willingness to switch to a hypothetical low risk tobacco product. Conclusions: These students were largely unaware that smoke inhalation causes most of the health risk from cigarettes but were interested in safer nicotine products. If this is true then providing accurate information about the risks of different nicotine products to students could lead to a major public health improvement.

Introduction

Most people in Western society are aware of the health risks from smoking. However, most people, including many public health and medical experts, mistakenly believe that other sources of nicotine, such as smokeless tobacco (ST) and pharmaceutical nicotine products, pose similar risks to smoking. This is despite overwhelming evidence that these products only cause about

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1/100th the health risk of smoking and are a promising smoking cessation method (Phillips, 2007; Phillips, Rabiu & Rodu, 2006; Rodu & Godshall, 2006). Overall, smokers are misinformed about tobacco harm reduction and the safety and efficacy of pharmaceutical nicotine products (Bansal, Cummings, Hyland & Giovino, 2004; Cummings, Hyland, Giovino, Hastrup, Bauer & Bansal, 2004; Heavner, Rosenberg & Phillips, 2009). Fewer than 11% of participants in four studies in the United States, including one of university students (Indiana, 2004; Broome County, 2006; O'Connor, Hyland, Giovino, Fong & Cummings, 2005; Smith, Curbow & Stillman, 2007), and less than 3% of health care providers (Prokhorov, Wetter, Padgett, de Moor, Le, & Kitzman, 2002) realize that ST is safer than cigarettes. In addition, few Canadians realize that chewing tobacco and snuff are less harmful than cigarettes (18% and 19%, respectively) (Health Canada, 2006). In a study of military recruits, most participants did not know that switching from cigarettes to ST would reduce tobacco users' risk (Haddock, Lando, Klesges, Peterson & Scarinci, 2004). Tobacco harm reduction, the substitution of highly-reduced risk sources of nicotine for smoking, is a promising intervention (see www.tobaccoharmreduction.org for more details). It is unrealistic to expect that all the college students who smoke will eventually quit using nicotine entirely so other ways of attenuating the morbidity and mortality from their tobacco use are needed. However, the widespread belief that using ST and other non-smoked nicotine products are as risky as smoking is a substantial barrier to harm reduction.

Previous research has shown that people are confused about the risks from 1) inhaling smoke (quite high), 2) consuming nicotine (relatively low), 3) contact with unburned tobacco (too low to be reliably measured), and 4) additives in tobacco products (largely mythical). Most people (67%) in a survey in the United States (Cummings et al., 2004) and 60% of a sample of nurses (Borrelli & Novak, 2007) believed that nicotine causes cancer. In addition, a survey of Canadians found that many believed that chewing tobacco and snuff contain "tar" (i.e., aerosolized particulate matter that results from combustion) (81% and 75%, respectively) and carbon monoxide (41% and 38%, respectively) (Health Canada, 2006). "Smoking," "tobacco," and "nicotine" are often seen as synonymous by the general public and are haphazardly treated as such in the scientific literature. This misperception has substantial practical implications given the growing recognition of the need for a harm reduction strategy for the substantial proportion of the population who continue to smoke. These smokers do not realize that switching to a non-combustion source of nicotine, be it ST, over-the-counter pharmaceutical nicotine products (patches, gum, etc.), or the new "electronic cigarettes," would almost eliminate their health risks.

To expand upon the existing literature about perceived risks that may be barriers to tobacco harm reduction, we conducted a survey of students who smoke at a western Canadian university. This study largely focused on a question designed to elicit smokers' perception of the apportionment of the total health risk to different aspects of the exposure to cigarettes.

Methods

This cross-sectional survey was conducted during April 2006, on the University of Alberta campus in Edmonton, Canada. Trained research staff approached people who were smoking outside and appeared to possibly be students (e.g., not people wearing staff uniforms or hardhats) on campus between 10 am and 4 pm. People who self-identified as undergraduate students were asked to complete an anonymous self-administered survey. Of the 130 potential subjects who did not explicitly state that they were not undergraduate students, 113 participated. Seven participants indicated on the survey that they were not undergraduate students and one survey was left mostly blank, leaving 105 surveys included in this analysis.

The study was approved by the Arts, Science and Law Research Ethics Board at the University of Alberta. Potential participants were told about the purpose of the study and informed that it was an anonymous survey and that no identifying information other than age and gender would be collected. Completion of the self-administered survey signified consent to participate since having participants sign a consent form would have rendered the survey non-anonymous.

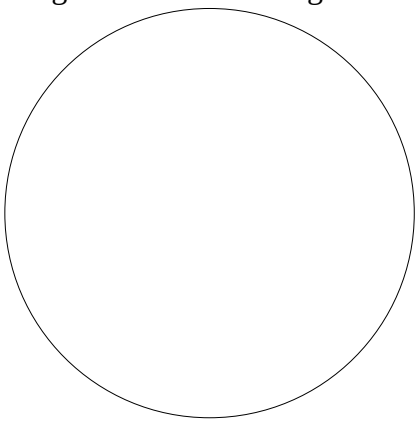
The survey assessed participants': 1) sociodemographic characteristics; 2) history of cigarette, pharmaceutical nicotine and ST use; 3) perceptions of smoking and ST; and 4) willingness to use reduced harm products. Student smokers who never or rarely (1-9 times) used ST were asked about their reasons for not using ST. The survey did not inform participants about the comparative risks of cigarettes and ST, so their willingness to use ST was assessed by a question about willingness to use a hypothetical oral nicotine product that costs about the same as cigarettes and has about 1% of the health risk of smoking. A major barrier to harm reduction was assessed by asking if participants would consider switching from cigarettes to this hypothetical product if it required occasional spitting (the common perception of ST) and if it did not require spitting (like many modern ST products). The questionnaire and data are available at http://www.tobaccoharmreduction.org/research/uofasmokesurvey.htm.

Students completed a pie chart to assess their beliefs about the source of the health risks from smoking (Figure 1). Filling in a pie chart is an unusually difficult question for a survey, but it was a uniquely effective way to assess the question and appropriate for the population. The question was within the capabilities of undergraduate students who had completed college-preparatory math. We estimated divisions of the circle by measuring the linear distance between the points where the lines dividing the pie segments intersected the circumference using calipers, and calculating the resulting portion of the circle using trigonometry. This approach assumed that the arc encompassed between two intercepts was the intended measure and ignored small deviations from straight lines between the center and circumference of the circle.

Figure 1: Pie chart question

I would just like to know where you think the health risks from smoking comes from by dividing the circle into pie slices for the nicotine, other chemicals that occur naturally in the tobacco plant, other ingredients added by the tobacco manufacturers, or from inhaling the smoke. Please divide up this circle into pie chart slices each of which represents the portion of the health risk from cigarettes due to:

a) Nicotine
b) Other chemicals in the tobacco plant
c) Ingredients added to the tobacco by the manufacturer
d) Inhaling the smoke from cigarettes.



In addition to assessing the responses to the pie-chart question, we computed univariate summaries for all other questions using SAS version 9.1 (SAS Institute, Cary, NC).

Results and Discussion

Table 1 summarizes the students' demographic characteristics, tobacco use history and perceptions of the risks of tobacco products. The students reported limited experience with non-smoked sources of nicotine. One-quarter of the sample had ever used ST, most (65%) of whom had used ST fewer than 10 times. About one-quarter (29%) of the sample had ever used pharmaceutical nicotine. Males were more likely than females to have used ST (38% and 11%, respectively). In addition, 60% had ever smoked tobacco in a form besides cigarettes, including cigars, hookahs or pipes.

The students exhibited substantial misperceptions about the health risks of different tobacco products. The majority (75%) believed that ST is as risky as cigarettes. This proportion is somewhat better than results of previous surveys, possibly due to a more educated sample or our research at the university. (We had made no directed effort to educate the students about tobacco harm reduction, but they may have found our public education materials due to local media coverage or word-of-mouth.) Nevertheless, this illustrates the widespread misperception that there is no potential for tobacco harm reduction, even in a relatively educated sample.

Table 1: Undergraduate Student Smokers' Demographic Characteristics, Tobacco Use History and Perceived Risks From Various Tobacco Products

	n	%
Demographics		
Age		
Mean	104	23
Median (range)	104	22 (18, 42)
Male	53	50%
Tobacco Use History		
Cigarettes smoked per day		
0-5	42	40%
6-10	32	30%
11-15	24	23%
16+	7	7%
Ever used ST use		
Yes	26	25%
No	79	75%
Are you considering the idea of quitting smoking?		
Yes, I plan to quit soon.	38	37%
Yes, but I have no specific plans	51	49%
No, I am not interested in quitting.	13	12%
I have not thought much about it.	2	2%
	n	**% (95% CI)**
Perceived Risks From Various Tobacco Products		
Compared to cigarettes, ST:		
Poses a higher health risk	13	15% (7%, 22%)
Poses about the same risk	53	60% (50%, 70%)
Poses a lower health risk	22	25% (16%, 34%)
ST products cause oral cancer		
Definitely	47	48% (38%, 58%)
Probably	30	31% (21%, 40%)
Possibly	21	21% (13%, 30%)
Reasons for not using ST*		
Just never really considered using ST.	54	56% (46%, 66%)
I don't like the idea of spitting.	52	54% (44%, 64%)
I like smoking and have no desire to use ST.	46	48% (38%, 58%)
I don't believe using ST has the same social benefits as smoking.	20	21% (13%, 29%)
I am worried about the health risks from ST.	19	20% (12%, 28%)
I don't believe I will get the same nicotine fix.	5	5% (1%, 10%)
Would you consider switching from cigarettes to a product you could hold inside your mouth to provide you with nicotine, just like a cigarette, which costs about the same as cigarettes, and has only about 1% of the health risk of smoking cigarettes?		
Yes, even if it requires spitting	22	21% (13%, 29%)
Yes, but only if it does not require spitting	45	43% (33%, 52%)
No	38	36% (27%, 45%)

*Limited to the 79 students who had never used ST and the 17 students who had used ST less than 10 times.

Nearly half of participants believed that ST definitely causes oral cancer. Fear of oral cancer and spitting are major barriers to tobacco harm reduction. Ironically, smoking is the major cause of oral cancer in North America (U.S. Department of Health and Human Services (USDHHS), 2000) and the relative risk from modern ST products is negligible. As predicted, an aversion to spitting was a commonly cited reason for not using ST. More than half (54%) cited this reason compared to 20% who did not consider using ST because of the perceived health risks.

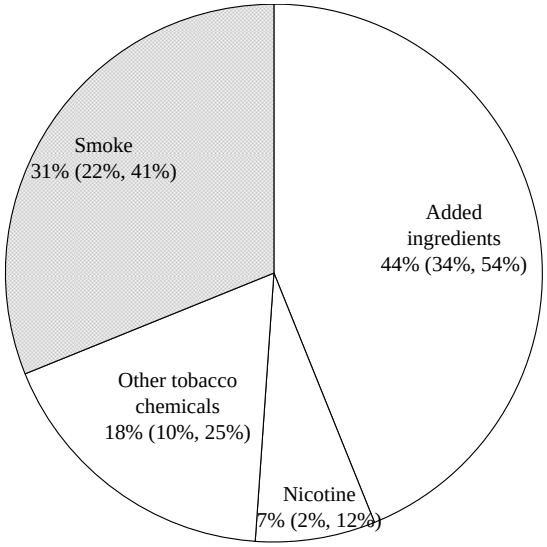
The stated aversion to spitting – a great irony coming from a subpopulation that exposes people to environmental tobacco smoke and very often litters their cigarette butts – was so great that many considered it more important than almost eliminating health risk. Many (43%) respondents would consider switching to the spit-free hypothetical product (e.g., snus and other modern satchel-style ST products) but only 21% would switch if it required spitting. Spitting was more of a deterrent for female than male students (15% and 27% were willing to switch to a product that required spitting, respectively).

Results from the pie chart question are summarized in Figure 2.

Figure 2: Students' Perceptions of the Source of the Health Risks from Cigarettes

	Median (range)	**Mean (95% CI)**
Smoke	24% (0%, 70%)	26% (23%, 29%)
Nicotine	12% (0%, 100%)	16% (14%, 19%)
Other tobacco chemicals	20% (0%, 100%)	24% (21%, 27%)
Added ingredients	32% (0%, 93%)	33% (29%, 36%)

Percentage of students who attributed the greatest health risk from cigarettes to:



Only 31% of the students correctly identified smoke inhalation as the major cause of the health effects of smoking. The average attribution of the total risk to smoke was similarly low (median=24%; mean=26%). If subjects had randomly divided the pie, 25% would have correctly identified the largest source of risk. While the exact portion of the total risk attributable to inhaling smoke is unknown, the correct answer is clearly more than 90%. Failure to realize this represents a substantial misperception of the potential health benefits of switching to non-combustion nicotine products.

The students' apportionment of the remaining risk offers further insight. If smoke is not sufficiently implicated then it must be that nicotine, additives and/or tobacco itself are misperceived as causing more harm than they do. Overall, participants believed that nicotine (median=12%; mean=16%), and other chemicals in the tobacco plant (median=20%; mean=24%) caused no more than 40% of the risk. Presumably the sum of these two would represent the perceived risk from using ST, though 75% of the students believed that ST was at least as harmful as smoking. This contradiction provides further evidence suggesting that the equation of smoking, tobacco, and nicotine in anti-tobacco messages (Phillips, Wang & Guenzel, 2005) has effectively misled even educated smokers.

A surprisingly large portion of the sample attributed major risks to ingredients (other than tobacco) that manufacturers add to cigarettes. This was considered the greatest source of harm, with 44% ranking it highest and attributing one-third of the risk to these additives (median=32%; mean=33%). However, most manufactured cigarettes contain no ingredients that substantially change the health risks from inhaling burning organic matter. The leading Canadian manufacturer adds only water and menthol to the tobacco (Imperial Tobacco Canada, 1998). This belief may explain the common misperception that other smoked tobacco products (e.g., hookahs/shisha, natural/organic cigarettes, and hand rolled cigarettes) are safer than manufactured cigarettes (Labib, et al. 2007). It is particularly troubling since these alternative products may actually pose greater health risks (World Health Organization, 2005). This misperception is likely attributable to the tendency to demonize corporations rather than to honestly educate consumers about the risks from smoke.

Although the generalizability of our specific numbers is limited due to the use of a small sample of one socio-demographic group, the results support existing evidence about the misperceptions about ST, and show that such misperceptions may even extend to fairly educated university populations. The answers to the pie question, like responses to any question, involve some predictable bias. In this case, there is probably a tendency to homogenize the four probabilities, though this alone is unlikely to account for the huge misperceptions found in this study. The pie chart is more informative than many standard types of questions, though attempts at precise

numerical interpretations should be avoided since a statement like “inhaling smoke causes 26% of the total risk” might be interpreted as attributable risk based on counterfactuals, but it is not clear exactly what a subject meant by it. This question allowed for bivariate comparisons (i.e., “how does the risk from X compares to that from Y”) and a quantification of intensity. Though even without an exact quantitative meaning, the comparisons are at least as useful as typical questions (e.g., 5 versus 6 on a Likert scale or “agree” versus “strongly agree”), and the pie forces an explicit apportionment. No subjects expressed confusion about the pie chart and only eight completed most of the survey but did not complete this question. We believe that this would be a useful tool for future research.

Conclusions

The major findings of this study emphasize the importance of educating students about the source of the health risk from smoking and the consequent health benefits of switching from smoking to non-smoked nicotine products. Our results suggest that among university students who are interested in smoking cessation, but have not quit, there is little awareness of the potential for harm reduction. Moreover, this population shows a strong willingness to switch to hypothetical reduced-risk oral products, but few realize that these exist in the form of modern ST. While it might be too optimistic to think that 43% of this population would switch to ST or similar nicotine products if they had accurate information, this estimate is lower than the percent of young males in Sweden who use ST instead of smoking (Stegmayr, Eliasson & Rodu, 2005).

Effective anti-ST propaganda will make it challenging to inform student smokers of the truth. However, overcoming the misplaced worry about spitting (particularly among women) is just as important as, and perhaps easier than, overcoming the misinformation about health effects (Phillips, Bergen & Guenzel, 2006).

Our research further suggests that the ends-justify-the-means attitude among anti-tobacco advocates has interfered with harm reduction and convinced smokers that their options are to quit nicotine entirely, which many students will not do, or to die from it. Additionally, it seems possible that misunderstanding the immense risks of inhaling smoke might lead people to believe that smoking is less risky than it actually is, particularly smoking products other than brand name cigarettes. While many college-age smokers eventually quit, almost all of the eventual quitters will smoke for long enough that the health risk exceeds that of using ST or similarly low-risk alternatives for a lifetime (Phillips, 2009). Thus educating the college student population to eliminate the barriers to harm reduction, rather than waiting to focus on those who are still smoking in middle-age, could provide substantial public health benefits. Moreover, this more-educable subpopulation could then become opinion leaders in the larger population.

References

Bansal MA, et al. Stop-smoking medications: who uses them, who misuses them, and who is misinformed about them? *Nicotine.Tob.Res.* 6 Suppl 3: S303-S310, 2004.

Borrelli B, Novak SP. Nurses' knowledge about the risk of light cigarettes and other tobacco "harm reduction" strategies. *Nicotine.Tob.Res* 9 (6): 653-661, 2007.

British Columbia government. What is in Cigarettes? http://www.health.gov.bc.ca/ttdr/. 3-28-2003. 2007.

Broome County Health Department Tobacco Free Broome and Tioga. Community Tobacco Survey of Adult Residents of Broome County, New York: Opinions, Behaviors, and Perceptions Related to Tobacco Use, The Dangers of Tobacco, Tobacco Cessation, Tobacco Advertising, and Exposure to Secondhand Smoke. 2006.

Cummings KM et al. Are smokers adequately informed about the health risks of smoking and medicinal nicotine? *Nicotine.Tob.Res* 6 Suppl 3: S333-S340, 2004.

Haddock CK et al. Modified tobacco use and lifestyle change in risk-reducing beliefs about smoking. *Am J Prev.Med.* 27 (1): 35-41, 2004.

Health Canada. Consumers' Awareness and Perceptions of Potential "Harm Reduced" Products. 2006.

Heavner K, Rosenberg Z, Phillips CV. Survey of smokers' reasons for not switching to safer sources of nicotine and their willingness to do so in the future. *Harm Reduction Journal* 6 (1): 14, 2009.

Imperial Tobacco Canada. Imperial Tobacco Canada announces ingredients and additives in cigarettes and cigarette tobacco. Imperial Tobacco Canada . 2007.

Indiana Tobacco Prevention and Cessation. Adult Tobacco Survey Highlight Report. 2004.

Labib N. et al. Comparison of cigarette and water pipe smoking among female university students in Egypt. *Nicotine Tob.Res* 9 (5): 591-596, 2007.

O'Connor RJ, et al. Smoker awareness of and beliefs about supposedly less-harmful tobacco products. *Am.J.Prev.Med.* 29 (2): 85-90, 2005.

Phillips CV. Debunking the claim that abstinence is usually healthier for smokers than switching to a low-risk alternative, and other observations about anti-tobacco-harm-reduction arguments. *Harm Reduction Journal,* 6:29, 2009.

Phillips CV. Highly-reduced-harm nicotine products: Which products are promising substitutes for cigarettes? 18th International Conference on the Reduction of Drug Related Harm, Warsaw, Poland. 2007.

Phillips CV, Bergen P, Guenzel B. Persistent misleading health advice about smokeless tobacco on the Web. 11th World Congress on Internet in Medicine. 11th World Congress on Internet in Medicine . 2006.

Phillips CV, Rabiu D, Rodu B. Calculating the comparative mortality risk from smokeless tobacco versus smoking. *American Journal of Epidemiology* 163: S189, 2006.

Phillips, C. V., C. Wang, and B. Guenzel, You might as well smoke; the misleading and harmful public message about smokeless tobacco. *BMC.Public Health* 5: 31, 2005.

Rodu B, Godshall WT. Tobacco harm reduction: an alternative cessation strategy for inveterate smokers. *Harm.Reduct.J.* 3: 37, 2006.

Smith SY, Curbow B, Stillman FA. Harm perception of nicotine products in college freshmen. *Nicotine.Tob.Res* 9 (9): 977-982, 2007.

Stegmayr B, Eliasson M, Rodu B. The decline of smoking in northern Sweden. *Scand.J Public Health* 33 (4): 321-324, 2005.

U.S.Department of Health and Human Services (USDHHS). Oral Health in America: A Report of the Surgeon General. 2000.

World Health Organization. Waterpipe Tobacco Smoking: Health Effects, Research Needs and Recommended Actions by Regulators. 2005.

Chapter 11

Comment to the U.S. Food and Drug Administration summarizing the rationale for tobacco harm reduction

Brad Rodu

Reprinted from public archives of public comments to the Food and Drug Administration on the Regulation of Tobacco Products Docket FDA-2009-N-0294 (0652.1) (Available at: http://www.regulations.gov/search/Regs/home.html#documentDetail?R=0900006480a5a183).

Editors' Note: Rodu was almost alone in vigorously advocating THR in the 1990s, and most of us working in the area can trace our interest and intellectual development to him. He has written several important summaries of the topic, including his Harm Reduction Journal article with Godshall and his recent advocacy pieces with Nitzkin. We include this particular work because it falls within the right time period and provides a snapshot of what he presumably sees as the most expedient arguments to make in the political arena. Also, this is one of the best recent catalogs of the relevant evidence, particularly regarding how adoption of THR is practical and ongoing.

Our own approach differs from Rodu's somewhat. In particular, he is more of a "strict constructionist" when interpreting the published literature and epidemiology methods than we are, citing results that elsewhere we argue are dubious in spite of being peer-reviewed publications (though his desire to be extra conservative in a document like this one might have exaggerated the contrast some). But an advantage of this is that he has created, in this document, the cleanest possible collection of evidence that affirmatively supports promoting THR without overcomplicating it (as we admit that we tend to do) by trying to simultaneously respond to misleading claims about evidence that supposedly denies the value of THR.

BR is a Professor of Medicine at the University of Louisville.

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November 17, 2009

Jeffrey Shuren, MD, JD
Associate Commissioner for Policy and Planning
Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Docket No. FDA-2009-N-0294

Dear Dr. Shuren:

I am a professor of medicine and hold an endowed chair in tobacco harm reduction research at the University of Louisville. I have continually conducted research on tobacco harm reduction for over 15 years, and I have published 31 studies on this subject in the peer-reviewed medical and scientific literature.

I believe that FDA regulation of tobacco products will be effective and beneficial for public health if it incorporates tobacco harm reduction, which involves the substitution of alternative sources of nicotine, including smokeless tobacco products, for cigarettes by smokers who are unwilling or unable to abstain altogether from nicotine and tobacco.

In the attached document I have summarized the strong medical, scientific and public health rationale for tobacco harm reduction.

Sincerely,

Brad Rodu

Brad Rodu
Professor of Medicine
Endowed Chair, Tobacco Harm Reduction Research

Tobacco Harm Reduction: Medical, Scientific and Public Health Rationale

I. Introduction

According to the Centers for Disease Control and Prevention, about 45 million Americans continue to smoke, even after one of the most intense public health campaigns in history, now over 40 years old. Each year over 400,000 Americans die from smoking-related diseases, including lung and other cancers, cardiovascular disorders and pulmonary diseases.

Many smokers are unable or unwilling to achieve cessation through complete nicotine and tobacco abstinence; they continue smoking despite the very real and obvious adverse health consequences. Conventional smoking cessation policies and programs based on abstinence present smokers with only two unpleasant alternatives: quit, or die.

Tobacco harm reduction involves the use of alternative sources of nicotine, including modern smokeless tobacco (ST) products, by smokers who can not achieve abstinence. A substantial body of research, much of it produced over the past decade, establishes the scientific and medical foundation for tobacco harm reduction using ST products.

II. The Adverse Health Effects of Smoking and Smokeless Tobacco Use

The adverse health effects of tobacco use are frequently described in terms of relative risk (RR), an established measure used by epidemiologists to compare the probability of developing a disease among a population exposed to a specific risk factor with the risk among an unexposed population (1). RRs may be accompanied by a confidence interval (CI), which is the range within which the RR lies with 95% confidence. An RR of 1.0 indicates that the risk among the exposed population is the same as that among the unexposed, and any CI that includes 1.0 indicates that the RR is not statistically significant. An RR of 1.2 indicates an increased risk of 20%, while an RR of 2.0 indicates a doubling of the risk. The U.S. National Cancer Institute notes that small RRs (those less than 2.0) “are viewed with caution,” because they “are sometimes difficult to interpret” (1). In addition, a risk is likely to be legitimate if it demonstrates a dose-response (1). In other words, an increased dose or duration of exposure should result in an increased risk.

A. Smoking

According to the Centers for Disease Control and Prevention, “smoking harms nearly every organ of the body.” (2) A multitude of epidemiologic studies over the past 50 years have documented the health risks of smoking, and for over two decades the CDC has provided estimates of the number of deaths from cancers, cardiovascular diseases and respiratory disorders each year in the U.S. that are directly attributable to smoking. The CDC utilizes national survey data on smoking prevalence and risks from published epidemiologic studies to establish precise estimates, which are released in publications

and on its SAMMEC (Smoking Attributable Mortality, Morbidity, and Economic Costs) website (3).

1. Cancers

According to the CDC, smokers have elevated risks for cancers of the lung (RR = 13-23), oral cavity and pharynx (RR = 5-11), pancreas (RR = 2.3) and numerous other sites (3). In 2008 the CDC estimated that 158,529 Americans die each year from lung and other cancers directly attributable to smoking (Table 1)(4).

2. Cardiovascular Diseases

The CDC reports that smokers have elevated risks for several diseases of the heart and circulatory system, including heart attack (RR up to 3.0) and stroke (RR up to 4)(3). In 2008 the CDC estimated that 137,979 Americans die each year from cardiovascular diseases attributable to smoking (Table 1)(4).

3. Respiratory Disorders

The CDC reports that smokers have elevated risks respiratory diseases including bronchitis and emphysema (RR = 12-17) and chronic airway obstruction (RR = 11-13)(3). In 2008 the CDC estimated that 101,454 Americans die each year from cardiovascular diseases attributable to smoking (Table 1)(4).

4. Second-hand smoke

In 2008 the CDC estimated that 38,000 Americans die each year from lung cancer and cardiovascular diseases that are due to exposure to second-hand smoke (Table 1)(4).

B. Smokeless Tobacco Use

The CDC characterizes ST as “a significant health risk” and “a known cause of human cancer; it increases the risk of developing cancer of the oral cavity and pancreas” (5). However, in contrast to smoking, the CDC provides virtually no information about the magnitude of these risks. Fortunately, dozens of published epidemiologic studies provide credible information about the health risks associated with ST use.

1. Cancers

In 2009 Peter Lee and Jan Hamling, two epidemiologists based in the United Kingdom, were the authors of an exhaustive meta-analysis of the epidemiologic evidence regarding ST use and cancer (6). A meta-analysis is a technique used by epidemiologists to combine the results from numerous studies, and the results are reported as summary RRs.

Lee and Hamling compiled the statistics from 89 studies, and they used a straightforward technique to separate the risk related to ST use from the risk related to smoking and alcohol consumption. In other words, the risks from ST use were adjusted for those from smoking and alcohol use, which is important because ST users often have a history of smoking and heavy drinking, both of which are risk factors for cancers of the oral cavity, throat and esophagus. Lee and Hamling reported summary RRs for cancer among ST users compared with non-users of tobacco.

a. Oral Cancer

Lee and Hamling found 41 studies that reported risks for oral cancer, and the important findings are summarized in Table 2. For all studies the RR was 1.79 (CI = 1.36-2.36), indicating a modest elevation in risk. However, in the 19 studies that accounted for smoking the RR was 1.36 (CI = 1.04-1.77), and in the 10 studies that accounted for both smoking and alcohol the RR was 1.07 (CI = 0.84-1.37). Thus, the evidence that ST causes oral cancer is very weak, virtually nonexistent. Lee and Hamling also found that, for studies published since 1990, the RR for smokeless use was 1.28 (CI = 0.94-1.76), a small, statistically significant increase that disappeared almost completely when only studies that accounted for smoking or smoking and alcohol were considered. This means that any possible risks from using ST 40 or 50 years ago have not been seen in studies conducted since 1990.

The Lee-Hamling results for oral cancer were very similar to those obtained by a comprehensive review by Rodu and Cole in 2002 (7). They reviewed 21 epidemiologic studies published from 1957 to 1998, and they derived summary RR estimates for cancers of the oral cavity and associated upper respiratory sites related to use of American-style chewing tobacco and moist snuff. The summary RRs for chewing tobacco users and moist snuff users were 1.2 (CI = 1.0-1.2) and 1.0 (CI = 0.8-1.2) respectively.

b. Other Cancers

Lee and Hamling examined the epidemiologic evidence linking ST use with many other cancers, and summary RRs are listed in Table 3. It is noteworthy that the only statistically significant finding was a minimally elevated risk for prostate cancer (RR = 1.29, CI = 1.07-1.55). Lee and Hamling commented that “Prostate cancer is not considered smoking related [original citations removed], and more information on its relationship with ST is needed before any clear conclusion can be drawn.”

2. Cardiovascular Diseases

There have been at least ten epidemiologic studies evaluating the risks for cardiovascular diseases (primarily heart attack and stroke) among ST users. Two meta-analyses by Peter Lee in 2007 (8) and Paolo Boffetta and Kurt Straif in 2009 (9) have provided summary RRs from these studies.

a. Heart attack

Both studies found that ST use is not associated with statistically significant elevated RRs for heart attack (RRs = 1.12, CI = 0.99 – 1.27 (8) and 0.99, 95% CI = 0.89 – 1.10 (9)). However, Boffetta and Straif (9) reported an elevated risk for fatal cases among ever users (RR = 1.13, CI = 1.06 – 1.21), almost entirely derived from one large Swedish study (10) and a very large study in the U.S. (11).

Boffetta and Straif (9) did not find a dose-response effect for ST use and fatal heart attack, so the elevated risk from their study is somewhat tentative. In addition, although no elevated risks were observed in the majority of studies, the large American study (11) that reported elevated risks comprised 85% (by weight) of the Boffetta-Straif analysis. This is noteworthy because smokeless users in this study also had elevated risks for emphysema (RR = 1.28, CI = 1.03-1.59) and lung cancer (RR = 2.0, CI = 1.23-3.24), two diseases closely associated with smoking. Thus, it is likely that some smokeless users in this study were smokers, which may have been responsible for some of the heart attack risk.

b. Stroke

The Lee (8) and Boffetta-Straif (9) meta-analyses also reported the risk of stroke among ST users. Lee reported an increase in stroke risk among smokeless users (RR = 1.42, CI = 1.29 – 1.57)(8). Boffetta and Straif (9) found no risk overall (RR = 1.19, CI = 0.97 – 1.47), but they found an elevated risk for fatal cases (RR = 1.40, CI = 1.28 – 1.54). Boffetta and Straif (9) did not find a dose-response effect for ST use and fatal stroke, so this risk is also somewhat tentative. The American study (11) comprised 89% of the Boffetta-Straif analysis, so the likelihood of smoking among smokeless users discussed in the previous paragraph is equally important for the elevated fatal-stroke risk.

3. Respiratory Disorders

There is no evidence that ST use is associated with respiratory diseases. According to the 2007 statement on harm reduction by the Royal College of Physicians in London, “ST products have little or no effect on the risk of chronic obstructive pulmonary disease or lung cancer.” (12)

In 2008 a European Commission report on the health effects of ST products included the following statements: “Respiratory diseases, predominantly lung cancer, COPD and pneumonia, account for 46% of the deaths caused by cigarette smoking in the EU [original citation removed]. There is no consistent evidence that any ST products cause any of these major respiratory diseases. Complete substitution of ST products for tobacco smoking would thus ultimately prevent nearly all deaths from respiratory disease currently caused by smoking, which in total represent nearly half of all deaths caused by smoking.” (13)

4. Second-hand Smoke

ST use does not result in exposure to smoke by users or bystanders.

III. Comparison of the Health Risks from Smoking and Smokeless Tobacco Use

Section IIa described the precision with which the CDC estimates the number of cancer, cardiovascular and respiratory disease deaths in the U.S. each year that are attributable to smoking. It is important to note that the CDC is in possession of information regarding the prevalence of ST use in the U.S. and the relative risk information discussed in Section IIb, such that the agency could readily formulate directly comparable estimates of morbidity and mortality associated with smoking and ST use. Unfortunately, the CDC has never released any estimates or other statistics comparing these two forms of tobacco use.

Comparison of the health risks associated with smoking and ST use has been addressed by numerous studies in the medical literature. Starting in 1994, Rodu and Cole provided a quantitative assessment of the difference in risks for the two products. Using established risk estimates from accepted sources, Rodu and Cole documented that ST use confers only about 2% of the health risks of smoking (14,15,16). In addition, they estimated that the average reduction in life expectancy from long-term ST use was about 15 days, compared with an average reduction of about 8 years from smoking (15).

In 2002 the Royal College of Physicians of London issued a report called "Protecting Smokers, Saving Lives," which stated, "As a way of using nicotine, the consumption of non-combustible [smokeless] tobacco is on the order of 10-1,000 times less hazardous than smoking, depending on the product." The report continued with an even bolder statement, acknowledging that some ST manufacturers may want to market their products "as a 'harm reduction' option for nicotine users, and they may find support for that in the public health community." (17)

In 2004 a study funded by the U.S. National Cancer Institute assembled an international panel of experts (including epidemiologists from the U.S. National Institutes of Health and the American Cancer Society) to compare the risks of ST use with those of smoking. The study authors reported that, "In comparison with smoking, experts perceive at least a 90% reduction in the relative risk of low-nitrosamine smokeless tobacco use." The authors concluded that "This finding raises ethical questions concerning whether it is inappropriate and misleading for government officials or public health experts to characterize smokeless tobacco products as comparably dangerous with cigarette smoking." (18)

In 2006 Phillips et al. provided a detailed and direct comparison of risks from use of Swedish or American ST products and from smoking, using a spectrum of risk estimates for ST use ranging from well-substantiated and plausible to highly speculative and implausible (19). They estimated that, compared with smoking, risks from ST use "in the range of 1% or 2%, and possibly less, are most consistent with the epidemiologic

evidence. Perhaps most important, our calculation shows that comparative risk estimates as high as 5%, let alone 10% or more, cannot be justified based on the evidence."

In 2008, Nitzkin and Rodu (4) estimated that, if all American smokers had instead used ST, there would be 2,668 deaths each year from cancer of the oral cavity and pancreas (Table 4). This represents only 1.7% of the cancer deaths currently attributable to smoking and 0.6% of all smoking-attributable deaths.

In addition to the meta-analysis described earlier, Lee and Hamling (6) also directly compared cancer deaths among smokers and ST users in the U.S. They estimated that 104,737 men in the U.S. died from cancers associated with smoking in 2005. Using the RRs from their study, Lee and Hamling calculated the number of cancer deaths that would have occurred if all smokers had instead used ST. The number cancer deaths attributable to ST would have been 1,102, which is only 1.1% of the deaths currently attributable to smoking.

Lee and Hamling then calculated another estimate, involving a worst-case scenario in which every man in the U.S. used ST. In that case, there would be 2,298 deaths attributed to ST use, which is only 2.2% of the deaths attributed to smoking among approximately 22 million male smokers.

IV. Evidence that ST Is an Effective Substitute for Cigarettes

A. Evidence From the U.S.

1. Population-level evidence from the U.S. National Health Interview Survey

In 2008 Rodu and Phillips provided the first population-level evidence that American men have quit smoking by switching to ST (20). Using data from the 2000 National Health Interview Survey, which the CDC uses to estimate smoking prevalence in the U.S., Rodu and Phillips estimated that 359,000 American male smokers had tried to switch to ST during their most recent quit attempt. Of these smokers, 73% (261,000, termed switchers) were former smokers at the time of the survey, representing the highest proportion of successes among all methods. In comparison, the nicotine patch was used by an estimated 2.9 million men in their most recent quit attempt, but only 35% were former smokers at the time of the survey. Of the 964,000 men who had used nicotine gum, 34% became former smokers. Of the 98,000 men who used the nicotine inhaler, 28% quit successfully. None of the estimated 14,000 men who had tried the nicotine nasal spray became former smokers. Forty-two percent of switchers reported quitting smoking all at once, which was higher than among former smokers who used medications (8–19%). Although 40% of switchers had quit smoking less than 5 years before the survey, 21% had quit over 20 years earlier. Forty-six percent of switchers were current ST users at the time of the survey.

Rodu and Phillips showed that switching to ST compares very favorably with pharmaceutical nicotine as a quit-smoking aid among American men, despite the fact that few smokers know that the switch provides almost all of the health benefits of complete

tobacco abstinence. The results of this study show that tobacco harm reduction is a viable cessation option for American smokers.

2. An American Clinical Trial

One clinical trial, an open-label, nonrandomized pilot study, has been conducted assessing the efficacy of an ST product in helping cigarette smokers become smoke-free (21,22). The investigators used a low-intensity approach, consisting of a 20-minute lecture about the health effects of all forms of tobacco use, followed by information about and samples of pre-portioned single-dose tobacco packets available throughout the U.S. The investigators used exhaled carbon monoxide levels to validate participant self-reports regarding smoke-free status at the conclusion of the original study after one year (21) and after seven years of follow-up (22). Of 63 subjects starting the study, 16 had successfully quit smoking by switching to ST after one year, and 12 were still smoke-free after seven years.

B. The Swedish Tobacco Experience

1. Smokeless Tobacco Use Has Had a Profound Effect on Smoking in Sweden

For the past 100 years, cigarette smoking has been the dominant form of tobacco consumption in almost all developed countries. One notable exception is Sweden, where smoking rates, especially among men, have been considerably lower than those of comparable countries for decades.

Per capita consumption of nicotine from tobacco in Sweden is quite high and on par with other countries such as Denmark, the U.S. and Austria (23). The difference between Sweden and the other countries is how nicotine is consumed. In Denmark, the U.S., Austria and many other developed countries, almost all nicotine consumption is derived from tobacco combustion. In Sweden, ST use (in the form of snus) accounts for almost 50% of all contemporary nicotine consumption in Sweden. Snus use in Sweden is much more common among men than among women; over 60% of nicotine consumption among Swedish men is from snus. This is not a new phenomenon; for over a century, Swedish men have had among the world's highest per capita consumption of ST (24).

Beginning in 2002, an American-Swedish research group used a World Health Organization database to describe in detail the impact of snus use on smoking among the population in northern Sweden during the period 1986-2004 (25,26,27).

Among men, the prevalence of all tobacco use was stable during the study period, at about 40%. However, there were striking, and opposite, changes in prevalence of smoking and snus use. Smoking prevalence was 19% in 1986, and it was lower in all subsequent surveys, reaching 9% in 2004. The prevalence of exclusive snus use increased from 18% in 1986 to 27% by 2004. Snus use was the dominant factor in the higher prevalence of ex-smoking among men compared to women (prevalence ratio 6.18, 95% CI 4.96 – 7.70).

Among women the prevalence of all tobacco use also was steady at 27 to 28%, and women smoked at higher rates than men in all surveys. But these studies showed that snus use was associated with lower smoking rates among women in 1999 and 2004. Smoking prevalence was about 25 to 27% in 1986, 1990 and 1994, but declined to 21% in 1999, and 16% in 2004. The prevalence of snus use was 0.5% in 1986 and increased to 1.9% in 1990, 2.0% in 1994, 5.1% in 1999 and 8.9% in 2004.

In these reports snus use was not associated with smoking initiation, as the prevalence of smoking among former snus users was low in all survey years (3-4%). The evidence showed that among adult men in northern Sweden the dominant transition is from smoking to snus, not vice versa.

In 2003, Gilljam and Galanti reported the results of a telephone survey of current and former smokers in Sweden (28). They reported that using snus increased the probability that male smokers would be smoke-free by 50% (OR 1.54, 95% CI = 1.3-2.5).

In 2003 Foulds et al. reviewed the evidence relating to the effects of snus use on smoking and concluded, “Snus availability in Sweden appears to have contributed to the unusually low rates of smoking among Swedish men by helping them transfer to a notably less harmful form of nicotine dependence.” (29) The investigators noted that “in Sweden we have a concrete example in which availability of a less harmful tobacco product has probably worked to produce a net improvement in health in that country”.

In 2005 Furberg et al examined tobacco use data from the Swedish Twin Registry, finding that regular snus use was associated with smoking cessation, not initiation, among almost 15,000 male participants (30). Both regular and occasional snus use were protective against having ever smoked.

In 2006 Ramström and Foulds examined data from a 2001-02 nationally representative Swedish social survey (31). They found that snus use among men was significantly protective against smoking initiation (OR = 0.3, CI 0.2-0.4). They also found that snus was the most commonly used cessation aid among men (used by 24% of men on their most recent quit attempt). Men who used snus as a quit-smoking aid were more likely to quit successfully than those using nicotine gum (OR=2.2, CI=1.3-3.7) or the patch (OR=4.2, CI=2.1-8.6), which was also true for women.

2. Smokeless tobacco Use Has Had a Profound Effect on Smoking-Related Deaths in Sweden

Over the past 50 years Swedish men have had the lowest rates of smoking-related cancers of the lung, larynx, mouth and bladder in Europe (32), and the lowest percentage of male deaths related to smoking of all developed countries (33,34).

