

The Seduction of Harm Reduction

Proceedings from the September 2004 Summit



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Edited by Rhonda Robins

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The willingness of these individuals to take a position and express their views at the summit and within these proceedings greatly aided TCS's understanding of the issue. The risk these individuals have taken is no small matter and is a demonstration of the integrity of these professionals.

TCS would like to especially acknowledge David Altman, Ph.D., Vice President of Research and Innovation, Center for Creative Leadership, who had the unenviable role at the summit of being a neutral listener and storyteller. Dr. Altman brought a remarkable level of creativity and patience to that role as he reflected back and summarized to the summit participants key areas of agreement and divergence. His skillful listening, reflection and storytelling brought a level of humanity to a discussion that was dense with graphs, charts, and divergent interpretations of data.

Our thanks to all of those who presented, attended, or submitted comments to TCS. Your willingness to speak up is no small matter.

Sincerely,

Dileep G. Bal.

MD, MPH, Chief Cancer Control Branch

California Department of Health Services
On behalf of the entire staff at TCS



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Introduction

The Seduction of Harm Reduction Summit, held on September 8th and 9th, 2004, in Sacramento, California, was convened by the California Department of Health Services, Tobacco Control Section (TCS), to gather feedback on an early draft of a position paper that explored the ramifications of the so-called “harm reduction” strategy.

The draft position paper, written by TCS staff, was distributed to all speakers and audience members prior to the invitation only summit. The position paper sets forth the reasons TCS decided to oppose the harm reduction strategy, as well as recommendations for meaningful regulation of tobacco and medicinal nicotine products.

The term “harm reduction” refers to a strategy that encourages tobacco users who cannot or will not quit smoking to switch to an alternative nicotine-delivery product that is potentially less harmful than their regular product. TCS prefers to call this a “nicotine maintenance” strategy.

The speakers at the summit, as well as members of the audience, comprised a diverse group, with representatives from public health, epidemiology, medicine, public relations, law and the private sector sharing their views on the emergence of harm reduction as a tobacco control strategy. Many speakers offered specific comments, both pro and con, about the statements and conclusions in the draft position paper. Participation in or attendance at the summit did not in any way imply endorsement of TCS’s position on nicotine maintenance/harm reduction.

TCS staff considered the feedback received at the summit as they finalized the nicotine maintenance position paper and action plan (scheduled for release in the spring of 2005).

These proceedings seek to capture the summit presentations, commentary from summit participants, and written comments sent to TCS by invited participants to the Seduction of Harm Reduction Summit held in September 2004 in Sacramento, California. The presentations were transcribed from tape recordings and sent to the respective presenters for review. We have done our best to accurately capture and reflect the information presented and dialog that followed the presentations, but acknowledge there may be some errors in transcription or editing in an attempt to make a readable, coherent document. Our sincere apologies are extended to any of those who believe these proceedings fail to accurately capture their remarks.





Summit Presentations

Session 1 Overview of the California Position

Welcome and Opening Remarks

Dileep G. Bal, MD, MS, MPH

Chief, Cancer Control Branch

California Department of Health Services

On behalf of the California Department of Health Services, Tobacco Control Section (TCS), Dr. Bal thanked all of the guests in attendance, as well as the TCS staff who put the program together. He added a special note of thanks to Jon Lloyd, who recently retired from TCS.

Dr. Bal began the discussion by asserting that this summit was overdue. The ramifications of “harm reduction” are serious; too many lives are at stake, as well as the future of tobacco control. The intentionally provocative position paper being discussed at the summit has raised a buzz in the tobacco control community, an indication that TCS is, once again, threatening the interests of industries with a financial stake in perpetuating the use of nicotine.

California’s proven tobacco control success over the last fifteen years, including the realization of one of the nation’s lowest cancer incidence rates, a low rate of cigarette consumption, and significant reductions in adult and youth prevalence rates, has earned TCS the right to challenge the rest of the public health community on the issue of “harm reduction.”

TCS is concerned about the possible implications of harm reduction for the state’s comprehensive tobacco control program for several reasons. First, California’s approach focuses on norm change in the state’s population. Currently, little information is available on population-based impacts of harm reduction protocols. Second, making nicotine maintenance products ubiquitous in the marketplace may lessen the motivation of smokers to quit using nicotine products altogether if they can replace their current products with “less harmful” ones. Third, easy accessibility of nicotine maintenance products may facilitate relapse among former tobacco users. And fourth, tobacco control advocates are troubled by the possibility that the tobacco and pharmaceutical industries may exert undue influence on federal agencies that create policy or promulgate regulations pertaining to nicotine maintenance products.

As the tobacco control community proceeds with its study of harm reduction, it must not repeat the mistakes of the past, as when the tobacco industry duped well-meaning health practitioners into recommending low-yield cigarettes to patients concerned about their health. Similarly, many tobacco control advocates thought the Master Settlement Agreement (MSA) was going to solve



the nation's tobacco problems; instead, the tobacco industry is spending more than ever to promote and market its products, and many state tobacco control programs have been gutted at a time when much of the public believes that the tobacco industry has been punished enough.

Tobacco control advocates have learned to be wary of using terminology co-opted by the tobacco industry. After all, who can be against "harm reduction?" However, it is more than just semantics. In the harm reduction discussion, the terms must be defined, the meanings must be clear, and the burden must rest with the tobacco and pharmaceutical industries to show that their nicotine maintenance products meet an acceptable standard of "safety."

So, where does the tobacco control movement go from here? The future remains to be seen, or as one of Dr. Bal's favorite philosophers, Søren Kierkegaard, once said, "Life can only be understood backwards, but it must be lived forwards."

Overview and Purpose of the Summit

April Roeseler, MSPH

Chief of Local Programs and Evaluation

California Department of Health Services, Tobacco Control Section

Ms. Roeseler joined Dr. Bal in welcoming all of the guests to the summit, and noted the diversity of opinions on harm reduction and nicotine maintenance represented. She expressed appreciation for the fact that, in spite of their differences, all of the guests were driven by their passion for public health and saving lives.

Ms. Roeseler explained the purpose and background of the summit as well as the agenda for the next two days.

The meeting was defined as a summit, not a conference. The goal was to educate the California Department of Health Services, Tobacco Control Section (TCS), and to gather both positive and negative feedback on the draft position paper distributed to participants prior to the summit. TCS was not seeking to establish a consensus, and participation was by invitation only. Invited speakers included national experts on nicotine maintenance/harm reduction, as well as many of California's tobacco control leaders. The audience was also diverse, with representatives from public health, academia, food and drug control, the Office of the California Attorney General, advocacy groups, and public relations.

The draft position paper, "Nicotine Maintenance, Regulation of Tobacco, and Public Health," written by TCS staff and sent to participants prior to the summit, had its origins in a meeting sponsored by the Technical Assistance Legal Center (TALC) in the summer of 2003. This meeting convened public health professionals, representatives from attorneys general offices, and consumer protection experts from across the country to discuss how tobacco control advocates could use existing consumer protection laws and state regulatory food and drug authority to go beyond the Master Settlement Agreement (MSA) to regulate tobacco.