In 2004 Rodu and Cole documented that if men in the (15-country) European Union had the smoking prevalence of Sweden, almost 200,000 deaths attributable to smoking would be avoided each year (35). In contrast, women in Sweden smoke at rates much more

similar to women in other European countries, and this is reflected in similar rates of smoking-related illnesses. They found that only 1,100 deaths would be avoided in the EU at Swedish women's smoking rates.

In 2009 Rodu and Cole contrasted Swedish lung cancer mortality rates and smoking-related deaths with those in 24 other European Union countries (36). They concluded that snus use has had a profound effect on smoking prevalence and smoking-associated deaths among Swedish men for the past 50 years. In 2002, 274,000 smoking-attributable deaths would have been avoided in the European Union if men in all countries had the smoking rate of Swedish men.

V. Smokeless Tobacco Use is Not a Gateway to Smoking

A. Evidence from Sweden

In Sweden, a country with a very high prevalence of ST use (in the form of moist snuff called snus), there is no evidence that ST is a gateway to smoking, especially among youth. A 2003 policy statement published in *Tobacco Control*, coauthored by Clive Bates, former director of Action on Smoking and Health (U.K.) and five other eminent tobacco research and policy experts, dismissed the notion that ST use led to smoking in Sweden: "To the extent there is a 'gateway' it appears not to lead to smoking, but away from it and is an important reason why Sweden has the lowest rates of tobacco related disease in Europe" (37). Foulds et al. reached a similar conclusion: "This review suggests…that in Sweden snus has served as a pathway from smoking, rather than a gateway to smoking among Swedish men" (29).

A 2005 study by Rodu et al. examined tobacco use among 15- to 16-year old schoolchildren in Sweden over a 15-year period, from 1989 to 2003 (38). The investigators found that the prevalence of regular snus use among Swedish boys increased from about 10% to 13% from 1989 to 2003, but the prevalence of regular smoking was very low and declined, from about 10% to under 4%. The prevalence of smoking among girls was about double that of boys over the entire period (snus use among girls was very low). The authors concluded that snus use did not appear to be a gateway to smoking among Swedish boys but instead was associated with low smoking prevalence.

Other recent studies based in Sweden have come to similar conclusions. In 2005 Furberg et al. investigated whether snus use was associated with smoking initiation or smoking cessation using data from the population-based Swedish Twin Registry. They concluded that snus use was "inversely associated with initiation." (30)

In 2006 Ramström and Foulds examined data on tobacco use from a national Swedish survey. They found that "Use of snus in Sweden is associated with a reduced risk of becoming a daily smoker…" (31) In 2008, the European Commission's Scientific Committee on Emerging and Newly Identified Health Risks concluded that "The

Swedish data…do not support the hypothesis that…snus is a gateway to future smoking." (13)

Evidence from the U.S.

Opponents of tobacco harm reduction in the U.S. believe that it will lead to increased teenage ST use, which will function as a "gateway" to smoking (39). It has been observed that teenagers who use ST are more likely than non-users to subsequently smoke (40,41,42,43,44). But a close examination of the evidence suggests only that ST use is one of several behaviors associated with smoking, not that it leads to smoking.

In the U.S., concomitant use of cigarettes is common among ST users (45). However, investigators have not found credible evidence that ST use is a gateway to smoking among American youth. In 2003 Kozlowski et al. analyzed data from the 1987 NHIS survey and concluded that there was little evidence that ST use was a gateway to smoking, because the majority of ST users had never smoked or had smoked cigarettes prior to using ST (46).

The belief that ST is a gateway to smoking is based mainly on two longitudinal studies comparing subsequent smoking among adolescent ST users and non-users (44,47). The first study, which used the 1989 Teenage Attitudes and Practices Survey (TAPS) and its 1993 follow-up, found that young males who used ST were significantly more likely to have become smokers at follow-up than non-users of tobacco (OR = 3.5, CI = 1.8 – 6.5) (44). However, a subsequent analysis revealed that the earlier study did not take into account well-known psychosocial predictors of smoking initiation that were in the TAPS, including experimenting with smoking, below average school performance, household member smoking, depressive symptoms, fighting and motorcycle riding (48). Inclusion of these variables into a multivariate model reduced the odds ratio of smoking among regular ST users to 1.7, which was not statistically significant. The investigators concluded that the earlier "analysis should not be used as reliable evidence that smokeless tobacco may be a starter product for cigarettes."

The second study found that 7th and 9th grade students who had used ST (in the past 30 days) were more likely than nonusers to be smoking two years later (OR = 2.6, 95% CI = 1.5 – 4.5), after controlling for smoking by family and friends, low grades, alcohol use and deviant behavior (47). However, Timberlake et al. (49) have observed that regression analysis may not adequately control for imbalances in covariate distributions between ST users and nonusers. They analyzed data from the National Longitudinal Study of Adolescent Health after propensity score matching and found that adolescent ST use was not associated with an increased risk of smoking in later adolescence or young adulthood (49).

In 2005 O'Connor et al. examined data from the 2000 National Household Survey on Drug Abuse to determine if ST use caused smoking. They described the impact of ST use on subsequent cigarette smoking initiation as "minimal at best," and they concluded

that the association of ST use and smoking seen in other reports "is likely a manifestation of dual experimentation rather than a causal relationship." (50)

Claims of a gateway effect persist, even with lack of credible evidence, prompting O'Connor et al. to note in 2005, "Continued evasion of the [harm reduction] issue based on claims that ST can cause smoking seems, to us, to be an unethical violation of the human right to honest, health-relevant information". (50)

VI. The Growing Consensus Among Tobacco Research and Policy Experts and Organizations that Tobacco Harm Reduction Is a Viable Public Health Strategy

Over the past few years studies of tobacco harm reduction have been conducted by tobacco research and policy experts, government agencies and health organizations throughout the world, resulting in a growing consensus that this is a viable public health strategy for inveterate smokers.

In 2005, the Royal Australasian College of Physicians and the Royal Australian and New Zealand College of Psychiatrists issued a report on tobacco policy that concluded: "Harm reduction means doing all of the following things, preferably together, to obtain maximum effect: [1] Reaffirming the health benefit of smoking cessation and offering support to quit; [2] Regulating smoking tobacco products to minimise their toxicity; [3] Providing less dangerous (that is, non-cigarette forms) of nicotine (usually [nicotine replacement therapy] or **oral tobacco**); [4] Regulation for fire safer manufactured cigarettes to reduce fire injuries and fatalities. [5] Partial combined approaches." (emphasis added) (51)

In 2006, the American Council on Science and Health became the first health-oriented organization in the U.S. to endorse tobacco harm reduction. A comprehensive review of the subject by Rodu and Godshall (52) served as the basis of the official ACSH position, which concluded: "The American Council on Science and Health believes that strong support of tobacco harm reduction is fully consistent with its mission to promote sound science in regulation and in public policy, and to assist consumers in distinguishing real health threats from spurious health claims. As this report documents, there is a strong scientific and medical foundation for tobacco harm reduction, which shows great potential as a public health strategy to help millions of smokers." (53)

In 2007 the Royal College of Physicians issued a landmark report on tobacco harm reduction (12). Its findings were unequivocal: "Compiled by leading experts in the field, this report makes the case for harm reduction strategies to protect smokers. It demonstrates that smokers smoke predominantly for nicotine, that nicotine itself is not especially hazardous, and that if nicotine could be provided in a form that is acceptable and effective as a cigarette substitute, millions of lives could be saved." "Harm reduction is a fundamental component of many aspects of medicine and indeed everyday life, yet for some reason effective harm reduction principles have not been applied to tobacco smoking. This report makes the case for radical reform to the way that nicotine products

are regulated and used in society. The ideas presented are controversial, and challenge many current and entrenched views in medicine and public health. The principles behind them have the potential to save millions of lives. They deserve consideration."

In 2007 and 2008, tobacco harm reduction was endorsed in manuscripts published in the world's most prestigious medical journals.

The Lancet, one of the world's most prestigious medical journals, has published two major articles endorsing the strategy. In 2007, Foulds and Kozlowski provided a global perspective: "Around a billion people are addicted to nicotine in deadly cigarettes and many have no immediate plans to quit. Young people will also continue to try dangerous and addictive products. We believe it is preferable that, if people become addicted to cigarettes or decide to try tobacco, they can use a product that is markedly less harmful than cigarettes. In Sweden, primary use of [smokeless tobacco] is associated with reduced risk of cigarette smoking in adulthood. The Lancet papers published today, when added to mounting epidemiological evidence, indicate that we should not delay in allowing [smokeless tobacco] to compete with cigarettes for market share, and we should be prepared to accurately inform smokers about the relative risks of cigarettes, [smokeless tobacco], and approved smoking-cessation medications. In light of all the available evidence, the banning or exaggerated opposition to [smokeless tobacco] in cigarette-rife environments is not sound public-health policy." (54)

In a 2008 Lancet article, Britton and Edwards lamented the lack of progress against smoking and urged governments to incorporate tobacco harm reduction into tobacco regulatory frameworks: "In the 50 years since the health risks of smoking first became widely recognized, the political and public health responses to smoking at national and international levels have been grossly inadequate."
"A logical harm reduction approach for the millions of smokers who are unlikely to achieve complete abstinence…is to promote the substitution of tobacco smoking with an alternative, less hazardous means of obtaining nicotine."
"We believe that the absence of effective harm reduction strategies for smokers is perverse, unjust, and acts against the rights and best interests of smokers and the public health."
"The regulatory framework should therefore apply the levers of affordability, promotion, and availability in direct inverse relation to the hazard of the product, thus creating the most favourable market environment for the least hazardous products while also strongly discouraging use of smoked tobacco." (55)

Sweanor et al. assessed the global public health implications in a 2007 article in the International Journal of Drug Policy: "The relative safety of smokeless tobacco and other smokefree systems for delivering nicotine demolishes the claim that abstinence-only approaches to tobacco are rational public health campaigns." "Applying harm reduction principles to public health policies on tobacco/nicotine is more than simply a rational and humane policy. It is more than a pragmatic response to a market that is, anyway, already in the process of undergoing significant changes. It has the potential to lead to one of the

greatest public health breakthroughs in human history by fundamentally changing the forecast of a billion cigarette-caused deaths this century." (56)

It is ironic that vocal and enthusiastic calls to implement tobacco harm reduction have come from tobacco experts in New Zealand and Australia, where ST is effectively banned. Writing in the New Zealand Medical Journal in 2007, Laugesen urged government action: "Added to the mountain of evidence against cigarettes, sufficient evidence now exists for [the New Zealand] government to use [smokeless tobacco] to create safer tobacco choices for smokers, end cigarette sales altogether, and thus end the cigarette smoking deaths epidemic – in which 200,000 New Zealanders have died so far." (57)

Australian researchers Coral Gartner and Wayne Hall made an interesting comparison between ST use and alcohol consumption in a 2007 Public Library of Science Medicine article: "On current evidence the health risks of [smokeless tobacco] are comparable to those of regular alcohol use rather than cigarette smoking…"If the goal of tobacco control is to reduce tobacco-related disease, rather than tobacco use per se, then the promotion of [smokeless tobacco] use by inveterate smokers is a promising public health policy." (58)

In 2008 Gartner and Hall also criticized the provision of misinformation by public health authorities in the U.S. and Australia in the Medical Journal of Australia: "Public health authorities in Australia and the United States have also claimed that SLT products: 'are just as bad for your health as cigarettes.' The epidemiological evidence shows that this is untrue. Dissemination by governments of misinformation on the relative harms of [smokeless tobacco] creates scepticism and mistrust of public health messages. It is paternalistic to misinform smokers about the risks of smokeless tobacco products for fear of increasing population nicotine use. We think it is also unethical to deny smokers access to a product that may reduce their health risk while cigarettes are readily available and very few quit attempts succeed." (59)

In 2008 the American Association of Public Health Physicians became the first medical organization in the U.S. to formally adopt a policy of "…encouraging and enabling smokers to reduce their risk of tobacco-related illness and death by switching to less hazardous smokeless tobacco products." (4) The Association concluded that implementation of tobacco harm reduction in the U.S. would have enormous public health impact: "Addition of a harm reduction component… could yield a 50% to 80% reduction in tobacco-related illness and death over the first ten years, and a likely reduction of up to 90% within 20 years."

References

1. Nelson N. Epidemiology in a nutshell. BenchMarks Volume 2, July 2002. U.S. National Institutes of Health, National Cancer Institute. Available at: http://www.cancer.gov/newscenter/benchmarks-vol2-issue7/page2

2. Centers for Disease Control and Prevention. Smoking and Tobacco Use: Basic Information. Available at: http://www.cdc.gov/tobacco/basic_information/index.htm

3. Centers for Disease Control and Prevention. Smoking-attributable mortality, morbidity, and economic costs (SAMMEC). Available at: https://apps.nccd.cdc.gov/sammec/login.asp

4. Nitzkin JL, Rodu B. The case for harm reduction for control of tobacco-related illness and death. Resolution and White Paper, American Association of Public Health Physicians. Adopted October 26, 2008. Available at: http://www.aaphp.org/special/joelstobac/20081026HarmReductionResolutionAsPassedl.pdf

5. Centers for Disease Control and Prevention. Smoking and Tobacco Use: Smokeless Tobacco. Available at: http://www.cdc.gov/tobacco/data_statistics/fact_sheets/smokeless/smokeless_facts/index.htm

6. Lee PN, Hamling JS. Systematic review of the relation between smokeless tobacco and cancer in Europe and North America. BMC Medicine 7: 36, 2009.

7. Rodu B, Cole P. Smokeless tobacco use and cancer of the upper respiratory tract. Oral Surgery 93: 511-515, 2002.

8. Lee PN. Circulatory disease and smokeless tobacco in Western populations: a review of the evidence. International Journal of Epidemiology 36: 789-804, 2007.

9. Boffetta P, Straif K. Use of smokeless tobacco and risk of myocardial infarction and stroke: systematic review with meta-analysis. BMJ, Aug 18;339:b3060. doi: 10.1136/bmj.b3060, 2009.

10. Hergens M, Alfredsson L, Bolinder G, Lambe M, Pershagen G, Ye W, 2007. Long-term use of Swedish moist snuff and the risk of myocardial infarction amongst men. Journal of Internal Medicine 262: 351-359, 2007.

11. Henley SJ, Thun MJ, Connell C, Calle EE. Two large prospective studies of mortality among men who use snuff or chewing tobacco (United States). Cancer Causes and Control 16:347-358, 2005.

12. Royal College of Physicians, 2007. Harm reduction in nicotine addiction: helping people who can't quit. A report by the Tobacco Advisory Group of the Royal College of Physicians. London, United Kingdom. Available at: http://www.rcplondon.ac.uk/pubs/brochure.aspx?e=234

13. Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR). Health Effects of Smokeless Tobacco Products. Health & Consumer Protection, Directorate-General, European Commission, 6 February 2008. Available at: http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_013.pdf

14. Rodu B. An alternative approach to smoking control. American Journal of the Medical Sciences 308: 32-34, 1994.

15. Rodu B, Cole P. Tobacco-related mortality. Nature 370: 184, 1994.

16. Rodu B, Cole P. The rewards of smoking cessation. Epidemiology 7: 111-112, 1995.

17. Royal College of Physicians of London, 2002. Protecting Smokers, Saving Lives: The case for a Tobacco and Nicotine Authority, London. Available at: http://www.rcplondon.ac.uk/pubs/books/protsmokers/index.asp

18. Levy DT, Mumford EA, Cummings KM, Gilpin EA, Giovino G, Hyland A, Sweanor D, Warner KE. The relative risks of a low-nitrosamine smokeless tobacco product compared with smoking cigarettes: estimates of a panel of experts. Cancer Epidemiology Biomarkers and Prevention 13: 2035-2042, 2004.

19. Phillips CV, Rabiu D, Rodu B, 2006. Calculating the comparative mortality risk from smokeless tobacco versus smoking. Congress of Epidemiology, June 23, 2006.

20. Rodu B., Phillips C.V. Switching to smokeless tobacco as a smoking cessation method: evidence from the 2000 National Health Interview Survey. Harm Reduction Journal 5: 18, 2008 (Open Access, available at http://www.harmreductionjournal.com/content/pdf/1477-7517-5-18.pdf

21. Tilashalski K, Rodu B, Cole P. A pilot study of smokeless tobacco in smoking cessation. American Journal of Medicine 104: 456-458, 1998.

22. Tilashalski K, Rodu B, Cole P. Seven year follow-up of smoking cessation with smokeless tobacco. Journal of Pscyhoactive Drugs 37: 105-108, 2005.

23. Fagerström K. The nicotine market: an attempt to estimate the nicotine intake from various sources and the total nicotine consumption in some countries. Nicotine & Tobacco Research 7: 343-350, 2005.

24. Nordgren P, Ramström L. Moist snuff in Sweden: tradition and evolution. British Journal of Addiction 85: 1107-1112, 1990.

25. Rodu, B, Stegmayr, B, Nasic, S, Asplund, K. Impact of smokeless tobacco use on smoking in northern Sweden. Journal of Internal Medicine 252: 398-404, 2002.

26. Rodu, B, Stegmayr, B, Nasic, S, Cole, P, and Asplund, K. Evolving patterns of tobacco use in northern Sweden. Journal of Internal Medicine 253: 660-665, 2003.

27. Stegmayr B, Eliasson M, Rodu B. The decline of smoking in northern Sweden. Scandinavian Journal of Public Health 33: 321-324, 2005.

28. Gilljam H, Galanti MR. Role of snus (oral moist snuff) in smoking cessation and smoking reduction in Sweden. Addiction 98: 1183-1189, 2003.

29. Foulds J, Ramström L, Burke M, Fagerström K. Effect of smokeless tobacco (snus) on smoking and public health in Sweden. Tobacco Control 12: 349-359, 2003.

30. Furberg H, Bulik CM, Lerman C, Lichtenstein P, Pedersen NL, Sullivan PF. Is Swedish snus associated with smoking initiation or smoking cessation? Tobacco Control 14: 422-424, 2005.

31. Ramström L, Foulds J. Role of snus in initiation and cessation of tobacco smoking in Sweden. Tobacco Control 15: 210-214, 2006.

32. LaVecchia C, Lucchini F, Negri E, Boyle P, Maisoneuve P, Levi F, 1992. Trends of cancer mortality in Europe, 1955-1989: II and IV. European Journal of Cancer 28, 514-599; 28A, 1210-1281.

33. Peto R, Lopez AD, Boreham J, Thun M, Heath C Jr., 1992. Mortality from tobacco in developed countries: indirect estimation from national vital statistics. Lancet 339, 1268-1278.

34. Peto R, Lopez AD, Boreham J, Thun M, 2006. Mortality from Smoking in Developed Countries 1950-2000, (2nd edition, revised June 2006). CTSU, Oxford University 2006, available at www.ctsu.ox.ac.uk/~tobacco/ .

35. Rodu B, Cole P. The burden of mortality from smoking: comparing Sweden with other countries in the European Union. European Journal of Epidemiology 19: 129-131, 2004.

36. Rodu B, Cole P. Lung cancer mortality: comparing Sweden with other countries in the European Union. Scandinavian Journal of Public Health 37: 481-486, 2009.

37. Bates C, Fagerstrom K, Jarvis MJ, Kunze M, McNeill A, Ramström L. European Union policy on smokeless tobacco: a statement in favour of evidence based regulation for public health. Tobacco Control 12: 360-367, 2003.

38. Rodu B, Nasic S, Cole P. Tobacco use among Swedish schoolchildren. Tobacco Control 14: 405-408, 2005.

39. Tomar SL, Fox BJ, Severson HH. Is smokeless tobacco use an appropriate public health strategy for reducing societal harm from cigarette smoking? International Journal of Environmental Research and Public Health 6: 10-24, 2009.

40. Ary DV, Lichtenstein E, Severson HH. Smokeless tobacco use among male adolescents: patterns, correlates predictors and the use of other drugs. Preventive Medicine 16: 385-401, 1987.

41. Ary DV. Use of smokeless tobacco among male adolescents: concurrent and prospective relationships. National Cancer Institute Monograph 8: 49-55, 1989.

42. Dent CW, Sussman S, Johnson CA, Hansen WB, Flay BR. Adolescent smokeless tobacco incidence: relationship with other drugs and psychosocial variables. Preventive Medicine 16: 422-431, 1987.

43. Glover ED, Laflin M, Edwards SW. Age of initiation and switching patterns between smokeless tobacco and cigarettes among college students in the United States. American Journal of Public Health 79: 207-208, 1989.

44. Tomar SL. Is use of smokeless tobacco a risk factor for cigarette smoking? The U.S. experience. Nicotine & Tobacco Research 5: 561-569, 2003.

45. Wetter DW, McClure JB, de Moor C, Cofta-Gunn L, Cummings S, Cinciripini PM, Gritz ER. Concomitant use of cigarettes and smokeless tobacco: prevalence, correlates, and predictors of tobacco cessation. Preventive Medicine 34: 638-648, 2002.

46. Kozlowski LT, O'Connor, Edwards BQ, Flaherty BP. Most smokeless tobacco use is not a causal gateway to cigarettes: using order of product use to evaluate causation in a national U.S. sample. Addiction 98: 1077-1085, 2003.

47. Severson, H.H., Forrester, K.K., & Biglan, A. Use of smokeless tobacco is a risk factor for cigarette smoking. Nicotine & Tobacco Research 9: 1331-1337, 2007.

48. O'Connor RJ, Flaherty BP, Edwards BQ, Kozlowski LT. Regular smokeless tobacco use is not a reliable predictor of smoking onset when psychosocial predictors are included in the model. Nicotine & Tobacco Research 5: 535-543, 2003.

49. Timberlake, D.S., Huh, J., & Lakon, C.M. Use of propensity score matching in evaluating smokeless tobacco as a gateway to smoking. Nicotine & Tobacco Research 11: 455-462, 2009.

50. O'Connor RJ, Kozlowski LT, Flaherty BP, Edwards BQ. Most smokeless tobacco use does not cause cigarette smoking: results from the 2000 National Household Survey on Drug Abuse. Addictive Behaviors 30: 325-336, 2005.

54. The Royal Australasian College of Physicians and the Royal Australian and New Zealand College of Psychiatrists. Tobacco Policy: Using evidence for better outcomes. Sydney: RACP and RANZCP, 2005.

52. Rodu B, Godshall WT, 2006. Tobacco harm reduction: an alternative cessation strategy for inveterate smokers. Harm Reduction Journal 3:37. Open access, available at: http://www.harmreductionjournal.com/content/3/1/37 (Accessed May 5, 2008)

53. Meister MA. Helping smokers quit: a role for smokeless tobacco? October 10, 2006. Available at: http://www.acsh.org/publications/pubid.1403/pub_detail.asp

54. Foulds J, Kozlowski L. Snus [smokeless tobacco] – what should the public-health response be? Lancet 369: 1976-1978, 2007.

55. Britton J, Edwards R. Tobacco smoking, harm reduction, and nicotine product regulation. Lancet 371: 441-445, 2008.

56. Sweanor D, Alcabes P, Drucker E. Tobacco harm reduction: how rational public policy could transform a pandemic. International Journal of Drug Policy 18: 70-74, 2007.

57. Laugesen M. Snuffing out cigarette sales and the smoking deaths epidemic. New Zealand Medical Journal 120: 120(1256):U2587, 2007.

58. Gartner CE, Hall WD. Should the health community promote smokeless tobacco (snus) as a harm reduction measure? Smokers who switch to snus reduce their health risks. PLoS Medicine 4(7): e185. doi:10.1371/journal.pmed.0040185.

59. Gartner CE, Hall WD. Should Australia lift the ban on low nitrosamine smokeless tobacco products? Medical Journal of Australia 188: 44-46, 2008.

Table 1. Annual Smoking-Attributable Deaths in the United States Among 45 Million Smokers

Cancer		**158,529**
Site (RR)		
Oral-pharynx (5-11)	4,868	
Pancreas (2.3)	6,509	
Lung (13-23)	123,836	
Other	23,316	
Cardiovascular Diseases		**137,979**
Respiratory Disorders		**101,454**
All Deaths Among Smokers		**397,962**
Second-hand Smoke		**38,000**
Lung cancer	3,000	
Cardiovascular	35,000	
All		**435,962**

Source: Nitzkin JL, Rodu B. The case for harm reduction for control of tobacco-related illness and death. Resolution and White Paper, American Association of Public Health Physicians. Adopted October 26, 2008. Available at: http://www.aaphp.org/special/joelstobac/20081026HarmReductionResolutionAsPassedl.pdf (4).

Table 2. Summary Relative Risks (95% CI) for Smokeless Tobacco Use and Cancer of the Oral Cavity and Pharynx

Description (number of studies)	
All Studies (41)	1.79 (1.36 – 2.36)
Adjusted for smoking (19)	1.36 (1.04 – 1.77)
Adjusted for smoking and alcohol (10)	1.07 (0.84 – 1.37)
All Studies published since 1990 (18)	1.28 (0.94 – 1.76)
Adjusted for smoking (14)	1.00 (0.83 – 1.20)
Adjusted for smoking and alcohol (10)	1.07 (0.84 – 1.37)

Source: Lee PN, Hamling JS. Systematic review of the relation between smokeless tobacco and cancer in Europe and North America. BMC Medicine 7: 36, 2009. (6)

Table 3. Smoking-Adjusted Summary Relative Risks (95% CI) for Smokeless Tobacco Use and Other Cancers

Site (No. Studies)	RR (95% CI)
Esophagus (7)	1.1 (0.95 – 1.4)
Stomach (8)	1.0 (0.9 – 1.2)
Pancreas (7)	1.1 (0.7 – 1.6)
Any Digestive (5)	0.9 (0.6 – 1.3)
Larynx (2)	1.3 (0.6 – 3.0)
Lung (6)	1.0 (0.7 – 1.4)
Prostate (4)	1.3 (1.1 – 1.6)
Bladder (10)	1.0 (0.7 – 1.3)
Kidney (5)	1.1 (0.7 – 1.7)
Lymphoma (3)	1.4 (0.6 – 2.9)
All Cancer (7)	1.0 (0.8 – 1.2)

Source: Lee PN, Hamling JS. Systematic review of the relation between smokeless tobacco and cancer in Europe and North America. BMC Medicine 7: 36, 2009. (6)

Table 4. Annual Deaths Attributable to Tobacco Use in the United States, 45 Million Smokers or ST Users

Smokers			ST Users	
Cancer		**158,529**		**2,668**
Site (RR)			Site (RR)	
Oral-pharynx (5-11)	4,868		Oral-pharynx (2)	665[+]
Pancreas (2.3)	6,509		Pancreas (1.4)	2,003[+]
Lung (13-23)	123,836		Lung	0
Other	23,316		Other	0
Cardiovascular Diseases		**137,979**		**0**
Respiratory Disorders		**101,454**		**0**
All Deaths Among Users		**397,962**		**2,668**
Second-hand Smoke		**38,000**		**0**
Lung cancer	3,000			
Cardiovascular	35,000			
All		**435,962**		**2,668**

Source: Nitzkin JL, Rodu B. The case for harm reduction for control of tobacco-related illness and death. Resolution and White Paper, American Association of Public Health Physicians. Adopted October 26, 2008. Available at: http://www.aaphp.org/special/joelstobac/20081026HarmReductionResolutionAsPassedl.pdf (4)

Chapter 12

Public comment regarding tobacco harm reduction to the U.S. Food & Drug Administration from TobaccoHarmReduction.org

Carl V. Phillips, Paul L. Bergen, Karyn K. Heavner & Catherine M. Nissen

Editors' note: Anticipating that others would provide the full lesson on the science of THR, and thus seeing little reason to write a new version of the various summaries that we and others have written (if they genuinely want to learn, they will find them), and not wanting to comment on legalistic issues, we chose to narrowly focus our comment on political and institutional points. We realize, of course, that we were unlikely to change any disinclination to engage with the tobacco industry. And obviously warning an institution that it is likely to be captured by extremists (and arguably already has been), or warning someone about specific predictions of hubris risks, are inherently doomed to have no effect. It is difficult to assess one's own work from any distance, but looking back at this we suspect that a more cynical editor might suggest that these authors were intentionally making observations that did little other than offer the possibility to someday say "we told you so." Of course, most everyone submitting comments surely realized that those on the receiving end think they already know what is best and will likely ignore the content except where it serves to rationalize their existing views, and thus ours would not be the only comment written just to get a point on the record for future use of one sort or another.

CVP is an independent researcher and consultant, and directs the TobaccoHarmReduction.org research group that produced this book; cvphilo@gmail.com. PLB is a researcher and director of communications for the TobaccoHarmReduction.org research group; pbergen1@gmail.com. KKH is an epidemiologist specializing in studies of behavioral risk factors including harm reduction, with particular expertise in complex data analysis and misclassification of behavior measures. CMN is a researcher on tobacco harm reduction at Carl V. Phillips's research institute.

We are writing to urge the FDA, as part of its new authority over tobacco products, to actively support tobacco harm reduction (THR), rather than interfering with or ignoring it. Because the scientific facts about THR are well-known and likely to appear in other comments, we will simply summarize them and move on to less obvious points. More details and links to summary documents can be found at our website, TobaccoHarmReduction.org.

- There are nicotine products that are proven to be about 99% lower risk than smoking (Western smokeless tobacco of either the American or Swedish style) and others that are strongly believed to be roughly as low risk though there is no direct evidence of the exact magnitude of the risks (pharmaceutical nicotine, a.k.a. NRT; electronic cigarettes).

- Smokers who switch to these products, even if they continue to use them for the rest of their lives, get health benefits that are barely different from quitting nicotine entirely.

Most smokers do not know that switching to smokeless tobacco or other low-risk products is such a good option. There is an active campaign to tell smokers that the only options are to quit or die, which keeps many from switching. This persists despite the fact that switching to a low-risk product and using it for a lifetime is, on average, lower risk than continuing to smoke for just a few more months (see: Phillips CV, Harm Reduction Journal, 2009, for the calculations that produce that estimate).

With that background, we would like to focus on three observations that are not so well known:

1. It seems extremely likely that fifty years from now, unless an even better substitute drug is invented, a substantial portion of the world's population (perhaps as much as one-third of those who can afford it) will use nicotine in low risk forms. There will still be some smokers, but far fewer than there are today. What is not yet predictable is how long smoking will remain the dominant form of nicotine use in particular societies, a question that hinges substantially on public policy decisions.

2. The FDA is very skilled in many areas of science, but should avoid exceeding its core skills, mission, and mandate to engage in social engineering. The political actors who dominate quasi-scientific discourse around tobacco will try to steer the FDA's tobacco policy toward actively pushing the moralistic social engineering goal of eliminating all self-administration of nicotine, regardless of health or welfare concerns.

3. Companies that make nicotine products, including many of the major tobacco companies, will be the biggest engines of innovations in reducing the health effects of smoking if they are pushed toward and allowed to go in that direction.

Regarding point 1., nicotine is so vilified that many people do not even pause to think about its benefits. This is quite strange given that such a large portion of the population chooses to use it despite the costs and is quick to espouse its virtues. Nevertheless, the benefits are great and range from medication for clinical-level psychiatric disorders, self-treatment for subclinical or undiagnosed (including depression, schizophrenia, post-traumatic stress, attention deficit), and a mild drug to promote pleasure, relaxation, focus, productivity, and alertness. While the FDA does not officially recognize these benefits, any honest scientist or casual observer of the human condition cannot help but recognize them. Moreover, nicotine is quite simple to produce and acquire. Thus, we can confidently predict that many people throughout the world will choose to use nicotine indefinitely.

What happens in the near term in the United States, however, is not so predictable. If the government policy discourages THR, by interfering with the introduction of low-risk products or by communicating to the public that all nicotine products are similarly unhealthy, smoking prevalence might continue to slowly creep down. But there is reason to expect that nothing other than a heavily-enforced prohibition would cause the last 10-15% of the population to give up the benefits they get from nicotine. The only proven method of reducing smoking prevalence much below what it now is in the U.S. is substitution of a low risk alternative. If such substitution is discouraged in the U.S., THR will likely not catch on until it is well-established elsewhere in the world, resulting in tens of thousands of needless deaths every year.

Inaccurate scientific claims about the risks from smokeless tobacco and other low-risk products can discourage switching. So do literally true but obviously misleading claims like the warning that smokeless tobacco "is not a safe alternative to smoking", which most people read as "equally unhealthy". This message tells nicotine users that they might as well smoke rather than using low-risk alternatives. On the other hand, if the FDA gives consumers honest information about comparative risks, or even just allows manufacturers to freely provide such accurate information, widespread switching – which is roughly as good as abstinence from the perspective of life-threatening disease and much better for many people in terms of psychological conditions and general welfare – is likely to begin almost immediately.

This leads in to point 2. The steps necessary to promote THR and thus dramatically reduce the health burden from nicotine use (i.e., from smoking) are simply to provide honest scientific information and let people make an informed autonomous choice. Short of nicotine product prohibition (which is not allowed and would be a law-enforcement nightmare), this scientific honesty would also best fulfill the mission of serving the nation's health and welfare. Health and welfare are not, however, the goals of many of the people who dominate the discourse on tobacco

and nicotine use. The dominant activist faction makes it quite clear that their goal is to eliminate the use of tobacco (and, increasingly, other nicotine products like electronic cigarettes). They are unconcerned with the welfare effects of denying nicotine to those who benefit from it. Indeed, they are even unconcerned with health, making no distinction about whether nicotine is being used in a way that is clearly extremely harmful (smoking) or in ways that present minor risks, comparable to everyday hazards and consumption choices; they generally actively oppose THR.

This extremist faction will inevitably try to enlist or co-opt the FDA into supporting their goals. A key part of supporting that mission is discouraging the long-term use of low-risk nicotine products, even more than discouraging the use of high-risk products, because a consumer who knows he is using a low risk product – and who gets substantial benefit from doing so – is unlikely to be persuaded to quit entirely. His health risks will be minimal and the net welfare effects will be positive, but the extremist activists will consider him to represent a failure rather than a success because he is still choosing to use nicotine. Thus, they will try to steer the FDA into not providing accurate comparative risk information, discouraging the use of low-risk products far more aggressively than their real health risks warrant, and other acts of social engineering (i.e., manipulation of the population to do what they would not otherwise choose to do). Does the FDA really want to join other agencies of the U.S. government in participating in a "war on drugs" with all that implies for the Agency's reputation and public image?

Regarding point 3., once it is recognized that harm reduction and low-risk products should be encouraged, it follows immediately that the innovators and manufacturers of such products are part of the solution. They might, of course, be part of the problem too. The FDA's core missions leave little doubt that while food and drug manufacturers are tremendously beneficial sources of nutrition and treatment, they also need to be pushed in the right direction and forbidden from taking profitable but harmful actions. Thus, the FDA can extrapolate from the regulation of pharmaceutical companies to tobacco companies and other manufacturers of low-risk nicotine products (some of whom are pharmaceutical companies who could be encouraged to market their nicotine products as long-term substitutes rather than marginally useful cessation aids). The situation is quite similar: Those companies are the only source of the good products we should want to encourage the development and marketing of, but like most any organization will also often favor self-interest over social welfare.

Thus, regulation of various kinds of low-risk products is in order, though not regulations that are intended to strangle the companies or discourage innovation or marketing of low-risk products (as the FDA will be encouraged to pursue as noted above). Indeed, regulations that are designed to hurt companies rather than help consumers are very likely to backfire, and would likely encourage companies to retreat to their core business rather than trying to switch their cigarette

customers to their low-risk innovations. Regulatory action that encourages manufacturers to innovate and help consumers switch to low-risk products is perfectly aligned with doing good science and honestly communicating it, as well as standard government policy that tries to penalize and discourage health hazards and negative externalities.

In summary, regulating tobacco calls for recognizing that nicotine is a popular drug that it is a "lifestyle" consumption decision and/or self-treatment for many conditions that are not formally diagnosed, making it different from carefully controlled medical treatments for specific diseases. Demand will likely never be eliminated, and trying to eliminate it will take the FDA far beyond its mission and competencies. Like the products that FDA is experienced at regulating, the market will be dominated by major corporations; this should be recognized and turned into an asset rather than futilely resisted. Because this popular drug is caught up in so much politics, attempts at social engineering often overwhelm the good science. However, good science and honest provision of information will improve people's health efficiently and without causing a net reduction in overall welfare.

Chapter 13

Submission to the UK Department of Health (from British American Tobacco): The role for harm reduction within tobacco control

David O'Reilly

Editors' Note: This submission reflects the strong pro-THR stance that one of the world's leading tobacco companies is taking, and its official communication of this to the government in its home country. The subsequent chapter presents a petition from Altria to the U.S. government.

For reasons that are easy to understand, BAT has made much weaker claims about THR than independent researchers offer, so the case presented here falls close to the border between "weakest legitimate case for THR" and "so conservative that it should be considered misleading". In spite of this and the necessarily limited details of a brief memo, this still may be the most boldly pro-THR public document to be presented as the official position of any large institution, whether corporation, NGO, or government.

A key message from BAT in this document, one that many people might find surprising, is the official concession about the dire harm caused by their main product, cigarettes, and the clear desire and substantial effort to migrate their own customers to something better. Many advocates of THR, some of whom are as fiercely anti-industry as are the anti-tobacco extremists, might find this to be useful information. Moreover, the analysis points out that the common accusations that tobacco companies still misrepresent the science are only true, at least in the case of THR, if interpreted to mean that the companies dramatically understate how strongly the science supports their claims. We hypothesize that were they not under attack by so many anti-THR activists, the many tobacco companies making pro-THR statements – this chapter, the following one from Dillard/Altria, and several other statements that are not represented in this volume – would more completely represent how strongly the science supports their positions. (Specifically, we suspect that this would not require ending the attacks by the leading THR opponents, who surely realize that they are hurting public health and human welfare in pursuit of extremist goals and are unlikely to ever stop; it would merely require that the fellow-travelers, who actually believe they are benefiting public health by opposing THR, to realize that they have been tricked.) We further hypothesize that if the tobacco companies were allowed to communicate accurate information about THR that it would have a huge impact on

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DO is Head of Public Health & Scientific Affairs at British American Tobacco. BAT is the world's second largest tobacco company.

public perceptions and cause major gains in public health, despite the widespread claims that no one would listen to what the companies said.

Since the content of this chapter falls at the conservative end of what might be said in favor of THR, readers should consider this document for its historical value and implicit political analysis, perhaps examining implications of specific claims, but not treat it as a complete scientific reference. [Note that CVP consults for BAT on matters of science related to THR, but had no involvement in this submission and has never been involved in creating policy statements, and thus we analyze this as independent scholars based only on what appears in the text.] For example, there is actually no evidence to support the claim that smokeless tobacco products are definitely more harmful than pharmaceutical nicotine. We might interpret this as representing the political necessity to include every possible message of, "of course, it would be better still if..., but....". It is also frustrating to see the continued acceptance of the claim that snus has been shown to cause a substantial risk for pancreatic cancer, given that those claims from anti-THR activists were debunked as junk science from the time that they were made. (See the Lee & Hamling article in this volume for the most recent of several such debunkings.) Perhaps authors writing for the political arena feel the need to concede some specific disease risk rather than just a nonspecific acknowledgment that the product is not completely safe. If so, we would recommend mentioning the small risks that are caused by nicotine-induced blood pressure increases rather than encouraging the production of anti-THR junk science.

The document also repeats the prediction that, even in the absence of THR, current policies will substantially reduce per capita tobacco consumption. But this prediction, made by those whose jobs are to reduce tobacco consumption, represents both wishful thinking and the classic mistake of confusing policies' stated intentions for actual results; there is no evidence that shows that, in the absence of prohibitions and extremely intense policing (i.e., the most tightly controlled prison-like conditions), it is possible to return a population's nicotine use to below about 20% prevalence. The prediction might or might not turn out to be true in the long run, but considering that the claim is a popular rationalization for opposing THR, conceding the unsubstantiated and seemingly unlikely claim that it will definitely occur in the short run is not without cost.

In fairness, these conservative claims read much like what the leading independent researchers would have written four or five years ago, and we should not expect a large corporation to be at the cutting-edge of a controversial social initiative. It is actually somewhat surprising that a few tobacco companies have gone as far as they have in their support of THR, given that anti-tobacco extremists simply use it as one more excuse to attack them, and that government regulators, almost all of which are captured by the extremists, have actively endeavored to make THR products fail in the marketplace. When these corporations succeed in their THR initiatives (and we predict that some of them will), the extremists may try to claim credit for it (e.g., by claiming that regulation caused the companies to embrace THR, rather than discouraging it); we hope that the historical snapshot provided in this volume, of corporations and pro-THR activists trying to overcome the fierce opposition coming from the faction that controls most of the levers of power, will provide a perspective on such claims.

SUBMISSION TO THE UK DEPARTMENT OF HEALTH: THE ROLE FOR HARM REDUCTION WITHIN TOBACCO CONTROL

1. Introduction and Summary

In September 2008, British American Tobacco responded[1] to the Department of Health's discussion paper "Consultation on the future of tobacco control"[2] (the "Consultation/Discussion document"). Among the points we put forward was a call for a broader approach to harm reduction to be accepted as a pillar of tobacco regulatory policy, alongside prevention and cessation. As the Government prepares to publish its Tobacco Control Strategy, we would again suggest that a broader approach to tobacco harm reduction for adult smokers should form part of that Strategy. We reiterate our readiness to engage in any such approach, both through the contribution we can make to the discussions surrounding appropriate assessment criteria for "modified risk tobacco products" (as defined below) and through our efforts in researching, developing and test marketing consumer acceptable products which pose reduced risks to health compared to conventional cigarettes.