TCS staff and other tobacco control advocates left the TALC meeting feeling somewhat uncomfortable about its conclusions and wanting to find a way to address those issues in California. As a result, TCS convened a task force to discuss harm reduction and nicotine maintenance that included TCS staff, lawyers from the Office of the Attorney General of California, TALC staff, food and drug authorities, staff of Rogers and Associates (TCS's public relations firm),



and media expert Paul Keye. This group's discussion of the issues culminated in the TCS policy paper and an action plan to answer the concerns generated by the 2003 TALC meeting.

Tobacco control advocates in California and elsewhere are concerned about the ramifications of the harm reduction strategy because the tobacco control movement is littered with unintended consequences. Ms. Roeseler pointed to the "light cigarette fiasco" as one of the primary examples of a harm reduction phenomenon that resulted in a public health disaster. She quoted Jack Henningfield's¹ testimony before the U.S. House of Representatives in June 2003: "Light cigarettes delayed quitting and supposedly safer smokeless tobacco was a magnet for athletes who had been considered at low risk for any form of tobacco use prior to the healthy image product marketing of the 1970s."

TCS is also concerned about the possibility of federal regulation of tobacco products. Had they gone into effect, the federal Food and Drug Administration (FDA) regulations proposed in 1996 would have pre-empted vending machine bans in 60 California communities and self-service display bans in 35 California communities without a special FDA waiver. State and local ordinances and regulations such as these bans often take from one to three years to get passed. Preemptive federal regulation that is weaker than state or local regulation could render moot a lot of hard work and would undermine activity at the local level that often serves as a launching pad for more aggressive work.

Tobacco control advocates saw a similar phenomenon with the youth-focused MSA. In some ways, the MSA has hindered California's tobacco control progress and created its own set of problems: marketing to young adults has exploded (including over 20,000 bar nights sponsored by the tobacco industry in California in 2004), the age at which people become regular smokers is now increasing, billboard bans were already underway here, and the retail environment has become an important venue for tobacco marketing, something California has had a very hard time regulating. Ad regulations in Massachusetts were a well-intentioned effort that unfortunately resulted in a June 2001 U.S. Supreme Court ruling that struck down local ordinances in 40 California communities restricting the placement of retail tobacco advertising. Again, a lot of work "went down the drain."

The bottom line for TCS is that tobacco and nicotine are unsafe. Public health professionals should not foster a culture that promotes nicotine maintenance. Products marketed as "reduced harm" might not be used in the way they are intended, or messages about these products may be perceived and acted upon in ways not intended. TCS is concerned that harm reduction may undermine and damage California's very successful social norm change strategy. It could create a safe harbor for the tobacco industry, protecting their profits. The promotion of harm reduction/nicotine maintenance also creates a new market for the pharmaceutical industry by giving another option to smokers who would otherwise quit. Nicotine maintenance criteria should be based on science that assesses performance standards of these products in terms of their population impact and not on the design standards of the products.

TCS also believes that nicotine maintenance conflicts with the FDA's mission. The FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, the nation's food supply, cosmetics, and products that emit radiation. The FDA is also responsible for advancing the public health by

¹ Jack Henningfield is Professor of Behavioral Biology (Adjunct), Department of Psychiatry, The Johns Hopkins University School of Medicine, and Vice President for Research and Health Policy, Pinney Associates.



helping to speed innovations that make medicines and foods more effective, safer, and more affordable, and helping the public get the accurate, science-based information they need to use medicines and foods to improve health. Promoting the continued use of nicotine products, whether they are cigarette-like products, smokeless tobacco products, or nicotine maintenance products, strikes TCS as inconsistent with FDA's mission.

TCS often hears that "California is different;" people say that actions or regulations that work in California are not feasible elsewhere. However, many of the innovations that began in California have been adopted in other states. Quit lines, secondhand smoke regulations, smoke-free bars, and anti-tobacco industry strategies have all been successfully implemented across the country. The tobacco control movement would not be well served by a federal regulatory approach that dismantles and cripples current local and state programs.

California's tobacco control program differs from some others in that it focuses on adults rather than youth. TCS believes that the world in which youth grow up must be changed, and it is adults that control that world. In this way, the social norm of both youth and adults is changed. California's program is about promoting denormalization of tobacco use, not institutionalizing tobacco and addiction to nicotine.

In California, tobacco control advocates currently have policy initiatives underway to restrict placement and density of tobacco retailers as well as to eliminate tobacco sales in pharmacies. Some of the current harm reduction proposals may undermine these initiatives.

Another measure of the denormalization of tobacco in California is reflected in the attitudes Californians hold toward the tobacco industry. When asked if the tobacco industry has been punished enough, 47% of Californians say "no," as opposed to 35% in the rest of the nation. California's program works—the signs of declining tobacco addiction are clear:

- ◆ Smokers smoke less.
- ◆ More are non-daily smokers.
- ◆ Fewer need to smoke soon after waking.
- ◆ Quit attempts are increasing.
- ◆ There has been no increase in the number of smokers who never expect to quit.

Harm reduction or nicotine maintenance is often framed as a way to help intractable smokers, but the results of California's norm change strategy refute the idea that there is a large group of hard-core smokers who refuse to quit.

The next steps for TCS in terms of the harm reduction/nicotine maintenance debate are as follows:

- ◆ TCS will consider the summit participants' input while revising and clarifying the position paper.
- ◆ The position paper and a communication strategy will be introduced in mid-2005.
- ◆ Working with TALC, TCS will promote a local model ordinance to require a moratorium on the sale of new "harm reduced" products until population data demonstrating the value of these products is available.



To assist TCS in this process, this summit was designed to focus on the following topics:

- ◆ Cigarette-like products
- ◆ Smokeless tobacco
- ◆ Medicinal nicotine
- ◆ A historical review of regulating the tobacco industry
- ◆ The current environment for regulation
- ◆ Communication issues

Ms. Roeseler concluded by saying that, to TCS, harm reduction is about convincing people who are worried about their health not to quit, while giving the illusion that they are doing something that will protect their health. As media expert Paul Keye has said, “In every con job, the victim is a willing participant.” Tobacco control advocates who accept this nicotine maintenance strategy are willing participants in the harm reduction con job.

The California Position on Harm Reduction and Tobacco Regulation

Greg Oliva, MPH

*Chief of the Program Planning and Policy Development Unit
California Department of Health Services, Tobacco Control Section*

Mr. Oliva’s presentation clarified the California Department of Health Services, Tobacco Control Section (TCS) position on the subject of harm reduction. He explained the following:

- ◆ TCS’s definition of harm reduction
- ◆ The rationale for TCS’s position
- ◆ TCS’s conclusions about the harm reduction strategy
- ◆ An overarching philosophy on the harm reduction strategy
- ◆ Criteria that could be the basis for ordinances in California
- ◆ Regulatory preconditions
- ◆ Recommendations for future action

The way the term harm reduction is being used today, it means nicotine maintenance, and that means switching from a more hazardous product to a less hazardous product. Harm reduction also can have a more global meaning. After all, a comprehensive tobacco control program can be viewed as harm reduction. Tax increases, clean indoor air policies, smoke free workplaces, cessation interventions, and anti-tobacco industry media campaigns all have certainly reduced harm in California, but the term “harm reduction” does not usually refer to these kinds of efforts.

As a side note, Mr. Oliva explained that TCS does not see cessation as nicotine maintenance. Cessation is quitting, maintenance is maintaining. TCS is not anti-cessation; the department supports cessation as part of a comprehensive tobacco control program.

To simplify the discussion of the issues, Mr. Oliva defined two camps. In the first camp are harm reduction proponents, people who characterize TCS’s position as one of telling smokers to “quit or die.” They believe that people who cannot quit smoking should be able to access alternative, potentially less harmful forms of nicotine addiction, thereby improving the health of those individuals, and perhaps improving the community’s health in the aggregate. In the second camp



are people more aligned with TCS's position. This group is somewhat skeptical of the tobacco harm reduction strategy and sees harm reduction as weakening public health efforts, leading to more tobacco use (through increased consumption and relapse, as well as youth initiation), and decreasing the perception of the danger from tobacco. TCS believes that supporting a nicotine maintenance strategy presents a big risk in the absence of scientific evidence for efficacy.

TCS concludes, therefore, that harm reduction in the form of a nicotine maintenance strategy threatens proven efforts to reduce the toll of tobacco. It is an unproven approach, and there is insufficient evidence that the use of any nicotine delivery product can produce an aggregate public health benefit.

California is concerned about the population impact of these strategies. At the present time, there is insufficient evidence to justify public health support for the use of any nicotine maintenance product as an alternative to the use of cigarettes or other tobacco products. Nicotine maintenance products encourage users to continue their addiction, even though there is evidence that nicotine is toxic. Some studies demonstrate that nicotine contributes to the development of heart disease. Other studies suggest that nicotine may contribute to cancer.

TCS sees an inherent contradiction in the public health community asking people to use medicinal nicotine products for cessation on the one hand, and encouraging them to switch to another type of tobacco or nicotine maintenance product on the other hand. Promoting nicotine maintenance is a diversion from higher priority policies and programs.

Nicotine maintenance products must deliver nicotine, satisfy the smoker, and be pleasurable to use. Satisfaction implies a rapid high spike of nicotine in the blood, which could pose a health risk. In the absence of definitive scientific studies, using exposure to toxicants as a measure of potential harm is insufficient; exposure should not be used as a proxy for actual risk.

The rationale for TCS's position on harm reduction is informed by three factors: lessons from history and the resultant distrust of the tobacco industry, the state of the relevant science, and consideration of the power and influence of the pharmaceutical industry.

The strongest example of the tobacco industry's history of deception comes from 1968 when the industry partnered with the National Cancer Institute to form the Tobacco Working Group, which was a committee charged with identifying a safer cigarette. The Tobacco Working Group issued reports stating that smokers of filtered cigarettes showed a remarkably decreased risk of disease. Quotes such as the following made their way into the mainstream media: "These studies give unequivocal proof in man that reduced tar and nicotine provide a first model of a less hazardous cigarette." Public health agencies and media outlets touted the Working Group's "scientific findings" long after the group itself had disbanded.

As recently as 1981, the Surgeon General was recommending that smokers switch to low yield cigarettes as a way to reduce health risks. This switching created an illusion of risk reduction and slowed the decline in smoking rates. Over a 20-year period, smokers who switched were more likely to consider quitting, but less likely to actually quit than those who smoked high yield brands. These low yield brands were designed to show lower tar and nicotine yields on the Federal Trade Commission (FTC) smoking machine, but the machine did not mimic how humans actually used low yield cigarettes. Promotion of low yield (filtered) cigarettes turned out to be a serious case of public health fraud.



The current state of the relevant science does not support harm reduction/nicotine maintenance as a viable public health strategy. The scientific literature describes negative health impacts from tobacco, as well as from nicotine. Nicotine contributes to heart disease and may act as a tumor promoter. TCS looked at the science in the *Clearing the Smoke* report commissioned by the U.S. Food and Drug Administration (FDA) and produced by the Institute of Medicine (IOM) in 2001. This group was charged with developing a framework for assessing tobacco products that may be less harmful and pharmaceutical preparations that may be used alone or concomitantly with a decreased use of tobacco. To TCS, the IOM report raised a lot of red flags, such as its assertion that the nicotine maintenance approach was so promising that the FDA should approve the marketing of any nicotine maintenance product that “substantially reduces the [user’s] exposure to one or more tobacco toxicants.” TCS was troubled by the report’s emphasis on toxicant exposure rather than disease effects.

TCS is concerned about the conclusions found in the IOM report for the following reasons:

- ◆ Harm reduction through potentially reduced exposure products (PREPs) has not been convincingly demonstrated.
- ◆ Current knowledge supports risk reduction as a goal for individuals, but the net impact at the population level may be negative.
- ◆ At the present time, there is no panel of biomarkers by which to evaluate the health effects of PREPs.
- ◆ The current knowledge base is inadequate to perform formal risk assessment of the products.

The IOM report stated that “harm reduction is a feasible and justifiable public health policy.” TCS found this to be a tremendous leap of faith. Since there is no evidence of a public health benefit at the population level, no such benefit should be implied in the marketing of these products. In addition, the regulatory principles articulated in the IOM report were too permissive. Nicotine maintenance products would be put under the purview of the FDA with no control over manufacturing, distribution, or marketing. The IOM report equated reduced tobacco toxicant exposure with tobacco harm reduction, yet there is no evidence that reduced toxicant exposure equals reduced tobacco harm. Instead of requiring clinical human trials that might answer questions about the products’ likely health effects, the IOM report essentially proposed letting the products go to market and watching what happens to the public’s health. The final problem with this report is that it was positively viewed by the tobacco industry. One tobacco industry executive was quoted as saying, “We are pleased that the IOM believes that reduced risk cigarettes should be part of a sound public health policy.”

The emergence of the pharmaceutical industry as a player in the harm reduction debate is cause for concern. Ordinarily, the pharmaceutical companies do not have the same *carte blanche* as the tobacco industry in manufacturing and marketing their products. They must obtain regulatory approval for gums, patches, and other nicotine replacement therapy (NRT) products through the same process required to approve other drugs. If that burden is removed, and products can be developed and marketed without FDA scrutiny, suddenly the tobacco industry and the pharmaceutical industry are on a similar footing. At least right now, the pharmaceutical industry has more credibility with most of the American public than the tobacco industry does. Should it be allowed to use its credibility to market products for which there is no scientific evidence that they produce improved health benefits at the population level?



TCS believes that the nicotine maintenance strategy threatens proven tobacco control efforts and that new federal regulatory criteria are needed to determine if these products should be allowed on the market. A product would need to show the following:

- ◆ Does not increase youth uptake
- ◆ Does not increase young adult prevalence
- ◆ Does not decrease quit attempts
- ◆ Does not increase relapse of former smokers
- ◆ Will not be widely misused
- ◆ Is deliverable only to identified tobacco users, not marketed to the general public
- ◆ Does not undermine comprehensive tobacco control programs
- ◆ Does not undermine tobacco policy advances

It is important to note TCS's belief that if these products are given regulatory approval, they should not be marketed or made available to the general public, but only to identified tobacco users.

TCS proposes the following preconditions to federal regulations:

- ◆ Repealing all federal statutory provisions preempting state and local regulations of tobacco advertising
- ◆ Increasing the federal tobacco tax by \$2.50
- ◆ Establishing a fully funded national comprehensive tobacco control program based on the California model and U.S. Centers for Disease Control best practices

TCS proposes the following standards for medicinal nicotine products:

- ◆ Products manufactured or marketed by tobacco or pharmaceutical companies would need to meet current FDA requirements.
- ◆ Medicinal nicotine products would be available under a physician's prescription only.
- ◆ The manufacturer would be responsible for paying for post-market testing for up to 10 years and would have to report their findings to the FDA.
- ◆ Products would not be advertised to the general public.
- ◆ The over-the-counter (OTC) availability of current FDA-approved cessation products would be revoked. Since NRT went OTC, its effectiveness has declined. In the current retail environment, consumers admit to putting patches on incorrectly, cutting them in half, or not wearing them long enough.