Smoking is a cause of various serious and fatal diseases such as lung cancer, emphysema, chronic bronchitis and heart disease. We strongly believe that smoking should only be for adults who are aware of the risks. The only way to avoid smoking-related risks is not to smoke in the first place, and the best way to reduce the risks is to quit. Public health policies based on discouraging smoking and encouraging quitting have led to significantly lower smoking rates, including in the UK. However, we believe that regulators now face a dilemma. While the proportion of adults who smoke is likely to continue declining, it is likely that millions of adults will continue to consume tobacco products. The World Health Organisation estimates that in the future, even with increasing tobacco control regulation, there will be as many or more smokers globally as there are today, as falling tobacco consumption is offset by a strongly rising world population.[3]

A key question for the Department of Health, as for regulators elsewhere, is whether public health policy with respect to tobacco should continue only to mean the advocacy of abstinence, or whether policy should accommodate the option of modified risk tobacco products for the millions of adults who continue to use tobacco products (the term "modified risk tobacco product" ("MRTP") is defined in the USA Family Smoking Prevention and Tobacco Control Act 2009 as meaning "any tobacco product that is sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products"[4]).

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[1] BRITISH AMERICAN TOBACCO, 2008. *British American Tobacco response to the Department of Health discussion document* [online]. Available from: http://www.bat.com/group/sites/uk__3mnfen.nsf/vwPagesWebLive/DO7J7CSX/$FILE/medMD7J7CUJ.pdf?openelement [Accessed 29 November 2009]

[2] DEPARTMENT OF HEALTH, 2008. *Consultation on the future of tobacco control* [online]. Available from: http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_085651.pdf [Accessed 29 November 2009]

[3] ERIKSEN, M. and MACKAY, J., 2002. *The Tobacco Atlas* [online], p. 90-91. Brighton: Myriad Editions Limited. Available from: http://www.who.int/tobacco/en/atlas38.pdf [Accessed 4 November 2009]

[4] H.R.1256, 2009. *Family Smoking Prevention and Tobacco Control Act* [Online]. Sec 911 (b.1). Modified Risk Tobacco Products, p.37. Available from: http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111_cong_bills&docid=f:h1256enr.txt.pdf [Accessed 29 November 2009]

Some regulators and tobacco control advocates reject the inclusion of MRTPs within a tobacco harm reduction policy framework, [5] suggesting that their availability may discourage smokers from quitting or may lead people to become tobacco consumers who would not otherwise have done so. However, the legitimacy of these concerns is unknown and there is some real-world experience that suggests they may be overstated.
Therefore, we, alongside a proportion of the public health community, believe that regulators could achieve further public health gains through regulatory approaches that include MRTPs. Accordingly, we would like to see tobacco harm reduction included as a pillar of tobacco regulatory policy, with a role for MRTPs alongside prevention and cessation. We believe that tobacco regulation should include provision for appropriate communication to adult tobacco consumers about MRTPs, to allow them to make informed choices.

We set out below the case for considering a broad approach to tobacco harm reduction which recognises that a significant proportion of adults will continue to smoke or to use other tobacco products. We hope that this information will help inform the preparation of the UK Tobacco Control Strategy. We would greatly welcome constructive discussion with the Department of Health on a broad tobacco harm reduction approach, including how suitable regulatory frameworks might be shaped to allow adult tobacco consumers the option to choose MRTP products such as low toxicant snus and for assessing and making available other MRTPs in the future.

2. Tobacco use in the UK

Smoking is in historic long-term decline in the UK. Prevalence has fallen from 30% of all over-16s in 1998 to 21% in 2007[6]; a continuation of a longstanding trend which has seen smoking prevalence fall from 45% in 1978 and even higher figures in the 1950s and 1960s.[7]

As the Consultation/Discussion document states: "To date, tobacco control policy has focused on preventing people from starting to smoke or on reducing smoking rates by promoting quitting through high taxation, media campaigns, advertising bans, smokefree policies and quitting support services. Those policies have had a significant impact in reducing smoking prevalence over the past decade."[8]

But the Consultation/Discussion document went on to observe that securing further significant reductions in smoking prevalence in the UK is likely to pose a challenge: "However, even if those policies continue to have an impact, it has been estimated by the Royal College of

[5] ASH UK, 2008. Submission *from Action on Smoking and Health to Department of Health Consultation on the future of tobacco control* [online], Section 165, p. 30. Available from: http://www.smokefreeaction.org.uk/consultation-response/responses/ASH_DH_Consultation_tobacco_control_final.pdf [Accessed 29 November 2009] / CANCER RESEARCH UK, 2008. *Cancer Research UK response to the Department of Health Consultation on the future of tobacco control* [online], Ref. 71, p. 19. Available from: http://www.smokefreeaction.org.uk/consultation-response/responses/CRUK_TCConsultation_response050908.pdf [Accessed 29 November 2009]
[6] OFFICE FOR NATIONAL STATISTICS. *General Household Survey 2007*, Smoking and drinking among adults, 2007, Table 1.1, p. 17 [online] Available from: http://www.statistics.gov.uk/downloads/theme_compendia/GHS07/GHSSmokingandDrinkingAmongAdults2007.pdf [Accessed 29 November 2009]
[7] UNIVERSITY OF OXFORD, 2000. *Clinical Trial Service Unit & Epidemiological Studies Unit Press Release*, 2 August 2000, Figure 1a, '1950-1998 trends in smoking prevalence at ages 35-59 in the UK men and women' [online] Available from: http://www.ctsu.ox.ac.uk/pressreleases/2000-08-02/uk-lung-cancer-deaths-halved-by-smoking-cessation-us-deaths-are-following-but-worldwide-tobacco-deaths-increase#graphs [Accessed 29 November 2009]
[8] DEPARTMENT OF HEALTH, 2008. *Consultation on the future of tobacco control* [online]. Section 5.1, p. 52. Available from: http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_085651.pdf [Accessed 29 November 2009]

Physicians that it will take at least two decades to halve current smoking prevalence….even on an optimistic scenario there will still be 5 million or more smokers in the UK in 10–12 years' time, most from socially disadvantaged groups."[9]

3. Harm reduction

Harm reduction is a well-established public health concept which seeks pragmatic ways to minimise the health impact of an inherently risky activity or behaviour, without seeking to stop it entirely. An example of harm reduction in action that is familiar to most people is the use of seat belts and airbags in cars.

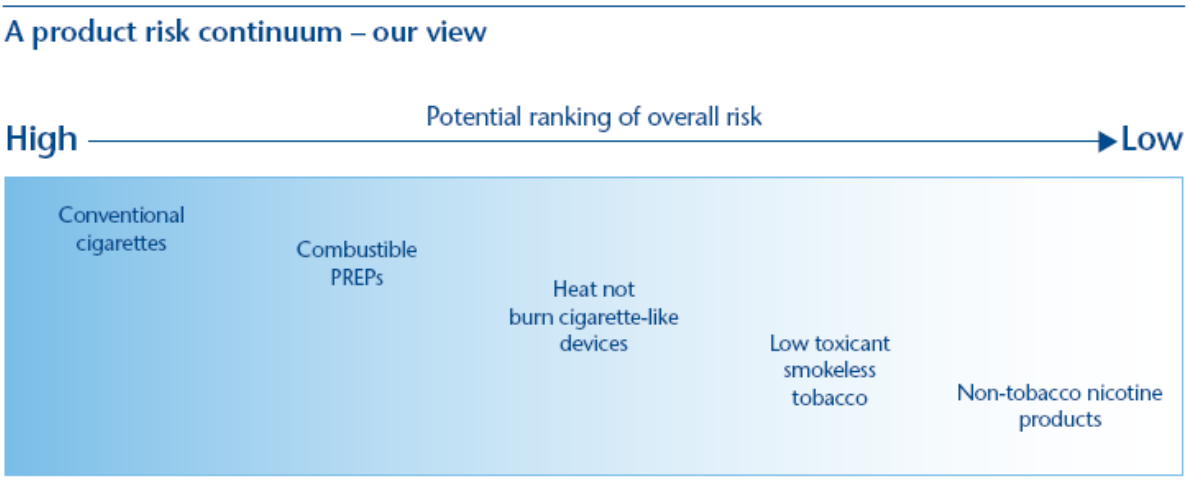
In respect of the term 'tobacco harm reduction,' this does not have a single meaning that is accepted by all. To the majority of public health policy makers, it means urging people not to start using tobacco products or to quit if they do. The US Institute of Medicine (IOM) has defined it as "minimizing harms and decreasing total morbidity and mortality without completely eliminating tobacco and nicotine use."[10] The IOM concept is gaining acceptance among a section of the public health community who believe it to be an important addition to current smoking prevention and cessation efforts.

For public health proponents of a broader approach, tobacco harm reduction means that, in addition to a continued emphasis on prevention and cessation efforts, adult tobacco consumers should have the option of being informed about and being able to choose MRTPs as well as non-tobacco nicotine product options. The smoking "ritual" involves many of the senses. A smoker will often describe pleasure from the feel of a cigarette in the hand, and from the taste, sight and smell of the tobacco smoke. Smokeless tobacco products provide gustatory and olfactory sensations and social ritual qualities that may provide a more acceptable alternative to cigarettes for smokers than would medicinal nicotine products. The Tobacco Advisory Group of the Royal College of Physicians noted, in their 2008 report "Ending tobacco smoking in Britain", that "All smokeless tobacco products are…more hazardous than medicinal nicotine and, in some cases especially so, but all are also substantially less hazardous than smoking" and that "It is possible that some of the associated tobacco characteristics of [smokeless tobacco] products, such as taste and smell, help to make them acceptable to smokers as a substitute for tobacco smoking."[11]

To help explain this approach, and to put our initiatives and what we see as our potential role into context, we have set out our view of a product risk continuum in Figure 1 below:

[9] *Ibid*, Section 5.2, p. 52.
[10] INSTITUTE OF MEDICINE, 2003. *Clearing the Smoke: Assessing the Science Base for Tobacco Harm Reduction* [online], p. 25. Available from: http://www.nap.edu/openbook.php?record_id=10029&page=25 [Accessed 29 November 2009]
[11] TOBACCO ADVISORY GROUP OF THE ROYAL COLLEGE OF PHYSICIANS, 2008. *Ending tobacco smoking in Britain: Radical strategies for prevention and harm reduction in nicotine addiction*. point 7, p. 4. [online] Available at: http://www.rcplondon.ac.uk/Pubs/contents/a7b2d652-288a-4c13-bc7b-25bf06597623.pdf [Accessed 29 November 2009]

Figure 1



Understandably, there is considerable debate about what the public health impact of MRTPs might be and whether they would actually contribute to a reduction in total tobacco-related harm on a population basis. The situation is further complicated by the fact that there is currently no scientifically recognised way of determining whether, for example, one type of cigarette is of potentially lower risk to an individual than another type. The use of conventional cigarette products presents the greatest risks to health while, arguably, non-tobacco nicotine products pose the least risks. Between these two poles there are some other potential MRTP categories, the different products within which might present differing levels of risk.

For some potential MRTP categories, products do not yet exist and for other potential MRTP categories, such as combustible potential reduced-exposure products or "PREPs"[12] (PREP is a predecessor term for MRTP), a scientific framework for the measurement of related potential health risks is still under development, principally by the US Food and Drug Administration (FDA) pursuant to the recently passed USA Family Smoking Prevention and Tobacco Control Act. However, in the low toxicant smokeless tobacco product category, there are products already available and acceptable to adult tobacco consumers in certain countries, such as Swedish-style snus for which there is increasing scientific consensus that its use is substantially less hazardous to health than smoking conventional cigarettes.

The following extract illustrates the arguments advocated by a segment of the public health community in favour of a regulatory approach that would facilitate the development and sale of consumer acceptable MRTPs: "If the goal is reduction of death, injury and disease, product regulation must be narrowly focused on reduction of harm. Regulators should replace the abstinence-only paradigm with a pragmatic science-based public health approach that includes risk reduction strategies for continuing users. With this approach we can achieve a great advance for global health."[13]

[12] The term, "PREP" was introduced by the US Institute of Medicine in its 2003 report "Clearing the Smoke: Assessing the Science Base for Tobacco Harm Reduction", p. 3. Available from: http://www.iom.edu/~/media/Files/Report%20Files/2003/Clearing-the-Smoke-The-Science-Base-for-Tobacco-Harm-Reduction/tobacco8pgfinal2.ashx [Accessed 29 November 2009]

[13] SWEANOR, D. and GRUNBERGER, R.C., 2005. The Basis of a Comprehensive Regulatory Policy for Reduced Harm Tobacco Products. *Journal of Health Care Law & Policy*, 11; 83, p. 92.

4 British American Tobacco's approach to tobacco harm reduction

It is the prerogative of public health authorities to develop and implement public health policy. However, as for all public policy, the policy development process should be evidence-based, grounded in sound science, take due consideration of the wider costs and benefits of all the policy options and include consultation with all interested parties.

Our approach to harm reduction is to pursue the research, development and test marketing of innovative tobacco products that will have consumer acceptability and that will be recognised by scientific and public health communities and regulators as posing reduced risks to health.

4.1 Our research and development activities in relation to combustible MRTPs

British American Tobacco has a scientific research programme, managed by its Group Research and Development Centre in the United Kingdom. In our view, developing a combustible MRTP can be interpreted as involving research to determine which toxicants in smoke are significant for disease and develop tools to measure smokers' exposure to them; develop combustible MRTPs that may substantially reduce exposure to these significant toxicants and, through clinical testing, demonstrate that they do; and, develop a scientific framework to assess whether this reduction in exposure can reasonably be expected to reduce the risk of one or more specific diseases.

There are significant scientific challenges around developing and assessing a combustible MRTP. We are making progress in determining how we might identify the most important smoke toxicants and substantially reduce exposure to these, and we are building our expertise in measuring human exposure to such toxicants. We have also been developing in vitro models of disease and biomarkers of biological effect to be used in the scientific assessment of a candidate combustible MRTP.

We recently submitted a summary[14] of our scientific research programme to the FDA, a copy of which is appended to this document.

4.2 Low toxicant smokeless tobacco products

Within the "product risk continuum – our view" set out earlier in Figure 1, the 'low toxicant smokeless tobacco' product category contains products which provide reduced-risk options with proven consumer acceptability for adult smokers who do not want to quit their existing tobacco use altogether. In particular, using Swedish-style smokeless 'snus' (Swedish for snuff) is acknowledged by several independent health experts to be at least 90 per cent less hazardous than smoking cigarettes.[15]

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[14] BRITISH AMERICAN TOBACCO (INVESTMENTS) LIMITED, 2009. *Docket No. FDA-2009-N-0294. Regulation of Tobacco Products. Request for Comments* [online]. Available from: http://www.bat.com/group/sites/uk__3mnfen.nsf/vwPagesWebLive/DO52AMGZ/$FILE/medMD7WECL5.pdf?openelement [Accessed 29 November 2009]

[15] ROYAL COLLEGE OF PHYSICIANS, 2002. *Protecting smokers, saving lives: the case for a tobacco and nicotine regulatory authority*, Section 3.5, p.5 [online]. Available from: http://www.rcplondon.ac.uk/Pubs/contents/36e53d82-ab68-428c-9d48-817a64b2ab08.pdf [Accessed 29 November 2009]

Swedish-style snus is finely ground, moist tobacco which is not smoked: it comes either loose or in pouches which are placed under the upper lip. Snus releases around the same amount of nicotine as a smoker would get from a cigarette, though just as cigarettes vary in the level of nicotine content contained in the tobacco so do varieties of snus. It is manufactured using a heat treatment process that is similar to pasteurisation. The heat treatment process reduces the formation of chemicals in the tobacco known as tobacco-specific nitrosamines, which are substances that can cause cancer and have historically been found at relatively high levels in other forms of oral tobacco, such as some types of chewing tobacco. In 2004, the Swedish National Food Administration Service reported research showing that nitrosamines in Swedish snus (which were already lower than most other smokeless tobacco products) had fallen by around 85 per cent over 20 years due to advances in tobacco sourcing and production.[16]

Snus has a long history of use in Sweden and amongst Swedish adult males is now more prevalent than cigarette smoking. Smokeless does not mean harmless and the best way to avoid the risks associated with consuming tobacco is not to consume it at all. However, there are indications that the wide availability of snus in Sweden has lessened the impact of smoking on public health. Sweden has the highest consumption of smokeless tobacco per capita in the world. As snus use has increased, cigarette consumption has fallen amongst adult males. More than 25 per cent of men in Sweden use snus regularly, while fewer than 15 per cent smoke cigarettes. Independent studies of snus use in Sweden suggest it leads to no increase in risk for lung cancer and chronic obstructive pulmonary disease, two diseases strongly associated with cigarette smoking. This is not surprising, as consuming snus does not involve inhaling smoke. Long-term studies have shown that Sweden has a lower rate of male lung cancer incidence than any comparable developed nation and that oral cancer rates have decreased.

In 2007, the Tobacco Advisory Group of the Royal College of Physicians came to a number of conclusions in its report on "Harm reduction in nicotine addiction,"[17] including:

- "Smokeless tobacco is not a single product, but rather a summary term for a range of different tobacco products which deliver nicotine without combustion.
- Smokeless tobacco products differ substantially in their risk profile in approximate relation to the content of toxins in the tobacco.
- On toxicological and epidemiological grounds, some of the Swedish smokeless products appear to be associated with the lowest potential for harm to health.
- These Swedish smokeless products appear to increase the risk of pancreatic cancer, and possibly of cardiovascular disease, particularly myocardial infarction.
- Some smokeless tobacco products also increase the risk of oral cancer, but if true of Swedish smokeless tobacco, the magnitude of this effect is small.
- All of the above hazards are of a lower magnitude than those associated with cigarette smoking.
- Smokeless tobacco products have little or no effect on the risk of chronic obstructive pulmonary disease or lung cancer.

[16] BRITISH AMERICAN TOBACCO. *Smokeless snus* [online]. Available from: http://www.bat.com/group/sites/uk__3mnfen.nsf/vwPagesWebLive/DO6CKJNP?opendocument&SKN=1 [Accessed 29 November 2009]
[17] TOBACCO ADVISORY GROUP OF THE ROYAL COLLEGE OF PHYSICIANS, 2007. *Harm reduction in nicotine addiction Helping people who can't quit* [online], p. 161. Available from: http://www.rcplondon.ac.uk/pubs/contents/bbc2aedc-87f7-4117-9ada-d7cdb21d9291.pdf [Accessed 29 November 2009]

- Therefore, in relation to cigarette smoking, the hazard profile of the lower risk smokeless products is very favourable.
- Smokeless tobacco use by pregnant women is harmful to the unborn fetus, but the hazard of smokeless use relative to maternal cigarette smoking is not clearly established.
- In Sweden, the available low-harm smokeless products have been shown to be an acceptable substitute for cigarettes to many smokers, while 'gateway' progression from smokeless to smoking is relatively uncommon.
- Smokeless tobacco, therefore, has potential application as a lower hazard alternative to cigarette smoking.
- The applicability of smokeless tobacco as a substitute for cigarette smoking if made available to populations with no tradition of smokeless use is not known."

The experience of snus use and the relative patterns of tobacco use and smoking-related disease incidence in Sweden have provoked a debate in Europe about the potential role which snus might play in a broader tobacco harm reduction approach. Some of the main contributions to this debate are summarised in the following section.

We think that future regulation of smokeless tobacco products should be science-based with product standards of principal importance and we support use of the constituent limits for smokeless tobacco products set out in the regulatory standard which is being proposed by the European Smokeless Tobacco Council (ESTOC).[18] [19] Use of a regulatory product standard would be a way of differentiating snus, and other smokeless tobacco products which meet that standard, from the many other forms of smokeless tobacco products (e.g. guthka) which are on the market in various countries.

We currently sell snus in Sweden and Norway, are test marketing the product in South Africa and Canada, and have held a limited consumer trial in Japan. Test marketing is enabling us to develop our understanding of consumer preferences.

In the USA, the smokeless tobacco category is forecast to grow by 4-5% per annum as the use of conventional cigarettes declines. While much of this category is accounted for by "chewing" style tobaccos, the share held by moist snuffs, including snus, is growing as new products become available.[20]

4.3 Snus and tobacco harm reduction: studies

The SCENIHR Scientific opinion on the Health effects of Smokeless Tobacco Products, 2008

The European Commission's Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) was asked to evaluate the health effects of smokeless tobacco products (STP),

[18] ESTOC, European Smokeless Tobacco Council, was established in 1989 and represents the interests of smokeless tobacco manufacturers and distributors as well as tobacco trade associations.
[19] ESTOC, 2009. *Proposed Regulation of Smokeless Tobacco Products within the EU - parts 1 and 2* [online]. Available from: http://www.estoc.org/uploads/Documents/documents/ESTOC_Regulation_Proposal_Part1.pdf and http://www.estoc.org/uploads/Documents/documents/ESTOC_Regulation_Proposal_Part2.pdf [Accessed 29 November 2009]
[20] KONCEPT ANALYTICS, 2007. *Smokeless Tobacco Market: High Growth Potential* [online], p. 9. Available from: http://www.reportlinker.com/p057485/Smokeless-Tobacco-Market-High-Growth-Potential.html [Accessed 29 November 2009]

with particular attention to tobacco for oral use, moist snuff (snus). SCENIHR adopted its opinion on 6th February 2008, following a public consultation.[21]

On the health effects of certain smokeless tobacco products, SCENIHR concluded: "Overall therefore, in relation to the risks of the above major smoking-related diseases, and with the exception of use in pregnancy, STP are clearly less hazardous, and in relation to respiratory and cardiovascular disease substantially less hazardous, than cigarette smoking. The magnitude of the overall reduction in hazard is difficult to estimate, but as outlined above, for cardiovascular disease is at least 50%, for oral and GI cancer probably also at least 50%, and for respiratory disease close to 100%."[22] SCENIHR cited a study[23] which used a modified Delphi approach to estimate the relative hazard of snus, concluding that the product was likely to be approximately 90% less hazardous than cigarette smoking.

SCENIHR's conclusion on the comparison of smokeless tobacco with smoking is as stated below:

"It is possible that introducing snus in EU countries that do not presently allow the product to be marketed would eventually contribute to some or all of the following beneficial outcomes:

• Reduced initiation of cigarette smoking
• Increased cessation by switching to smokeless tobacco
• Reduced smoking-associated disease

It also must be recognised that it is possible that the overall health outcome of introducing smokeless tobacco products could be adverse due to the following possible outcomes:

• Increased overall tobacco use without substantial decline in cigarette smoking prevalence
• Impaired tobacco prevention efforts due to 'mixed messages' that attempt to advise against any tobacco use, but favour certain forms over others
• Undermining tobacco cessation efforts
• Uptake of smokeless tobacco in populations who would otherwise have not likely used any tobacco product

The balance of the benefits and risks listed above will vary according to circumstances of individuals and population groups. However, for those who substitute smoking by STPs the benefits outweigh the risks."[24]

With respect to the potential role of snus in both cessation and harm reduction, SCENIHR stated: "Observational data from Sweden indicate that snus has been used more often than pharmaceutical nicotine products by some men as an aid to stop smoking. The data are consistent in demonstrating these male snus users are more likely to quit smoking than non users." They did, however, note that "… 60% or more smoking abstainers become chronic snus users. There

[21] SCIENTIFIC COMMITTEE ON EMERGING AND NEWLY IDENTIFIED HEALTH RISKS, 2008. Scientific opinion on the *Health Effects of Smokeless Tobacco Products*, 6 February 2008, [online] Available at: http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_013.pdf [Accessed 29 November 2009]
[22] *Ibid*, p. 114-5.
[23] LEVY, D.T., et al., 2004 The Relative Risks of a 36 Low-Nitrosamine Smokeless Tobacco Product Compared with Smoking Cigarettes: Estimates of a 37 Panel of Experts. *Cancer Epidemiol Biomarkers Prev* 13: pp. 2035-42.
[24] SCIENTIFIC COMMITTEE ON EMERGING AND NEWLY IDENTIFIED HEALTH RISKS, 2008, *Op. Cit.*, p. 118.

are no published randomised clinical trials of use of smokeless tobacco in smoking cessation, and in the absence of such evidence it is not possible to draw reliable conclusions as to the relative effectiveness of smokeless tobacco as an aid to clinical smoking cessation in comparison with either placebo or other established therapies."[25]

SCENIHR also commented that "While there is no doubt that complete abstinence from tobacco use would be the safe and preferred option for all of these snus users, the pragmatic argument is that if in practice the alternative for them would be to smoke tobacco, then if snus use is less hazardous than tobacco smoking, substitution of snus for smoking may be beneficial to individual and public health."[26]

The Norwegian Institute for Alcohol and Drug Research (SIRUS) Report, 2009

In 2009, SIRUS funded a report by Dr. Karl Erik Lund entitled "A tobacco-free society or tobacco harm reduction? Which objective is best for the remaining smokers in Scandinavia?"[27]

Lund considered that "despite the fact that measures to prevent smoking have been effective, and the proportion of smokers is decreasing in Scandinavia, the need for harm reduction measures has become greater" for various reasons, including that:

- "…the effect of nicotine replacement products and the effect of interventions provided by doctors is very limited."

- "The remaining group of smokers increasingly contains a higher proportion of people with social, mental and demographic characteristics associated with reduced ability to stop smoking."

- "In Scandinavia, nearly all the political measures recommended by [the World Health Organization] for reducing smoking have already been implemented. There is probably little potential for further reduction by using publically-regulated control of tobacco. Despite the fact that tobacco control measures are utilized to such a degree, the proportion of deaths due to smoking among adults is still very high."

- "Intensifying the existing measures against smoking that have been effective up to now would probably give only a moderate return (diminishing marginal returns)."

- "Cigarette smoking is ideal for a harm reduction strategy, because the substance that causes addiction – nicotine – is not the cause of the health risk. People smoke because of nicotine, but die from tobacco smoke. Much less hazardous nicotine products are available."[28]

Lund's conclusions included: "Without encouragement to use harm-reducing nicotine products, a large proportion of the remaining smokers will continue to smoke, and will thus have a 50 per

[25] *Ibid*, p. 110
[26] *Ibid*, p. 112
[27] LUND, K.E. 2009. *A tobacco-free society or tobacco harm reduction?* SIRUS-Report no. 6/2009, Norwegian Institute for Alcohol and Drug Research [online] Available at: http://www.sirus.no/files/pub/484/sirusrap.6.09.eng.pdf [Accessed 29 November 2009]
[28] *Ibid*, p. 7-8

cent chance of dying from a tobacco-related disease. With the status quo in the tobacco/nicotine policy that is given legitimacy by the authorities – that is a policy without an active harm-reduction strategy – use of tobacco will maintain and strengthen future social inequalities in health status…[29] To ignore harm reduction as a future strategy in the area of tobacco can be erroneous in this situation. An uncompromising attitude to a tobacco-free society can deny many nicotine-dependent smokers the possibility to survive, which they could have had if the authorities had assumed a more pragmatic attitude to harm reduction."[30]

Rodu & Cole

Writing in 2009 in the *Scandinavian Journal of Public Health*[31], Brad Rodu,[32] Professor of Medicine at the University of Louisville, and Phil Cole, an epidemiologist at the University of Alabama at Birmingham, estimated how smoking-attributable deaths might decline if other EU countries had smoking prevalence rates and smoking-related disease patterns identical to those in Sweden. They calculated that if all EU countries had the lung cancer mortality rates (LCMR) of men in Sweden, there would have be 54% fewer deaths from lung cancer in the EU. Expanding this logic to all smoking-related deaths in an individual country (extrapolated from their respective LCMRs), Rodu and Cole estimate that if the UK had a male smoking rate identical to that of Sweden there would be over 27,000 fewer tobacco-related deaths in the UK annually. Rodu and Cole conclude that their study shows that "snus use has had a profound effect on smoking prevalence and LCMRs among Swedish men. While it cannot be proven that snus would have the same effect in other EU countries, the potential reduction in smoking-attributable deaths is considerable."[33]

Gartner et. al.

Another recent modelling study by Gartner and others reported in the *Lancet*[34] assessed the potential population health effects of snus in Australia (where the sale of snus is currently not permitted). It concluded that current smokers who switch to using snus rather than continuing to smoke can avoid substantial health risk and that snus could produce a net reduction in future health risks at the population level if it is adopted in sufficient numbers by smokers. Relaxing current restrictions on the sale of snus was considered more likely to produce a net benefit than harm, with the size of the benefit dependent on how many smokers switch to snus. It was, they said, unlikely that these health gains would be offset by the adverse health effects of snus use, such as increased mortality due to cancers and cardiovascular diseases, among people who would have never used tobacco or current smokers who would have otherwise quit all tobacco use. The actual size of the probable population reduction in health risk would depend on the relative uptake rates of snus in smokers and non-smokers.

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[29] *Ibid*, p. 72
[30] *Ibid*, p. 73
[31] RODU, B. and COLE, P., 2009. Lung cancer mortality: Comparing Sweden with other countries in the European Union. *Scandinavian Journal of Public Health*, Jul 2009; vol. 37, pp. 481 – 486.
[32] Professor Rodu states that: "My research is supported by unrestricted grants from tobacco manufacturers to the University of Louisville and by the Kentucky Research Challenge Trust Fund."
[33] RODU, B. and Cole, P., 2009. *Op Cit*, p. 481.
[34] GARTNER, C., HALL, W., VOS, T., BERTRAM, M. WALLACE, A., and LIM, S., Assessment of Swedish snus for tobacco harm reduction: an epidemiological modelling study. *The Lancet*, Volume 369, Issue 9578, pp. 2010-2014.

Gartner et al stated that while "A detailed consideration of the pros and cons of snus use for tobacco harm reduction, and the most appropriate regulatory options, is necessary before changing current policies regarding snus"[35], they added that "Ethical concerns about the promotion of a harmful and addictive substance like snus must be balanced against the ethical implications of restricting access to a tobacco product with a much lower health risk when the main source of tobacco addiction—cigarettes—is so readily available, when tobacco addiction is so difficult for some smokers to overcome, and in light of evidence from Sweden that suggests smokers who use snus as a cessation aid have a substantially higher success rate than those who use nicotine medications and that primary snus users have a much lower rate of starting smoking than those without previous snus use."[36]

New Zealand Ministry of Health commissioned "Systematic review of the health effects of modified smokeless tobacco products,"[37] 2007

The New Zealand Ministry of Health commissioned a review to be carried out by the New Zealand Health Technology Assessment of the health effects of Swedish snus to inform the debate about whether snus and similar products have a role in reducing tobacco related harm in New Zealand.

This report was issued in 2007. The author, Marita Broadstock, points out in the report that "… it would appear from ecological evidence for Swedish men that the availability of snus can have a net population health gain... However the transferability of the Swedish experience to countries such as New Zealand is another question entirely… Nevertheless, it is worth considering that, if the use of snus was one-tenth as harmful as smoking, as a recent panel of experts concluded it was in relation to mortality…then the product would need to be used 10 times more often, taking into account duration of habit as well as number of users, in order to offset its benefit to public health."[38]

Broadstock also observed that "Regardless of the net impact of introducing PREPs at a population level, it has been argued that, ethically, smokers have the right to be informed about and have access to products that may reduce their individual harm…An approach to minimise risk for the population from the availability of snus or other PREPs is to ensure that snus is directed toward those who could most benefit…If snus was made available for harm reduction, health agencies could target access to consumers who may benefit from substituting smoking with snus, while also restricting unsupported use by non-smokers or former smokers. Priority could be given to inveterate smokers, low-income uninsured smokers, and/or smokers who have failed at existing cessation methods…Specific guidelines for use could also be advocated."

The Royal College of Physicians (UK)

The Royal College of Physicians (RCP) has spoken out on several occasions in support of a new structure governing the regulation of tobacco and nicotine within the UK. As part of this they

[35] *Ibid*, p. 7 of preprint edition [online]. Available at: http://espace.library.uq.edu.au/eserv/UQ:13766/gartner_lancetpreprint.pdf [Accessed 30 November 2009]
[36] *Ibid*, p. 6.
[37] BROADSTOCK, M., 2007. *Systematic review of the health effects of modified smokeless tobacco products*, NZHTA Report 2007[online] Available at: http://nzhta.chmeds.ac.nz/publications/smokeless_tobacco.pdf [Accessed 29 November 2009]
[38] *Ibid, p. 80.*

believe that, while the prime objective is "to encourage smokers to switch as completely as possible to use of medicinal nicotine in place of smoking,"[39] tobacco-based reduced-risk products have a part to play within a tobacco harm reduction strategy, subject to strict safeguards regarding both proof of effectiveness and control of availability.

In their 2002 report 'Protecting smokers, saving lives - The case for a tobacco and nicotine regulatory authority,' the RCP noted that "At present, nicotine replacement therapies are strictly controlled under medicines regulation, and oral tobacco is banned completely under EU law – yet both represent much less hazardous ways of administering nicotine than cigarettes and both may be used for smoking cessation. However, cigarettes are subject only to the most cursory regulation and restrictions. This perverse regulatory imbalance favours the most deadly means of delivering nicotine."[40]

In their 2008 Report "Ending tobacco smoking in Britain," the RCP further commented that: "In Sweden, the availability and use by men of an oral tobacco product called snus, one of the less hazardous smokeless tobacco products, is widely recognised to have contributed to the low prevalence of smoking in Swedish men and consequent low rates of lung cancer. Sale of snus is prohibited in other countries of the European Union, but the product is available in Norway where uptake to date has been low and with no appreciable influence on smoking prevalence. However, the Swedish data provide proof of concept that substitution of smokeless for smoked tobacco can be effective as a harm reduction strategy."[41]

Finally, in their response to the Consultation/Discussion document, the RCP concluded that: "We believe that harm reduction could play a vital role in reducing the death and disability caused by tobacco smoking…We argue that a drive to encourage as many smokers as possible to switch to less hazardous sources of nicotine should become a central component of UK tobacco control."[42]

5 Conclusions

We believe that there is a clear and compelling case for the Government to consider a broad approach to tobacco harm reduction as part of its forthcoming Tobacco Control Strategy: one which would allow for regulation permitting both MRTPs and information about those MRTPs to be made available to adult tobacco consumers to provide them with the option of reduced-risk products.

There is now a considerable impartial body of international public health opinion which supports this view and which regards current policy towards tobacco products, which regulates the least harmful products in the strictest fashion, as inconsistent if not incoherent. There is evidence showing that higher levels of snus usage can correlate with a reduced incidence of smoking-related deaths and an overall reduction in total tobacco-related harm on a population basis. And there is evidence that smokeless MTRPs which present a significantly reduced-risk profile (e.g.

[39] TOBACCO ADVISORY GROUP OF THE ROYAL COLLEGE OF PHYSICIANS, 2008, *Op. Cit.*, p. 8.
[40] ROYAL COLLEGE OF PHYSICIANS, 2002, *Op Cit*, p. 2.
[41]TOBACCO ADVISORY GROUP OF THE ROYAL COLLEGE OF PHYSICIANS, 2008. *Op Cit*, p. 4.
[42] ROYAL COLLEGE OF PHYSICIANS, 2008. *Submission from the Royal College of Physicians to the Department of Health Consultation on the future of tobacco control* p. 6. [online]. Available from: http://www.smokefreeaction.org.uk/consultation-response/responses/RCP_DH_Future_of_tobacco_control.pdf [Accessed 29 November 2009]

Swedish-style snus products) are acceptable to adult tobacco consumers when they are made available to them.

Harm reduction is a proven approach in other areas of public health policy in the UK and elsewhere. While clearly there is further discussion to be had about an appropriate framework for assessment of potentially reduced-risk products and the conditions under which these might be made available, we would suggest that the Government recognise that a broader approach to harm reduction may yield greater public health benefits than the current narrow approach, which focuses solely on medicinal nicotine replacement therapy products and abstinence and which fails to recognise the potential importance of there being a range of consumer acceptable, reduced-risk products available as alternatives to conventional cigarettes.

We believe that, as a responsible tobacco business, we can contribute as a stakeholder, through information, ideas and practical steps, to helping regulators in the UK and elsewhere address the key issues surrounding our product, including on product information and the development of MRTPs. As manufacturers of the products, we have substantial knowledge about their design, manufacture, distribution, sale and use, and we believe that we have essential expertise and capability to contribute to this important public health debate. We are open and willing to do so.

Chapter 14

Comment to the U.S. Food and Drug Administration from Philip Morris USA and U.S. Smokeless Tobacco Company regarding harm reduction

James E. Dillard

Reprinted from the open archives of public comments to the Food and Drug Administration on the Regulation of Tobacco Products Docket FDA-2009-N-0294 (1014.3). (Available at: http://www.regulations.gov/search/Regs/home.html#docketDetail?R=FDA-2009-N-0294).

Editors' Note: These comments show the strong interest in THR at the largest cigarette and smokeless tobacco company in the U.S. While there were vociferous controversies about Altria's involvement in the law that created FDA authority, and thus the invitation for these comments, that discussion included little insight about THR and so is not addressed here.

Continuing the themes from our previous chapter note, about BAT's petition to the British government, readers should note that though tobacco companies are still accused of misrepresenting science in their favor, this document clearly understates the case that could be made. Such understatement almost always characterizes scientific communication from tobacco companies today. For example, the letter implies that the health risks from smokeless tobacco are higher than they actually have been shown to be, and cites only the most tentative supporters of THR (with the exception of the strong and clear supporters of THR at the American Council on Science and Health). In particular, the "Strategic Dialogue" that is cited several times is a group of anti-THR activists who tried to co-opt the concept of THR, setting impossible standards and trying to redefine it so it differs little from their standard abstinence-only approach. Similarly, the Levy estimate of the risk from using smokeless tobacco was an unsubstantiated wild guess and has been shown to be an overestimate by at least a factor of two, and probably closer to a factor of ten.

(We are, however, pleased to see someone citing Henley's 2007 article as offering compelling evidence about the benefits of switching products. It takes some effort to extract the information since the American Cancer Society took great pains to hide that fact when they published the article, and basically said exactly the opposite in their public rhetoric.)

JED is Senior Vice President of Altria. Altria is the parent company of Philip Morris USA and U.S. Smokeless Tobacco Company.

Thus, if Altria is misrepresenting the science, it is in the same direction that most anti-THR activists misrepresent it. In fairness, given the accusations that flow without regard to truth, it is understandable that a company would be wary about saying anything that is not extremely conservative, particularly in the U.S. where there is a history of individuals and governments using the legal system to attack companies for making scientifically accurate statements. Moreover, it is easy to see the political value in citing anti-THR activists as the basis for making pro-THR arguments (though giving too much credit to these sources might make it a bit harder for those of us trying to educate the community about what the good science shows).

Dr. Dillard, when he was at U.S. Smokeless Tobacco Company before it was acquired by Altria, was instrumental in providing the unrestricted grant (i.e., absolutely no funder input into the research that was supported) to the University of Alberta that helped support much of our research during the years when we were at the School of Public Health there. We acknowledge our appreciation of this, but believe that it did not influence our choice to include this chapter, and note that neither the UASPH grant nor Dillard (other than through the indirect contribution of submitting this document to the government) was involved in this book project.

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December 22, 2009

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
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Re: **Docket No. FDA–2009–N–0294 (74 Federal Register 31457 (July 1, 2009)) Request for Comments: Regulation of Tobacco Products Under the Family Smoking Prevention and Tobacco Control Act**

Philip Morris USA Inc. ("PM USA") and U.S. Smokeless Tobacco Company LLC ("USSTC") welcome this opportunity to respond to the Food and Drug Administration ("FDA" or the "Agency") Notice and Request for Comments on the implementation of the Family Smoking Prevention and Tobacco Control Act ("FSPTCA"). PM USA and USSTC are both wholly owned subsidiaries of Altria Group, Inc. ("Altria").[1] PM USA is the nation's leading cigarette manufacturer and has been in operation for over 100 years. PM USA's cigarette brands include the trademarks Marlboro, Basic, L&M, Parliament, and Virginia Slims. PM USA also manufactures and markets Marlboro Snus moist smokeless tobacco. USSTC is a leading producer and marketer of moist smokeless tobacco products and has been in business for over 185 years. USSTC's brands include the trademarks Copenhagen, Skoal, Red Seal, and Husky.

We support the purpose of the FSPTCA to decrease the harm from tobacco use. The FSPTCA seeks to protect the public health by delegating broad regulatory authority to FDA and empowering FDA to address the risk and harm associated with current tobacco product use. FDA has indicated that, in implementing this legislation, it "will perform its duties by using the best available science to guide the development and implementation of effective public health strategies to reduce the burden of illness and death caused by

[1] Altria Client Services ("ALCS") is making this submission on behalf of Philip Morris USA Inc. and U.S. Smokeless Tobacco Company LLC. ALCS provides certain services, including managing regulatory affairs, to the Altria family of companies. "We" is used throughout to refer to PM USA and USSTC.

tobacco products."[2] Based on available scientific evidence, we respectfully urge the Agency to craft a regulatory scheme for tobacco products under the FSPTCA that encompasses a broad spectrum of effective harm reduction approaches.
In this submission, we offer thoughts on opportunities to reduce the harm caused by cigarette smoking based on the "continuum of risk," including a role for smokeless tobacco products, to complement effective prevention and cessation strategies.