In its draft position paper, TCS proposes the following regulatory actions related to conventional tobacco products:

- ◆ Creating a new regulatory agency, the "Tobacco Control Authority," which would determine tar and nicotine yields of tobacco products. TCS believes the FDA's mission makes it an inappropriate body to regulate tobacco.
- ◆ Restricting the sale and advertising of tobacco to tobacco-only outlets. The hearts and lungs of smokers are being lost in the retail environment, and tobacco control programs need to gain control of that environment.
- ◆ Establishing and enforcing a single toxicant exposure standard so that competing products could not make claims to being safer than any other



- ◆ Placing simple black and white labeling on tobacco product packaging, along with strongly worded warning messages
- ◆ Eliminating all liability caps and appeal bond caps in legal cases against tobacco companies

Mr. Oliva read an excerpt from the draft position paper that summarized his points: "Nicotine maintenance is not just an alternative strategy; it is a contradictory, competing strategy, in terms of both its message and the interests of its promoters. Promoting the use of a nicotine maintenance product as a second best alternative to quitting will inevitably weaken the efforts of federal, state, and local comprehensive tobacco control programs aimed at preventing uptake and promoting and supporting cessation of tobacco use."

Is California too optimistic on this issue? Probably. It would be difficult if not impossible to achieve most of these recommendations, but TCS recommends a strong focus on the preconditions: the repeal of preemption on states' rights to regulate tobacco advertising, the \$2.50 federal tobacco tax, and the creation of a fully funded comprehensive national tobacco control program.

In summary, TCS believes that nicotine maintenance

- ◆ Is an unproven approach
- ◆ Encourages tobacco users to continue their addiction
- ◆ Presents a contradiction between quitting and switching
- ◆ Diverts resources away from higher priority policies and programs
- ◆ Requires products to continue to deliver nicotine, a known toxin
- ◆ Is based upon insufficient toxicant exposure measures

First Set of Questions and Comments from the Floor

Steve Hansen, a physician practicing in San Luis Obispo, requested that all speakers declare any and all possible conflicts of interest (and noted that he had none).

Alan Blum, of the University of Alabama, stated that he had no pharmaceutical, tobacco industry, or Legacy Foundation connections to declare, and then mentioned a concern of his, the failure of many pharmacies to eliminate tobacco sales. As a clinician, it is distressing to Dr. Blum to have to send patients to get prescription medications at locations where tobacco products are sold. According to surveys that he has conducted in Texas and Alabama, more pharmacies sell cigarettes today than sold them 10 years ago, and this is especially true for the large chain pharmacies, together with the supermarket chains. Pharmaceutical companies, health insurers, and medical organizations have all been silent on this issue.

Dileep Bal asked April Roeseler (both with the California Department of Health Services) to describe an incident related to the issue of tobacco sales in pharmacies. TCS has been funding an effort in California for over a decade to try to get pharmacies to stop selling tobacco products. The effort has been successful with independent pharmacies, but not the large chains. A few years ago, the California Medical Association Foundation developed an ad campaign that targeted the Rite-Aid chain of pharmacies. The ad said, "To help a persistent cough, go to aisle 8. To get a persistent cough, go to aisle 14." It continued, "Pharmacies shouldn't sell products that kill. Call Rite-Aid and urge them to stop selling tobacco. 1-800-Rite-Aid." The ad campaign did not last long: According to an editorial by Daniel Weintraub in the Sacramento Bee dated May 7, 2002, then-Governor Gray



Davis “received \$130,000 from the Rite Aid corporation before his administration cancelled print ads criticizing the company for selling tobacco in its pharmacy stores.”

Mitch Zeller, of Pinney Associates, Inc., stated that his company does consulting work for GlaxoSmithKline. He made a strategic point, a substantive point, a personal point, and a process point.

- ◆ Strategic point: If the disagreements erupt into the next phase of the ongoing civil war within tobacco control, that only benefits the tobacco companies. There is probably universal agreement among the members of the audience about combustible tobacco products, yet it seems that, in the draft paper and in the summit presentations, TCS wrongly tried to imply that there is disagreement about the legitimacy of “reduced harm” combustible products.
- ◆ Substantive point: The linchpin of the entire draft paper is whether the science of nicotine safety is stated correctly. If TCS is wrong about the safety of nicotine, TCS may be going down the path of unintended consequences that the program so strongly seeks to avoid. If TCS is wrong, smokers may stay on the path of smoking if they think they are simply trading one form of cancer for another.
- ◆ Personal point: The report violates one of TCS’s principles of agreement. The report crosses the line in its tone and in its accusations about bias and financial interest in a way that is unfair to a lot of people in the room. TCS is urged to pay close attention to tone, character assassination, and things along those lines.
- ◆ Process point: Do not use the participation of people in the summit as validation of the report. If the final report bears a strong resemblance to the draft, it would benefit from publishing dissenting views for the record. There are going to be strongly held views in the final report, and there should be some way for people to state for the record to let others know there are important and significant areas of disagreement.

Dileep Bal reiterated that it is not TCS’s intent to impugn anyone’s integrity but rather to acknowledge that influence plays an undeniable role in the genesis and implementation of public policy.

Jonathan Foulds, of the University of Medicine and Dentistry of New Jersey, who receives funding primarily from the New Jersey comprehensive tobacco control program, emphasized that public health statements should be based on the best available evidence and questioned the statement in the draft paper and in the summit presentations that nicotine causes cancer. Dr. Foulds stated that he is unaware of any evidence in the scientific literature that supports this statement.

Dian Kiser, of the American Lung Association of the East Bay/BREATH, shared an observation that the pharmaceutical industry began contacting her for the first time after her organization started working on tobacco control advocacy issues in Asia. She also mentioned that progress is being made on the issue of pharmacies selling tobacco products, and that two California cities may be close to enacting prohibitions of such sales.

Tom Glynn, of the American Cancer Society, repeated the call for TCS to revisit the data concerning nicotine harm and suggested that the draft paper has a lot of flaws as a result of mischaracterizing the science on that issue. He also questioned the draft paper’s tendency to treat harm reduction as an either/or choice rather than as part of a comprehensive tobacco control program. Harm reduction must be considered as a potential tool in places where tobacco control meets with more resistance than it does in California. He stated that the best way to deal with harm reduction is with good science, not rhetoric.



John Pierce, of the University of California, San Diego, reiterated Mitch Zeller's request not to use people's attendance at or participation in the summit as implied endorsement of the policy paper.

Cynthia Hallett, of Americans for Nonsmokers' Rights, expressed her view that the long and laborious process of enacting local ordinances lay the foundation for norm change in California. Other states may lag behind California right now, but they should not latch onto harm reduction as a replacement for the hard work of norm change. She also expressed appreciation for the opportunity to clarify the issues around harm reduction because she believes it will be difficult to communicate these issues to the general public.

Larry Gruder, of the Tobacco-Related Disease Research Program at the University of California, encouraged TCS to reach out to experts in other areas of public health who have embraced a harm reduction philosophy as part of their activities, such as methadone maintenance and needle exchange programs.