I. The Major Hazards of Tobacco Use

There is a substantial continuum of risk across different types of tobacco or nicotine-containing products. We agree with the overwhelming medical and scientific consensus that cigarette smoking causes lung cancer, heart disease, emphysema, and other serious diseases in smokers and is addictive. Cigarette smoking is the most hazardous form of tobacco consumption, due to the inherent risks of combusting tobacco and inhaling the smoke.[3] The weight of scientific evidence establishes the following conclusions about the harm caused by tobacco use.

First, the harm caused by tobacco use is primarily attributable to cigarette smoking. The Surgeon General has described cigarette smoking as "the single greatest cause of avoidable morbidity and mortality in the United States."[4] According to the Centers for Disease Control and Prevention ("CDC"), "[s]moking is the primary causal factor for at least 30% of all cancer deaths, for nearly 80% of deaths from chronic obstructive pulmonary disease, and for early cardiovascular disease and deaths."[5]

Second, the harm caused by cigarette smoking can be reduced in the following ways, listed from greatest impact to least impact.

- Not smoking

Cigarette smokers have a significantly higher risk than nonsmokers of developing lung cancer, cardiovascular disease, emphysema, and other serious diseases. Therefore, over time, decreasing the number of individuals who smoke will have a positive impact on the population harm from cigarette smoking.[6]

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[2] FDA, *Frequently Asked Questions on the Passage of the Family Smoking Prevention and Tobacco Control Act (FSPTCA)*, *available at* http://www.fda.gov/TobaccoProducts/NewsEvents/ucm173174.htm.
[3] *See* D.K. Hatsukami et al., *Developing the science base for reducing tobacco harm*, Nic. & Tob. Res.; vol. 9: S537-S553 (2007) (hereinafter, Hatsukami et al., 2007"); Royal College of Physicians of London, Tobacco Advisory Group of the Royal College of Physicians, *Protecting Smokers, Saving Lives* 5, 28 (London: RCP 2002).
[4] US Surgeon General, *The Health Consequences of Smoking: A Report of the Surgeon General* (2004), ch. 1, p. 3 (hereinafter "US Surgeon General 2004 Report"), *available at* http://www.surgeongeneral.gov/library/smokingconsequences/index.html.
[5] Centers for Disease Control and Prevention, *Smoking-Attributable Mortality, Years of Potential Life Lost, and Productivity Losses -- United States, 2000-2004,* MMWR; vol. 57(45): 1226-1228 (2008), *available at*, http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5745a3.htm.
[6] *See, e.g.,* U.S. Surgeon General 2004 Report, *supra*; International Agency for Research on Cancer, *Tobacco Smoking: Summary of Data Reported and Evaluation*; vol. 38 (1998), *available at* http://monographs.iarc.fr/ENG/Monographs/vol38/volume38.pdf.

- Decreasing the number of years smoked

Epidemiological studies have shown that the duration of smoking is an important determinant of a smoker's overall disease risk. According to the Surgeon General and other public health authorities, decreasing the number of years of smoking reduces an individual's smoking-related disease risk.[7]

- Decreasing the number of cigarettes per day

Epidemiological studies have shown that smokers who smoke fewer cigarettes per day have lower smoking-related disease risk. The 2004 Surgeon General's Report stated that "[a] dose-response relationship has been demonstrated between cigarette smoking and cancer of the lung, larynx, oral cavity and urinary bladder."[8] Furthermore, the landmark 2001 Institute of Medicine ("IOM") report "Clearing the Smoke" stated that, "[c]urrently, available data allow estimation, albeit imprecise, of a dose-response relationship between exposure to whole tobacco smoke and major diseases that can be monitored for evaluation of harm reduction potential."[9]

- Decreasing smoke exposure per day

Although various public health authorities have questioned the role of cigarette design changes in reducing the risk and harm of cigarette smoking, the fundamental toxicological principle of dose-response remains valid.[10] The level of exposure to

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[7] US Surgeon General, *The Health Benefits of Smoking Cessation: A Report of the Surgeon General* (1990), *available at* http://profiles.nlm.nih.gov/NN/B/B/C/T/.

[8] U.S. Surgeon General 2004 Report, *supra*, at ch. 1, p.12.

[9] Institute of Medicine, Committee to Assess the Science Base for Tobacco Harm Reduction, *Clearing the Smoke: Assessing the Science Base for Tobacco Harm Reduction*, Executive Summary at 9 (K. Stratton et al., Washington, D.C.: National Academies Press 2001) (hereinafter "2001 IOM Report"), *available at* http://books.nap.edu/openbook.php?record_id=10029.

[10] The International Association for Research on Cancer concluded in 2004 that "[c]hanges in cigarettes since the 1950s have probably tended to reduce the risk for lung cancer associated with the smoking of particular numbers of cigarettes at particular ages." *See* International Association for Research on Cancer, *Tobacco Smoke and Involuntary Smoking*; vol. 83: 171 (2004), *available at* http://monographs.iarc.fr/ENG/Monographs/vol83/mono83.pdf. In contrast, NCI Monograph 13 concluded in 2001 that, "[t]here is no convincing evidence that changes in cigarette design between 1950 and the mid-1980s have resulted in an important decrease in the disease burden caused by cigarette use either for smokers as a group or for the whole population." NCI, Smoking and Tobacco Control Monograph 13, *Risks Associated with Smoking Cigarettes with Low Tar Machine-Measured Yields of Tar and Nicotine* at 146 (2001) (hereinafter, "NCI Monograph 13"), *available at* http://cancercontrol.cancer.gov/tcrb/monographs/13/m13_complete.pdf; *see also* US Surgeon General, *The Health Consequences of Smoking: A Report of the Surgeon General* (2004), *available at* http://www.surgeongeneral.gov/library/smokingconsequences/index.html. At the same time, however, NCI Monograph 13 also agreed that "[s]everal careful reviews of the available scientific data have suggested that there is a reduction in lung cancer risk for populations of smokers who use lower yield cigarettes if

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cigarette smoke remains a consideration in developing effective responses to the harm caused by cigarette smoking: "the theoretical basis for reduced exposure resulting in reduced disease in continuing tobacco users remains credible and compels further consideration of this approach."[11] An objective assessment of the epidemiological literature requires that this point be made, though its impact, while significant, is relatively small compared to not smoking.

II. The Harm Reduction Concept

Millions of adults are likely to continue using tobacco products, notwithstanding efforts by government, public health, and others to encourage them not to use tobacco at all.[12] According to CDC statistics, an estimated 46 million U.S. adults were current cigarette smokers in 2008.[13] In 2008, approximately 70% of U.S. adult smokers reported that they want to quit smoking,[14] and 45.3% (20.8 million) of U.S. adult smokers reported that they tried to quit smoking during the preceding 12 months.[15] Yet, the overall smoking prevalence did not significantly change from 2007 to 2008, and during the past five years, smoking prevalence rates "have shown virtually no change."[16]

Discouraging initiation and promoting cessation, particularly among those not legally permitted to buy tobacco products because they are underage, are and should remain core strategies to reduce tobacco-related harm. While prevention and cessation efforts can successfully reduce harm, however, it is highly unlikely that they will eliminate tobacco use altogether. There is growing consensus that public health policies based solely on prevention and cessation are not sufficient in the real world. Indeed, a regulatory approach that forces cigarette smokers to choose between smoking, on the one hand, and not using tobacco at all, on the other, could have the consequence of preserving cigarette smoking as the dominant form of tobacco use in the U.S.

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they did not increase the number of [cigarettes smoked per day], that the "[c]lear impression from [the epidemiology] studies taken as a whole is that there is a lower risk of lung cancer among populations who use lower yield products," and that "most [epidemiological] studies conducted in different geographic locations demonstrated differences in lung cancer risks for filter and low-tar (machine-measured) smokers compared with non-filter and high-tar smokers...." NCI Monograph 13 at 71, 81, 96.

[11] J.E. Henningfield et al., *Guidance for research and testing to reduce tobacco toxicant exposure*, Nic. & Tob. Res.; vol. 7(6): 821-26 (2005).

[12] Institute of Medicine, Committee on Reducing Tobacco Use, *Ending the Tobacco Problem: A Blueprint for the Nation* (Washington D.C.: National Academies Press 2007), *available at* http://books.nap.edu/openbook.php?record_id=11795.

[13] Centers for Disease Control and Prevention, *Cigarette Smoking Among Adults – United States, 2008.* MMWR; vol. 58(44): 1227-1232 (2009) (hereinafter "CDC, 2009"), at 1229, *available at* http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5844a2.htm.

[14] Centers for Disease Control and Prevention, *Smoking and Tobacco Use: Smoking Cessation*, *available at* http://www.cdc.gov/tobacco/data_statistics/fact_sheets/cessation/quitting/index.htm (last updated Sept. 16, 2009).

[15] CDC, 2009, *supra*, at 1229.

[16] *Id.* at 1230.

A third approach is needed to *complement* proven prevention and cessation strategies, *not to compete* with them. This third approach should focus on reducing tobacco-related morbidity and mortality among the population of adults who continue to use tobacco products by making available, and providing accurate information about, tobacco products that are acceptable to consumers and proven to be lower on the continuum of risk.

A 2009 article entitled "The Strategic Dialogue on Tobacco Harm Reduction: a vision and blueprint for action in the United States ("Strategic Dialogue")" critically examines this approach.[17] The Strategic Dialogue is the outcome of more than two years of dialogue by a group of twenty-six scientists and researchers, which convened to develop guidance for future efforts to reduce the harm caused by tobacco products.[18] It confirms that there is a "very pronounced" continuum of risk among different tobacco and nicotine-containing products.[19] Others have similarly confirmed the continuum of risk concept,[20] which can be represented as follows:

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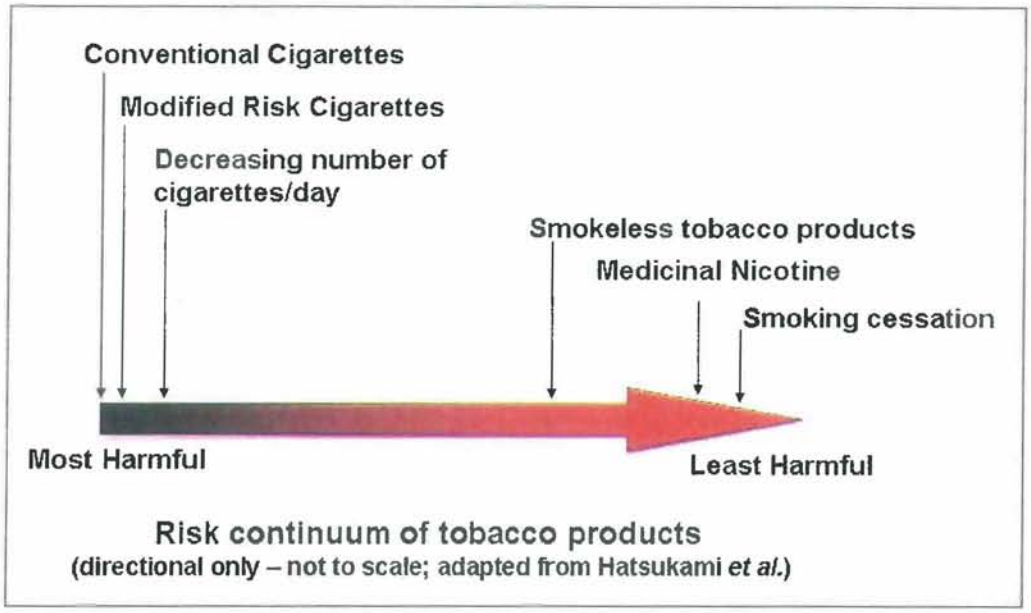
[17] *See* M. Zeller et al., *The Strategic Dialogue on Tobacco Harm Reduction: a vision and blueprint for action in the United States*, Tob. Control J.; vol. 18: 324-332 (2009).

[18] The Strategic Dialogue participants were: Cathy Backinger (National Cancer Institute, Bethesda, Maryland, USA); Neal Benowitz (University of California, San Francisco, California, USA); Lois Biener (University of Massachusetts, Boston, Massachusetts, USA); David Burns (University of California, San Diego, California, USA); Pamela Clark (University of Maryland, College Park, Maryland, USA); Greg Connolly (Harvard School of Public Health, Boston, Massachusetts, USA); Mirjana Djordjevic (National Cancer Institute, Bethesda, Maryland, USA); Thomas Eissenberg (Virginia Commonwealth University, Richmond, Virginia, USA); Gary Giovino (University at Buffalo, SUNY, Buffalo, New York, USA); Dorothy Hatsukami (University of Minnesota, Minneapolis, Minnesota (co-chair)); Cheryl Healton (American Legacy Foundation, Washington, DC, USA); Stephen Hecht (University of Minnesota, Minneapolis, Minnesota, USA); Jack Henningfield (Pinney Associates, Bethesda, Maryland, USA); Corinne Husten (Partnership for Prevention, Washington, DC); Kimberly Kobus (University of Illinois, Chicago, Illinois, USA); Scott Leischow (University of Arizona, Tucson, Arizona, USA); David Levy (Pacific Institute for Research & Evaluation, Calverton, Maryland, USA); Stephen Marcus (National Cancer Institute, Rockville, Maryland, USA); Matthew Myers (Campaign for Tobacco-Free Kids, Washington, DC, USA); Mark Parascandola (National Cancer Institute, Rockville, Maryland, USA); Prabhu Ponkshe (HealthMatrix Inc., McLean, Virginia, USA); Peter Shields (Georgetown University, Washington, DC, USA); Paul Slovic (Decision Research, Eugene, Oregon, USA); David Sweanor (University of Ottawa, Ottawa, Ontario, Canada); Kenneth Warner (University of Michigan, Ann Arbor, Michigan, USA); and Mitchell Zeller, (Pinney Associates, Bethesda, Maryland (co-chair)). *Id.* at 331.

[19] *Id.* at 325.

[20] *See, e.g.,* Hatsukami et al., *supra*, at S546.



Risk continuum of tobacco products
(directional only – not to scale; adapted from Hatsukami *et al.*)

Conventional cigarettes are positioned at one end of the risk continuum, presenting the highest risk due to the combustion and inhalation of tobacco smoke. Smoking cessation is at the opposite end of the continuum, because the best way to reduce the risks of smoking is to quit. Medicinal nicotine, which is positioned at slightly higher risk than smoking cessation on the continuum, is an option for smokers who want to quit. Such medicinal nicotine products, however, have been limited in their success.

For those who continue cigarette smoking, we have devoted substantial research and development efforts for more than 40 years in support of reducing the hazards of cigarette smoke. This has proven a challenge. To succeed, such a cigarette must be supported by sufficient evidence relating to potential reduced exposure, risk or harm; meet the taste and flavor expectations of adult smokers; be technically and commercially feasible; and not result in unintended adverse changes to the complex mixture of the thousands of chemical compounds which comprise smoke. We would be happy to share relevant scientific information and data with FDA. Moving forward, reducing actual smoke exposure may offer some opportunity for adults who continue to smoke, but it remains a difficult challenge.

Some adults who would otherwise continue to smoke may be willing to move to a smokeless tobacco alternative to cigarettes. Smokeless tobacco products are substantially lower on the risk continuum than cigarettes – closer, in fact, to medicinal nicotine and smoking cessation than to continued smoking.[21] We summarize scientific evidence in support of this finding in Section III below.

[21] Strategic Dialogue, *supra*, at 325; *see also* Hatsukami et al., *supra*, at S546.

By recognizing – and regulating based on – the continuum of risk, FDA has an opportunity to reduce tobacco-related harm to a greater extent than would be possible by focusing on prevention and cessation strategies alone. Reflecting on this concept, the Strategic Dialogue observed:

> There is potential for an ever-wider range of consumer-acceptable alternatives to the cigarette for smokers who will not otherwise cease their dependence on nicotine. With US status quo trends in smoking estimated to lead to 10 million additional deaths in the next 25 to 30 years, with virtually all of these to occur among people already smoking, and with the vast majority of them motivated to reduce their risks, the primary reduction in tobacco-related death will come from increased cessation. But the intelligent application of harm reduction principles has the potential to achieve public health gains.[22]

Although support from the public health community at large and the regulated industry is important, harm reduction based on the continuum of risk should be a cornerstone of FDA's regulatory policy to achieve the greatest and most sustainable benefit to the public health. A regulatory framework based on the continuum of risk would recognize scientific studies and other evidence demonstrating that smokeless tobacco products have a lower risk profile than cigarettes. Also, it would encourage innovation with respect to smokeless tobacco products that could enable safer alternatives to cigarette smoking, which would align with FDA's efforts generally to encourage innovation across all FDA-regulated products.[23] Effective, science- and evidence-based approaches that recognize the continuum of risk could provide a platform to develop, assess, commercialize, and communicate with adult consumers about tobacco products that reduce the risk and harm from cigarette smoking.

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[22] Strategic Dialogue, *supra*, at 325.

[23] For example, FDA has been engaged in its Critical Path Initiative since 2004, which has been described as "FDA's national strategy for driving innovation to modernize the sciences through which FDA-regulated products are developed, evaluated, manufactured, and used." FDA, *FDA's Critical Path Initiative: Transforming the way FDA-regulated products are developed, evaluated, manufactured, and used*, *available at* http://www.fda.gov/ScienceResearch/SpecialTopics/CriticalPathInitiative/ucm076689.htm. In addition, the FDA Amendments Act of 2007 established FDA's Office of Chief Scientist, which is responsible for developing FDA's scientific priorities going forward and specifically with "[f]ostering development and use of innovative technologies to meet public health needs[.]" FDA, *About FDA: Office of the Chief Scientist*, *available at* http://www.fda.gov/AboutFDA/CentersOffices/OC/OfficeofScientificandMedicalPrograms/default.htm. With respect specifically to medical device innovation, FDA recently announced an upcoming public meeting entitled "Incorporation of New Science into Regulatory Decisionmaking Within the Center for Devices and Radiological Health[CDRH]," at which FDA is seeking public input regarding how CDRH "should anticipate and respond to new or evolving scientific knowledge that is consistent with [FDA's] mission to protect and promote the public health . . . ." 74 Fed. Reg. 67, 237 (Dec. 18, 2009).

III. Smokeless Tobacco as a Means to Reduce Cigarette Smoking Harm

A. Non-combustible, smokeless tobacco products are substantially lower than cigarettes on the continuum of risk

The case for FDA regulation based on the continuum of risk is made even more compelling because less hazardous tobacco products are available now. Quitting is the most effective means of reducing the risk of tobacco-related disease for smokers, but for those who do not quit, encouraging them to move from cigarettes to smokeless tobacco products can have a significant public health benefit. The Surgeon General and other public health authorities have determined that smokeless tobacco products are addictive and cause serious diseases. However, transitioning adult smokers from cigarettes to demonstrably less hazardous smokeless tobacco products could impact both smoking cessation (number of years smoked) and number of cigarettes per day, thereby significantly reducing risk and harm.

There is an overwhelming scientific, medical, and public health consensus that moist smokeless tobacco products, including those widely available in the U.S. and Sweden (snuff and snus), are substantially less hazardous than cigarettes. This consensus is based on extensive and compelling scientific evidence, including epidemiological disease risk data in human populations from the U.S. and other countries. As early as 2001, the IOM observed that smokeless tobacco products pose a lower overall risk than cigarettes.[24] Since that time, panel after panel of experts have critically, thoroughly examined the evidence and reached the same conclusion: using smokeless tobacco products is undeniably far less hazardous than smoking cigarettes. While debate continues over how publicizing that finding would impact public health, the finding itself is now beyond any credible dispute.

A recent, significant example of this consensus is found in the Strategic Dialogue, which concludes that cigarette smoking is "undoubtedly" more hazardous than smokeless ("non-combustible") tobacco:

> There is a very pronounced continuum of risk depending upon how toxicants and nicotine, the major addictive substance in tobacco, are delivered. Cigarette smoking is *undoubtedly* a more hazardous nicotine delivery system than various forms of non-combustible tobacco products for those who continue to use tobacco, which in turn are more hazardous than pharmaceutical nicotine products.[25]

The Scientific Committee on Emerging and Newly Identified Health Risks ("SCENIHR") advises the European Commission's Health & Consumer Protection Directorate-General,

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[24] *See* 2001 IOM Report, *supra*, at 167.

[25] Strategic Dialogue, *supra*, at 325 (emphasis added). *See also id.* at 327 ("On the continuum of risk, non-combustible tobacco products are more likely to reduce harm than a smoked form of tobacco for individuals who would otherwise be using conventional cigarettes.").

which is responsible for updating various European Union laws relating to the safety of food and other products, consumer rights, and the protection of public health. In 2008, after examining the scientific evidence, SCENIHR issued a final report concluding that the overall health risks of smokeless tobacco products of the types found in Sweden and North America are "clearly" and "substantially" less than the overall health risks of cigarettes:

> Overall therefore, in relation to the risks of the above major smoking-related diseases, and with the exception of use in pregnancy, [smokeless tobacco products] are *clearly less hazardous*, and in relation to respiratory and cardiovascular disease *substantially less hazardous*, than cigarette smoking. The magnitude of the overall reduction in hazard is difficult to estimate, but as outlined above, for cardiovascular disease is at least 50%, for oral and GI cancer probably also at least 50%, and for respiratory disease close to 100%.[26]

SCENIHR found the body of evidence so compelling that it described its finding regarding the relative risks of cigarettes and smokeless tobacco as "undeniable":

> It is *undeniable* that for an individual substitution of tobacco smoking by the use of moist snuff would decrease the incidence of tobacco related diseases.[27]

In addition to those noted above, many other medical and scientific organizations have examined the relative health risks of smokeless tobacco products and cigarettes and reached similar conclusions. In a 2002 report, the Royal College of Physicians ("RCP"), the oldest medical organization in England, concluded that "the consumption of non-combustible tobacco is of the order of 10-1,000 times less hazardous than smoking, depending on the product," and that "[s]ome smokeless tobacco products . . . may offer substantial reductions in harm compared to smoking.[28] The RCP followed up with a second study in 2007,[29] again concluding that the overall health risks of using smokeless tobacco are "considerably" and "substantially" less than those of cigarette smoking:

> The health risks of smokeless tobacco are considerably lower than those associated with combustible tobacco products as *it is largely the combustion process that makes tobacco use so deadly.*[30]

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[26] *See* European Commission, Health & Consumer Protection Directorate-General, Scientific Committee on Emerging and Newly Identified Health Risks ("SCENIHR"), *Health Effects of Smokeless Tobacco Products* (Feb. 6, 2008) at 114-15 (emphasis added), *available at* http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_013.pdf).
[27] *Id.* at 14 (emphasis added).
[28] Royal College of Physicians 2002, *supra*, at 5, 28.
[29] Royal College of Physicians of London, Tobacco Advisory Group of the Royal College of Physicians, *Harm Reduction in Nicotine Addiction: Helping People Who Can't Quit* (London: RCP 2007).
[30] *Id.* at 18 (emphasis added).

In 2008, an international group of experts that provides scientific and technical advice on tobacco products to the World Health Organization ("WHO") similarly recognized that smokeless tobacco products are less hazardous than cigarettes. The WHO Study Group on Tobacco Product Regulation ("TobReg") concluded, "[u]sers of smokeless tobacco products generally have lower risks for tobacco-related morbidity and mortality than users of combustible tobacco products such as cigarettes."[31]

The American Council on Science and Health ("ACSH") has also weighed in, issuing a number of reports and statements about smokeless tobacco over the last several years. ACSH is a public health-oriented consumer education consortium with a board comprised of 350 physicians, scientists, and policy advisors.[32] In a report released in 2006, ACSH concluded that, "[o]verall, the use of smokeless tobacco confers only about 2% of the health risks of smoking," emphasizing that in contrast to cigarette smoking, smokeless tobacco poses no risk of lung cancer or other chronic pulmonary diseases and little risk, if any, of other cancers.[33] In a subsequent publication, ACSH noted that almost eighty peer-reviewed scientific and medical articles have acknowledged the differential risks between smokeless tobacco and cigarettes and concluded that the "health risks associated with ST [smokeless tobacco] use are *vastly lower* than those of smoking."[34]

In sum, these and many other scientific reports demonstrate beyond credible dispute that the health risks of moist smokeless tobacco products, including U.S. and Swedish moist smokeless tobacco (snuff and snus), are substantially less hazardous than cigarettes.[35] Epidemiological evidence from both the U.S. and Sweden clearly

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[31] *See* WHO Study Group on Tobacco Product Regulation ("TobReg"), *The Scientific Basis of Tobacco Product Regulation*, 951 WHO Technical Report Series, at 10 (WHO Press: 2008), *available at* http://www.who.int/tobacco/global_interaction/tobreg/publications/9789241209519.pdf.

[32] American Council on Science and Health Home Page, http://www.acsh.org/about/pageID.5/default.asp.

[33] *See* K. Meister, *Helping Smokers Quit: A Role for Smokeless Tobacco?* at 5 (American Council on Science and Health 2006) (hereinafter, "ACSH Report") (emphasis added).

[34] *See* ACSH, *Smokeless Tobacco as Harm Reduction for Smokers* (American Council on Science and Health 2007), *available at* http://www.acsh.org/publications/pubID.1538/pub_detail.asp (emphasis added). In February 2007, ACSH President Elizabeth Whelan and Executive and Medical Director Dr. Gilbert Ross released a statement on behalf of the ACSH for a Senate hearing on the then-proposed FDA regulation of tobacco. *See* ACSH Statement for Senate Hearing on FDA Regulation of Tobacco, Feb. 27, 2007, *available at* http://www.acsh.org/factsfears/newsID.929/news_detail.asp. In its statement, the ACSH addressed what it termed the "fallacy that all tobacco products are equally harmful to public health" and pointed out that "[s]cientific studies have proven that they are not, and a rapidly-growing body of evidence confirms that they are not." *Id.* In October 2008, ACSH Executive and Medical Director Dr. Ross stated in a letter to the medical journal Lancet that "the health risks of smokeless tobacco are at least an order of magnitude less than those of cigarettes." G. Ross, *Smokeless Tobacco for Cigarette Cessation*, Lancet; vol. 372: 1271 (2008).

[35] *See, e.g.*, L.T. Kozlowski L.T. & B.O. Edwards, *"Not Safe" is Not Enough: Smokers Have a Right to Know More Than There is No Safe Tobacco Product,* Tob. Control J.; vol. 14: ii3-ii7, ii5 (Suppl. II 2005) ("Smokeless tobacco (SLT), for example, is *substantially safer* than cigarettes.") (emphasis added); Kozlowski, L.T., "*Effect of Smokeless Tobacco Product Marketing and Use on Population Harm from Tobacco Use: Policy Perspective for Tobacco-Risk Reduction,* Am. J. of Preventative Medicine; vol. 33 (6S): S379-S386, S379 (2007) (recognizing the "*considerable scientific consensus* that smokeless tobacco

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demonstrate a substantial reduction in risk for people switching from smoking cigarettes to using smokeless tobacco. The following figure, based on that epidemiology, illustrates that smokers who switch from using cigarettes to smokeless tobacco products experience a significant decrease in risk from tobacco-related harm.

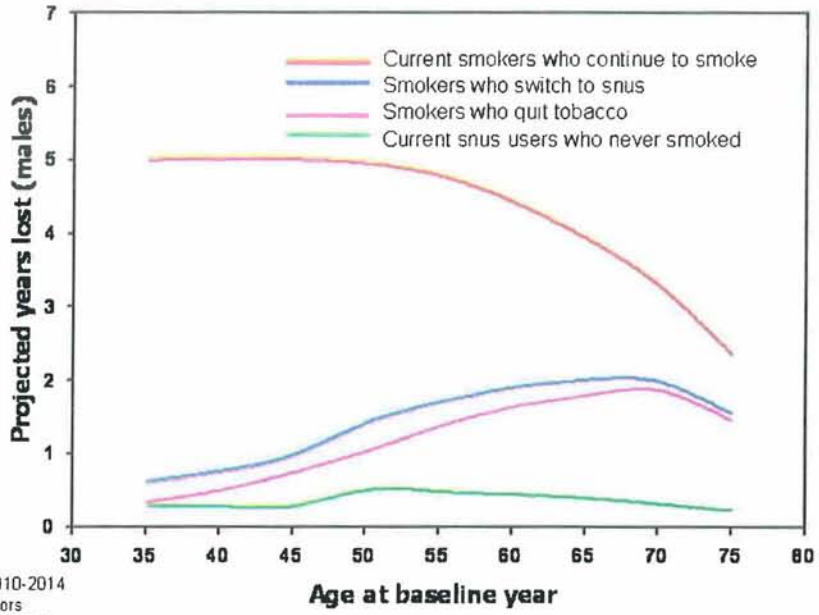
Modeling the Impact of Snus
(Swedish Moist Smokeless Tobacco)

Age dependent difference in health adjusted life expectancy (Males)

Smoking
– **Never used tobacco to continued smoking - 2.4 to 5 yrs lost**

Snus use
– **Never used tobacco to current snus user - 0.2 to 0.5 yrs lost**

Switching
– **Smoker who quits tobacco to a smoker who switches to snus - 0.1 to 0.4 yrs lost**



Data obtained from Gartner et al., 2007. Lancet 369:2010-2014
Smoking estimates included all major disease risk factors
Smokeless tobacco estimates were based on Levy et al., 2004

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products as sold in the United States, although not safe, are less dangerous than cigarettes to physical health.") (emphasis added); M. Broadstock, New Zealand Health Technology Assessment (NZHTA), Department of Public Health and General Practice, Christchurch School of Medicine and Health Science, *Systematic review of the health effects of modified smokeless tobacco products* at 82 (Christchurch, New Zealand: NZHTA 2007) ("The evidence from this review suggests that the harm of using snus, relative to non tobacco use, is *significantly less* than found for smoking with respect to cancers of the head, neck and gastro-intestinal region, and cardiovascular disease events.") (emphasis added); Gartner et al., *Assessment of Swedish snus for tobacco harm reduction: an epidemiological modelling study*, Lancet; vol. 369: 2010-2014, 2012 (2007) ("Individual smokers who switched to snus instead of continuing to smoke and new tobacco users who only used snus rather than smoking would achieve *large health gains compared to smokers.*") (emphasis added); C. Bates et al., *European Union policy on smokeless tobacco. A statement in favour of evidence-based regulation for public health*, Tob. Control J.; vol. 12: 360-67, 361 (2003) ("Even allowing for cautious assumptions about the health impact, snus – and other oral tobaccos - are *a very substantially less dangerous way to use tobacco than cigarettes.*") (emphasis in original).

As evident from the foregoing, estimates of years of life lost are indistinguishable between "smokers who switch to snus" and "smokers who quit tobacco." Both estimates are similar in the degree to which they are lower than for "current smokers who continue to smoke" and higher than for "current snus users who never smoked."

A close examination of data from the American Cancer Society Cancer Prevention Study II supports the same conclusion.[36] This study was the first known prospective cohort study to compare mortality among former U.S. cigarette smokers who substituted using smokeless tobacco for cigarette smoking with those who quit using tobacco entirely. Although all cause mortality after twenty years follow-up for smokers who switched to smokeless tobacco was higher than quitting altogether, this result was marginal and approached statistically non-significant levels.[37]

B. Consumers should be provided with accurate, non-misleading information about the comparative health risks of smokeless tobacco products and cigarettes

Despite the scientific evidence outlined above, recent studies show that the vast majority of smokers continue to believe that smokeless tobacco is as harmful as cigarette smoking. For example, in 2005, a survey of over 2,000 adult U.S. smokers found that only 10.7% correctly agreed that smokeless tobacco products are less hazardous than cigarettes, while 82.9% disagreed and 6.4% did not know.[38] As noted by the public health scientists who reported this finding:

> Here, smokers are *misinformed* in the opposite direction. Epidemiologic data suggest that [smokeless tobacco products] sold in the United States are significantly less dangerous than cigarettes.... In short, this U.S. national sample of adult smokers holds beliefs about the relative harm reduction potential of modified cigarettes and [smokeless tobacco products] that are *contrary to the available scientific evidence.*[39]

In the meantime, the public health community continues to debate whether scientifically substantiated facts about the relative risks of smokeless tobacco and cigarettes should, as a policy matter, be communicated to adult smokers. Some members of the public

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[36] Cancer Prevention Study II, sponsored by the American Cancer Society, is a large, ongoing prospective cohort study of 1.2 million U.S. adults that began in the fall of 1982. It was designed to examine the effect of tobacco use on death rates from cancer and other tobacco-related diseases.

[37] Henley et al., *Tobacco-related disease mortality among men who switched from cigarettes to spit tobacco*, Tob. Control J.; vol. 16(1): 22-8 (2007).

[38] R.J. O'Connor et al., *Smoker awareness of and beliefs about supposedly less harmful tobacco products*, 29 Am. J. Prev. Med. 85, 89 (2005).

[39] *Id.* (emphasis added). Another study, published in 2007, examined adult smokers' beliefs in the U.S., Australia, Canada, and the United Kingdom and found that among the four, "U.S. smokers were least likely to believe that SLT is less harmful, even though it is an available option for them." R.J. O'Connor et al., *Smokers' beliefs about relative safety of other tobacco products: Finding from the ITC Collaboration*, 9 Nic. & Tob. Res. J. 1033-42 (2007).

health community oppose providing this information to consumers, citing concerns that doing so might cause people who do not currently use tobacco products to start, or that smokeless tobacco may operate as a "gateway" to future cigarette smoking. It is reasonable to consider these concerns, but it is also essential to consider the potential for smokeless tobacco products to reduce disease among smokers who would otherwise continue to smoke cigarettes. As the Strategic Dialogue points out, "[p]olicies that shift the population to less harmful products should be explored taking into account their impact on prevention and cessation efforts *and* overall tobacco-related mortality."[40]

We believe that, because the difference in risk between cigarette smoking and using smokeless tobacco is so pronounced, the movement of adult smokers from cigarettes to smokeless tobacco products is likely to have a net public health benefit. Speaking to this issue, the ACSH concluded:

> Some government and health organizations and health professionals may be reluctant to tell people that smokeless tobacco use is less dangerous than cigarette smoking out of concern that this information might prompt nonusers of tobacco to start using smokeless tobacco. However, the overall public health impact of any increase in smokeless tobacco use is extremely unlikely to outweigh the beneficial effect of cigarette smokers switching to smokeless tobacco, since it would require 50 people to start using smokeless tobacco to equal the degree of health risk associated with one person smoking.[41]

This observation is bolstered by the results of two research studies sponsored by the National Cancer Institute ("NCI"). In the first study, a team of U.S. public health researchers, including experts in epidemiology, medicine, statistics, and economics, evaluated the health risks of smokeless tobacco products compared to cigarettes.[42]

To assist in its assessment of the evidence, it also engaged a group of nine experienced tobacco epidemiologists "based on their knowledge of the health risks associated with both smokeless tobacco and cigarette use."[43]

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[40] Strategic Dialogue, *supra*, at 331 (emphasis added).
[41] ACSH Report, *supra*, at 7.
[42] *See* D.T. Levy et al., *The Relative Risks of a Low-Nitrosamine Smokeless Tobacco Product Compared with Smoking Cigarettes: Estimates of a Panel of Experts*, Cancer, Epidemiology, Biomarkers & Prevention; vol. 13: 2035-2042, 2037 (2004) (hereinafter, "Levy et al., 2004").
[43] *Id.* at 2035-36. The members of the epidemiology panel were: Graham A. Colditz (Channing Laboratory, Boston, MA, USA); Martin Jarvis (Health Behaviour Unit of Cancer Research UK, Department of Epidemiology and Public Health, University College London, London, United Kingdom); Michael Kunze (Institute of Social Medicine, University of Vienna, Vienna, Austria); Freddi Lewin (Department of Oncology, Huddinge University Hospital, Stockholm, Sweden); Jonathan M. Samet (Bloomberg School of Public Health, Johns Hopkins University, Baltimore, MD, USA); Peter Shields (Cancer Genetics and Epidemiology, Lombardi Cancer Center, Georgetown University Medical Center, Washington, DC, USA); Steven D. Stellman (Mailman School of Public Health, Department of Epidemiology, Columbia University,

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They reached a consensus, following a systematic evaluation of epidemiological disease risk data for U.S. and Swedish smokeless tobacco products, that smokeless tobacco products were less hazardous than cigarettes by "a wide margin" of "at least 90%."[44]

In a follow-up study, the research team used statistical and modeling techniques to estimate the impact on tobacco use of marketing smokeless tobacco products in the U.S. with a warning label consistent with the risk profile of smokeless tobacco products marketed in the U.S. and Sweden.[45] It assembled a panel of seven experts "based on their knowledge of the behavioral trends associated with both smokeless tobacco and cigarette use" to aid in its assessment.[46] They predicted that a harm reduction policy including well-regulated smokeless tobacco products would result in "a net public health benefit through reduced mortality," notwithstanding the potential for a modest increase in smokeless tobacco use, due to the substantially lower health risks of using smokeless tobacco products and a likely acceleration in the decline of cigarette smoking.[47]

We urge FDA to consider the 2001 IOM Report, which states that "the regulatory process should not discourage or impede scientifically grounded claims ... so long as steps are taken to ensure that consumers are not mislead [sic]."[48] The Strategic Dialogue recognizes that principle as well, recommending that "[c]onsumers should be accurately informed and educated about relative risks of the use of different types of nicotine containing products." [49] Although the Strategic Dialogue participants did not fully agree on the role of smokeless tobacco in harm reduction, "there was a consensus about the value and concept of this continuum of risk."[50] Indeed, they expressly recognized that "if smokers who cannot or will not quit their dependence on nicotine switched completely to smokeless tobacco products, they would likely experience a reduction in tobacco-caused mortality and morbidity."[51]

A risk management strategy, based on continuum of risk principles, represents an important opportunity to reduce the harm caused by cigarette smoking. Such a strategy, thoughtfully conceived and effectively implemented, would complement proven

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New York, NY, USA); Michael Thun (Department of Epidemiology and Surveillance, American Cancer Society, Atlanta, GA, USA); and Deborah M. Winn (Epidemiology and Genetics Research Program, Division of Cancer Control and Population Sciences, NI). *Id.* at 2036, Table 1.

[44] *Id.* at 2035, 2038.

[45] D.T. Levy et al., *The potential impact of a low-nitrosamine smokeless tobacco product on cigarette smoking in the United States: Estimates of a panel of experts*, Addictive Behaviors; vol. 31: 1190-1200, 1194 (2006) (hereinafter, "Levy et al., 2006").

[46] The behavioral panel experts were: Frank Chaloupka (University of Illinois at Chicago, Chicago, IL, USA); Karl-Olov Fagerstrom, (Fagerstrom Consulting, Helsingborg, Sweden); Hans Gilljam, (Karolinska Institute, Stockholm, Sweden); Dorothy Hatsukami, (University of Minnesota, Minneapolis, MN, USA); Jack Henningfield (Pinney Associates, Bethesda, MD, USA); Martin Jarvis (University College London, London, UK); and Ann McNeil (University College London, London, UK). *Id.* at 1194.

[47] *Id.* at 1199.

[48] 2001 IOM Report, *supra*, at 218.

[49] Strategic Dialogue, *supra*, at 331.

[50] *Id.* at 327.

[51] *Id.*

prevention and cessation approaches by addressing a population that those approaches do not address – specifically, adult smokers who would otherwise continue to smoke. A continuum of risk strategy need not, and should not, conflict with proven approaches based on prevention and cessation. To the contrary, these approaches are in harmony, in that they agree that the best option is not to use any tobacco product, and that reducing the health risks of smokers is the primary objective.

C. Smokeless tobacco products must be acceptable to cigarette smokers

Consumer acceptability is crucial to the ultimate success of this strategy. In order to have any real impact in driving movement from cigarettes to products lower on the risk continuum, less hazardous products must be acceptable to current cigarette smokers.

Smokeless tobacco is an available option on the market today with proven consumer appeal. Many adult smokers express an interest in smokeless tobacco alternatives to cigarette smoking. In the U.S., despite evidence of some adult consumer movement from cigarettes to smokeless tobacco, most continue to smoke cigarettes. One of the challenges in developing products that adult smokers will accept is to find ways to address the significant differences in experience between cigarette smoking and smokeless tobacco use, such as taste, smell, and ritual. It is in the interest of the public health to further the movement of adults who would otherwise continue to smoke from cigarettes to a tobacco product lower on the continuum of risk and to avoid inadvertently discouraging adult smokers from transitioning to a proven lower risk tobacco product like smokeless tobacco.

IV. Conclusion

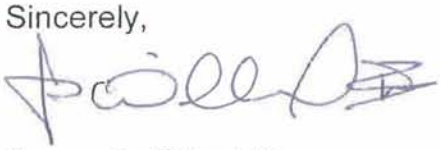
FDA has an opportunity to define a thoughtful and effective risk management strategy, including appropriate communications regarding the continuum of risk, that would reduce tobacco-related harm by successfully helping move individuals who would otherwise continue to smoke cigarettes to a demonstrably less hazardous product like smokeless tobacco. The FSPTCA provides FDA with a wide array of new authorities to draw upon to create a coherent regulatory system for tobacco products that reflects the continuum of risk. Indeed, Congress itself recognized the potential for risk reduction to advance the ambitious public health objectives of the legislation – for example, by creating a pathway to communicate information to consumers regarding modified risk tobacco products.

It bears repeating that the objective of this strategy is to complement, not compete with, efforts to prevent the initiation of tobacco use and encourage those who use tobacco to quit. Although the issues are complex, this objective advances FDA's mission to protect the public health, given that millions of smokers are likely to continue using tobacco products, despite efforts directed toward prevention and cessation. Indeed, a regulatory approach that does not take advantage of the opportunity presented by consumer-acceptable, demonstrably lower risk smokeless tobacco products might have the

consequence of preserving cigarette smoking as the dominant form of tobacco use in the U.S.

We thank FDA for this opportunity to provide our views. We look forward to future opportunities to express our views, provide information and internal data, and engage in discussions with FDA as it implements the FSPTCA.

Sincerely,



James E. Dillard III

Chapter 15

An analog visual comparison of best, current and worst case scenarios in (tobacco) harm reduction; numeracy-aiding tools to get the message across

Paul L. Bergen & Courtney E. Heffernan

This chapter is adapted from a poster presented at the 2010 IHRA meeting; the authors expect to produce a more complete analysis of the methods and theory, as well as education material based on the graphics, so future readers should consult TobaccoHarmReduction.org to find these; the authors thank Carl V. Phillips for editing and for providing thoughtful suggestions.

> "Do good judgments need complex cognition? A glance into the literature, which is populated with complex Bayesian and other models, suggests that the answer is yes. Countering this view, here we have reviewed evidence to suggest that actually the opposite may be true: Simple cognitive mechanisms can outperform more complex cognitive machinery, which is prone to overfit irrelevant, noisy, and meaningless information in a fundamentally uncertain world." (Marewski, Gaissmaier & Gigerenzer 2009).

Coffee and cigarettes are both legal stimulants with addictive properties, and both contain benign to moderate drugs – caffeine and nicotine, respectively. Neither can ever be considered absolutely safe. Yet the pursuing a goal of absolute safety remains one of the most persistent goals of health policies – smoking bans and drug prohibitions being good examples of this aim made flesh. But, this goal of achieving absolute safety is one of the most persistent impediments to effective tobacco harm reduction (THR).

Tobacco harm reduction involves exploring for and promoting alternative (safer) methods of delivering nicotine to would-be smokers. Viable candidates such as smokeless tobacco (ST) or

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electronic cigarettes do exist, but many ostensible health advocates and authorities refuse to share this information with consumers. Routinely, their response to the question of whether smokers should switch to a safer mode of tobacco use (ST) or of smoking (electronic cigarettes), is negative. Setting aside the question of the real motives of anti-tobacco activists, this is typically justified by assuming the goal is one of achieving absolute safety. For example, in many question-and-answer formats, questions like, "is smokeless tobacco really less harmful than smoking?" are answered with the *non sequitur* "smokeless tobacco still causes risks, including...., so don't do it!"

While most health authorities accept that caffeine poses a small risk, they will not allow a comparable level of risk from nicotine. The truism that is disguised as an argument is that there is "there is no safe tobacco product, and there is no safe level of exposure to tobacco smoke" (NCI 2009), thereby declaring – without ever actually arguing the case – that unlike for basically all other consumption choices which are allowed to cause some risk, tobacco is unique in that the only acceptable level of risk is zero. In other words, by comparing all tobacco use to no use, all tobacco use is technically unsafe, and thus falls on the wrong side of the dichotomizing line that anti-tobacco extremists have declared and somehow socially established. For health conscious consumers this obscures the salient fact that some ways of obtaining nicotine are so much more similar in effects to no tobacco use than they are to smoking and thus should be classified with the former and not the latter. Here we present a visualization of the comparative risk posed by ST use, which shows just how much safer non-combustible forms of nicotine are when compared to smoking.

Much of the population, including those with a post-secondary education, are functionally innumerate when it comes to understanding risks (see Nelson et al 2008, Gigerenzer et al 2008, Gardner 2008, Kabat 2008, as well as the extensive body of work of Kahneman, and Tversky tracing back to the 1970s). People do not have an intuition that allows us to distinguish between 1-in-one million versus 1-in-100, so any risk, no matter how trivial, so long as it is nonzero, seems worth worrying about. There is widespread misuse of terms among supposed experts in health science that further contributes. In discussions of tobacco use and health it is not uncommon to hear the claim that the reason the rate of oral cancer in ST users is lower than in smokers is because there are fewer of them, confusing individual risk among the exposed group with population prevalence. And though one could argue for improving the educational system so that people could better critically use the available resources – and there is a cottage industry of books that try to provide that education – working with the actual situation is more immediate and practical. There are probably millions of tobacco users who are sufficiently persuadable, but lack numerical understanding, and thus could benefit immediately from this information if it could be provided in way that did not require remedial education.

One structure for analyzing information processing strategies (there are many other variations, though the basic themes are similar) is Marewski, Gaissmeier & Gigerenzer's, where they define four basic information processing strategies and apply them to a health context. The classic conceptualization of these presented similar concepts in terms of decision-making heuristics (Kahneman, Slovic & Tversky 1982). Marewski et al.'s list, in simplified form, is: Recognition (simply choosing the recognized or known alternative over the unknown), Fluency (choosing between two knowns by selecting the one which occurs to one's thinking more quickly), Take the Best (selecting the one that dominates the other based on all factors being considered), and Tallying (counting the respective aspects and choosing the one with the most). What is critical here is that the latter has some element of adding and subtracting benefits and costs, but lacks a quantification of the magnitude of the entries on the list. It requires some effort to get people to recognize that costs and benefits do not merely exist, but that they have magnitude.

Those who intend to confuse people into making the wrong decision can easily take advantage of this in their marketing efforts. In the case of tobacco harm reduction, those who have campaigned to discourage it (the reasons *why* anyone would want to discourage it are beyond the present scope) have found it easy to sow a bit of concern about ST or electronic cigarettes. This eliminates the dominance comparison and plays to the tendency to choose the familiar risk rather than a novel one. In addition, by listing downsides of using the alternative products, the toting-up heuristic has many entries on both sides. Never mind that the oral cancer that is erroneously blamed on ST is so rare that even the exaggerated claims about that risk made by anti-ST activists would still leave it about 1000 times less likely than lung disease from smoking, smokers almost invariably react by saying "if I smoke I might get lung cancer but if I dip I might get mouth cancer, so it is all the same". (For examples of this strategy of convincing potential product switchers that they might as well smoke, see Phillips, Wang & Guenzel 2005).

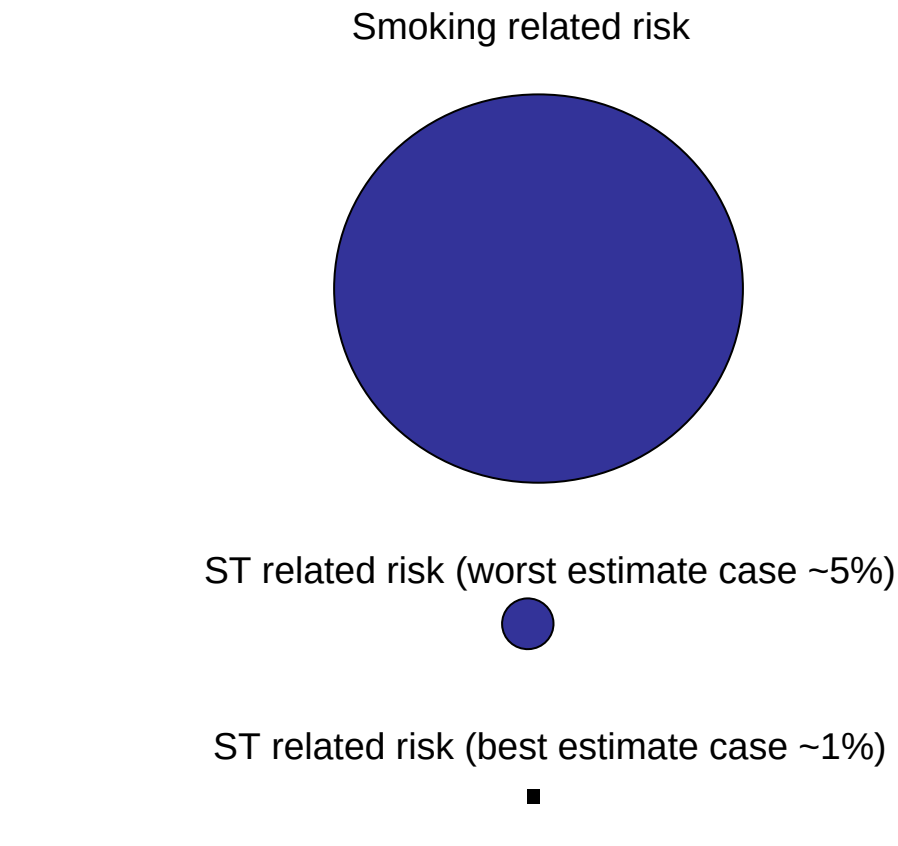
Information about tobacco has become so culturally primed that only by transposing these examples into other areas is the absurdity obvious. If someone asked "I worry about getting into an accident so I am thinking of getting rid of my old junker car that has bad brakes and no seatbelts and only using public transportation. Would it be safer?" and the response given was "Buses have been involved in some serious accidents and in some cases many people have been injured, far more than in any passenger car accident. In India there are reports of hundreds being killed when one crashes or plunges down a hillside". Since transportation is not as politically charged it is more likely that the questioner would recognize the non sequitur. Indeed, the straight comparative answer, "yes", might be considered enough. When it comes to tobacco, the most convoluted reasoning and obvious propaganda is often interpreted as normal reasonable health communication or "straight talk". As a result, even the straight answer "yes, but there is

still risk" seems to undermine the simple heuristic that would favor the bus as a superior strategy. It seems only understanding the magnitudes involved can help this, but the homogenization of probabilities stated as numbers makes this difficult.

A form of visual display could reintroduce transparency where the potential benefit of a message has been lost due either to a lack of capacity for numerical or logical reasoning or from unwittingly accepting the deliberate restructuring of the information to force a false conclusion. Indeed, for the case of tobacco harm reduction we hope that a graphical representation renders blindingly obvious what has been intentionally made a muddle.

An analog illustration, in which areas correspond to total risk, and thus the stark contrast between them, shows how small "still risky" really is. To provide useful perspective, and possibly to provide beneficial application in other spheres, we have also constructed comparisons from other areas. These contrasts show how unusually substantial the savings are in effective THR. This shows how unusually dramatic the savings are in effective THR.

Figure 1: Mortality risk from a lifetime of smoking compared to a lifetime of smokeless tobacco use.

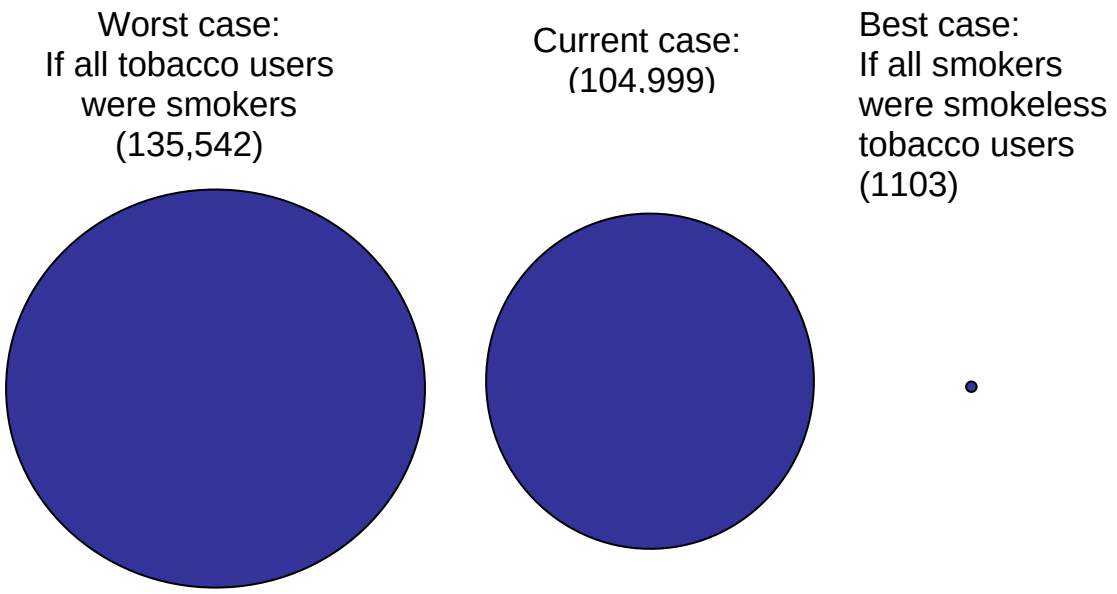


Based on Phillips CV, Rabiu D & Rodu B. (2006).

The most important comparison appears in Figure 1. Though it seems that the statement of the estimate – 1% as risky or 99% less risky – may be sufficient for most readers, it is difficult to ignore this comparison. Whether the worst-case scenario should be in the picture is an interesting pedagogic and ethical question. That number was calculated and presented to illustrate how absurd the common claim that ST is 90% or "at least 90%" less risk is, misleading by a factor based on even the most pessimistic interpretation of the evidence. Placing it in a graphic might distract from the real message, but for now it is included for completeness.

As stated the legend, the following is an illustration of the difference in the combined estimated mortalities of 7 particular cancers. One aim in this is not only to show the potential advantage of smokers switching to ST but to illustrate how close the current situation is to the worst possible situation in which all tobacco users were smokers[1].

Figure 2: Cancer risk from a lifetime of smoking compared to a lifetime of smokeless tobacco use.



Based on American estimates of 7 cancer mortalities for 35+ males (re Lee & Hamling, 2009).

Figure 2 limits the analysis to cancer, the risk that most people associate with smoking and ST use, though actually a minority of the estimated risk in both cases. This version of the graphic also illustrates an alternative presentation, comparing the present real case with how much worse

[1] Current situation represents the present mix of lifelong smokers and smokeless tobacco users in the population.

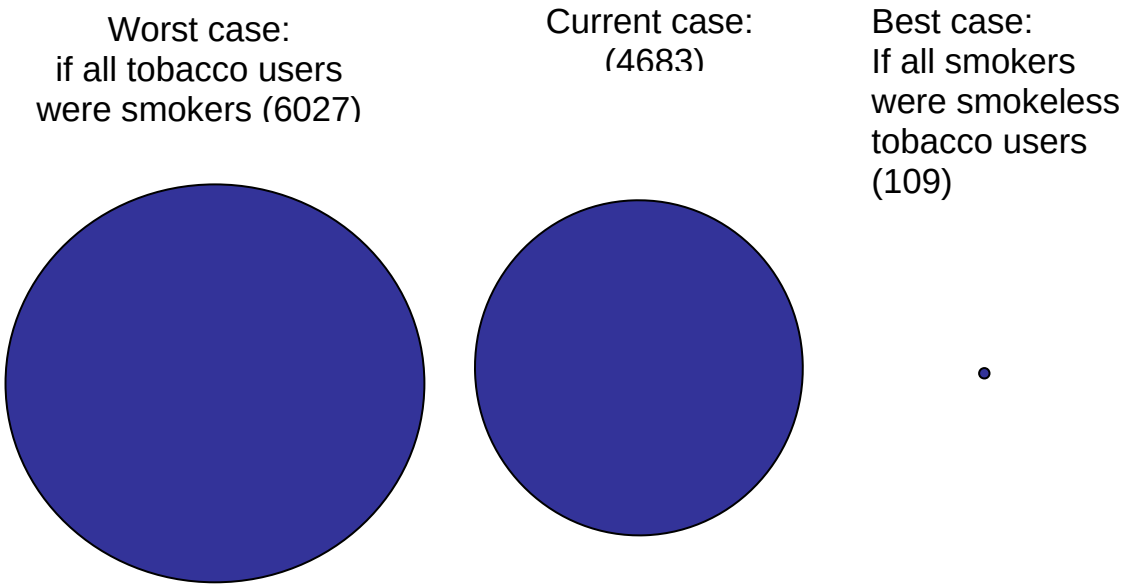
it would be if no one engaged in the reduced harm option. When compared to behaviors where harm reduction is the norm, this illustration could be useful.

By using the estimates of cancer risks for the two behaviors from Lee & Hamling (2009 (Table 33)) and estimates of prevalence of use for the United States from the source study time frame, the derived graphs were calculated with a population smoking incidence among males of 23% and a smokeless tobacco using incidence of 5.5%. These are not being promoted as reliable but as rough estimates given the difficulty of any accuracy in this area[2].

For each of the seven cancers, the Lee & Hamling estimates show similar comparisons; in each case the worst case is not that far from the current case, which is to be expected when the most popular modality of tobacco use is also the most harmful. While there would be limited educational value in presenting most of these, one stands out as worth showing. Figure 3 shows the cancer risk based on Lee & Hamling's review of published studies, illustrating that official health science wisdom is that smoking causes a high risk for oral cancer, and that the risk from smokeless tobacco is close to null. Presenting this creates a bit of an ethical dilemma, however, because it has long been apparent that not only do anti-tobacco activists exaggerate the trivial risk from ST, but they have also been wrong about the claim that smoking and drinking cause almost all oral cancer. A substantial portion of oral cancer is clearly caused by something else, and opinion is converging on papillomavirus. Thus, the anti-smoking propaganda presents an easy way to show the value of harm reduction, but those of us who are want to be honest have to hesitate to use that.

[2] 4.5% from MMRW 2005 and 6.5% from MMRW 2007.

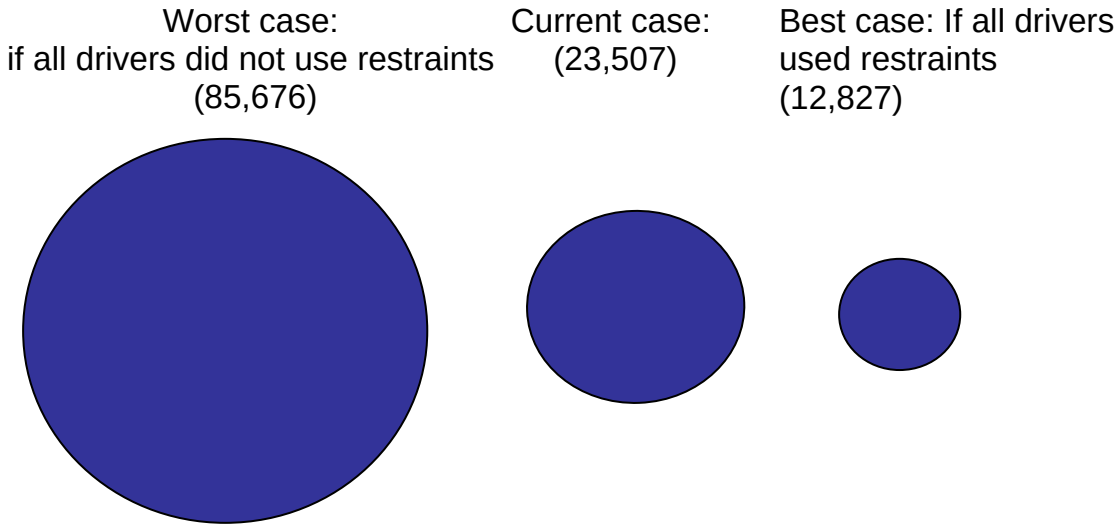
Figure 3: Risk of Oral and Pharyngeal Cancer from a lifetime of smoking compared to a lifetime of smokeless tobacco use (based on Lee & Hamling 2009)



Based on American estimates of oropharyngeal cancer mortality for 35+ males (re Lee & Hamling, 2009).

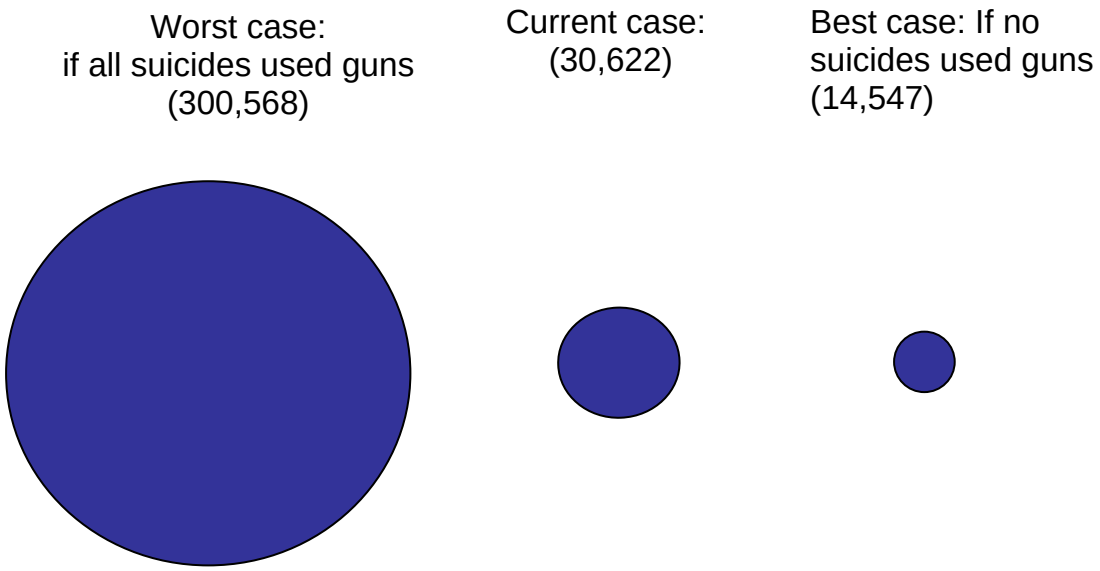
Figures 4 and 5 illustrate comparisons of the huge potential of THR, and its current lack of success, to other harm reduction arenas where the current case is much closer to the best case, though the reduction in risk is limited. This first figure illustrates what is probably the most widely-employed, understood, and appreciated harm reduction strategy. The quite dangerous activity that is being in a car has been made immensely safer though the use of seatbelts. Indeed, most of the potential benefits have been achieved, though even the best case scenario would not come close to THR's 99% reduction in risk. In a less typical comparison, limits on impulsive access to firearms result in many suicide attempts failing that otherwise would have succeeded. Interventions that are traditionally discussed under the harm reduction rubric – needle exchanges and such – affect relatively few people, and while the reduction in risk for infectious disease transmission is near perfect, the percent reduction in overall risk is not nearly so great.

Figure 4: Passenger Mortalities



Based on American National Highway Traffic Safety Administration record of passenger deaths where restraint use was known (restraints used:10642 deaths and not used: 12865 deaths, 2008.)

Figure 5: Suicide Mortalities



Based on Harvard School of Public Health Lethality of Suicide Methods (Case Fatality Ratio by Method of Self-Harm US 2001).

Thus, these graphs illustrate the oft-repeated point about THR, that the current political situation is very strange. (They would do so more effectively if they were scaled by total population risk, but that is not practical in the present medium. We will experiment with such presentations.) While many harm reduction interventions, even those that involve controversial subpopulations, are embraced, the harm reduction intervention that appears to offer the greatest potential improvement, in absolute and relative terms, is violently opposed. The reasons for this are beyond the present scope, but since it is so, and since the opposition seems readily able to confuse people based on the current discourse, perhaps the truth could be better illustrated with areas than with digits. These particular graphs are unlikely to be the best possible presentation, but they offer a basis for exploration and we hypothesize that some variation on the theme could be quite effective at educating people.

References

American National Highway Traffic Safety Administration. Traffic Safety Facts 2008 Data. (Available at: http://www-nrd.nhtsa.dot.gov/Pubs/811160.PDF).

Gardner D. The Science and Politics of Fear. McClelland & Stewart 2008.

Gigerenzer G, Gaissmaier W, Kurz-Milcke E, Schwartz LM &Woloshin S. Helping Doctors and Patients Make Sense of Health Statistics Psychological Science in the Public Interest. 2008 Vol 8 (2): 53-96.

Harvard School of Public Health. Means Matter Lethality of Suicide Method (Available at: http://www.hsph.harvard.edu/means-matter/means-matter/case-fatality/index.html).

Kabat GC. Hyping Health Risks: Environmental Hazards in Daily Life and the Science of Epidemiology, Columbia University Press 2008.

Kahneman D, Slovic P & Tversky A. Judgment under Uncertainty: Heuristics and Biases. Cambridge University Press 1982.

Lee P & Hamling J. Systematic review of the relation between smokeless tobacco and cancer in Europe and North America. BMC Medicine 2009, 7:36. (Available at: http:// www.biomedcentral.com/1741-7015/7/36).

Marewski JN, Gaissmaier W & Gigerenzer G. Good judgments do not require complex cognition Cognitive Processing. 2009 Sept 27. (Available at: http://www.springerlink.com/ content/ g96m1741jvr236gv).

MMWR Weekly. Tobacco use among adults – United States 2005. Oct 27, 2006. (Available at: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5542a1.htm). Re: the 2005 figure (also has 23.9 for male smoking).

MMWR Weekly. Cigarette Smoking Among Adults – United States, 2007. November 14, 2008. (Available at: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5745a2.htm). Re: smoking men 22.3.

National Cancer Institute. Fact Sheet: Cigar smoking and cancer. Oct 27, 2009. (Available at: http://www.cancer.gov/cancertopics/factsheet/Tobacco/cigars).

Nelson W, Reyna VF, Fagerlin A, Lipkus I & Peters E. Clinical Implications of Numeracy: Theory and Practice Ann. Behav. Med. (2008) 35:261–274.

Phillips, CV, Wang W & Guenzel B. You might as well smoke; the misleading and harmful public message about smokeless tobacco. BMC Public Health 2005, 5:31. (Available at: http://www.biomedcentral.com/1471-2458/5/31).

Substance Abuse and Mental Health Services Administration. Results from the 2007 National Survey on Drug Use and Health: Detailed Tables. Rockville (MD): Substance Abuse and Mental Health Services Administration, Office of Applied Studies, 2007 . (Available at: http://www.oas.samhsa.gov/NSDUH/2k7NSDUH/tabs/Sect2peTabs1to42.htm#Tab2.31B).

Chapter 16

The fluid concept of smoking addiction

Stanton Peele

Editors' Note: The relevance of this chapter may not be immediately apparent, so it is worth making explicit. Once the harm from nicotine use is reduced to close to zero, it is difficult for anti-tobacco/nicotine activists to justify their animosity and demands for eliminating it despite people's desire to consume it. A typical first response is "but it is still addictive," neatly damning the consumption pattern while implicitly denying, without having to try to defend the point, that people consume nicotine because it is beneficial to them. A standard response is, "addiction is still a lot better than lung cancer." While this is undoubtedly true, anyone who really thinks through the claim about addiction sees that there is a far more comprehensive and deeper response, along the lines of, "what is this 'addiction' of which you speak, and what is so bad about it that it justifies interfering with public health, individual choice, free markets, etc.?" This response may produce sputtering rage, but it seldom produces an answer to either half of the question.

Peele's summary of history of the addiction concept as applied to tobacco use explains why. It has not been agreed what addiction means and whether this applies to tobacco, let alone whether a particular definition implies a condition that is inherently so bad as to warrant massive policy action to avoid it. A case can be made that some particular definition applies to tobacco/nicotine use and Peele indicates that he has long felt that smoking fell into contemporary definitions of addiction. But more important, Peele illustrates, based on the historical plasticity and political construction of the term, that merely calling something "addictive" actually tells us very little about it.

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The History of the Addiction Concept

As I have described elsewhere (Peele, 1985; 1990), although addiction is generally viewed as an irreducible scientific and biological syndrome, the concept of addiction has evolved and continues to do so. Through antiquity and into the late nineteenth and early twentieth centuries, addiction referred to the strength of people's habits in many different areas. "Addicted to" was equivalent to "had a passion for." At the beginning of the twentieth century, a medical conception of addiction was consolidated, particularly in the United States, and an addiction syndrome was outlined for narcotics, particularly heroin. In this conception, use of narcotics – unlike use of any other drug – inevitably created a deepening and irreversible physical condition marked by the impossibility of cessation without traumatic withdrawal. This notion was a departure from many centuries in which narcotics use was widespread, yet they were not regarded as causing a special state different from that resulting from the use of other substances or, indeed, non-drug activities.

Once this modern version of the addiction concept grew, it was only late in the twentieth century that the idea of addiction was broadened, in some ways coming to resemble its pre-modern medical definition. Through the 1950s, World Health Organization pharmacologists presented a clear-cut description of addiction that they assumed was linked only to narcotics. But in order to respond to the growing use of a range of illicit substances, in 1964 the World Health Organization (WHO) Expert Committee on Addiction Producing Drugs changed its name by replacing "Addiction" with "Dependence." At that time, these pharmacologists identified two kinds of drug dependence, physical and psychic, where the latter "is the most powerful of all factors involved in chronic intoxication with psychotropic drugs . . . even in the case of most intense craving and perpetuation of compulsive abuse" (see Peele, 1985, p. 20).

In the 1980s, as cocaine use became more popular, attention shifted from the classical withdrawal syndrome that marked narcotics use to intensive bursts of drug intoxication typical with cocaine. Although cocaine became the illicit substance of greatest public health concern, it was not classified as being capable of producing physical dependence. This drove pharmacologists to focus on the experiential effects that compel continued drug use in theorizing about addiction, to wit: "[That] cocaine produces no gross physiological withdrawal symptoms...demonstrate[s] that subjective experiences or symptoms other than physiological discomfort are crucial in addiction to cocaine and to other substances of abuse.... [I]nvestigators are now exploring how psychological symptoms in drug withdrawal, particularly unpleasant mood states and craving for drug euphoria, maintain chronic drug addiction" (Gavin, 1991, p. 1580). A similar expansion of the addiction concept occurred with marijuana in the 1990s.

As the 1964 WHO Report and the definition of cocaine addiction indicate, throughout the second half of the twentieth century and into the present, experts have labored to separate addiction into physical and psychological components, and just as often found this distinction unsupportable. This is illustrated in the development of the American Psychiatric Association (APA, 2000; originally published in 1994) manual, the *Diagnostic and Statistical Manual of Mental Disorders* (DSM-IV-TR). DSM-IV-TR divided substance use disorders into two categories – abuse and dependence. DSM's use of dependence to replace addiction includes what were previously regarded as both psychic and physical dependence symptoms such as a failed effort to halt or cut back use, along with tolerance and withdrawal.

In February 2010, the APA offered a draft version of DSM-V for comment (the final version of the document was scheduled for publication in May, 2013). The sections concerning addiction and substance abuse had two especially interesting elements. In the first place, the APA proposed returning to the usage "addiction," re-replacing dependence. This change was based on the idea that reliance on any powerful substance – including most medications – results in tolerance and withdrawal phenomena, but that such dependence was not the concern of a psychiatric manual. Second, DSM-V proposed to create an entirely new "behavioral addiction category" into which it (as of February 2010) placed a single activity – pathological gambling.

If any further proof were needed that the meaning and application of the addiction concept evolves, these changes surely erase them. After more than a century of medical usage, modern medicine and psychiatry are still trying to decide whether or not the term should be used, and what it includes. This of course indicates that the meaning of addiction is still up for grabs.

Neurobiological Model of Nicotine Addiction

Fitting nicotine (tobacco) within the addiction paradigm has occurred (as with cocaine) relatively recently. All of the conflicting trends of thinking about addiction manifest themselves in the case of nicotine because the designation of a substance as addictive inevitably entails social, legal, and political considerations. We have seen that both cocaine and marijuana were reclassified as addictive because public health professionals wanted to highlight the abuse of these substances. Tobacco only began to be listed as a dependence-producing substance in the 1980 DSM-III. When I asserted that smoking was addictive in my 1975 book, *Love and Addiction*, this was not customary usage. This shortsightedness occurred due to popular and scientific biases against the idea that a legal, non-intoxicating substance could be addictive.

This reluctance has now largely disappeared, and the history of the development of the nicotine-dependence (or addiction) model illustrates one phase of the modern evolution of the addiction

concept. For several decades – really only a relatively short time – pharmacologists and addiction theorists have developed a neurobiological model of nicotine addiction. In brief, this view maintains, smokers become physically habituated (develop tolerance) to nicotine at a cellular level, so that any substantial depletion in cellular nicotine impels the smoker to consume nicotine (most notably by smoking), and the failure to do so produces traumatic withdrawal. From this perspective, every significant aspect of smokers' use of tobacco – and much else of their behavior – over their lifetimes, is driven by this process, conceived as a physiological imperative.

The neurobiological model of addiction is static. It is built on the difficulty – often stated as the near impossibility – of quitting or moderation. The model does not attempt to explain how (or, more accurately, why) people cease addictions – even though such cessation is more typical than not with every type drug. The neurobiological model really has nothing to say about why smokers quit (as a majority do), for example due to the pleading of a spouse or a child. In the terms of the model, cessation is unexpected, unexplained, unpredictable, and simply falls beyond its purview or boundaries.

The History of Nicotine Dependence (Addiction) Concept

1. 1964 Surgeon General's Report, *Smoking and Health*. The treatment of the addictiveness of cigarettes in the original 1964 Surgeon General's *Smoking and Health* (SGR64; U.S. Department of Health, Education, and Welfare, 1964) can only be understood with reference to the history of the addiction concept. That is, WHO pharmacologists had not yet recognized parallels among addicting drugs and so labeled "non-narcotic substances" as "habituating," as did the 1964 SGR, which concluded that *tobacco is not addictive but only "habituating,"* as follows (p. 351):

Drug Addiction	**Drug Habituation**
Drug addiction is a state of periodic or chronic intoxication produced by the repeated consumption of a drug. Its characteristics include:	Drug habituation (habit) is a condition resulting from the repeated consumption of a drug. Its characteristics include:
1) an overpowering desire or need (compulsion) to continue taking the drug and to obtain it by any means;	1) a desire (but not a compulsion) to continue taking the drug for the sense of improved well-being which it engenders;
2) a tendency to increase the dose;	2) little or no tendency to increase the dose;
3) a psychic (psychological) and generally a physical dependence on the effects of the drug;	3) some degree of psychic dependence on the effect of the drug, but absence of physical dependence and hence of an abstinence syndrome [withdrawal]:
4) detrimental effect on the individual and on society.	4) detrimental effects, if any, primarily to the individual.

Smoking and Health claims that the main factors promoting smoking for the individual are experiential: smoking "will relax and sedate us when we are tense and excited" (p. 350). Furthermore, "Heavy cigarette smokers who inhale often describe the act as a pleasant sensory experience which constitutes for them one of the prime drives to continue to smoke." In summary, "*The habitual use of tobacco is related primarily to psychological and social drives, reinforced and perpetuated by the pharmacological actions of nicotine on the central nervous system, the latter being interpreted subjectively either as a stimulant or tranquilizing [sic] dependent upon the individual response*" (p. 354, italics added).

As a result, the SGR64 section entitled "Tobacco Habit Characterized as Habituation" (p. 351) contrasts cigarettes to physically addicting drugs for which "Proof of physical dependence requires demonstration of a characteristic and reproducible abstinence syndrome upon withdrawal of a drug or chemical which occurs spontaneously, inevitably, and *is not under control of the subject*" (p. 352, italics added). SGR64 concludes, "The tobacco habit should be characterized as an habituation rather than an addiction, in conformity with accepted World Health Organization definitions, since once established ... psychic but not physical dependence is developed.... *No characteristic abstinence syndrome is developed upon withdrawal*" (p. 354, italics added).

Given that people had been consuming tobacco for centuries, and smoking cigarettes for a century or more, why hadn't people noticed that smoking causes withdrawal? In part, what defines withdrawal had changed and the redefining of withdrawal increased the likelihood it was observed with smoking. The SGR64 assertion that smoking does not lead to withdrawal is especially notable since the publication making this claim was written to highlight the dangers of smoking. However, this omission did not mean that SGR64 did not recognize the difficulty in quitting smoking:

> Psychogenic dependence is the common denominator of all drug habits and the primary drive which leads to initiation and relapse to chronic drug use or abuse. Although *a pharmacologic drive is necessary it does not need to be a strong one or to produce profound subjective effects in order that habituation to the use of the crude material becomes a pattern of life*. Besides tobacco, the use of caffeine in coffee, tea, and cocoa is the best example in the American culture. . . . *Thus correctly designating the chronic use of tobacco as habituation rather than addiction carries with it no implication that the habit may be broken easily*. (p. 351; italics added)

Note that SGR64 placed tobacco in the same dependence-producing category as caffeine. SGR64 further noted, "Discontinuation of smoking, although possessing the difficulties attendant

upon extinction of any conditioned reflex, *is accomplished best by reinforcing factors which interrupt the psychogenic drives*. Nicotine substitutes or supplementary medications have *not* been proven to be of major benefit in breaking the habit" (p. 354, italics added). This assertion is an example of how views of addiction impact treatment – i.e., since cigarette habituation was regarded as behavioral and setting-related, nicotine replacement per se was not considered an effective treatment.

In the 1957 WHO report *Addiction Producing Drugs*, addiction was ascribed to psychologically debilitated people, and is thus highly pejorative. The image of the drug (heroin) addict was of an uncontrolled sociopath. That this did not describe most smokers also contributed to the SGR64's determination that smoking was not addictive: "It [calling smoking habituation] does, however, carry an implication concerning the basic nature of the user and this distinction should be a clear one. It is generally accepted among psychiatrists that addiction to potent drugs is based upon serious personality defects from underlying psychologic or psychiatric disorders which may become manifest in other ways if the drugs are removed. [Yet e]ven the most energetic and emotional campaigner against smoking and nicotine would find little support for the view that all those who use tobacco, coffee, tea and cocoa are in need of mental care...." (pp. 351-352). Indeed, SGR64 concludes, "Medical perspective requires recognition of significant beneficial effects of smoking primarily in the area of mental health" (p. 356).

2. 1988 Surgeon General's Report, *Nicotine Addiction*. In retrospect, that the Surgeon General a quarter century later issued a report to establish what it had specifically denied in the original SGR is a remarkable cultural phenomenon. Although SGR88 (U.S. Department of Health and Human Services, 1988) was presented as a research-based document, it has a strong cultural subtext. How societies choose to regard drugs, including defining them as addictive, is a cultural phenomenon that extends beyond specific drug effects (Peele, 1990). It was not new research discoveries that motivated SGR88, but a societal need to explain that regular smokers are addicted. Even so, SGR88 falls far short of the standard contemporary neurobiological model of nicotine addiction.

Although SGR88 contains a great deal of information to establish that smoking causes adjustments in the nervous system and that cessation causes withdrawal, in large part SGR88's task was the redefinition of addiction, now called drug dependence (p. 7):

CRITERIA FOR DRUG DEPENDENCE

Primary Criteria

Highly controlled or compulsive use
Psychoactive effects
Drug-reinforced behavior

Additional Criteria

Addictive behavior often involves

- stereotypic patterns of use
- use despite harmful effects
- relapse following abstinence
- recurrent drug cravings

Dependence-producing drugs often produce

- tolerance
- physical dependence
- pleasant (euphoriant) effects

By these criteria, smoking could have been labeled as addictive in 1964. In fact, a cultural shift had occurred in defining addiction. The key elements in this shift were:

a. SGR64, which explicitly claimed that smoking was not addictive, was now seen as not having gone far enough.

(1) Public health professionals wanted more ammunition to discourage smoking.

(2) Although smoking rates had dropped substantially since SGR64, smoking remained a significant presence in American life – that is, simply acknowledging and propagating information about smoking harms did not eliminate smoking.

b. Addiction was being redefined beyond narcotics, extending to cocaine.

c. Greater realism prevailed about the variability in responses to effects of – and usage patterns with – powerful illicit substances.

d. Legality of a substance was no longer seen to be critical to the definition or presence of addiction.

e. Experiential effects of a substance were recognized to be quite powerful even if a drug was not conventionally intoxicating.

f. Addiction was marked primarily by the simple phenomenological fact of people's difficulty in quitting.

g. Addiction was no longer limited to people regarded as having neurotic personalities.

The additional research in SGR88 demonstrating cellular nicotine regulation, nicotine withdrawal, and smoking relapse was not necessary for the purposes they were used. After all, SGR64 had already asserted what was well-known – many people smoked compulsively (consider the term "chain smoker"), quitting smoking was often difficult, and a large number of people continued smoking despite saying they wished to quit. These phenomena were sufficient

to allow people to recognize smoking was addictive (by the new broader definitions) before 1988, as I did in 1975 (Peele, 1975). Everything else was additional frosting.

SGR64 had already clearly indicated that some people were able to quit while others did not, as well as identifying the experiential "rewards" people gained from smoking. Leading to SGR88, a greater awareness had emerged that smoking patterns often resembled patterns of use of what had traditionally been classified as addictive drugs, including spontaneous cessation and similar or parallel experiential benefits. These parallels were outlined in SGR88 in Chapter V, "Tobacco Use Compared to Other Drug Dependencies." With this more realistic picture of addiction to other drugs available, it was easier to see how smoking fit the addictive paradigm.

According to SGR88, people were in large part motivated to continue using both narcotics and tobacco because they welcomed their experiential effects. Chapter VI outlined "Effects of Nicotine That May Promote Tobacco Dependence," such as enhanced attentiveness and stress reduction. Additionally, SGR88 noted strong social and contextual impacts on smoking rates, including social class and stress. It discussed the impact of the availability of information on smoking's negative consequences, such that about half of all smokers had quit, typically without treatment, and overall smoking rates had declined substantially in the U.S.

Although SGR88 labeled and defined nicotine as addictive, it did so in a way that actually contradicts the ways nicotine addiction is currently characterized by nicotine addiction experts, who claim that the process is irreversible and exclusively biological. As opposed to this "hard wired" model of addiction, note this formulation in Chapter VII of SGR88 (p. 465):

> It is evident that smoking is maintained by both pharmacologic and psychological determinants. The relative contributions of these factors are virtually impossible to separate and are likely to vary dramatically not only among individual smokers, but perhaps also within individuals at different times and stages of their smoking histories.