Mike Cummings, of the Roswell Park Cancer Institute, suggested that the basic premise that harm reduction is in conflict with a comprehensive tobacco control program is flawed. In reality, the California tobacco control program, with all its successes, has existed in the context of a world in which nicotine maintenance is the norm. It is a question of how harm reduction products are regulated, and that goes back to how TCS defines harm reduction. TCS defines it as nicotine maintenance, but harm reduction is actually disease reduction. The tobacco control community should be in the business of helping smokers; cessation should receive greater attention as part of comprehensive tobacco control programs.

Matt Myers, of the Campaign for Tobacco Free Kids, noted that his organization does receive some funding from the pharmaceutical industry and thanked TCS for producing a paper that is very useful for provoking debate and discussion. However, he asserted that the report is badly hurt by dismissing every opponent as biased and unduly influenced by monetary support of various kinds. The report is also hurt by its failure to explore the conclusions of the IOM report before dismissing them. He also questioned TCS's interpretation of the science on nicotine safety. Overstating the dangers of nicotine undermines the paper's conclusions and calls into question the paper's credibility. Finally, he suggested that TCS should think about what is realistic; for example, the First Amendment exists, and some states are more constrained than others in their abilities to implement comprehensive tobacco control programs. People need to ask themselves whether some form of harm reduction may be a helpful part of the tobacco control arsenal in some places and in some situations.





Session 2

Cigarettes and Cigarette-like Products—It’s Still a Cigarette

Harm Reduction through Cigarettes and Cigarette-like Products—Prove it!

David Cowling, Ph.D.

Research Scientist

California Department of Health Services, Tobacco Control Section

The theme of Dr. Cowling’s presentation was “prove it,” not only prove that harm reduction works but that it works as a population-level strategy. After all, California already has population strategies that work.

Dr. Cowling began his presentation by stating the California Department of Health Services, Tobacco Control Section (TCS) position on cigarettes and cigarette-like products:

- ◆ Federal tobacco policy should not allow for the legitimization of cigarette-like products without proof that they will demonstrably reduce overall disease risk, not merely reduce exposure.
- ◆ TCS policy will not allow any of its existing funded programs to promote the use of cigarettes that claim to reduce the exposure to tobacco toxicants.
- ◆ No evidence exists that any cigarette or cigarette-like product on the market reduces overall disease risk.

TCS’s position is that federal tobacco policy should not allow for the legitimization of cigarette-like products without proof that they will demonstrably reduce overall disease risk, not merely reduce toxicant exposures. The burden of proof must fall on the products to prove the reduction of overall disease risk because history has shown that the public will interpret the marketing of reduced exposure products to mean that they are reduced risk products.

The harm reduction strategy is a very narrow approach aimed at those smokers who will not or do not want to quit. The strategy seems to assume a closed population, yet youth are continually moving into the adult population, and clearly there are plenty of smokers who do want to quit. California smokers are making more quit attempts than they were 15 years ago, California smokers are more successful in quitting than they were 15 years ago, California smokers are less addicted than they were fifteen years ago, and smokers who never expect to quit make up a smaller portion of California’s population than they did in 1996.



Dr. Cowling finished his presentation with a summary of California’s positions on the issues surrounding cigarette-like products:

- ◆ The measure of toxicant exposure is inadequate.
- ◆ The burden of proof should fall on the products’ manufacturers to show reduced disease risk.
- ◆ The harm reduction strategy is a narrow approach aimed at addressing the needs of a very small proportion of the California population, one that is shrinking day by day.
- ◆ TCS policy will not allow any of its existing funded programs to promote the use of cigarettes that claim to reduce the exposure to tobacco toxicants.
- ◆ No evidence exists that any cigarette or cigarette-like product on the market reduces overall disease risk.

Cigarette Harm Reduction: Is It Possible?

Gary Giovino, Ph.D.

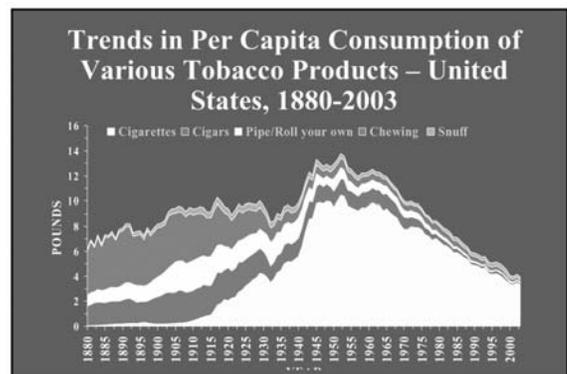
*Senior Research Scientist and Director of the Tobacco Control Research Program
Roswell Park Cancer Institute*

Dr. Giovino mentioned that he receives research funding from the National Cancer Institute, the American Cancer Society, the Robert Wood Johnson Foundation, and the American Legacy Foundation.

Dr. Giovino began his presentation by stating that, although he had served on the Institute of Medicine (IOM) committee that produced the report, *Clearing the Smoke*, he remained a skeptic about harm reduction. His interest in this topic began when he worked for the U.S. Centers for Disease Control and Prevention (CDC), where he was concerned that the most dangerous products were the least regulated and that a regulatory vacuum existed when products such as Premier and Eclipse were being introduced.

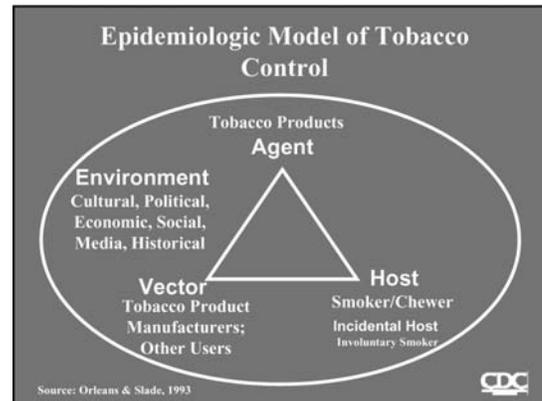
Dr. Giovino noted that terminology is important and that he would be using harm reduction as defined by the IOM report. The IOM report defines harm reduction as reducing harm and decreasing morbidity and mortality without completely eliminating tobacco and/or nicotine use. Harm avoidance, which the IOM report recognized as the optimal goal, means never using tobacco or being exposed to secondhand smoke. Harm minimization is quitting tobacco use or eliminating exposure to secondhand smoke. The IOM committee also said that reduced exposure does not ensure reduced risk or reduced harm to the population.

A good place to begin is with the per capita consumption of tobacco products in pounds in the U.S. from 1880 to 2003. The mildly acidic smoke of cigarettes introduced in the early 1900s led to a dramatic increase in the proportion of tobacco consumed in the form of manufactured cigarettes. From the 1900s to the 1950s, there was a 50% increase in the amount of tobacco consumed in pounds; there has been a decline ever since. Some,

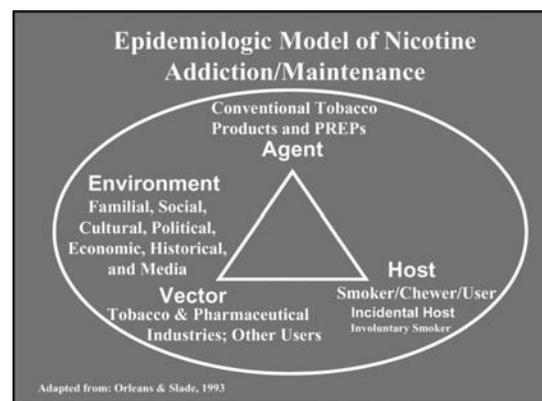


including Dr. Giovino himself, have argued that the rate would have decreased faster in the absence of low tar cigarettes. At this juncture, the question becomes, what will happen to all forms of tobacco consumption over the next 30 years? Also, what effect will nicotine maintenance products have on the rate of tobacco consumption?