3. *Those Who Continue to Smoke* (DHHS, 2002). Although smoking declined following SGR64 through the 1980s, many people nonetheless continued to smoke. In 2002 the DHHS released Smoking and Tobacco Control Monograph #15, entitled *Those Who Continue to Smoke,* to address why the prevalence of smoking had not declined further. Research in the volume explored whether remaining smokers were more addicted in strictly biological terms than quitters, whether they had different biological or personality profiles, or whether cigarettes had somehow become more chemically addictive. The basic hypothesis was expressed in the subtitle to Monograph 15, "Is Achieving Abstinence Harder?"

Despite great efforts, this research volume found, "Surprisingly, none of the papers presents compelling evidence that this is the case" (p. 2). On its last page (p. 143), the Monograph states, "In summary, these trends do not suggest that the population of smokers who remains is more addicted, more resistant to cessation messages, less likely to attempt cessation, or increasingly composed of those with limited activities or poor mental health." These statements are made in the 2002 volume with a kind of surprise and regret, coming as they do from the perspective of the hardening of the neurobiological model that SRG88 had more tentatively advanced.

Ordinarily, a scientific theory is evaluated by its effectiveness – does it explain the world that we encounter, and is it useful for affecting outcomes? The neurobiological model on which the hypotheses underlying Monograph #15 were based does not succeed by these criteria. After two decades when this model has held sway, it has failed in the following ways we can identify:

• While scores of millions of people quit smoking due to concerns about cigarettes' negative health effects, a sizable group continued smoking.

• This group of remaining smokers, contrary to the neurobiological model, is *not* more addicted: "trends in measured dependence do not support the view that U.S. tobacco control efforts have led to proportionately more quitting among less dependent smokers or left behind a population of proportionally more dependent smokers." (p. 5)

• In particular, the neurobiological model would lead us to expect that older, long-term dependent smokers should be less likely to quit. The opposite is true: "Older adults represent a population in which the prevalence of smoking has declined to a very low level (10.6% in 2000) and thus comprises a group in which the most 'hardening' should have occurred, a group with the greatest potential recalcitrance to standard treatment approaches. However. . . population-targeted self-help and primary care treatments designed specifically for them produced rates quite as high, if not higher, than those same general approaches in younger populations." (p. 5)

• Despite the acceptance of the neurobiological model, "there has been a decline rather than an increase over the last two decades in the fraction of smokers smoking 25 or more cigarettes per day, and the mean number of cigarettes smoked per day as reported by smokers has declined as well." (p. 42)

Conclusion

Although the irreversible, neurobiological model of nicotine addiction is now considered ironclad, irrefutable, and destined by biology, this has never been the case, as demonstrated most clearly by key U.S. government reports that have contributed to the creation of the currently dominant model of nicotine addiction. This model – and the image of smoking that underlies it – appeared relatively recently, despite centuries of experience with tobacco. It achieved supremacy as the definition of addiction shifted, a different cultural view of tobacco came to prevail, and tobacco moved from the non-addictive category to the addictive one. However, the underlying epidemiology of tobacco use has not changed. People give up tobacco more or less as their needs dictate they should or must, like all harmful habits. All of this shows, of course, that addiction is politically and social defined, despite repeated but mistaken claims to have identified a purely biological, asocial basis for defining and recognizing addiction.

References

American Psychiatric Association. *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision*. Washington, DC, American Psychiatric Association, 2000.

American Psychiatric Association. *Diagnostic and Statistical Manual of Mental Disorders, Third Edition*. Washington DC, American Psychiatric Association, 1980.

Berridge V, Edwards G. *Opium and the People: Opiate Use in Nineteenth-Century England.* New Haven, CT, Yale University Press, 1987.

Gawin FH. Cocaine addiction: Psychology and neurophysiology. *Science* 251:1580-1586, 1991.

Peele S. *Love and Addiction.* New York, Taplinger, 1975. http://www.peele.net/lib/laa.html.

Peele S. *The Meaning of Addiction*. San Francisco, Jossey-Bass, 1998 (originally published 1985).

Peele S. Addiction as a cultural concept. *Annals of the New York Academy of Sciences* 602:205-220, 1990.

Peele S, DeGrandpre RJ. Cocaine and the concept of addiction: Environmental factors in drug compulsions. *Addiction Research* 6:235-263, 1988. http://www.peele.net/lib/cocaine.html

Substance Abuse and Mental Health Services Administration. *2007 National Survey on Drug Use & Health.* Rockville, MD, SAMHSA's Office of Applied Studies, 2008.

U.S. Department of Health, Education, and Welfare. *Smoking and Health* (Public Health Service Publication No. 1103). Washington, DC, USGPO, 1964.

U.S. Department of Health and Human Services. *The Health Consequences of Smoking; Nicotine Addiction*. Rockville, MD, Office on Smoking and Health, Rockville MD, 1988.

U.S. Department of Health and Human Services. *Those Who Continue to Smoke* (Monograph 15). Rockville, MD: Smoking and Tobacco Control Series, 2002.

Wilson MC, Grant BF, Colliver JD, Glantz MD, Stinson FS. Prevalence of marijuana use disorders in the United States: 1991-1992 and 2001- 2002. *Journal of the American Medical Association* 291:2114-2121, 2004.

World Health Organization Expert Committee on Mental Health. *Addiction Producing Drugs: 7th Report of the WHO Expert Committee*. Geneva: World Health Organization, 1957.

World Health Organization. *Expert Committee on Dependence Producing Drugs, Thirteenth Report*. Geneva, World Health Organization, 1964.

World Health Organization. *Expert Committee On Drugs Liable To Produce Addiction, Report on the Second Session*. Geneva, World Health Organization, 1950.

Chapter 17

Electronic cigarettes are the tobacco harm reduction phenomenon of the year - but will they survive?

Paul L. Bergen & Courtney E. Heffernan

Probably the most important occurrences in tobacco harm reduction (THR) for the period covered by this yearbook relate to the emergence of electronic cigarettes, also known as e-cigarettes, or personal vaporizers. While millions of words about e-cigarettes appeared online over the last year or two, it is difficult to find anything that serves as a primer on the topic and a recounting of recent events. Because the topic is so important, we chose to create this original analysis for the book to fill that gap.

As described in more detail below, the e-cigarette is typically a cigarette shaped device that aerosolizes nicotine and delivers it via a propylene glycol vapor. Though it mimics smoking, it is a combustion-free source of nicotine, making it a candidate for tobacco harm reduction given that smoke has been associated with almost all of the harm from smoking (Phillips & Heavner 2009, Royal College of Physicians 2007, Rodu 1994). Based on currently available evidence, the e-cigarette appears to cause only a fraction of the risk of smoking, but in many other respects seems to be quite similar. In the paragraphs that follow, a brief history of the e-cigarette, along with its merits and limitations for THR will be discussed.

A brief history of losing the combustion but keeping the cylinder

In general, variants on cigarettes have been based on substituting for or modifying the smoke itself, filtering the smoke before it is inhaled, or removing the smoke altogether.

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One of the earlier versions of an alternative cigarette states within the patent application:

> "It is well known that in the burning of tobacco in smoking, …many products or compounds are formed, which have a harmful or irritating effect upon the human organs generally, and particularly on the mucous membrane in the nasal passage and respiratory organs….All of the usual disadvantageous characteristics of smoking have been eliminated by my method of smoking. It is not necessary for the user to carry on any combustion whatsoever." -Joseph Dalinda (1936).

Significantly, the underlying tenets of tobacco harm reduction were evident to Dalinda as early as 1932. Dalinda's concept was to process smoke into a vapor, which was then was compressed into cylinders that the user would draw on. It is difficult to know if this variation would have been better than traditional cigarettes because the smoke was simply compressed and stored to be inhaled at a later point in time. However, the point remains the same: there was a strong sense even eight decades ago that the products of combustion are the main source of the risk. (However, even now, among the general population, this knowledge remains largely unknown.)

In 1958, another patent was filed which described a smokeless cigarette which delivered nicotine and smoke flavor via rupturing cells using finger pressure around the cigarette like tube (H2O 1972). This device was designed so that, if so desired, a tube of tobacco could be put into one end of it and lit, which would add the smell of burning tobacco to the experience of this version of smoking. The design ensured, however, that the smoker would not actually be able to inhale that smoke; it would burn but the smoker would only receive the products released by rupturing the cells.

There were a few other examples of nicotine delivering smokeless cigarettes. One product, which is currently promoted by the airline RyanAir, is a cigarette-like tube impregnated with nicotine which the user obtains by simply drawing air through the hollow center (Gordon 2009, JetSet 2010, Similar 2010). This does not give any real sensory feedback and the nicotine is not evident to many users.[1] A similar product consists of a hollow tube with a nicotine-impregnated tip (Valadi 2008).

Tobacco companies have sought similar alternatives as well, and no doubt still do. To date, the most prominent product from the industry was the RJ Reynold's Premier cigarette, later renamed Eclipse, which eliminated combustion by substituting the heating of tobacco pellets (PBS 2001). The product had a poor reception and while it is still available it has never gained much of a following. Phillip Morris had a similar product called Accord (California 2002). Another

[1] While it may ease airplane trips for smokers (though our own experiments did not produce noticeable nicotine delivery) and create not even a puff of fog to disturb those nearby, the lack of vapor partially eliminates part of the advantage of e-cigarettes compared to smokeless tobacco or nicotine lozenges.

variation called Heatbar from Phillip Morris, also not widely available, heats rather than burns tobacco and delivers an aerosol (O'Connell 2008).

Apart from removing combustion from the process, the common feature of all these products is that their construction is meant to provide some of the benefits of smoking beyond simple drug delivery, in particular the learned pleasure of drawing a gaseous volume in and out of the mouth, the accompanying time-and-motion experience, and the easy control over dosing that are absent from smokeless tobacco and other products.

There have also been a few attempts at keeping the combustion while claiming some health advantage, though nothing remotely successful. One awkward variation from 2007 (Baker 2009) encapsulated a cigarette which burned within a chamber from which the smoker would inhale and also into which they would exhale, probably doing nothing to reduce harm to the smoker, but eliminating second-hand smoke. Perhaps the most bizarre development comes from Japan where a group is attempting to create a tobacco plant that is nicotine free in the hopes of removing the chemical addictive component of smoking (Vieru 2009). Perhaps motivated by the misperception that nicotine is highly harmful, or perhaps by those who worry more about addiction than actual harm, this seems to offer no health benefits and for smokers who enjoy smoking more than the nicotine itself, or who only find pleasure in the act of smoking, this would allay none of the harm nor would it affect their likelihood of continuing to smoke.

Development of the product we now think of as the e-cigarette is generally attributed to Hon Lik at the Chinese company Ruyan in 2004 (Hon 2007), though there are currently intellectual property disputes.

The current product

Hon, who states he was motivated by the premature smoking related lung cancer death of his father (Demick 2009), pioneered production of the product which was copied by other Chinese manufacturers[2]. The resulting proliferation of brands is now widely available for delivery from many online merchants, and on a few store shelves in some countries.

Some commercially available e-cigarettes look like regular cigarettes, cigars or pipes, while others look more like pens or nondescript tubes. Their battery-powered atomizer (i.e., a hot wire that evaporates a liquid) heats the e-liquid, a solution usually containing nicotine, flavoring, water and propylene glycol or vegetable glycerine[3]. This produces a fine aerosol or vapor that is taken

[2] Currently there appears to be no commercial manufacture outside China.

[3] Vegetable glycerine (a marketing term for propan-1,2,3-triol) is considerably less common in marketed products and not as well studied. It creates a denser vapor and is thus preferred by many users; it is also an alternative for those sensitive to propylene glycol.

into the mouth or inhaled. Many brands sell variations with different nicotine concentrations, and thus deliver varying amounts of nicotine per puff, and even offer non-nicotine versions. Some brands come in a variety of flavors, though controversy about flavoring caused some companies, particularly including the two best-known brands (NJOY and Ruyan), to restrict flavoring[4] to a bland imitation of tobacco smoke. Some products are self-contained and disposable, while others disassemble and users can buy replacement cartridges or "e-liquid" from which they can refill cartridges. There are users who mix their own e-liquid from commercially available components (reagent-grade nicotine is inexpensive, though unlike the diluted form in the e-cigarettes is quite dangerous to handle).

E-smoking, or "vaping" (a shortening of what would be the analog to "smoking", "vaporing") as some aficionados have advocated calling it, is almost physically identical to cigarette smoking. Drawing on the end will activate the device which turns on an LED resembling a lit end, and produces vapor that is then inhaled. One difference between traditional smoking and e-smoking is that to get comparable densities of vapor requires more effort on the part of the e-smoker. No fire is created and the smoke-like vapor has almost no smell and dissipates more quickly than cigarette smoke. (For more details on the product and how it works see Electronic Cigarette Review 2008; Image courtesy J.Dunworth at E.CigaretteDirect.co.uk.)

Product reception

E-cigarettes have spread rapidly to many parts of the world. However, because there are so many small producers and distributors, and because regulations vary so much from place to place, there are no good estimates of either the user population or how many units have been sold.[5]

The evidence strongly suggests that e-cigarettes are much safer than cigarettes, probably not too different from Western smokeless tobacco products, which have been shown to be roughly 1/100th as risky as smoking. Pharmaceutical nicotine products are generally believed to be similarly low-risk and e-cigarettes are basically a variation on those, albeit with better delivery. However, several factors combine to keep their legal status tenuous while cigarettes remain freely available. Legalistically, an e-cigarette can be called a "novel drug

[4] Other than menthol.

[5] A partial assay of the commercial sales of a few major distributors can be found in United States District Court for the District of Columbia 2010.

delivery device", thus subjecting it the scrutiny of pharmaceutical regulators. Since those regulators typically have a very narrow and faulty understanding of scientific epistemology they demand expensive studies that no one in the currently atomized industry can afford. Thousands of people testifying that they stopped smoking by switching to e-cigarettes is far better information than a clinical trial could ever provide, but that is not generally understood by regulators. Moreover, those regulators are generally incapable of considering the lifestyle advantages of a product (e-cigarettes help people not just to quit smoking, but also to keep enjoying much of what they liked about smoking), especially when it competes with the cessation products made by their major constituents in the pharmaceutical industry.

More practically, it is simply easier to ban a new product with currently limited popularity. It could reasonably be argued that the current production situation[6] creates unacceptable quality control risks.

E-cigarettes have already been banned in many countries and are likely to be banned in more. But none of the bans seem to be based on demanding better quality control, and few seem to be tied to any health claims at all. Rather, they seem more to result from "not invented here" syndrome: Perhaps this is too cynical, but it seems that had these products been invented by white Western anti-smoking activists (see, e.g., Niconovum) and given over to the control of wealthy Western institutions (physicians and pharmaceutical companies, or perhaps even tobacco companies), they probably would have been embraced as a miracle and rushed through for approval. But because they were created by a Chinese engineer and supported by a grass roots education and distribution network, they trigger most every imaginable institutionalized knee-jerk.

In some instances, for example, in Canada, there was a perfunctory ban with no serious discussion or justification (Health Canada 2009a). In March of 2009, the government agency Health Canada banned the sale and purchase, though not the use of e-cigarettes, and designated the product as "under consideration". Since that date there has been no further information about whether this might change. Procedures are provided for introducing the products for official consideration (Health Canada 2009b), however the language implies insurmountable barriers. Extensive and lengthy testing, though manageable for a large pharmaceutical firm with clear intellectual property rights, is not practical for an individual electronic cigarette company in a competitive market.

[6] The only known provenance for many of these products is "made in a barely regulated factory somewhere in China".

In other jurisdictions authorities are being more thoughtful, though it is possible the results may be similar. In Britain, e-cigarettes are still fully available but the Medicines and Healthcare products Regulatory Agency has opened a consultation on the further status and has already indicated that it desires to impose restrictions on the product that could seriously erode any incentive for suppliers to remain in the market (MHRA 2010). However, the quasi-governmental National Institute for Clinical Excellence Citizen Council (NICE 2009) and the NGO Action on Smoking and Health-UK (ASH 2009) have openly advocated for e-cigarettes as vectors of harm reduction.

In the United States, the issue is more complicated. The Food and Drug Administration, which has the authority to regulate and ban drug delivery devices, as well as the authority to regulate (but not ban) tobacco products launched a propaganda broadside against e-cigarettes (Rodu 2009; Siegel 2009; Whelan 2009). Many major health NGOs, which in the U.S. are basically all dedicated to the anti-tobacco extremist position regardless of actual health concerns, have not only come out against electronic cigarettes, but have made claims that they may be even more dangerous than cigarettes. These include the American Cancer Society and, in a bit of almost comedic irony, the American Lung Association (ACS 2009) as well as many of anti-smoking groups such as ASH-US (Banzhaf 2009). At the time of this writing, only one major American health NGO, the American Association of Public Health Physicians (Nitzkin & Kevin 2009) has come out in support of the product as a tobacco alternative.

The situation in America is still far from settled. While the FDA had been seizing shipments of electronic cigarettes, in January of 2010 a federal court ruling stated that while the devices might in the future be interdicted under the purview of the new tobacco division, the drug division which had been the agency doing the confiscating did not have the required authority (Wilbur & Layton 2010; U.S. District Court 2010). The FDA has since appealed and won a stay, which has reinstated their ability to halt shipments until September 2010 (AAFP 2010).

At the same time, the U.S. appears to have the most vociferous user groups which, aided by that society's ethos of resisting arbitrary government authority, may mobilize to keep these alternative products available. However, it is difficult to tell whether e-cigarettes will remain legal, though it seems safe to predict that any ban will work about as well as the prohibition against cannabis use. Britain also seems to have fairly substantial and active consumer groups unlike in Canada, where not only is the population smaller and less inclined to resist government authority, but the ban was in place before these groups had the same amount of time to develop.

Electronic cigarettes have already been banned in Australia, Brazil, Hong Kong, Jordan, Mexico, Panama, Singapore, and Thailand. In some countries, only personal use is legal and in some

others they require a prescription. It is not clear how widely they are used in these countries, in spite of the bans, or elsewhere

E-cigarettes as a smoking alternative

A contentious issue is whether e-cigarettes can be properly characterized as smoking cessation devices. For instance, the Electronic Cigarette Association (2009) asks its members not to make any cessation, health or safety claims despite making health and safety claims themselves. To be fair, this is probably in response to this unregulated small business explosion in which some individuals were making other health claims that could not be supported, but there are concerns over legal definitions. In common language, if someone has stopped smoking by switching to e-cigarettes then it was a successful smoking cessation aid. However, legally, in many jurisdictions this phrase requires extensive testing which could not be completed for years even if it were funded and started. It seems that if e-cigarettes are effective cessation devices, the most likely way for them to survive in the market, and to be actually used as cessation devices, is for them to be simply promoted as devices for pleasure.

In general, e-cigarettes are safer for both smokers and others, and established cigarette smokers find them to be a satisfying substitute. For those not familiar with the debate, the basic arguments in favor of widespread availability and promotion of e-cigarettes as an alternative for smokers are:

1. A safer nicotine delivery

Murray Laugesen in New Zealand has done considerable testing and believes the e-cigarette to be "100 to 1000 times safer than a tobacco cigarette" (Laugesen 2009). Though many of us estimate that nicotine alone might be 1/100th as bad as smoking, and while the more optimistic end of this range might not be attainable, there is currently no reason to question the other end of the range. Testing of various versions of the liquid constituent in e-cigarettes has given no indication of anything harmful (Alliance 2009; Laugesen 2008; Lerut 2007; Valence & Ellicott 2008). The one study presented with claims that it showed harm, the FDA study, really showed no such thing and has been roundly criticized by experts in the field (Kiklas 2009). No reports of substantially adverse reactions have been reported to date.

2. Smokers find product attractive and smokers are switching

Though good data is hard to find (though there is some published research: Bullen et al. 2010, or see Heavner et al. 2010 in this volume), extensive anecdotal evidence gleaned from e-cigarette user forums, consumer testimonials and letters in response to articles in the press (see e.g., Godshall's, 2010, journalistic research in this volume[7]), indicates that users identify almost exclusively as former smokers. Despite nost e-smokers having a history of unsuccessful quit

[7] See Bill Godshall's report on his experiences at VapeFest 2010 in this volume.

attempts, most report having managed to switch over entirely away from smoking cigarettes (Care2 2010; Heavner et al 2010).

3. Do not produce second hand smoke or fire

Many non-smokers and smokers are concerned about the effects of second hand smoke or other environmental effects such as litter or unintended fires, and this is a device that cannot produce either.

4. Are cheaper in the long run

Though the initial investment in the non-disposable products may seem high, replacement cartridges are inexpensive and within a few weeks, vaping becomes very much cheaper than smoking anywhere with cigarette excise taxes.[8]

5. Will undermine the black market given the severity of anti-tobacco regulations

Canadian cigarette taxes are so high that roughly half of all cigarettes sold are black market. Recently Finland floated a plan to ban all smoking in the near future (Henley 2010). Few other nations have been as aggressive but almost all regularly introduce regulations to further limit tobacco availability and to increase the cost of smoking. Black markets flourish under these conditions. E-cigarettes could undercut the need for smokers to avail themselves of cheaper illicit markets. Of course when e-cigarettes are themselves banned (or if they were taxed highly), a black market for them will likely develop, though the profit provided for criminal enterprises by most prohibitions would be reduced because e-cigarette users can buy replacement e-liquid (often legally even after product bans) or even manufacture their own at a low cost.

Attacks on e-cigarettes

For those new to the debate, the basic arguments against widespread availability and promotion of e-cigarettes are:

1. No quality control regulation

The main legitimate concern with this product is a lack of quality control in manufacturing. The ease of production and the notorious lack of effective regulation in China means that many manufacturers are, without serious oversight, making products that deliver chemicals into the body. The controversial FDA study (Westenberger 2009) turned up some evidence of quality control problems, though nothing harmful. A few companies have had independent analyses run, and these have demonstrated the purity of those particular products, but a bad actor or a bad batch could easily result in acutely dangerous products reaching consumers before anyone realized it. Voluntary trade association and consumer groups have made some attempt to check on quality control, but they cannot effectively substitute for government oversight. Unfortunately, one of

[8] Though most of the disparity stems from the high taxes on cigarettes, this is only a price difference for the consumer, not a real resource cost difference from a social cost-benefit perspective.

the downsides of banning something is that it then becomes nearly impossible to regulate it, so governments that have pursued bans have abdicated their responsibility to regulate.

2. Lack of epidemiology

While there is no particular reason to believe that e-cigarettes cause any harm not caused by the nicotine, there is some uncertainty about the effects of regular long term propylene glycol inhalation. This is a known substance which has been well studied for short term high exposure (in one case being considered safe as a delivery medium for lung transplant patients, Wang et al 2007) and in that regard has been found to be of little concern but there are no good long term population data (CHEM 2001)[9].

3. Handling danger

The one certain safety issue concerns people using refillable versions and handling liquid nicotine. Though most people purchase replacement cartridges for their e-cigarettes, some buy either e-liquid (ready refill solution) or liquid nicotine and the other chemical ingredients and create their own solutions. While the e-liquid is weak enough to cause little danger (though it could be a swallowing hazard for children) it is possible to get an unpleasant high dose through dermal absorption. Pure nicotine is quite dangerous and (unlike any actual nicotine product) presents risks of a fatal overdose, even from skin contact.

Other arguments presented against e-cigarettes, however, are groundless.

4. It is as dangerous as cigarette smoking or is a source of second hand smoke

Representatives of some health organizations and some politicians have argued that e-cigarettes are as dangerous as smoking both for smokers and others around them. Typically there is little elaboration to this claim and it is difficult to understand any basis for it. The amount of nicotine put into the air is utterly trivial and the propylene glycol is far less than there might be in a club or theater that is simulating fog. Since there is nothing else, there simply is no second hand smoke or second hand anything of consequence.

5. It is addictive, a gateway to smoking, and/or encourages dual use, and undermines smoke free regulations

These are the stock arguments against any THR product (though, strangely enough, seldom mentioned for pharmaceutical products). If the ill-defined term "addictive" is assumed to describe nicotine use via cigarettes then it will include THR products also. The best response to opposition based on addictiveness is simply "so what?" What exactly is the problem with being

[9] Propylene glycol has been suggested as a healthier smoke substitute for use in a realistic artificial fireplace product, the aim being to reduce the harm from that common source of airborne particulate. (Swiatosz 1982).

addicted to a very low-risk activity? Moreover, if someone is going to be addicted to nicotine, it is better they use a low-risk delivery method.

There is a claim that people who have never used or would have used nicotine are attracted to the idea of safe smoking with e-cigarettes, and then will, for some reason, switch to smoking. This is a baseless proposition, and not just because the evidence shows that nonsmokers do not seem interested in adopting e-cigarettes. The claim would mean that non-nicotine-users, those who avoided smoking, would be attracted because the products are low risk but then somehow lose this motivation and switch to smoking. It also means that they will switch from a product with few public restrictions to one which is both more difficult to accommodate and which is considered more dangerous to others in the vicinity.

Others hold the belief that users will not switch from smoking but will only use this as a bridging behavior for when circumstances do not allow them to smoke. In other words, all this product would do is extend the time in which nicotine can be used, and get around barriers that were put in place to curb the behavior. This is conceivably true, though again such use is not what the evidence suggests is happening. In any case, it is only objectionable if it is considered a proper goal of smoking place restrictions to intentionally make smokers unhappy, an ethically dubious claim that is addressed elsewhere in this book.

The objection is that this product will undermine the progress toward a smoke, tobacco and nicotine free society, which some activists make clear that they want, though there is not actually widespread support for this. There is a feeling that if people can smoke e-cigarettes in non smoking areas that that somehow invalidates that restriction. This argument has also been used for smokeless tobacco products but has not been applied to pharmaceutical nicotine.

Others are concerned that confusion could arise from someone misconstruing vaping for smoking and either becoming upset over the perceived breach of non-smoking regulations.

> Furthermore, the inability to easily distinguish between a normal and an e-cigarette leads to confusion and upset amongst the public which can give rise to complaints as they believe that breaches of the legislation are taking place, and they are being subjected to cigarette smoke whilst in a no-smoking area. The use of e-cigarettes in premises where the law prohibits smoking could well encourage people to smoke, either in the mistaken belief that the law does not apply or is not being enforced, or that individuals concerned will not be noticed and reported. There is also real potential for public order offences being committed where individuals are approached and asked or told to stop and this is challenged (from Allen, Jukes & Gainsford 2009).

But arguing to ban something on the basis of it nor being but resembling an illicit activity is not likely to be considered legitimate (Bergen 2009).

6. Youth-friendly

This is another stock argument against THR products that seems to ignore the much greater allure of smoking as compared to sucking on a strange device that does not seem very bold, tough, or sexy. It has been argued that these are available for youths to purchase and come in youth friendly flavors.

> A big concern of health experts is that e-cigarettes are marketed and sold to young people. The devices are available online and in shopping malls and could be a gateway to smoking actual cigarettes, they noted.
>
> "It looks like a cigarette, and it's used like a cigarette," Dr. Jonathan Winickoff, chairman of the American Academy of Pediatrics' tobacco consortium, said during the news conference. "It's marketed as a cigarette, and thus has the potential to normalize and cue smoking behavior."
>
> Winickoff noted that cartridges for e-cigarettes are available in flavors, including chocolate, mint and bubblegum. "Past experience suggests that these products may be particularly appealing to young people," he said. (Reinberg 2009)

Some of the e-cigarette associations have actively campaigned for strict age supervision of product sales and some suppliers have removed their own flavored versions in anticipation of either youth attraction or to remove this source of future complaints.[10]

In conclusion

Many smokers are finding this almost certainly low-risk alternative one of the most satisfying and, to varying degrees, available. In mimicking the essential attractions of traditional smoking, they provide a welcome change from failed attempts to become nicotine-abstinent, or successful quitting that leaves people with dramatically lowered welfare. It overcomes shortfalls of pharmaceutical nicotine products which are not optimized for long-term use and do not even work very well for transitioning to abstinence (Chapman & MacKenzie 2010).

As with any alternative to smoking that exists outside dominant institutions and does not focus on purifying everyone completely, e-cigarettes face a great challenge. All the powerful institutions involved with tobacco policy (government agencies, major NGOs, competing companies) seem to oppose their existence, caring little about their public health benefits. These products seem to

[10] The last few years have seen an increasingly popular movement against flavored tobacco products as being specifically designed to attract new and younger users. Rather than seen as increasing product diversity and attractiveness for adults who might prefer new flavors, it is seen as a nefarious plot of Big Tobacco. These claims, like many others, are presumably mostly a tactical maneuver intended to make the products less appealing to everyone, thus lowering the welfare of users.

bother anti-tobacco extremists, who have been quite successful in their tactics of demonizing and misleading people about nicotine, even more than low-risk inter-oral products. Presumably they fear that clean modern products that prompts learning and a devoted following is a threat to their propaganda. It tends to make nicotine consumption seem less like the "moral" or "values" issue they wish to make it, and it becomes a rational consumption decision by adults. However, unlike with smokeless tobacco in most places, it is conceivable that educated nicotine users who want to engage in THR might be physically prevented from getting this low risk alterative.

References

AAFP. FDA fighting for authority to regulate electronic cigarettes. Mar 2, 2010. (http://www.aafp.org/online/en/home/publications/news/news-now/health-of-the-public/20100302e-cig-fda.html).

Action on Smoking and Health (UK). ASH briefing on Electronic Cigarettes, October 2009 (http://www.ash.org.uk/files/documents/ASH_715.pdf).

Allen D, Jukes G & Gainsford R. (http://www.cieh.org/uploadedFiles/Furniture/ Policy/ Letter_to_DH _about _electronic_cigarettes_Sept_2009.pdf).

Alliance Technologies. Chemical composition of "Instead" electronic cigarette juice and vapor. 2009. (http://www.e-cig.org/pdfs/Instead-ELiquid-Report.pdf)

American Cancer Society. Statement of the American Cancer Society Cancer Action Network, American Heart Association, American Lung Association and the Campaign for Tobacco-Free Kids 2009. (http://news.prnewswire.com/DisplayReleaseContent.aspx? ACCT= 104&STORY= /www/story/03-24-2009/0004993931&EDATE=)

Baker, M. United States Application US20090056728 Smokeless smoker. March 5, 2009. (http://www.freepatentsonline.com/20090056728.pdf).

Banzhaf J. ASH Seeks Regulation of E-Cigarettes Action on Smoking and Health (US) (http://ash.org/ecigpetition).

Bergen P. Proposed UK legislation based on perception rather than reality. Tobacco Harm Reduction: News & Opinions. Dec 30, 2009. (http://smokles.wordpress.com/2009/ 12/30/ proposed-uk-legislation-based-on-perception-rather-than-reality/).

Bullen C, ,McRobbie H, Thornley S, Glover M, Lin R & Laugesen M. Effect of an electronic nicotine delivery device (e cigarette) on desire to smoke and withdrawal, user preferences and nicotine delivery: randomized cross-over trial. Tobacco Control 2010:19:98-103.

California Tobacco-Related Disease Research Program for the National Conference on Tobacco or Health. Summary of New Tobacco Products. November 2002. (http:// ncth.confex.com/ ncth/ viewHandout.epl?uploadid=101).

Care2. Keep electronic cigarettes available. 2010. (http://www.thepetitionsite.com/ 1/keep-life-saving-electronic-cigarettes-available#signatures).

Chapman S & MacKenzie R. The Global Research Neglect of Unassisted Smoking Cessation: Causes and Consequences. PLoS Med 7(2): e1000216. (http:// www.plosmedicine.org/ article/ info:doi/ 10.1371/ journal.pmed.1000216).

CHEM. \1,2-DIHYDROXYPROPANE CAS:57-55-6SIDS Initial Assessment Report for 11th SIAM (USA, January 23-26, 2001) (http://www.chem.unep.ch/irptc/sids/ OECDSIDS/ 57-55-6.pdf.)

Dalinda J. United States Patent US2051030 Method and Apparatus for Smoking. August 18, 1936. (http://www.freepatentsonline.com/2051030.pdf).

Demick, B. A high-tech approach to getting a nicotine fix The electronic cigarette – a gadget that looks like the real thing and delivers nicotine without smoke – is established in China, and companies are taking aim at the U.S. market. LA Times April 25, 2009. (http:// articles.latimes.com/2009/apr/25/world/fg-china-cigarettes25).

Electronic Cigarette Association. (http://www.ecassoc.org/downloads/ The_Facts_About_ Electronic_Cigarettes.pdf).

Electronic Cigarette Review. Electronic Cigarettes FAQ Dec - 21 - 2008 (http:// www.electroniccigarettereview.com/faq/#How do electronic smoking devices work?.)

Gordon S, Ryanair introduces smokeless cigarettes on its flights. MialOnline Sept 22, 2009. (http://www.dailymail.co.uk/travel/article-1215233/Ryanair-introduces-smokeless-cigarettes-flights.html#ixzz0k9NlOZUh).

The H-2-O Filter Corporation. United States Patent 3683936 Substitute for a smoking article such as a cigarette 08/15/1972. (http://www.freepatentsonline.com/ 3683936.html).

Health Canada. Health Canada Advises Canadians Not to Use Electronic Cigarettes Advisory 2009-53 March 27, 2009. (http://www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/_2009/ 2009_53-eng.php)

Health Canada. To All Persons Interested in Importing, Advertising or Selling Electronic Smoking Products in Canada March 27, 2009. (http://www.hc-sc.gc.ca/dhp-mps/prodpharma/ applic-demande/pol/notice_avis_e-cig-eng.php).

Heavner K, Dunworth J, Bergen PL, Nissen C & Phillips CV. Electronic cigarettes (e-cigarettes) as potential tobacco harm reduction products: Results of an online survey of e-cigarette users.

Henley P. Finland aims to stub out smoking habit. BBC 15Feb 2010. (http:// news.bbc. co.uk/ 2/hi/europe/8459947.stm)

Hon L. Electronic Atomization Cigarette United States Patent Application 20070267031 11/22/2007. (http://www.freepatentsonline.com/y2007/0267031.html)

JetSetCD. Cigarettes Designed for In-Flight Smoking: Ryanair's 'Smokeless' Packs. Jaunted March 17, 2010 (http://www.jaunted.com/story/2010/3/17/02014/4366/travel/ Cigarettes+Designed +for+In-Flight+Smoking:+Ryanair's+'Smokeless'+Packs).

Kiklas TR. Prominent Public Health Physicians and Tobacco Researchers Expose Double Standard in the FDA's Recent Study of Electronic Cigarettes and Challenge the FDA's Alarmist Attitude Toward the Devices. July 27, 2009 (http://www.standardnewswire.com/ news/ 162574365.html).

Laugesen M. Safety report on the Ruyan e-cigarette cartridge and inhaled aerosol. Health New Zealand. 2008. (http://www.healthnz.co.nz/RuyanCartridgeReport30-Oct-08.pdf).

Laugesen M. E-Cigarette Interview with Dr Murray Laugesen. May 26, 2009. (http:// www.ecigarettedirect.co.uk/interviews/murray-interview.html).

Lerut H. Supersmoker Expert Report. Catholic University, Leuven. 2007. (http:// tobaccoharmreduction.org/supersmoker.pdf).

MHRA. Public consultation (MLX 364): The regulation of nicotine containing products (NCPs). (http://www.mhra.gov.uk/Publications/Consultations/Medicinesconsultations/ MLXs/ CON065617).

NICE Report on NICE Citizens Council Meeting: Smoking and harm reduction October 15-17, 2009. (www.nice.org.uk/media/756/7F/CCReportOnHarmReduction.pdf).

Nitzkin J & Sherin K. Don't Write Off Current Smokers. Aug 29, 2009. (http:// www.ecassoc.org/downloads/AAPHP.pdf).

O'Connell V. Philip Morris Readies Aggressive Global Push Division Spinoff Enables Blitz of New Products; High-Tar Smokes in Asia . Leader US Jan 29, 2008. (http:// online.wsj.com/ article/SB120156034185223519.html).

PBS. "Search for a safe cigarette" Airdate: October 2, 2001) (http:// www.pbs.org/ wgbh/nova/transcripts/2810cigarette.html

Phillips CV, Heavner KK. Smokeless Tobacco: the Epidemiology and Politics of Harm. Biomarkers. 2009; 14(S1): 79-84.

Reinberg S. E-Cigarettes Pose a Health Hazard, FDA Warns Agency says testing shows devices contain carcinogens, other toxins: July 22, 2009 (http://www.usnews.com/ health/ family-health/childrens-health/articles/2009/07/22/e-cigarettes-pose-a-health-hazard-fda-warns.html).

Rodu B. An alternative approach to smoking control. The American Journal of the Medical Sciences, Volume 308, pp 32-34, 1994

Rodu B. The FDA Crusade Against E-Cigarettes. Tobacco Truth July 24, 2009. (http://rodutobaccotruth.blogspot.com/2009/07/fda-crusade-against-e-cigarettes.html).

Royal College of Physicians. Harm reduction in nicotine addiction: helping people who can't quit. A report by the Tobacco Advisory Group of the Royal College of Physicians. London: RCP, 2007 (http://www.rcplondon.ac.uk/pubs/contents/bbc2aedc-87f7-4117-9ada-7cdb21d9291.pdf)

Siegel M. FDA Quoted as Stating that It's Not Sure Cigarette Smoking is Any More Dangerous than the Use of Electronic Cigarettes. Rest of the Story Oct 1, 2009. (http:// tobaccoanalysis.blogspot.com/2009/10/fda-quoted-as-stating-that-its-not-sure.html).

Similar. 2010. (http://www.similarshop.eu/commerce/smokelesscigarettes/ company/ smokeless.jsf)

Swiatosz E. Electrically heated non-toxic smoke generator United States Patent 4349723 09/14/1982. (http://www.freepatentsonline.com/4349723.html).

United States District Court for the District of Columbia Smoking Everywhere, Inc.,) Plaintiff, and Sottera, Inc., d/b/a NJOY, Intervenor-Plaintiff, v. U.S. Food and Drug Administration, et aI., Defendants. tv-) Civil Case No. 09-771 (RJL) Memorandum Opinion (January H, 2010) [# 2 and 24] Plaintiff. (http://www.e-cig.org/pdfs/FDA-Lawsuit-Ruling.pdf).

Valadi M. United States Patent Application 20080000487 Smokeless Cigarette. 01/03/2008. (http://www.freepatentsonline.com/y2008/0000487.html).

Valence C & Ellicott M. Analysis of chemical components from high medium and low nicotine cartridges. LPD Laboratory Services, Blackburn Microtech Solutions. 2008. (http:// tobaccoharmreduction.org/tox1.pdf).

Vieru T. Japan to Create Nicotine-Free Tobacco. Softpedia Jan 22, 2009 (http:// news.softpedia.com/ news/Japan-to-Create-Nicotine-Free-Tobacco-102661.shtml).

Wang T, Noonberg S, Steigerwalt R, Lynch M, Kovelesky RA, Rodríguez CA, Sprugel K & Turner N. Preclinical safety evaluation of inhaled cyclosporine in propylene glycol. Journal of Aerosol Medicine. December 2007, 20(4): 417-428. (http://www.liebertonline.com/ doi/ abs/ 10.1089/ jam.2007.0626).

Westenberger, BJ. Evaluation of e-cigarettes. (http://www.fda.gov/downloads/ Drugs/ ScienceResearch/UCM173250.pdf))

Whelan E. FDA smoke screen on e-cigarettes. Washington Times August 6, 2009. (http:// www.washingtontimes.com/news/2009/aug/06/fda-smoke-screen-on-e-cigarettes/).

Wilbur DQ & Layton L. FDA can't block importing of electronic cigarettes. WashingtonTimes Jan 15, 2010. (http://www.washingtonpost.com/wp-dyn/content/article/2010/01/14/ AR2010011402995.html).

Chapter 18

VapeFest 2010: A report from a conference of electronic cigarette supporters

Bill Godshall

Editors' Note: The following report is rather informal compared to the other documents in this volume but it has unique value. Godshall offers a cross between journalistic report, casual anthropology, and personal narrative about a grassroots organization, being a new e-cigarette user, and the experience of being subjected to a full day of enthusiastic "vaping" within an enclosed space.

This is a report from the front lines – a direct experience with user activism from the e-cigarette or vaper camp. The gathering can be characterized as a user group, but it is also a meeting of people who were able to quit smoking successfully. It is part of a grassroots harm reduction movement based simply on individuals having the right information and making a smart choice to switch to a safer product, without the need for more aggressive interventions. For those of us interested in harm reduction, this shows promise on a number of fronts. Above all, it shows that a fairly destructive pattern of drug use can, with very little cost to the user or society, be transformed into net-beneficial indulgence in a mildly risky activity. Moreover, self-reports suggest this group includes many among the most recalcitrant smokers, and thus their approach might offer unparalleled opportunity for cessation success.

Unfortunately, however, the vapers clearly feel besieged, mostly by the government. (A cynical observer might find some basis for that government hostility in Godshall's estimates of lost cigarette sales, since in many jurisdictions the government profits substantially more from each pack sold than do tobacco companies.) Probably because of that, vapers seem much more politically active than smokers or smokeless tobacco users. It is interesting to consider whether this is due to tobacco users internalizing social stigma or whether smokers simply do not feel they can defend something they themselves often consider contrary to their best interests; part of the explanation is probably the withdrawal of the tobacco industry from supporting socio-political initiatives, in contrast with the political mobilization of the e-cigarette industry. For such a large part of the population, tobacco users seem to be politically impotent. Vapers, who can present their habit as posing a generally acceptable level of risk, and the e-cigarette as being modern, clean, and technological, seem uninhibited about vocally advancing their agenda. The question remains as to whether they can stand up to the more powerful activists, anti-tobacco extremists who are now anti-self-administration-of-nicotine-in-any-non-pharmaceutical-form extremists.

BG is the executive director of SmokeFree Pennsylvania.

This past Saturday morning (13 March 2010) I drove to Vapefest 2010 at the Hilton Garden Inn in Fredricksburg, Virginia to attend the world's largest gathering (so far) of electronic cigarette consumers (who prefer being called "vapers"), organized by the National Vapers Club. Since those lobbying for laws/regulations to prohibit the sale and/or indoor usage of electronic cigarettes (also called "personal vaporizers") have alleged the products are carcinogenic / toxic / hazardous for users and/or nonusers, and since some have claimed there is no evidence that cigarette smokers can quit smoking by switching to vaping, I wanted to learn more about these novel products (whose sales have skyrocketed in the past two years) and their users. Considering that the fundamental tenet of all toxicology is "the dose makes the poison" (e.g. consuming two gallons of water can kill a person) and that I experience severe headaches when exposed to even low levels of secondhand tobacco smoke, pesticides, glues and perfumes, I decided to expose myself to massive levels of e-cigarette vapor to find out what would happen.

One hundred people registered for this free event held in the hotel's conference room about 25′ by 50′ with a 10′ ceiling that displayed a Fire Marshall's sign stating a room capacity of 98 people (although there were rarely more than 80 people in the room at any given time). Virtually everyone in attendance was vaping, typically taking a puff or two every five or ten minutes. Not wanting to stick out in the crowd, I also decided to try vaping an e-cigarette for the first time. Since I haven't consumed nicotine since 1979 when I quit, cold turkey, my two to three pack per day cigarette addiction, Vapefest 2010 organizer Spike Babaian gave me a nicotine-free vaporizer (these are used by about 10%-20% of vapers who have weaned themselves off nicotine). It contained a "one day" disposable cartridge. Similar one-day cartridges that contain nicotine are roughly equivalent to 15 tobacco cigarettes. Over the next six hours, I deeply inhaled about 100 puffs from the vaporizer before it stopped emitting vapor. The only noticeable symptom during or after my vaping experience was a bit of dry mouth that was alleviated by an occasional drink.

My conversations with and observations of nearly all Vapefest 2010 participants revealed that:

- every vaper had been a cigarette smoker until they discovered vaping during the past year or two,
- nearly all vapers had been heavy smokers who had previously consumed one to three cigarette packs per day,
- most attendees vape more often and in greater quantities than typical e-cigarette users,
- the vast majority of vapers switched entirely from smoking to vaping, while 10%-20% still smoked cigarettes occasionally,
- nearly all vapers I spoke to indicated that their breathing, taste and smell had significantly improved,

- many vapers had unsuccessfully tried to quit smoking using nicotine gums, lozenges, patches and/or prescription drugs,
- all attendees distrusted and had an intense dislike for the FDA and others that are trying to ban vaporizers or vaping,
- most attendees had considered themselves either apolitical or liberal, but nearly all now dislike Democrats due to government e-cigarette polices,
- all attendees enjoyed the rally/party-like atmosphere, and most plan to attend similar events in the future,
- all attendees but one were Caucasian, with one Asian, no Blacks and no Hispanics,
- nearly all attendees were between the ages of 30 and 60, several were older, nobody was under 25,
- participants came from about 20 different states mostly east of the Mississippi, and virtually all drove to the event,
- nearly all attendees were low- or middle-income, and a key reason many switched to vaping was to save money,
- nearly all graduated from high school, about 30% had a college degree, most lived in cities or suburbs.

As the only smoke-free policy activist in attendance, the most common questions I was asked included: Why do e-cigarette opponents...

- lie and scare people about the health risks/benefits of vaping compared to cigarette smoking?
- have no respect for my right to decide what I put in my own body?
- want to ban these products that are the only thing that got me off cigarettes?
- want to force me to go back to smoking cigarettes now that I have finally quit?
- hate smokers and vapers, or want to harm/kill us?

These were not easy questions to answer, especially since I've been asking many similar questions during the past 18 months about e-cigarettes (and during the past decade about smoke-free tobacco products as harm reduction alternatives).

In response to these questions, I responded that the goal of most public health and tobacco control advocates is to reduce tobacco disease and death (nearly all of which is caused by daily cigarette smoking) by encouraging/helping smokers to quit, raising cigarette taxes, preventing/reducing youth smoking, and reducing secondhand smoke exposure to nonsmokers. I

also mentioned that a growing number of public health advocates are advocating e-cigarettes and other smoke-free tobacco harm reduction products for smokers.

But I also explained that some abstinence-only activists (many of whom are government health officials or heads of anti-tobacco groups that have received drug industry funding) want to eliminate all tobacco/nicotine use or even ban all tobacco/nicotine products (except nicotine gums, lozenges, and patches that are marketed only for temporary use as smoking cessation medicine). But since the new federal Family Smoking Prevention and Tobacco Control Act, lobbied for by CTFK, ACS, AHA, ALA, et al., prohibits the FDA from banning traditional tobacco products (cigarettes, cigars, other smoked tobacco, smokeless tobacco), I explained that these same groups and others are now trying to ban any new smoke-free nicotine product alternatives even if they appear to be at least 99% less hazardous than cigarettes and pose no known risks for nonusers.

During the ten hours I was in the Vapefest 2010 conference room on Saturday, participants collectively vaped the equivalent of 2,000-3,000 tobacco cigarettes. While most visible vapor disappeared one or two seconds after vaping occurred, there was a slightly visible vapor mist in the room (but insignificant compared to outdoor fog or theatrical fog) since dozens of people were vaping simultaneously most of the day. There also was a mild pleasant smell in the room due to the many different flavorings that most vapers added to their e-cigarettes (by putting a drop of flavoring into their vaporizer), and that were being sold by most of the ten e-cigarette vendors who paid $50 to sponsor (i.e. cover the costs of) the event.

As one who experiences severe headaches, sneezing, watery eyes and other sinus problems from exposure to very little secondhand tobacco smoke (a key reason I have been an outspoken activist for smoke-free indoor rules since 1986), I am delighted and relieved that I experienced *no* adverse reactions during or after my intense exposure to e-cigarette vapor.

Realizing that personal experiences are not a substitute for air quality data or other scientific research, I've been advocating laboratory emission tests, air quality tests and other studies on e-cigarettes and vapers for the past several years with limited success. Several days before Vapefest 2010, I invited many tobacco control advocates, researchers and public health officials to attend the event (and invited some researchers to bring testing equipment to measure air quality inside the conference room). Unfortunately, I was the only person from the tobacco control community that was interested enough to attend the event.

Ironically, it appears that the grassroots volunteer organizers and participants of Vapefest 2010 are now doing more than tobacco control professionals to help cigarette smokers quit and to truthfully inform the public about the known health risks and benefits of vaping e-cigarettes versus smoking cigarettes.

An estimated 300,000-500,000 cigarette smokers in the US have switched to e-cigarettes in the past two years. And an estimated $100-200 million of e-cigarettes (and related vaping equipment and supplies) were sold in the US in 2009, which reduced tobacco cigarette sales by an estimated $200-400 million (as vaping e-cigarettes costs about half the price of smoking cigarettes). It is critically important to understand that every dollar that smokers and ex-smokers spend on e-cigarettes eliminates $2 that previously had been (and would otherwise be) spent on tobacco cigarettes.

If the number of vapers and e-cigarette sales continue growing at similar rates, another million cigarette smokers will switch to vaporizers in 2010, and sales may surpass the estimated $600 million in combined sales of nicotine gums, lozenges and patches. And if e-cigarette usage and sales continues growing at similar rates in future years, the number of e-cigarette users and sales could surpass smokeless tobacco products in several years, and could surpass tobacco cigarettes within a decade.

Ironically and tragically, while e-cigarettes appear to pose the greatest threat yet to the future of the cigarette industry, efforts by the FDA and others to ban the sale and/or use of e-cigarettes primarily protect cigarette markets and make it even more difficult for smokers to quit. So it is vitally important to continue asking why some tobacco control activists are aggressively campaigning to protect the cigarette industry at the expense of smokers and public health.

That is also why Smokefree Pennsylvania and other tobacco harm reduction advocates have been urging the FDA to reclassify and to responsibly regulate e-cigarettes as tobacco products (instead of trying to ban them by claiming they are drug devices), and have been urging the FDA to begin to truthfully inform smokers and the public that e-cigarettes and other smoke-free tobacco/nicotine products are far less hazardous alternatives to cigarettes, and that they pose no known risks to nonusers.

Since 1990, Smokefree Pennsylvania and I have advocated policies that have reduced indoor tobacco smoke pollution, increased cigarette taxes, reduced tobacco marketing to youth, preserved civil justice remedies for those injured by cigarettes, expanded and funded smoking cessation services, and to inform smokers that smoke-free tobacco/nicotine products are far less hazardous alternatives to cigarettes.

Chapter 19

Electronic cigarettes (e-cigarettes) as potential tobacco harm reduction products: Results of an online survey of e-cigarette users

Karyn K. Heavner, James Dunworth, Paul L. Bergen, Catherine M. Nissen & Carl V. Phillips

Abstract

Electronic cigarettes (e-cigarettes), which surged in popularity in 2008, may be the most promising product for tobacco harm reduction yet. E-cigarettes deliver a nicotine vapor without the combustion products that are responsible for nearly all of smoking's health effects. Other than anecdotal accounts, there is little information about who uses e-cigarettes, and whether people who switch from cigarettes to e-cigarettes experience changes in symptoms caused by smoking. This pilot online survey, conducted by a UK-based online e-cigarette merchant (E Cigarette Direct), investigated e-cigarette use for smoking cessation and changes in health status and smoking caused symptoms. A convenience sample (n=303) was enrolled by e-mail and links on various blogs and forums in May-June 2009. The data were analyzed by independent university researchers at the tobaccoharmreduction.org project.

All respondents previously smoked and 91% had attempted to stop smoking before trying e-cigarettes. Most respondents resided in the USA (72%) and 21% were in Europe. About half (55%) were 31-50, while 32% were >50 years old. Most (79%) of the respondents had been using

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e-cigarettes for <6 months and reported using them as a complete (79%) or partial (17%) replacement for, rather than in addition to (4%), cigarettes. The majority of respondents reported that their general health (91%), smoker's cough (97%), ability to exercise (84%), and sense of smell (80%) and taste (73%) were better since using e-cigarettes and none reported that these were worse. Although people whose e-cigarette use completely replaced smoking were more likely to experience improvements in health and smoking caused symptoms, most people who substituted e-cigarettes for even some of their cigarettes experienced improvements.

These are highly motivated and passionate e-cigarette users who may have different experiences than average e-cigarette users or smokers, and thus the estimates cannot be extrapolated to all smokers or e-cigarette users. However, the results still suggest that very few e-cigarette users are not using them to replace cigarettes and there are many switchers and current smokers who could have the reported experience. Unfortunately e-cigarettes have been banned in some jurisdictions (e.g., Canada, Victoria (Australia)) where switching from cigarettes to e-cigarettes was documented. The lack of available and legal e-cigarettes may cause some users to resume smoking.

Introduction

Awareness and use of electronic cigarettes (e-cigarettes) has dramatically increased in the past two years. These devices, which are manufactured and sold by several different companies, deliver nicotine by vaporizing a gel composed of water, propylene glycol, flavorings, and nicotine (Laugesen M, 2008). E-cigarettes deliver nicotine without the products of combustion that are inhaled by smoking cigarettes. Therefore, the health risks are likely similar to those from smokeless tobacco, which has approximately 1% of the mortality risk of smoking (Phillips, Rabiu & Rodu, 2006). There is likely some remaining risk due to the stimulant effects of nicotine. E-cigarettes are one category of non-combustion nicotine product (others being smokeless tobacco and pharmaceutical nicotine products) that are promising for tobacco harm reduction, the substitution of less harmful nicotine products for cigarettes (Phillips, Heavner & Bergen, 2010; Rodu & Godshall, 2006).

E-cigarettes are widely available in the United States and Europe and are also available online through many different distributors. E-cigarettes have been banned in some jurisdictions including Canada (Health Canada, 2009; State Government of Victoria, 2008) and Victoria (Australia) (State Government of Victoria, 2008) and are subject to the indoor "smoking" bans in others (e.g.,Kelton, 2009). Although there are legitimate concerns about quality control and product tampering, the importation/sale bans have been criticized by public health advocates because they do not merely address the products' flaws, but eliminate a promising smoking cessation intervention, offering few realistic options for bringing the product back to market.

There is a high likelihood that some people who switched from cigarettes to e-cigarettes but lose access to e-cigarettes will resume smoking.

There are many testimonials and anecdotes on the internet about people switching from cigarettes to e-cigarettes but, to our knowledge, there have been no quantified data published. One online e-cigarette distributor based in the United Kingdom (E Cigarette Direct) conducted an online marketing survey of their e-cigarette users and made their data available to researchers at the University of Alberta School of Public Health for re-analysis. The objectives of this study were to describe e-cigarette users' patterns of cigarette and e-cigarette usage and smoking cessation attempts and to compare health status and smoking-attributable symptoms between people who completely switched from smoking to e-cigarettes, those who partially switched, and those who supplemented cigarette smoking with e-cigarette usage.

Methods

The study was initiated and conducted by E Cigarette Direct (ecigarettedirect.co.uk). A convenience sample was enrolled by sending an e-mail to their consumers and links to the survey were available on their website and on various blogs and online forums. Most of the survey respondents were directed to the survey from an e-cigarette forum. Participants completed an online survey in English on the SurveyMonkey website in May and June 2009. The survey was not anonymous as SurveyMonkey tracks respondents' IP addresses and E Cigarette Direct gave participants the option of providing their e-mail address to be entered in a raffle (as is common practice for marketing surveys). Duplicate IP and e-mail addresses were identified and then these variables were deleted (by JD) prior to sending the data to the University of Alberta research team (tobaccoharmreduction.org) for analysis. Secondary analysis of the anonymized version of the dataset was approved by the Health Research Ethics Board at the University of Alberta.

The survey assessed respondents' use of cigarettes, e-cigarettes, smoking cessation (including use of pharmaceutical products and switching to e-cigarettes) and changes in smoking-caused symptoms since using e-cigarettes. The dataset included 304 observations, one of which was excluded from all analyses because only country of residence and comments were entered. There were two sets of two observations each which had the same IP address. There were no entries with the same e-mail address. In addition, there were 31 observations with no IP or e-mail address.

All analyses were conducted for the whole sample and for a subsample of the dataset that excluded potential duplicates. The subset excluded all observations without an IP or email address and the observation that was completed last in each of the two sets with the same IP address. The results section focuses on the analysis of the whole sample with differences

between the whole sample and the subsample noted. The data were analyzed in SAS (version 9.2, SAS Institute, Cary, North Carolina). Our analysis included frequencies of all variables. Our protocol specified conducting cross tabulations for switching behavior and health status and smoking symptoms. Tests of significance were not conducted as no specific hypotheses were tested and confidence limits are not presented because they tend to mislead most readers into thinking they represent the important source of error. Confidence intervals only convey information about random error, while the greatest potential sources of error in this and other surveys of self-reported health and behavior are non-random. Freehand comments made by 176 participants are also summarized.

Results

The frequencies of all survey questions are listed in Table 1. Approximately half of the sample was between the ages of 31 and 50, one-third were more than 50 years old and none were under the age of 18. Nearly three-quarters resided in the US, followed by 17% from the UK. Most of the respondents had been using e-cigarettes for less than six months and all had smoked prior to using e-cigarettes. Most of the respondents had previously tried to stop smoking multiple times. The majority (86%) of respondents had tried pharmaceutical products to quit smoking, nearly two-thirds of whom indicated that these products did not help them to stop smoking. However, most of the sample was able to use e-cigarettes as a complete replacement for cigarettes.

The majority of the respondents indicated that their general health, smoker's cough, ability to exercise, sense of smell and sense of taste were better since starting to use e-cigarettes and none indicated that these were worse when responding to these five questions. However, one participant (whose data was excluded from the rest of the analysis because he/she only entered country of residence and comments) indicated in the comments that his/her health was generally worse since starting to use e-cigarettes but believed that this was due to a concurrent dramatic decrease in caffeine intake. In addition to the quantitative results, other health and quality of life improvements that were reported in the comments were: improved sleep, fewer migraines, better gum health, better lung function and oxygen saturation levels, no more need for asthma medication, no anxiety or depression when switching (unlike other attempts at smoking cessation), easier breathing, feeling better in the mornings, more energy, and no more snoring. Several respondents also reported the absence of environmental tobacco smoke or the smell of smoke as benefits of e-cigarettes.

There were only minor differences in the univariate results when possible duplicates were excluded. However, there were a few more substantial differences in the bivariate results in the smaller strata.

On average, respondents who lived in Europe had used e-cigarettes for longer than respondents in the US, but were less likely to use e-cigarettes as a complete replacement for cigarettes (Table 2). There was a positive relationship between the number of times participants had tried to stop smoking and using e-cigarettes as a complete replacement for cigarettes. Most (81%) of the respondents who indicated that pharmaceutical products did not help them stop smoking used e-cigarettes as a complete replacement for cigarettes.

Although the majority of respondents reported that their health and smoking-caused symptoms improved since using e-cigarettes, there were some notable trends in which groups were more likely to report improvements (Table 3). Respondents who had been using e-cigarettes for a longer period of time, who had completely replaced their cigarettes with e-cigarettes, or were younger, were more likely to report improvements.

Discussion

This sample is mostly composed of people who tried to quit smoking and failed, but then succeeded in switching to e-cigarettes. This contradicts claims put forth by extremist nicotine-abstinence proponents that e-cigarettes are appealing disproportionately to non-smokers and former smokers (supposedly as a result of marketing directed toward these groups, which also represents an unsubstantiated claim). There were only two respondents who indicated that they had quit permanently using pharmaceutical products and it is not known how long ago they quit or whether they would have resumed smoking if e-cigarettes were not available.

Although few people responded that they use e-cigarettes in addition to cigarettes, there are a few noteworthy observations about this group of respondents. Some of these smokers may be supplementing their cigarette smoking with e-cigarette use in places where they are not allowed to smoke. It should be noted that this applies to no more than the 4% of the sample who indicated that they use e-cigarettes in addition to cigarettes. This is one of the main concerns that e-cigarettes opponents have voiced, though the objection to dedicated smokers seeking relief from time and place restrictions involves ethical claims that are seldom made and beyond the present scope (Phillips, 2009; or see Nissen, Phillips & Heffernan in this volume). It is not possible to determine whether the total nicotine intake increased for these respondents, as 75% had tried pharmaceutical quit smoking aids and it is possible that they replaced use of pharmaceutical nicotine products with e-cigarettes in places where they cannot smoke. The wording of these questions was rather imprecise (the exact wording of each question appears in Table 1) and may have resulted in misclassification and future surveys should attempt to quantify this by asking respondents to indicate the number of cigarettes that they smoked (per day) before using e-cigarettes and the number that they smoked after starting to use e-cigarettes, as well as when and where they smoke and use e-cigarettes. Approximately half of the few respondents

who supplemented their cigarette use with e-cigarettes indicated that their general health was better since starting to use e-cigarettes. This could indicate misclassification (they actually reduced their smoking) or benefits of not suffering nicotine withdrawal symptoms in situations where they are not allowed to smoke.

It is not surprising that none of the respondents indicated that their health got worse after they started using e-cigarettes, as this sample was very interested in, or in other words favourably disposed towards, e-cigarettes (given their participation in the e-cigarette forum and blogs and that very few of the comments were negative). If people had started using e-cigarettes and their health got worse or they did not enjoy using e-cigarettes, they would likely have stopped using/purchasing e-cigarettes and therefore would not have been aware of the survey. Thus the results have to be seen as a proof of concept, but not an estimate of what portion of potential users receive the benefits. This study demonstrates that some e-cigarette users replace all or some of their cigarette use for e-cigarettes, and perceive health benefits subsequent to this behavioral change. E-cigarettes (like all other smoking cessation strategies) do not work for everyone, but this survey does demonstrate that e-cigarettes have enabled some people to quit smoking, including some people for whom other methods had proven ineffective. These health benefits will likely be reversed if the trend towards banning e-cigarettes continues and people who replaced e-cigarettes for cigarettes resume smoking.

Table 1: Preliminary results of the e-cigarette survey				
	Whole sample (n=303)		Excluding possible duplicates[1] (n=270)	
	n	%	n	%
How old are you?				
18 – 30	39	13%	37	14%
31 – 50	165	55%	148	55%
>50	98	32%	84	31%
Missing	1		1	
Please enter your country of residence:				
Europe	62	21%	43	16%
USA	215	72%	206	77%
Canada	8	3%	7	3%
Australia/New Zealand	4	1%	4	1%
Other	9	3%	7	3%
Missing	5	--	3	
Did you smoke before using the electronic cigarette?				
Yes	303	100%	270	100%
No	0	0%	0	0%
Missing	0		0	
How long have you been using electronic cigarettes?				
0 - 5 months	239	79%	210	78%
6 - 12 months	54	18%	51	19%
13 - 18 months	5	2%	5	2%
19 - 24 months	1	0.3%	1	0.4%
>24 months	3	1%	2	1%
Missing	1		1	
Did you try to stop smoking before starting to use the electronic cigarette				
Yes	276	91%	248	92%
No	26	9%	21	8%
Missing	1		1	
If tried to stop smoking before starting to use the electronic cigarette:				
How many times did you try to stop smoking?				
1 - 3 times	95	35%	81	33%
4 - 9 times	120	44%	113	46%
>=10 times	58	21%	51	21%
Missing	3	--	3	--
Did you ever try to use pharmaceutical products				

Table 1: Preliminary results of the e-cigarette survey				
	Whole sample (n=303)		Excluding possible duplicates[1] (n=270)	
	n	%	n	%
such as nicotine patches or nicotine gum to quit?				
Yes	236	86%	215	87%
No	39	14%	32	13%
Missing	1	--	1	--
If you ever tried to use pharmaceutical products such as nicotine patches or nicotine gum to quit?: Pharmaceutical Aids				
Helped me to stop smoking permanently.	2	1%	2	1%
Helped me to stop smoking temporarily (<12 months).	46	20%	39	19%
Helped me to reduce the amount I smoked, but did not help me to stop smoking.	38	17%	34	16%
Did not help me to stop smoking.	144	63%	134	64%
Missing	6	--	6	
Do you use the electronic cigarette:				
In addition to cigarettes	13	4%	7	3%
As a partial replacement for cigarettes	49	17%	41	15%
As a complete replacement for cigarettes	234	79%	217	82%
Missing	7		5	
Since starting to use the electronic cigarette, do you in general feel your health is:				
Better	267	91%	249	94%
The same	28	9%	17	6%
Worse	0	0%	0	0%
Missing	8	--	4	--
If you had a smoker's cough before using the electronic cigarette, is it now:				
Better	226	97%	210	98%
The same	6	3%	4	2%
Worse	0	0%	0	0%
Not applicable	64	--	52	--
Missing	7	--	4	--
How has your ability to do exercise changed since using the electronic cigarette?				
Better	225	84%	211	88%
The same	42	16%	30	12%
Worse	0	0%	0	0%
Not applicable	26	--	22	--
Missing	10	--	7	--

Table 1: Preliminary results of the e-cigarette survey

	Whole sample (n=303)		Excluding possible duplicates[1] (n=270)	
	n	%	n	%
How has your sense of smell changed since using the electronic cigarette?				
Better	235	80%	217	82%
The same	58	20%	47	18%
Worse	0	0%	0	0%
Missing	10	--	6	--
How has your sense of taste changed since using the electronic cigarette?				
Better	216	73%	202	77%
The same	78	27%	62	23%
Worse	0	0%	0	0%
Missing	9	--	6	--

1. Possible duplicates are all observations without IP address or e-mail address and 2nd observation in each of 2 sets of observations with the same IP address.

Table 2: Use of electronic cigarettes (n=303)

	How long have you been using electronic cigarettes?(months)				Do you use the electronic cigarette:			
	n	0-5	6-12	>12	n	In addition to cigarettes	As a partial replacement for cigarettes	As a complete replacement for cigarettes
How old are you?								
18 – 30	38	79%	21%	0%	38	5%	16%	79%
31 – 50	165	80%	18%	2%	162	3%	18%	79%
over 50	98	78%	17%	5%	95	6%	15%	79%
Please enter your country of residence:								
Europe	62	69%	27%	3%	62	8%	26%	66%
USA	214	81%	16%	2%	213	3%	13%	84%
Canada	8	100%	0%	0%	8	12%	38%	50%
Australia/New Zealand	4	50%	25%	25%	4	0%	0%	100%
Other	9	89%	11%	0%	9	11%	33%	56%
How long have you been using electronic cigarettes?								
0 - 5 months		--	--	--	234	4%	15%	81%
6 - 12 months		--	--	--	54	6%	28%	67%
>12 months		--	--	--	7	0%	0%	100%
How many times did you try to stop smoking?								
0 times	26	88%	12%	0%	25	8%	20%	72%
1 - 3 times	95	76%	20%	4%	93	3%	27%	70%
4 - 9 times	119	80%	19%	1%	119	3%	14%	82%
>=10 times	58	79%	16%	5%	57	7%	4%	89%
Pharmaceutical aids								
Helped me to stop smoking permanently	2	100%	0%	0%	2	0%	0%	100%
Helped me to stop smoking temporarily	46	72%	26%	2%	45	7%	24%	69%
Helped me to reduce the amount I smoked, but did not help me to stop smoking	38	87%	13%	0%	37	5%	14%	81%
Did not help me to stop smoking	143	75%	20%	5%	142	3%	13%	84%

Table 2a: Use of electronic cigarettes, excluding potential duplicates (n=270)

	How long have you been using electronic cigarettes?(months)				Do you use the electronic cigarette:			
	n	0-5	6-12	>12	n	In addition to cigarettes	As a partial replacement for cigarettes	As a complete replacement for cigarettes
How old are you?								
18 – 30	36	81%	19%	0%	36	6%	17%	78%
31 – 50	148	78%	19%	3%	146	1%	18%	81%
over 50	84	76%	19%	5%	82	4%	11%	85%
Please enter your country of residence:								
Europe	43	58%	37%	5%	43	2%	28%	70%
USA	168	82%	16%	2%	204	2%	13%	85%
Canada	7	100%	0%	0%	7	14%	29%	57%
Australia/New Zealand	4	50%	25%	25%	4	0%	0%	100%
Other	7	86%	14%	0%	7	14%	14%	71%
How long have you been using electronic cigarettes?								
0 - 5 months		--	--	--	207	2%	13%	85%
6 - 12 months		--	--	--	51	4%	27%	69%
>12 months		--	--	--	6	0%	0%	100%
How many times did you try to stop smoking?								
0 times	21	86%	14%	0%	21	5%	19%	76%
1 - 3 times	81	74%	21%	5%	80	2%	25%	72%
4 - 9 times	112	79%	20%	1%	112	2%	14%	84%
>=10 times	51	78%	18%	4%	50	4%	2%	94%
Pharmaceutical aids								
Helped me to stop smoking permanently	2	100%	0%	0%	2	0%	0%	100%
Helped me to stop smoking temporarily	39	72%	26%	3%	39	3%	28%	69%
Helped me to reduce the amount I smoked, but did not help me to stop smoking	34	85%	15%	0%	33	3%	12%	85%
Did not help me to stop smoking	133	74%	21%	5%	132	2%	11%	87%

Table 3: Changes in health status and symptoms since using electronic cigarettes (n=303)

	Since starting to use the electronic cigarette, do you in general feel your health is:			If you had a smoker's cough before using the electronic cigarette, is it now:			How has your ability to do exercise changed since using the electronic cigarette?			How has your sense of smell changed since using the electronic cigarette?			How has your sense of taste changed since using the electronic cigarette?		
	n	Better	Same	n	Better	Same	n	Better	Same	n	Better	Same	n	Better	Same
How old are you?															
18 – 30	38	97%	3%	30	100%	0%	35	94%	6%	48	89%	11%	38	87%	13%
31 – 50	162	90%	10%	129	97%	3%	151	85%	15%	160	84%	16%	162	78%	22%
over 50	94	88%	12%	72	97%	3%	80	79%	21%	94	70%	30%	93	60%	40%
How long have you been using electronic cigarettes?															
0 - 5 months	233	89%	11%	182	97%	3%	210	81%	19%	232	79%	21%	232	72%	28%
6 - 12 months	54	96%	4%	42	98%	2%	51	94%	6%	53	81%	19%	54	78%	22%
>12 months	7	100%	0%	7	100%	0%	5	100%	0%	7	100%	0%	7	100%	0%
Do you use the electronic cigarette:															
In addition to cigarettes	11	55%	45%	9	78%	22%	9	56%	44%	12	42%	58%	12	25%	75%
As a partial replacement for cigarettes	49	78%	22%	32	90%	9%	45	69%	31%	48	62%	38%	49	59%	41%
As a complete replacement for cigarettes	234	95%	5%	190	99%	1%	212	89%	11%	232	86%	14%	232	79%	21%

Table 3a: Changes in health status and symptoms since using electronic cigarettes, excluding potential duplicates (n=270)

	Since starting to use the electronic cigarette, do you in general feel your health is:			If you had a smoker's cough before using the electronic cigarette, is it now:			How has your ability to do exercise changed since using the electronic cigarette?			How has your sense of smell changed since using the electronic cigarette?			How has your sense of taste changed since using the electronic cigarette?		
	n	Better	Same	n	Better	Same	n	Better	Same	n	Better	Same	n	Better	Same
How old are you?															
18 – 30	36	100%	0%	28	100%	0%	34	94%	6%	36	89%	11%	36	86%	14%
31 – 50	147	93%	7%	119	97%	3%	136	89%	11%	145	86%	14%	146	82%	18%
over 50	82	93%	7%	66	98%	2%	70	81%	19%	82	72%	28%	81	62%	38%
How long have you been using electronic cigarettes?															
0 - 5 months	208	92%	8%	167	98%	2%	188	86%	14%	207	82%	18%	206	75%	25%
6 - 12 months	51	98%	2%	40	98%	2%	48	94%	6%	50	82%	18%	51	78%	22%
>12 months	6	100%	0%	6	100%	0%	4	100%	0%	6	100%	0%	6	100%	0%
Do you use the electronic cigarette:															
In addition to cigarettes	7	86%	14%	6	83%	17%	5	60%	40%	7	57%	43%	7	43%	57%
As a partial replacement for cigarettes	41	80%	20%	29	93%	7%	38	71%	29%	40	62%	38%	41	59%	41%
As a complete replacement for cigarettes	217	96%	4%	178	99%	1%	197	91%	9%	216	87%	13%	215	81%	19%

References

Health Canada. Health Canada Advises Canadians Not to Use Electronic Cigarettes. http://www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/_2009/2009_53-eng.php. 17 March 2009.

Kelton P. Suffolk Passes E-cigarette Ban. LongIslandPress.com http://www.longislandpress.com/2009/08/18/suffolk-passes-e-cigarette-ban/. 18 August 2009.

Laugesen M. Safety Report on the Ruyan® e-cigarette Cartridge and Inhaled Aerosol. Christchurch. Health New Zealand Ltd. 2008.

Phillips CV. The affirmative ethical arguments for promoting a policy of tobacco harm reduction. TobaccoHarmReduction.org working paper 10, http://tobaccoharmreduction.org/wpapers/010.htm. 2009.

Phillips CV, Heavner K, Bergen P. Tobacco - the greatest untapped potential for harm reduction. Harm Reduction, in this volume, 2010.

Phillips CV. Rabiu D. Rodu B. Calculating the comparative mortality risk from smokeless tobacco versus smoking. *American Journal of Epidemiology, 163* S189, 2006.

Rodu B. Godshall WT. Tobacco harm reduction: an alternative cessation strategy for inveterate smokers. *Harm.Reduct.J 3* 37, 2006.

State Government of Victoria. Victorian ban on battery-powered cigarette. http://hnb.dhs.vic.gov.au/web/pubaff/medrel.nsf/LinkView/3AA04FD559FB4ADACA25752F0079EB07?OpenDocument. 2008.

Chapter 20

Two petitions to the U.S. Food and Drug Administration from the American Association of Public Health Physicians

Joel L. Nitzkin

Reprinted from public archives of public comments to the Food and Drug Administration on the Regulation of Tobacco Products Docket FDA-2009-N-0294 (1014.3), (Available at:http://www.regulations.gov/ search/ Regs/home.html#docketDetail?R=FDA-2009-N-0294); some items referenced in the chapter and related statements by the AAPHP can be found at http://www.aaphp.org/.

Editors' Note: We conclude this book with an entry that is an important piece of the history of THR, both because of its content and because it represents what could be the beginning of a push-back by genuine public health organizations against the anti-tobacco extremists who try to claim the mantle of public health. While other multi-issue health organizations have expressed recognition of the value of THR, they have failed to step up and fight for THR, and have mostly backed off from any hint of advocacy in the face of political pressure from the powerful extremist lobby (see, e.g., the Royal College of Physicians).

Both as a member of a recognized health group and as a concerned individual, Nitzkin is probably the most prominent American voice speaking out in favor of electronic cigarettes. These documents were written in his capacity as Chair of the American Association of Public Health Physicians (AAPHP) Tobacco Control Task Force. The first document in this chapter (co-authored with AAPHP President Kevin Sherin) is included as a quick read to sketch the position of the Association. The second illustrates part of the organization's strategy, which could be characterized as demanding that the government obey laws and ethics and to argue the legal side of the case for THR. This has been pursued by a few individuals over the years but seldom, if ever, has been employed by non-industry organizations. This approach has some promise in the U.S. where the independent judiciary and legislature and watchdog agencies, have shown a willingness to stand up to the bureaucratic agencies involved with tobacco policy which, as in most jurisdictions, are captured by the extremist faction.

Both of these documents were written to the U.S. Food and Drug Administration in defense of THR, primarily in the form of e-cigarettes, as a potentially effective means to reduce the mortality

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JLN is Chair of the American Association of Public Health Physicians' Tobacco Control Task Force.

associated with chronic smoking. They point out that though much effort is expended on discouraging new users, very little is done that helps established smokers. Nitzkin notes that the law governing the FDA effectively endorses THR, but there are several ways in which actions taken under the law could undermine (and already have, in some cases) real efforts to promote THR. In particular, tobacco companies are required to develop safer products but are effectively forbidden from promoting the existing low-risk products. Left unsaid is that this leaves the education about THR largely in the hands of those who have a history of trying to prevent people from learning about low-risk nicotine products.

Nitzkin specifically responds to one example of such anti-education, the FDA's own limited and ill-formed study of e-cigarette chemistry. For those not familiar, the FDA aggressively publicized the results of assays it ran on two brands of e-cigarettes – interestingly, the two brands that were suing the Administration for exceeding its authority – issuing statements that tricked the public into thinking that the insignificant traces of contaminants they found represent health risks comparable to those from smoking. Nitzkin urges the FDA to back away from its misleading public touting of its study.

Perhaps most important, he argues, legally and practically, that the FDA should treat e-cigarettes as a tobacco product and in so doing, place the associated harms of e-cigarette use within the context of tobacco and pharmaceutical nicotine products. This action would ensure that e-cigarettes would be put in the proper context, "immensely less harmful than cigarettes and comparable to anti-smoking pharmaceuticals", rather than the inflammatory context, "slightly more harmful than most other consumer products".

American Association of Public Health Physicians
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August 29, 2009

Lawrence Deyton, MD
Incoming Director
FDA Center for Tobacco Products

Re: **Don't Write Off Current Smokers**

Dear Dr. Deyton:

For the past half century, the American Association of Public Health Physicians (AAPHP) has served as the national voice of physician directors of state and local health departments and other like-minded physicians. We have long been involved with tobacco control, with the singular goal of doing everything in our power to reduce tobacco related illness and death.

As you assume leadership of the new FDA Center for Tobacco Products, we urge you to consider the actions FDA can take, within the powers granted by this new legislation, to rapidly and substantially reduce tobacco-related illness and death in current adult smokers.

Unfortunately, FDA has not gotten off to a good start. FDA condemnation of electronic cigarettes, in its July 22 press conference, and FDA insistence that electronic cigarettes should be regulated as a drug/device combination rather than as a tobacco product makes no sense from a public health perspective. It flies in the face of FDA laboratory findings on other products already approved by FDA. If one looks at electronic cigarettes as a sentinel for all tobacco products less hazardous than conventional cigarettes – the outlook for FDA action reducing tobacco-related illness and death among current adult smokers is dismal.

With this in mind, we respectfully request your consideration of the following actions:

1. We urge FDA to make public the laboratory data behind the July 22 condemnation of electronic cigarettes, along with comparable data on pharmaceutical nicotine products and conventional cigarettes. Then, on the basis of these data, either fully justify or retract the July 22 condemnation of electronic cigarettes.

2. We urge FDA to reclassify electronic cigarettes from a drug/device combination to a tobacco product. This will enable FDA to immediately regulate manufacturing and impose marketing restrictions during this initial period of FDA Tobacco Center development. This reclassification will eliminate pressure on the several hundred thousand current American users of electronic cigarettes to switch back to the much more hazardous conventional cigarettes.

This year, about 400,000 American adult cigarette smokers will die of a tobacco-related illness. Their second hand smoke will kill about 48,000 non-smokers. About 700 more will die in residential fires. Despite progress on other measures of tobacco use, per CDC estimates, this death count continues to inch up from year to year. In contrast, even though smokeless tobacco products represent about 20% of nicotine intake in the United States, the number of deaths per year from these products is too small for reliable estimates from the CDC.

Our (AAPHP) best estimate is that smokeless tobacco products currently cause about 700 cancer deaths per year in the United States. This is less than 1% of the more than 110,000 deaths that would occur each year if smokeless products carried the same mortality as conventional cigarettes.

This last week, Boffetta and Straif published a paper alleging evidence of an increased risk of fatal heart disease and stroke among smokeless tobacco users. This is a study sure to be referenced by those seeking evidence of the harmfulness of smokeless tobacco products. Unfortunately, this study suffers from major technical and ethical flaws, including failure to note in the abstract that they found no increased risk of non-fatal heart attack or stroke. Even worse, of the many studies reviewed, only two showed evidence of even a slight increase in risk of death – and these were the ones selected for the conclusion and abstract. That having been said, their allegations of a 13% increase in risk of fatal heart attack and 40% increase in risk of fatal stroke pale in comparison with the 180% to 300% increases in risk for men and women 35-64 years of age posed by smoking conventional cigarettes.

Contrary to prevailing conventional wisdom, virtually all the heart and lung disease from conventional cigarettes, and an estimated 98% of the cancer mortality, are due to direct inhalation of fresh products of combustion deep into the lung. Our best estimate (based on the work of Pankow et al and others) is that only about 2% of the cancer mortality from cigarettes is from the named carcinogens commonly found in tobacco products. Smokeless tobacco products carry little or no risk of heart disease and no risk of lung disease. They do not kill innocent bystanders and they do not burn down houses. The risk of cancer of any kind from smokeless products ranges from a high of about 5% of the risk of cancer posed by conventional cigarettes to a low well under 1% of the risk of cancer posed by conventional cigarettes. While definitive studies have not been done, we have reason to believe that tobacco products, such as electronic cigarettes, consisting of nicotine extracted from tobacco with only trace amounts of other chemical substances, should carry even less risk.

Most of the discussion to date around the new FDA/Tobacco bill has focused on reducing initiation of nicotine use by children and teens. The only discussion of current smokers has been limited to encouraging use of pharmaceutical products to aid cessation. This has been touted as doubling quit rates – but without mentioning that this doubling is from about 3% to about 5% per year. In other words, this option fails 95% of smokers willing to try it, even under study conditions with optimal counseling.

It should be possible to save the lives of 4 million or more of the 8 million adult American smokers who will otherwise die of a cigarette-related illness over the next twenty years. This could be done by making smokers aware of selected smokeless tobacco products (including but not limited to snus and electronic cigarettes) that promise to reduce the risk of tobacco-related illness by 99% or better for smokers who are unwilling or unable to quit. Rather than discouraging nicotine cessation, however, such an approach, even with no medical intervention, would be expected to triple the rate at which current smokers eventually discontinue their nicotine use.

Those writing the new FDA legislation endorsed a **harm reduction** component to current tobacco control programming, but in a most peculiar way. The law encourages cigarette manufacturers to develop "reduced exposure" products and market them with no scientific proof that such reductions in exposure will reduce risk. The law then requires presumably new "scientific evidence" for smokeless products, already known to be of substantially lower risk. This makes no sense. The law encourages a harm reduction component to current tobacco control programming that might reduce tobacco-related cancer mortality by one or two percent; while actively discouraging switching to lower risk tobacco products that promise to lower total tobacco-related illness and death by 99% or better.

The secret to success, as we see it, will be to add an effective harm reduction component to current tobacco control programming while using the tools made available by this new law to prevent this new harm reduction initiative from increasing the numbers of children and teens who initiate tobacco use.

Reconsidering the FDA stance on electronic cigarettes would be the most logical first step.

We look forward to working with FDA to use the powers granted by this new legislation to rapidly and substantially reduce tobacco-related illness and death, among both current and potential future tobacco users.