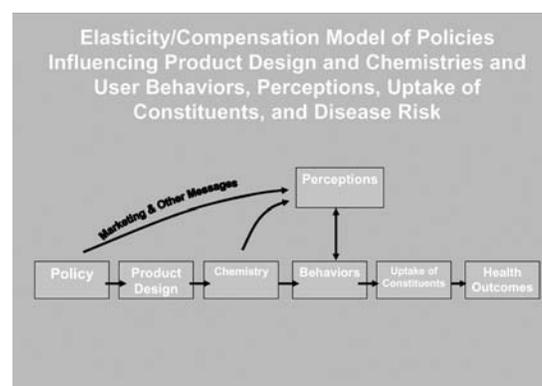
Dr. Giovino illustrated an epidemiologic model of tobacco control, in which tobacco products serve as the agent (the thing that causes disease), the host is the smoker or chewer (or potential smoker or chewer), and the vector, the organism that distributes the agent, is tobacco product manufacturers and other tobacco users.



The agent, the host, and the vector influence each other, influence the environment, and are operated on by the environment, which includes cultural, political, economic, social, familial, media, and historical factors. The Tobacco Control model can be expanded to include potential reduced exposure products (PREPs).



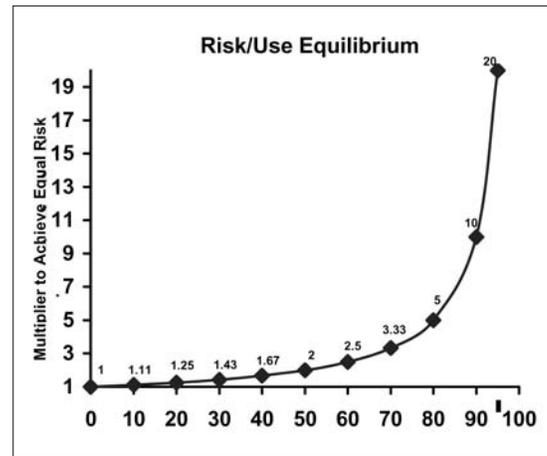
Dr. Giovino next showed an elasticity/compensation model of policies influencing product design and chemistries, user behaviors, perceptions, uptake of constituents, and disease risk. For example, policies can influence tobacco products. Research is needed into policy and how it influences product design, how product design influences chemistry, chemistry influences behavior, behavior influences uptake of constituents, and uptake influences health outcomes.



Along with policy come marketing and other messages. The industry will market the products in certain ways, and the government will disseminate its own messages. Messages can influence perceptions, chemistry will influence perceptions, perceptions influence behaviors, and so on.



Another way of looking at harm reduction is through the risk/use equilibrium concept, which looks at the decrease in danger and then uses a multiplier to achieve equal risk. It is a static population model, and real populations do not function this way, but it helps in the process of thinking about reduced risk products. For example, if a product reduces risk by 50%, twice as many people could use that product and the population would still have the same number of people dying. If a product reduced risk by 95%, then 20 times as many people could use the product and, at a population level, the harm would remain the same.



Dr. Giovino then turned his attention to California’s positions regarding harm reduction in terms of cigarettes and cigarette-like products.

1. Federal tobacco policy should not allow for the legitimization of cigarette-like products without proof that they will demonstrably reduce overall disease risk, not merely reduce exposures. *Agree.*
2. TCS policy will not allow any existing funded programs to promote the use of cigarettes that claim to reduce the exposure of tobacco toxicants. *Agree.*

Dr. Giovino noted that there was tension between members of the IOM committee who held the public health view and others who had spent years trying to get Federal Drug Administration (FDA) approval for various pharmaceutical products. The latter could not understand how anyone could be opposed to an individual’s right to get a product that might have the potential to save his or her life. They referred to AIDS drugs and other drugs, and they applied the same mindset to the IOM deliberations on PREPs. It is an issue that eventually the two sides will have to resolve.

3. No evidence exists that any cigarette or cigarette-like product on the market reduces overall disease risk. *Agree.*
4. Just because cigarette PREPs are on the market does not mean that the public health community should accept them and not want to control their marketing or not want to regulate them in a meaningful way. *Agree.*
5. Before these products are marketed, the public health community should demand that they reduce risk and not just reduce exposure. *Agree.*

However, it is possible that a product could come out that would have very low risks that could be marketed without health claims. Before these products are marketed *using health claims*, the public health community should demand that they reduce disease risk and not just toxicant exposure. People do take reduced exposure messages and interpret them as reduced risk.

6. How will scientists know which ones of the thousands of toxicants that if removed or reduced will actually reduce overall disease risk in the population? *Agree.*

If reduced harm products proliferate, people will switch to brands in ways that will make epidemiological research extremely difficult. Dr. Giovino explained that he just completed a review of the literature about menthol cigarettes. Reflecting on that experience, he realized that conclusions about PREPs will be made more difficult because the frequency with which



people switch brands over the course of their lifetimes will make measurement and attribution of effects to specific PREPs very difficult.

7. Critics say proving the reduction of overall disease risks takes too long. Why would we not want to be absolutely sure that these products reduce overall disease risk before allowing these products to be marketed? *Agree for cigarettes and PREPs (all combusted products).*
Dr. Giovino said he would reserve judgment about the risk to humans from smokeless tobacco products, and certainly about medicinal nicotine.
8. Why would society want to regulate the product or exposures, when what is really important is the reduced risk claims in their marketing and advertising? *Both are important.*
The proliferation of Marlboro is partly based on its marketing, but it is largely based on what Philip Morris did to the product. The same principle can apply to health. Government can regulate product claims and also regulate the product itself.
9. The harm reduction strategy is a very narrow approach to address those smokers who will not or do not want to quit. This strategy undermines proven tobacco control strategies. *Agree—readiness and motivation change.*

Readiness and motivation change in individuals all the time, and California has shown that readiness and motivation are even visible at the population level. Harm reduction done wrong will absolutely undermine successful tobacco control strategies, but, done right, it can complement tobacco control strategies.

Other considerations come into play when assessing harm reduction in terms of cigarettes and cigarette-like products. For example, there is considerable skepticism about the potential to reduce harm by reducing specific toxic chemicals from combusted products. Nevertheless, Dr. Giovino agrees with Bill Farrone (see *Tobacco Control 2004*; 13:1–2) when he calls for reductions in chemicals to levels that are suggested by available science as "acceptable" based on existing dose-response data for cumulative lifetime exposure (basing his thinking on the CalEPA criteria of background risk as acceptable). Dr. Farone doesn't endorse the approach of reducing one or some toxic components over time in products that might eventually lower premature death rates. In addition, research shows that length of time in years of cigarette smoking is more important than number of cigarettes per day in predicting lung cancer risk. Thus, continuing use may have more of a deleterious effect than reduced daily dose suggest.

It may be instructive to observe the behavior of the food industry. In her book, *Food Politics*, Marion Nestle points out that the food industry uses lobbying, lawsuits, public relations, and philanthropy; seeks to influence legislators; and broadcasts an industry response that says, essentially, it is too confusing for consumers to understand what is going on with foods, that all foods are okay, and that they should be eaten in moderation. "Low nitrosamines" could be the tobacco equivalent of "no cholesterol." Food manufacturers tell consumers which product constituents they took out, but what did they leave in? In what other ways did they manipulate the product?

Dr. Giovino thinks that the goal of the public health community should be to fully inform consumers, and the only way to get a fully informed population is in a regulated environment. Messages are important: Saul Shiffman's work in the journal *Tobacco Control* showed that when they surveyed a group of people about quitting after reading the text of an Eclipse ad, interest in quitting went down.

Tracy Swedrock and colleagues published a paper in *Tobacco Control* that looked at cigarette advertising in the 1950's. The authors found that soon after the cancer scare from the



experiments in which tar was painted on the backs of animals, the tobacco companies started advertising that their brands had less tar and that filters were protecting consumers from the toxic chemicals. Consumption went down, and consumption kept going down. Tobacco industry documents show that the marketers asked the cigarette companies to stop reminding people of the chemicals. When they switched to terms such as “smooth” and “mild,” consumption went back up. The same phenomenon is illustrated by the ads for Omni, which proclaimed the brand’s “low carcinogens.” The ads served to remind people that the products had carcinogens in the first place, and sales were low.

Dr. Giovino also expressed concerns with some of the IOM regulatory principles. He believes that Regulatory Principle 7 can be misinterpreted by the industry as endorsing the introduction of new cigarettes, which are extremely toxic products. He also is concerned that the implementation of Principle 4 can vary depending on the make-up of the scientific review committee. In addition, the Regulatory Principles suggested by the IOM Committee fail to require adequate pre-market surveillance. The tobacco industry is using the report to its advantage, using the parts it likes and ignoring the more difficult parts, such as the call for regulatory oversight before any new products are introduced.

Consumers are influenced by text messages, images, and smoking experiences. Saul Shiffman, Lynn Kozłowski, and others have pointed out that one of the reasons low tar cigarettes had credibility was that, when they went into the chest, they felt better; they were smoother. They seemed “less harmful” and nothing in the advertising text pointed to the inaccuracy of that perception.

Harm reduction will most likely succeed if the products that are the most dangerous are made the least desirable. This can be done by prohibiting all of the added ingredients that help make the smoking experience more desirable or pleasurable.

All of these actions are constituents of a paradigm for tobacco control: decrease access; decrease pro-tobacco marketing; increase price/economic incentives; reduce exposure to secondhand smoke; conduct strong media campaigns; promote cessation activities; conduct prevention activities; promulgate regulation; and leverage liability issues.

Dr. Giovino concluded that he did not believe the IOM recommendations were sufficient and that the tobacco control community needs to continue to emphasize preventing initiation, promoting quitting, and protecting nonsmokers.



Issues and Challenges Associated with Modified Cigarettes and Cigarette-like Products

Dorothy Hatsukami, PhD

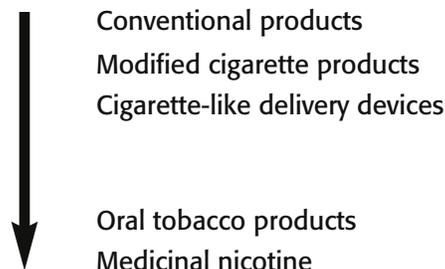
*Professor of Psychiatry and Adjunct Professor of Psychology and Epidemiology,
Director of Tobacco Use Research Programs
University of Minnesota*

Dr. Hatsukami stated that she has no affiliation with tobacco companies or pharmaceutical companies, although some pharmaceutical companies have provided her with sample products for her National Institutes of Health (NIH) studies.

Dr. Hatsukami aimed her comments at the issues and challenges surrounding modified cigarette products. She stated that it is crucial that science drives tobacco control policies, and even though the science is not complete at the present time, it is evolving and likely to burgeon in the near future.

When scientists examine the feasibility of potential reduced exposure products (PREPs), they need to recognize that there is a continuum of harm. Modified cigarettes and cigarette-like nicotine delivery products are likely to continue to be extremely hazardous and unlikely to lead to any substantial reduction in harm; smokeless tobacco products, because they do not have any combustion associated with them, are likely to be less hazardous than cigarettes; and medicinal nicotine, with its single constituent, is likely to produce the least harm.

Continuum of harm:

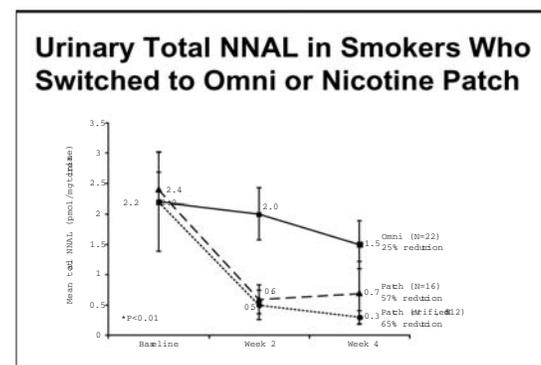


Dr. Hatsukami organized the remainder of her presentation as a series of questions and answers.

Question: Should claims for reduced exposure/disease risk be allowed for these products? *No.*

Dr. Hatsukami based her answer on the results of a study she conducted to see whether a reduced nitrosamine modified cigarette (in this case, Omni) significantly reduced tobacco toxins compared to conventional products. After all, Omni advertised that it “significantly reduces carcinogens that are among the major causes of lung cancer.”

She had a group of smokers smoke their usual brands for two weeks. Then, these smokers were randomly assigned to use either Omni or a

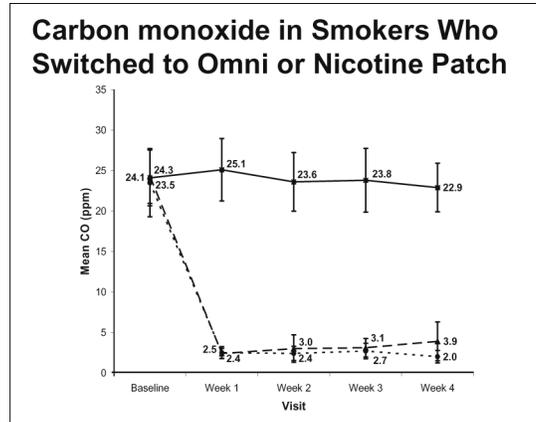


nicotine patch for four weeks. Over that period of time, she assessed for carcinogen exposure and a number of other toxins.

She found a 25% reduction in 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanol (NNAL), which is a byproduct of the tobacco-specific lung carcinogen 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone, known as NNK, as opposed to the 50% reduction claimed by Omni based on the machine-determined yields. There were significant reductions in total NNAL with the patch as compared to the Omni cigarette.

She also took a look at 1-hydroxy pyrene, which is a biomarker for polycyclic aromatic hydrocarbons, and she observed only a 5% reduction in levels in Omni users.