References:

The data on smoking attributable deaths on page 2 of this letter are from the Centers for Disease Control MMWR report of November 14, 2008. http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5745a3.htm

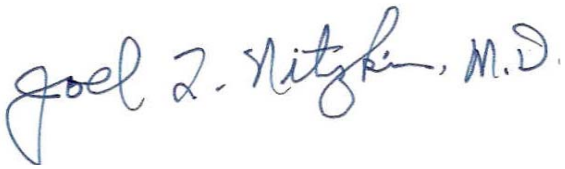
The estimate that 20% of current nicotine consumption in the United States is from smokeless tobacco was generated by Mr. William Godshall, based on the formula utilized by Fagerstrom et al, when estimating 2002 nicotine consumption by type of tobacco product in multiple countries.

The discussion on risk of heart disease and stroke from smokeless tobacco products is from Paolo Boffetta and Kurt Straif : Use of smokeless tobacco and risk of myocardial infarction and stroke: systematic review with meta-analysis. Published August 18, 2009. BMJ 2009; 339: b3060 [Abstract] [Full text]

The data on relative risk of fatal heart attack and stroke from smoking, in men and women 35-64 years of age, are data from the American Cancer Society as quoted in "Changes in cigarette-related disease risks and their implication for prevention and control." Smoking and Tobacco Control Monograph 8. Bethesda, MD: US Department of Health and Human Services, Public Health Service, National Institutes of Health, National Cancer Institute 1997;305-382. NIH Publication no. 97-1213.

The other references to the scientific literature that back-up the points made in this letter can be found on the Tobacco Issues page at the http://www.aaphp.org web site. There is an October 2008 "Resolution and White Paper on Tobacco Harm Reduction." This paper, on pages 6 and 13, includes then-current CDC and AAPHP mortality projections. "The Myth of the Safe Cigarette," is based on the paper by Pankow et al (http://cebp.aacrjournals.org/cgi/reprint/16/3/584) and others. It makes the case that conventional cigarettes cannot be made measurably safer. The exchange of correspondence with Zhu et al, from a paper published earlier this year, deals with the difference in quit rates, comparing conventional cigarettes to smokeless tobacco products.

Yours,



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Conflict of Interest Disclaimer: Neither of us, nor the American Association of Public Health Physicians, has received or anticipates receipt of any financial support from any tobacco product manufacturer or vendor, or any pharmaceutical firm making nicotine replacement products.

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American Association of Public Health Physicians
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Tobacco Control Task Force

February 7, 2010

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

Re: Citizen Petition to Follow-up July 22, 2009 Press Conference on E-cigarettes

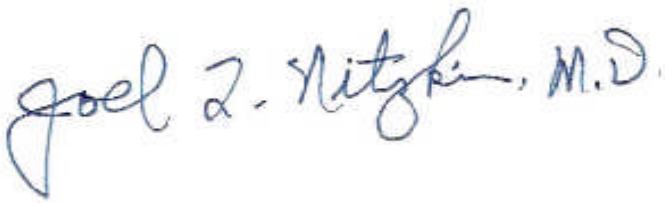
Dear FDA:

The undersigned submits this petition under the provisions of the new Tobacco Center legislation for which authority has been delegated to the Commissioner of Food and Drugs under 21 CFR 5.10 to request the Commissioner of Food and drugs to follow-up on its July 22, 2009 press release and press conference with another press release and press conference to amend certain statements on the basis of new information provided in text and as attachments to both of the petitions being submitted today by AAPHP..

This is the second of two petitions I am submitting today on behalf of the Tobacco Control Task Force of the American Association of Public Health Physicians. The other petition is a request to reclassify nicotine vaporizers, also known as "E-cigarettes" or "electronic cigarettes" from "drug-device combinations to "tobacco product."

We have generated these petitions because reclassification of E-cigarettes to tobacco products could open the door to a new harm reduction component to current tobacco control programming. That new component, in turn, could rapidly and substantially reduce tobacco-related illness and death without increasing the numbers of teens initiating nicotine use. This request for a follow-up press conference is intended to facilitate the proposed reclassification since the tone and content of the initial press conference presented comment that would rule out any consideration of the proposed reclassification.

Neither I nor AAPHP have received or anticipate receipt of any financial support from any electronic cigarette enterprise, any other tobacco-related enterprise, or any pharmaceutical enterprise.



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For Attachments, see separate Tables of Contents under Tabs A, B and C.

(please note the annotated index to appendices on pages 4 through 10)

A. Action requested

AAPHP urges the Food and Drug Administration (FDA) to follow-up the July 22, 2009 press release and press conference with another press release and press conference to amend certain statements on the basis of new information provided as text and attachments to the two AAPHP petitions being submitted today. The tone and content of the initial press conference left the impression that FDA would not consider either reclassification of E-cigarettes from drug-device combination to tobacco product or consider a related harm-reduction initiative. FDA is urged to review the content of the two petitions with consideration of the possibility that the information herein provided will justify a change in the current FDA stance on these issues.

B. Statement of grounds

Impact of FDA July 22, 2009 Press Conference

As a direct result of the FDA July 22, 2009 press conference, (Attachments B5a-c), many have concluded that E-cigarettes are as dangerous or more dangerous as conventional cigarettes and that they are likely to attract large numbers of teens to nicotine use who otherwise would have not initiated nicotine use. This has resulted in public statements, and political action to restrict or ban E-cigarettes. The strongly negative tone of the FDA press conference (Attachment B5B) created a situation in which people were encouraged to draw the incorrect conclusions noted above. One attachment has been added to this petition to document these interpretations (Attachment B4). This is a report from New Jersey GASP that summarizes the actions taken by others, mostly in response to the FDA press conference, as justification for their recommendations regarding E-cigarettes.

The two petitions being submitted today by AAPHP are intended to provide the evidence, data and scientific studies needed for FDA to consider revision of these statements, and, by doing so, consider the proposed reclassification of E-cigarettes from drug-device combinations to tobacco products (as proposed in the other AAPHP petition). In the other petitin, FDA is also urged to consider playing a lead role in promoting a new tobacco harm reduction initiative based on honest and direct communication to actual and potential tobacco users of tobacco products to inform them of the differences in risk profiles presented by the various categories of tobacco products. It is our (AAPHP) belief that such an initiative presents the only feasible means by which we, as the American public health community can take the action needed to rapidly and substantially reduce

tobacco-related illness and death in the United States and do so in a way that will not increase teen initiation of tobacco use.

Amended FDA Stance Proposed for Follow-up Press Conference

The relative safety of E-cigarettes compared to other tobacco products and compared to FDA approved pharmaceutical smoking cessation products currently on the market should not be an issue for the following reasons:

1. If regulated by FDA as tobacco products, FDA could require standards for chemical composition and quality of manufacture similar to those imposed on pharmaceutical products.
2. The limited studies done to date by FDA on E-cigarette liquid, and publicly announced July 22, 2009 (Attachments B5a-c) prove that the products tested have levels of carcinogenic contaminants similar to the concentrations of these same contaminants in nicotine replacement products already approved by FDA (AttachmentsB5d-i). These levels are several orders of magnitude less than conventional cigarette smoke. Both within this petition, and as a separate petition to FDA, AAPHP is requesting a follow-up to the July 22, 2009 press release to address the following:
    a. How the risk posed by E-cigarettes, based on chemical composition, compares to the risk posed by pharmaceutical nicotine replacement products and conventional cigarettes,
    b. The issue of "drug-device combination" vs. "tobacco product."
    c. The possible role E-cigarettes and other low-risk tobacco products might play relative to reducing future tobacco-related illness and death among current smokers.
    d. What is currently known about the attractiveness of E-cigarettes, compared to low-exposure conventional cigarettes and NRT products to teens and whether there is evidence that such products play a significant role in attracting teens to nicotine use.
3. With over three years of experience with E-cigarettes in the United States, we are not aware of any reports of illness directly attributable to their use. It is important to note that there were E-cigarette products on the American market prior to the February, 2007 date specified in the new FDA/Tobacco law relative to introduction of new products to the marketplace.
4. E-cigarettes use the same nicotine, with about the same level of trace contaminants as FDA approved NRT products. There are a large number of studies and reviews that demonstrate the safety of E-cigarettes in comparison with pharmaceutical NRT products and conventional cigarettes (Attachments B6a-j).
5. Propylene glycol and the other major ingredients in E-cigarettes are generally recognized as safe (Attachment B6i).
6. Judge Leon, in his January 14, 2010 opinion, stated the following: "Together, both Smoking Everywhere and NJOY have already sold hundreds of thousands of electronic cigarettes, yet FDA cites no evidence that those electronic cigarettes are any more an immediate threat to public health and safety than traditional cigarettes, which are readily available to the public" (Attachment B3).

Please note that a more detailed discussion of the major problems with the FDA July 22, 2009 press conference, and the urgent need for FDA to address these issues was the subject of correspondence forwarded to FDA by AAPHP August 29, 2009 (Attachment B5f).

Annotated index to attached reference materials

Please note that the attachments to this petition are identical in numbering, scope and content to the attachments to other AAPHP petition – the one requesting reclassification of E-cigarettes from drug-device combinations to tobacco products.

Attachment A: Harm Reduction References

1. **AAPHP Resolution and White Paper: The Case for Harm Reduction for control of tobacco-related illness and death**, October 26, 2008 (from www.aaphp.org web site). This well documented 37 page report does not directly address E-cigarettes, but makes the case for a harm reduction initiative based on commercially available tobacco products to achieve substantial personal and public health benefits not otherwise obtainable.
2. Rodu B; Phillips CV: **Switching to smokeless tobacco as a smoking cessation method: evidence from the 2000 National Health Interview Survey**. Harm Reduction Jounal 5:18 (2008)
3. Philips CV: **Debunking the cliam that abstinence is usually healthier for smokers than switching to a low-risk alternative, and other observations about anti-tobacco-harm-reduction arguments**. Harm Reduction Journal 6:29 doi 10-1186/1477-7517-6-29 2009
4. Nitzkin: J: **Promoting Snus Will Save Lives in the USA** – an article posted on the Tobacco Issues Page of the www.aaphp.org web site in response to the paper by Zhu et al, Tobacco Control, 2008 "**Quitting cigarettes completely or switching to smokeless tobacco: do U.S. Data replicate the Swedish Results**" This paper is remarkable in that the data show considerable potential benefit to switching to smokeless tobacco, but the abstract declares this point to be "unproven" on the basis that it has not been subjected to a controlled clinical trial. February 6, 2009 (from www.aaphp.org web site)
5. Fagerstrom K: **The nicotine market: An attempt to estimate the nicotine intake from various sources and the total nicotine consumption in some countries.** Nicotine & Tobacco Research, 7:3, pp 343-350, June 2005. In this paper Fagerstrom presents an approach to determining the amount of nicotine consumed by the population by type of tobacco product – from cigars to cigarettes, smokeless tobacco products and NRTs. He then provides estimates for a number of European countries based on this approach.
6. Godshall E-mail 12/29/09 5:12PM Godshall used the formula and data from the Fagerstrom paper to estimate the percentages of nicotine intake in the USA from cigarettes, smokeless and NRT products.
7. Rodu B, Godshall WT: **Tobacco harm reduction: an alternative cessation strategy for inveterate smokers.** Harm Reduction Journal 3:37 (2006). This literature review describes the traditional and modern smokeless products, their prevalence and use in the United States and Sweden and the epidemiologic evidence for their low health risks, both in absolute terms

and in comparison with smoking. This review does not consider E-cigarettes or tobacco-extracts. It covers smokeless tobacco products.

8. http://www.harmreduction.org This web site, developed and maintained by Dr. Carl Philips of the University of Alberta and Dr. Brad Rodu of the University of Louisville promotes itself as "The leading source of information of safer alternatives for smokers who cannot or do not wish to quit using nicotine. Attachment A8 is a print out of the home page as it appeared 11/10/2009.
9. Rodu B, Cole P: **Nicotine Maintenance for inveterate smokers**. Technology, Vol 6, pp 17-21, 1999. This paper makes the case for encouraging inverate smokers to switch to less harmful nicotine delivery products.
10. Petition by the NY state health commissioner to FDA requesting that NRT products be made more readily available and at lower cost. Downloaded from http://www.regulations.gov/search/Regs/home.html#docketDetail?R=FDA-2008-P-0116
11. O'Connor RJ, Hyland A, Giovino G, Fong GT, Cummings KM. **Smoker awareness of and beliefs about supposedly less harmful tobacco products**. Am J Prev Med 2005; 29: 85-90 Abstract only http://www.ncbi.nlm.nih.gov/pubmed/16005803?itool=EntrezSystem2.PEntrez.Pubmed.Pubmed_ResultsPanel.Pubmed_RVDocSum&ordinalpos=6
12. Cummings KM. **Informing Consumers about the Relative Health Risks of Different Nicotine Delivery Products**, presented at the National Conference on Tobacco or Health, New Orleans, LA, 2001.
13. O'Connor RJ, MCNEILL A, BORLAND R, et al. **Smokers' beliefs about the relative safety of other tobacco products: findings from the ITC Collaboration**. Nic & Tob Res 2007; 9: 1033-42. Abstract only http://www.ncbi.nlm.nih.gov/pubmed/17943619?itool=EntrezSystem2.PEntrez.Pubmed.Pubmed_ResultsPanel.Pubmed_RVDocSum&ordinalpos=2
14. Altria comment to FDA Dockets Management 12/22/2009 requesting that FDA recognize that smokeless tobacco products are less hazardous than cigarettes
15. Gartner CE, Hall WD, Vos T, Bertram MY, Wallace AL, Limm SS: **Assessment of Swedish snus for tobacco harm reduction: an epidemiological modeling study**. Lancet 369(9578) 2010-4, 2007. There was little difference in health-adjusted life expectancy between smokers who quit all tobacco and those who switched to snus. Current smokers who switch to snus rather than continuing to smoke can realize substantial health benefits. Abstract only
16. Ramstrom LM, Foulds J: **Role of snus in initiation and cessation of tobacco smoking in Sweden**. Tobacco Control 15:210-214 2006. Use of snus in Sweden is associated with a reduced risk of becoming a daily smoker and an increased likelihood of stopping smoking.
17. **Smoking-attributable mortality, Years of Potential Lief Lost and Productivity Losses – United States, 200-2004**. MMWR Weekly November 14, 2008 57(45); 1226-1228 http://www.cdc.gov/mmwr/preview/mmwrhtm/mm5745a3.htm "During 2000-2004, an estimated 443,000 persons in the United Stated died prematurely each year as a result of moking or exposure to secondhand smoke. This figure is higher than the average annual estimate of approximately 438,000 deaths during 1997-2001."

18. Smoking continues gradual decline among U.S. teens, smokeless tobacco threatens a comeback. Press release December 14, 2009 from the Monitoring the Future program at the University of Michigan. http://www.monitoringthefuture.org/pressreleases/09cigpr.pdf Annual reductions in the percentage of teens initiating smoking have slowed in recent years.

19. Murrelle L et al: **Hypotheses and fundamental study design characteristics for evaluating potential reduced-risk tobacco products. Part I: Heuristic**. Regulatory Toxicology and Pharmacology (2009), doi:10.1016/j.yrph.2009.12.002. In this paper, the authors explore the numbers of participants and numbers of years of observation needed to explore possible benefit from reduced risk tobacco products in reducing the risk of lung cancer. Depending on the product and end points being sought, duration of study ranged from five to more than fifteen years. Documenting the risk-reducing effect of a potential reduced-risk tobacco product by means of a long-term prospective study of smokers, switchers and quitters, could, depending on the expected level of risk reduction from the reduced risk tobacco product, require observations on 8,000 to more than 100,000. subjects. The authors of this study did not comment on the ethics, feasibility, or practicality of multi-year studies with such large numbers of participants.

20. Pankow JF, Watanabe KH, Toccalino PL, Luo W; Austin DF: **Calculated Caner Risks for Conventional and "Potentially Reduced Exposure Product" Cigarettes**. Cancer Epidemiol Biomarkers Prev 16(3) pages 584-592 (2007). This paper makes the case that since the major carcinogens in cigarette smoke only account for less than 2% of the lung cancer caused by cigarettes, reducing their concentration in cigarette smoke will be unlikely to reduce this cancer risk by any noticeable amount.

21. The home page of the Tobacco Control Research Branch of the National Cancer Institute has, as its opening line, "The vision of the TCRB is a world free of tobacco use and related cancer and suffering." http://www.cancercontrol.cancer.gov/tcrb/about.html. This item is included as an attachment to this petition to document the commitment of federal agencies and others to the concept of a tobacco free society. This commitment has been commonly interpreted as ruling out any consideration of use of any commercially available non-pharmaceutical tobacco product in a harm reduction mode.

Attachment B: Electronic Cigarette References

1. Ben Thomas Group LLC: **Study to Determine the Presence of TSNAs in NJOY Vapor**. A report to Scottera, Inc, dba NJOY December 9, 2009. Ben Thomas Group, LLC, 11200 Westheimer Rd, Suite 900, Houston TX 77042. This paper affirms the safety of the NJOY product.

2. **Experiences of Electronic Cigarette Users Suggests that These Could Be Life-Saving Devices and that They are Effective for Smoking Cessation**. Commentary on Dr. Siegel's tobacco policy blog, at: http://tobaccoanalysis.blogspot.com/2009/08/experiences-of-electronic-cigarette.html. Rcd as E-mail Message from M Siegel, 8/7/2009 9:38AM; with introduction edited by J. L. Nitzkin 2/27/2010 to adapt to FDA petition guidelines. The passionate testimonials of of electronic cigarette users suggest that these devices are effective in helping smokers to quit and stay off cigarettes. These are all the comments from electronic cigarette users in response to Dr. Whelan's *Washington Times* op-ed piece. They are taken from the *Washington Times* site as well as the *Digg* site for this article. Dr Siegel has not omitted any comments from electronic cigarette users, which is remarkable because there is not a single

comment from a user who has not found these devices to be satisfactory as a substitute for conventional cigarettes.

3. Judge Leon's 1/14/2010 opinion ordering FDA to allow importation of Smoking Everywhere and NJOY E-cigarette products as downloaded from https://ecf.dcd.uscourts.gov/cgi-bin/show_public_doc?2009cv0771-54. The Reuters description of this opinion reads, in part, as follows:

> A U.S. judge on Thursday granted a preliminary injunction barring the Obama administration from trying to regulate electronic cigarettes *(as drug-device combinations)* and prevent them from being imported into the United States.
>
> In a sharply worded decision, U.S. District Judge Richard Leon scolded the Food and Drug Administration for trying to assert jurisdiction over the cigarettes, which are battery-powered or rechargeable devices that vaporize a liquid nicotine solution.
>
> "This case appears to be yet another example of FDA's aggressive efforts to regulate recreational tobacco products as drugs or devices," he said in granting an injunction barring the FDA from regulating the cigarettes as a drug-device combination.

4. **New Jersey GASP report on Electronic Cigarettes (E-Cigarettes)** http://www.njgasp.org/E-Cigs%20White%Paper.pdf -- This nine page report erroneously is dated January 11, 2009 (should be January 11, 2010) (as downloaded 2/4/2010). This report is included to show the impact the July 22, 2009 FDA press conference had on many tobacco-related organizations who then, based on this severely flawed FDA report concluded that E-cigarettes are extremely harmful, should be banned; and even present significant hazard to non-smokers. On page 6 it cites calls for E-cigarettes to be banned. These calls were issued by the American Lung Association, American Cancer Society, American Heart Association and Campaign for Tobacco Free Kids – all on the basis of the FDA press conference. On page 6, based on the FDA report, it states as a fact that "E-cigarettes appeal to youth." Later in the report it cites multiple localities and even foreign countries taking action against E-cigarettes. Other sources of information showed that each of these that were subsequent to the FDA July 22, 2009 press conference were as a result of the press conference.

5. FDA Analysis and Responses to FDA Press Release

   a. News Events links to July 22, 2009 Press "to discuss potential health risks associated with electronic cigarettes."

   b. July 22, 2009 press release transcript – verbatim transcript condemning E-cigarettes as contaminated with carcinogens and being marketed to minors

   c. FDA E-cigarette laboratory analysis serving as basis for July 22 press conference **–** very limited study for contaminants of a few Smoking Everywhere and Njoy E-cigarette fluid and headspace vapor, with no comparisons to NRT products or cigarette smoke.

      http://www.fda.gov/downloads/Drugs/ScienceResearch/UCM173250.pdf

   d. **Scientific Review of FDA Report-** evaluation of FDA study prepared for NJOY by Exponent Health Services pointing out major deficiencies in FDA study design and

interpretation of data.
http://www.njoythefreedom.com/contactcommerce/images/press_releases/Response%20to%20the%20FDA%20Summary.pdf

e. **Prominent Doctors Specializing in Tobacco Harm Reduction Question FDA Study- report** by inLife summarizing criticisms of FDA report by prominent researchers and public health physicians.
http://www.standardnewswire.com/news/162574365.html

f. AAPHP letter to Dr. Deyton urging correction of misleading information in July 22 press conference.

g. Siegel M (Blog post 7/22/2009): **Tobacco-Specific Carcinogens Found in Nicotine Replacement Products; Will Anti-Smoking Groups Call for Removal of these Products from the Market? Despite Laboratory Finding of Carcinogens in Nicotine Replacement Medications, FDA Fails to Hold Press Conference to Express Concern About Potential Dangers of Nicotine Replacement Products.** This Blog entry criticizes FDA for condemning E-cigarettes on basis of trace carcinogens without also condemning NRT products for similar contamination.
http://tobaccoanalysis.blogspot.com/

h. Siegel M (Blog post 7/30/2009): **Comparison of Carcinogen Levels Shows that Electronic Cigarettes are Much Safer than Conventional Ones.** This Blog entry shows TSN levels in selected electronic cigarettes, NRTs, snus, smokeless tobacco and cigarettes. http://tobaccoanalysis.blogspot.com/2009/07/comparison.html.

i. Siegel M (from Blog): **List of Identified, Known Carcinogens in Electronic Cigarettes vs. Conventional Cigarettes.** This Blog entry shows no carcinogens in electronic cigarettes beyond trace quantities, and 57 in conventional cigarettes.
http://tobaccoanalysis.blogspot.com/2009/07/list-of-identified-known-carcinogens-in.html.

6. Liquid and Vapor Analyses

a. **Safety Report on the Ruyan E-cigarette Cartridge and Inhaled Aerosol** Study shows TSNA levels in vaporized nicotine liquid is below what would be considered carcinogenic. Report includes both laboratory analyses and literature review. Report done by Health New Zealand Ltd.
http://www.healthnz.co.nz/RuyanCartr...t30-Oct-08.pdf

b. **e- cigs.co.uk** – study of one bottle of "e-juice XX High 36mg/ml rated Nicotine Solution provided by Hertfordshire Training Standards showing concentrations of major ingredients by GC MS. The liquid conformed to manufacturing specs. Considered hazardous due to nicotine content, authors urged warning labels regarding ingestion, skin contact, and to keep out of reach of children.
http://www.e-cigs.co.uk/docs/E249A.pdf. Bulk E-cigarette liquid is commonly used by vapers (E-cigarette users) to refill the cigarette cartridges. This is easily done and is considerably less expensive than buying more cartridges.

c. **InLife** (Alliance Technologies) – two studies of Regal Cartridge Liquid by GCMS; first for major ingredients, second for TSNAs and TSIs
http://truthaboutecigs.com/science/8.pdf
http://truthaboutecigs.com/science/9.pdf

d. **esmoke.net –** Precision Testing Labs studies of eSmoke LLC liquid – 3 certificates showing no detectable diethylene glycol and one sheet showing no detectable

contamination by a long list of semivolatile organics.
http://www.esmoke.net/batch/090124/PGDrumGCFID.pdf (PG Raw Material)
http://www.esmoke.net/batch/090124/GLDrumGCFID.pdf (Glycerin Raw Material)
http://www.esmoke.net/batch/090124/090124-GCFID.pdf (GC/FID)
http://www.esmoke.net/batch/090124/090124-GCMS.pdf (GC/MS)

e. **Totally Wicked/TECC –** due diligence GC-MS analysis of 3 nicotine cartridges to confirm major constitutents and their relative concentrations
http://www.theelectroniccigarette.co...ogy_report.pdf

f. **Gamucci –** due diligence GC-MS analysis of 4 nicotine cartridges to confirm major constitutents and their relative concentrations
http://www.ecigaretteschoice.com/GamucciLabStudy.pdf

g. **Instead –** due diligence GC-MS analysis of 2 nicotine cartridges and vapor to confirm major constitutents and their relative concentrations
http://www.e-cig.org/pdfs/Instead-ELiquid-Report.pdf

h. **SuperSmoker** – lab analysis of the vapor from 20 SuperSmoker cigarettes, cigars and cartridges to document compliance with German and FDA GRAS standards of major ingredients. Attachment is summary report.
http://www.supersmokerjp.com/images/...anslatiion.pdf

i. **Propylene Glycol Studies** – a Vapers Club review of the literature and EPA assessments of the safety of Propylene Glycol, in response to the FDA condemnation of E-cigarettes as untested and of unknown safety. Vapers Club is a group of E-cigarette users organized to try to keep E-cigarettes on the American Market. They are not associated with any manufacturer or vendor.
http://www.vapersclub.com/pg.html

j. Siegel M (from Blog): **No tobacco-specific nitrosamines or diethlylene glycol dectected in inLife electronic cigarettes: Do anti-smoking groups still want ex-smokers to return to the real thing?** – This Blog entry sees the scare instilled into the American public by the FDA July 22 press release as damaging to the health of the public. : http://tobaccoanalysis.blogspot.com/2010/01/no-tobacco-specific-nitrosamines-or.html.

Attachment C: NRT Product References

JLN Note: The following references are provided in the context of this petition to document both the long term safety of nicotine replacement or inhalation and the relative ineffectiveness of Nicotine Replacement Therapy (NRT) re ultimate cessation of nicotine use. Attachments E6 and E7 address serious problems with some of the initial studies leading to the FDA approval of NRT products. Taken together, this set of attachments supports our impression that NRT therapy cannot stand as a cornerstone of a tobacco harm reduction initiative that could be expected to reduce overall illness and death rates from cigarettes.

1. Moore D, Aveyard P, Connock M, Wang D, Fry-Smith A, Barton P: **Effectiveness and safety of nicotine replacement therapy assisted reduction to stop smoking: systematic review and meta-analysis**. BMJ 338:b1024 2009. This paper documents the dismal track record of pharmaceutical NRT products in securing long-lasting cessation of cigarette smoking. The abstract cites a 93.25% failure rate of NRT products after 6 months (phrased as a 6.25% success rate). The 98.4% failure rate at 20 months is cited in the study, but not mentioned in the abstract

2. Waldum HL et al: **Long term effects of inhaled nicotine**. Life Sci. 58(16) 1339-46 1966. Study on long term (2 year) inhalation of nicotine by rats showing no ill effect. http://www.ncbi.nlm.nih.gov/pubmed/8614291
3. Murray RP, Connett, JE, Zapawa M: **Does nicotine replacement therapy cause cancer? Evidence from Lung Health Study** – abstract only – smoking predicts cancer, NRTuse does not http://ntr.oxfordjournals.org/cgi/content/abstract/11/9/1076
4. Ossip DJ et al: **Adverse effects with use of nicotine replacement therapy among quitline clients** – abstract only; adverse effects mild, few quit due to adverse effects; distribution of over the counter nicotine through quitlines declared safe. http://ntr.oxfordjournals.org/cgi/content/abstract/11//408
5. Sumner II W: **Estimating the health consequences of replacing cigarettes with nicotine inhalers** – abstract only; spreadsheet projection of health consequences assuming nicotine accounts for 1/3 of tobacco related illness and death shows substantial health benefit (JLN note: other research indicates nicotine accounts for less than 2% of tobacco relate illness and death – so expected public health benefit much more substantial than estimated in this study) http://tobaccocontrol.bmj.com/content/12/2/124.abstract
6. Siegel M (from Blog): **New study shows that at least two-thirds of patients receiving placebo in "double blind" NRT trials know that they are receiving placebo**. This blog entry casts doubt on conclusions regarding effectiveness of nicotine replacement therapy. http://tobaccoanalysis.blogspot.com/2009/07/new-study-shows-that-at-least-two.html
7. Siegel M (from Blog): **Effectiveness of nicotine replacement therapy needs to be re-examined**. This Blog entry lists ten problems, including but not limited to conflicts of interest, bias and blinding failures that permeate much of the literature in favor of NRT therapy. http://tobaccoanalysis.blogspot.com/2009/07/in-my-view-effectiveness-of-nicotine.html

C. Environmental impact

In accordance with the provision of CFR Title 21, Subpart C (Categorical Exclusions) Section 25.30 (General) paragraph (i) – I (Joel L. Nitzkin, MD – signatory to this petition) claim exclusion for need for environmental impact statement on basis that what we are requesting is limited to "corrections and technical changes in regulations."

D. Economic Impact

(CFR Title 21 specifies that an economic impact statement is required only when requested by the Commissioner following review of the petition.)

E. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition and attachments include all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are favorable to the petition.

Joel L. Nitzkin, M.D.

JLN:jln 20100207FDA Petition2.pdf

About the Authors

Paul L. Bergen, MSc (Psycholinguistics) MLIS, has alternated between studying and working in academia, and working in the book trade. He initially studied how individuals use contextual cues to determine the correct meanings of messages and now explores how messages are constructed to deliberately mislead individuals and the processing strategies that both help and hinder understanding. He has been with TobaccoHarmReduction.org since its inception.

James E. Dillard, PhD, is Senior Vice President at Altria and was Senior Vice President at U.S. Smokeless Tobacco Company before it was acquired by Altria. Previously he was Director of Cardiovascular, Respiratory, and Neurology Devices at the U.S. Food and Drug Administration. Altria, parent company of the tobacco companies Philip Morris USA, U.S. Smokeless Tobacco Company, and John Middleton, lists among its mission statements to actively participate in resolving societal concerns that are relevant to its business, including supporting the development and implementation of regulations that improve public health and recognize individual consumer rights and preferences. Additionally, its stated mission includes satisfying adult consumers, part of which is developing products for smokers that are lower risk than their current cigarettes and communicating openly and honestly about the health effects of tobacco products.

James Dunworth is the IT director and a shareholder of ECigaretteDirect.co.uk. Having had enough of the UK at the age of 21, he packed his bag and travelled abroad for four years, only returning (briefly) to first study and then teach at the University of Wales, Cardiff. He has lectured and taught in Thailand, Indonesia and the Middle East, created several websites, and has written for newspapers and magazines. At E Cigarette Direct he has reviewed, conducted, and reported on research on electronic cigarettes, and set up the Ashtray blog to provide electronic cigarette and tobacco harm reduction news. He has collected expert opinions on electronic cigarettes by conducting numerous interviews which are available online and have been translated into several languages, and has conducted several surveys of e-cigarette users.

Karen Geertsema, MSc, is an independent environmental consultant specializing in Ethnobotanical Impact Assessments and Environmental Planning. She works with the Canadian Institute of Planners and is working towards developing the first Alberta First Nation Land Use Plan, which focuses upon conservation and stewardship of flora used for Ethnobotanical purposes. Ms. Geertsema is specifically concerned with the sustainability of flora used for medicinal purposes given the intensity and pace of industrial and resource development in Alberta, and the resultant adverse impacts upon unique plant communities. She formally worked with the Ministry of Forests in British Columbia (B.C.) in Silviculture and then Ecology, and the B.C. Conservation Foundation where she managed environmental research. She worked with Carl V. Phillips's research group, conducting research on smokeless tobacco in the Department of Public Health Sciences at the University of Alberta while in her Master's program at the Faculty of Forestry and Agriculture.

Bill Godshall founded SmokeFree Pennsylvania in 1990, and has been its executive director since then. SmokeFree Pennsylvania has successfully advocated policies for smoke-free air, reducing tobacco marketing to youth, increasing tobacco taxes, expanding nicotine addiction treatment services, and educating smokers about less hazardous alternatives to cigarettes.. Originally a statewide grass roots organization, SmokeFree Pennsylvania has also been involved in numerous national level activities.

Jan Hamling gained a degree in mathematics at Imperial College, London University in 1978, completed a course in epidemiology in 1998, and gained a diploma in statistics from the Open University in 2005. Having previously worked as a systems analyst, she joined P.N. Lee Statistics and Computing Ltd. in 1994. She is a co-author of *International Smoking Statistics* and has contributed to a paper on techniques for meta-analysis, and several reviews of evidence on the health effects of smoking, environmental tobacco smoke exposure and smokeless tobacco use. She has two children and also enjoys singing and gardening.

Karyn K. Heavner, MSPH PhD, is an epidemiologist specializing in behavioral research, particularly issues of misclassification related to harm reduction (tobacco and otherwise). She completed a MSPH at the University of South Carolina, a doctorate at the University at Albany, where she focused on HIV-related harm reduction and epidemiology methods, and a postdoc at the University of Alberta where her work included tobacco harm reduction and epidemiology methods. In addition to the works represented here, Dr. Heavner recently completed the most complete population-level analysis to date that demonstrates the success of THR in one European subpopulation.

Courtney E. Heffernan has an honours degree in Philosophy from the University of Windsor and a Masters in Philosophy from the University of Waterloo. She formerly worked in the research group at the University of Alberta that included the editors of this volume. She is currently living in Edmonton with her cat, Beastly.

Peter N. Lee has, since 1979, been an independent consultant in statistics and adviser in epidemiology and toxicology to a number of tobacco, pharmaceutical and chemical companies. He has been director of P.N. Lee Statistics and Computing Ltd. since 1982. Having studied Mathematics and Statistics at Oxford University from 1962-66, he worked for the Tobacco Research Council as Statistician and Research Coordinator before going independent. He has published five books and over 200 papers on aspects of medical statistics, epidemiology and clinical trials. Smoking, environmental tobacco smoke exposure and, more recently, smokeless tobacco are special interests, and his papers review evidence on numerous potential health effects. He is the only person ever to have won the British Championship at both chess (at age 21) and bridge (at age 60). He is married with one daughter and two grandchildren.

Karl E. Lund, PhD, has been Research Director at the Norwegian Institute for Alcohol and Drug Research since 2006. He has been involved in tobacco control work since the mid 1980s, working at the Norwegian Council on Tobacco or Health (Deputy Leader), the Norwegian

Institute for Public Health (Researcher), and the Norwegian Cancer Society (Director for Department of Cancer Prevention). Dr. Lund received the Norwegian Medical Association's Award in preventive medicine in 2002. He is well published within tobacco research, has been a lecturer on tobacco topics in several countries worldwide, and has been a member of several expert committees on tobacco control including WHO's International Agency for Cancer Research (IARC) and the executive committee of the International Society for the Prevention of Tobacco Induced Diseases. He has also been an expert witness for the plaintiff in tort liability lawsuits brought before the Norwegian Supreme Court against the tobacco industry.

Catherine M. Nissen is a researcher with TobaccoHarmReduction.org. She has a B.Sc. in General Science from the University of Alberta (studying biology and psychology) and anticipates further education in public health. She has made a study of misinformation in public health messages, and her THR research focuses on this area. She is a practical statistician in the Pascalian tradition (i.e., avid poker player) and also enjoys running in the river valley of her hometown, Edmonton.

Joel L. Nitzkin, MD MPH DPA, is a public health physician, Board Certified in Preventive Medicine, and has been involved in tobacco control work since the mid 1970s. He served as a local health Director (Rochester, NY), State Public Health Director (Louisiana), and President of two national public health organizations (National Association of County and City Health Officials (NACCHO) and American Association of Public Health Physicians (AAPHP). He became Chair of the AAPHP Tobacco Control Task Force in February of 2007, at the time when the U.S. was contemplating granting regulatory authority over tobacco to the Food and Drug Administration. Choosing to review the FDA proposal rather than blindly heed the calls to support it, his task force was shocked and dismayed by the pro-cigarette and anti-harm reduction provisions written into the bill (which later became law with all these provisions intact), and the degree to which the language of the bill differed from the Campaign for Tobacco Free Kids' summary used to secure the endorsements of many other organizations. They conducted literature reviews which led to them to discovering nicotine vaporizers / electronic cigarettes, and conducted analysis which (to their surprise) caused them to become proponents of tobacco harm reduction, particularly including the use of nicotine vaporizers. AAPHP's analyses, literature review, and conclusions are in the public domain and available for download from the Tobacco Issues page at www.aaphp.org.

David O'Reilly, PhD, is Head of Public Health & Scientific Affairs at British American Tobacco (BAT). He has been with BAT since 1989 and has held various positions in both Research & Development and Corporate Affairs. In R&D he has led the company's Strategic Product Development and Risk Characterisation functions and most recently led BAT's global harm reduction program with the aim of the developing lower risk products and a framework for their assessment. In Corporate Affairs, Dr. O'Reilly pioneered Corporate Social Reporting for BAT, which became the first tobacco company to implement such a program, and led the development of the company's Statement of Business Principles and Framework for CSR. In his current role as Head of Public Health & Scientific Affairs, David is responsible for global strategic engagement on harm reduction amongst the scientific and public health communities. BAT is the world's second largest quoted tobacco group by global market share, with brands sold in more

than 180 markets. BAT publicly states that they manufacture products that can be harmful to the health of their consumers. They aspire to reduce the harm caused by smoking by evolving their products to a portfolio of commercially successful lower risk products that meet consumer and societal expectations. Their approach is to pursue the research, development and test marketing of innovative tobacco products that will have consumer acceptability and will be recognized by scientific and public health communities and regulators as posing reduced risks to health.

Adrian Payne, PhD, is an independent commentator on regulatory issues relating to tobacco harm reduction. Previously he was Head of International Public Health and Scientific Affairs at British American Tobacco (BAT), and prior to that, Head of Corporate Social Responsibility. Whilst at BAT, Adrian played a key strategic role in the development and initial test marketing of Swedish-style snus under cigarette brand names in Sweden and South Africa in 2005. This initiative was undertaken in response to suggestions from some Public Health Stakeholders that snus might be a useful tool in tobacco harm reduction because of the vastly reduced health risks of this type of tobacco product compared with smoking cigarettes.

Stanton Peele is a pioneering addiction psychologist who, beginning with *Love and Addiction* in 1975 and in numerous books and articles since, outlined a non-drug-based model of addiction, the value of harm reduction, and the frequent occurrence of untreated, non-12-step recovery. His most recent books are *7 Tools to Beat Addiction* and *Addiction-Proof Your Child*. He developed the Life Process Program, which is used residentially and for outpatients at St. Gregory Retreat Center.

Carl V. Phillips, MPP PhD, is an independent researcher and consultant focusing on tobacco harm reduction and on improving methods and epistemology in the health sciences. He spent most of his career as a professor of public health, with a teaching focus of how to make optimal decisions based on evidence. His work draws upon his studies in economics, ethics, philosophy of science, political science, and public health. Dr. Phillips directs the TobaccoHarmReduction.org research group and works as a consultant and advisor for various organizations and companies involved with tobacco harm reduction. He also provides litigation support and other consulting on a broader range of topics related to health science. Dr. Phillips is an award-winning researcher in epidemiology methods, focusing on making epidemiologic research more useful and honest by recognizing biased analyses and quantifying uncertainty. His writings and teaching have included these topics as well as environmental health, animal agriculture, diet and nutrition, and how non-experts can critically evaluate scientific claims. He received his PhD in public policy from Harvard University, completed fellowships in health policy research at the University of Michigan and philosophy of science at the University of Minnesota, and also has degrees in math and history.

Brad Rodu, PhD, is a Professor of Medicine at the University of Louisville, holds an endowed chair in tobacco harm reduction research, and is a member of the James Graham Brown Cancer Center at U of L. For the past fifteen years Dr. Rodu has conducted research on tobacco harm reduction, involving permanent nicotine maintenance with safer tobacco products by smokers who are unable or unwilling to quit smoking with conventional cessation methods. Dr. Rodu

earned his dental degree from the Ohio State University. After an oral pathology residency program at Emory University, Dr. Rodu completed fellowships at the University of Alabama at Birmingham (UAB) sponsored by the American Cancer Society and the National Cancer Institute. He was on the UAB faculty from 1981 to 2005, with appointments in several departments in the Schools of Medicine, Public Health and Dentistry. Dr. Rodu's research is supported by unrestricted grants from tobacco manufacturers to the University of Louisville and by the Kentucky Research Challenge Trust Fund.

Christopher Snowdon is an independent author and historian whose works include *Velvet Glove, Iron Fist: A History of Anti-Smoking* (2009). He has a degree in history from Lancaster University and has written about a wide range of issues relating to liberty and public health for Spiked, Environment & Climate News, Pipes and Tobaccos, and The Free Society. His most recent book is *The Spirit Level Delusion* (published May 2010).

TobaccoHarmReduction.org (THR.o) is a research and education group directed by Carl V. Phillips that produces scientific research and socio-political analysis about THR and related topics, advocates for THR at the policy and grassroots level, and disseminates information through the eponymous website, the associated blog, presentations, mass media, journal articles, and other publications (e.g., this book). THR.o has contributed research in epidemiology, consumer behavior, welfare economics, mass communication, epistemology, and ethics, and attempts to translate all of these into popular education. Originally established at the Department of Public Health Sciences at the University of Alberta Medical School (later part of the School of Public Health) in 2005 and launching the website there in 2006, the group became an independent research institute in 2010. Paul Bergen, who has been a researcher with THR.o from its inception, maintains the website and is director of communications. Catherine M. Nissen is THR.o's research coordinator. Several other contributors to this book are former students and trainees or current affiliates of the group.

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