It is important to look at other toxins besides carcinogens, as well. For example, she found no decrease in carbon monoxide exposure in smokers who switched to Omni. (Carbon monoxide is believed to be a contributor to cardiovascular disease.) With the patch, as expected, there was a significant reduction in carbon monoxide exposure.



Dr. Hatsukami concluded the following with regard to “reduced exposure” products such as Omni:

- ◆ When measured in humans, Omni cigarettes lead to only modest reductions in some but not all tobacco-specific nitrosamines (TSNA) and other toxins compared to conventional cigarettes.
- ◆ Significant individual variability exists in the decrease of TSNA exposure, with some individuals experiencing increased exposure.
- ◆ Reduction in exposure does not mean reduction in disease risk, yet people perceive a reduction in disease risk from these reduced exposure claims. This perception negatively impacts public health.

The example of Eclipse supports the contention that claims for reduced exposure/disease risk for these products may lead to a negative public health impact. Dr. Hatsukami showed an Eclipse ad that said, “May present less risk of cancer associated with smoking. Produces less inflammation in the respiratory system, which suggests a lower risk of chronic bronchitis, and possibly emphysema. Reduces secondhand smoke by 80%.”

In a study by Saul Shiffman, survey data showed that after risk reduction claims were read to smokers and ex-smokers, 81–91% of smokers and ex-smokers thought Eclipse was safer than regular cigarettes; 24–26% believed Eclipse was completely safe (equivalent to not smoking); 57% of smokers were interested in using Eclipse, with greatest interest in contemplators; and 21% lost interest in quitting after hearing about Eclipse. In addition, 6.2% of ex-smokers were interested in Eclipse, including 15.2% of young adults who had stopped smoking within the past two years. (Note: Contemplators are people thinking of quitting in the next six months. These products are supposedly aimed at non-contemplators.)

Question: Should tobacco companies be required to reduce toxins in their products? Yes.

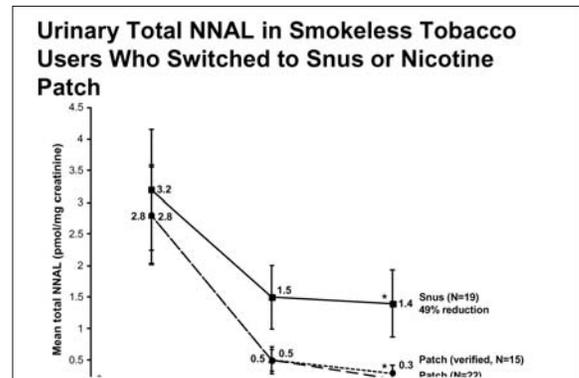
Question: Should reduced exposure products be sold even if these products have not shown reduced harm? *Probably.*



Dr. Hatsukami drew an analogy to studies comparing snus [the Swedish word for “snuff”] with nicotine replacement therapy (NRT) products, in which snus users experienced a 50% reduction in total uptake of NNAL and patch users saw an even more dramatic decrease of 90%.

If there are products that significantly reduce exposure to some toxins and do not increase exposure to other toxins, Dr. Hatsukami said it probably does not make sense to wait years and years to find out whether these products do in fact lead to harm reduction.

Question: Should tobacco companies ever be allowed to advertise products as reduced exposure? *No. The general public misinterprets reduced exposure claims as being equivalent to reduced risk.*



Question: Should tobacco companies indicate the type, amount, and range of toxin uptake in their products? *Yes. It is important to show not just the median of exposure but also the range of exposure.*

Question: Should tobacco companies be allowed to advertise their products as reduced risk? *Depends.*

If tobacco advertising continues to be allowed in the U.S. and if no performance standards are allowed for all tobacco products and if consumers have a right to accurate information to make an informed decision, then scientifically-based information should be conveyed to the consumer in a way that the information can be accurately interpreted and understood.

Dr. Hatsukami recited the pertinent IOM recommendations:

- ◆ Consumers must be fully and accurately informed of all the known, likely, and potential consequences of using these products.
- ◆ Promotion, advertising, and labeling of these products should be firmly regulated to prevent false or misleading claims, explicit or implicit.
- ◆ A well-designed program of public health education is necessary to help people understand that preventing the initiation of smoking and assisting smokers to quit is the only proven way to reduce tobacco related harm, that the health benefits of using PREPs remains uncertain, and that this uncertainty will not be resolved for many years to come.

Dr. Hatsukami stated what she believes is necessary for scientifically-based evidence of reduced disease risk:

- ◆ Identification of toxins in tobacco and smoke. This will be a challenge because of novel constituents introduced from PREPs and also new combinations of toxins when users combine PREPs with their conventional cigarette products.
- ◆ In vitro cell and in vivo animal studies. These studies should examine genotoxicity, cytotoxicity, mutagenicity, and tumor promotion of identified toxins.



- ◆ Clinical studies in humans to determine uptake of toxins. These trials should include the following:
 - A representative population of smokers interested in using reduced risk tobacco products. The people most interested in reduced exposure products tend to have medical diseases, or are in some way medically compromised. In that case, one might question whether a reduced exposure or reduced risk approach might be beneficial to them.
 - Controlled laboratory studies and outpatient clinical trials with adequate control groups, including groups that continue to use their conventional brands, smoke light and ultra-light cigarettes, and are abstinent
 - Biomarkers across disease states found to be reproducible, dose-sensitive, and predictive of disease risk
- ◆ Post-marketing surveillance and surveys to determine short-term and long-term consequences of using PREP; not only their health consequences but also issues involving initiation, cessation, and relapse

What are the research challenges?

- ◆ Having a comprehensive panel of biomarkers that are predictive of disease risk. Right now, this research is in its infancy; very few biomarkers are known that are predictive of disease states.
- ◆ Determining the threshold of toxin exposure that would allow a claim for reduced disease risk
- ◆ Determining disease risk given the individual variability that is observed in response to using these products
- ◆ Understanding disease risk resulting from variable patterns of tobacco use, introduction of new toxins, and novel combinations of toxins

Question: Will modified cigarette products ever have legitimate claims of reduced risk?
Very unlikely.

Currently, there is no evidence to support claims of reduced exposure or reduced risk associated with PREP use. No advertising should claim reduced exposure, and consumers should be told what the product constituents are. Claims for reduced risk need to be scientifically based. Dr. Hatsukami said she was very skeptical that this could occur with modified cigarettes or PREPs.

The challenge to policy makers and the public health community is to ensure that regulations do not deter efforts to develop reduced exposure products and do not deter the ultimate goal of reducing tobacco-related mortality and morbidity.

In closing, Dr. Hatsukami offered these recommendations:

- ◆ Regulatory oversight of all tobacco products
- ◆ Advancement of scientific knowledge related to the toxicology and effects of these products
- ◆ Independent assessment of the risks associated with the use of reduced exposure/reduced risk products
- ◆ Performance standards to set limits for the levels of toxicants, including nicotine, in all tobacco products
- ◆ Accurate and full information regarding toxicity of a product provided to consumers in a way that is not misleading
- ◆ Post-marketing surveillance to rapidly monitor impact of these products on public health



Second Set of Questions and Comments from the Floor

Alan Blum, of the University of Alabama, stated his opinion that people in tobacco control have become enamored of tobacco industry documents as sources of information and have substituted such documents for better scientific sources. He expressed surprise at Gary Giovino's assertion that it was primarily manipulation of the product rather than marketing that catapulted Marlboro to its status as the top-selling brand of cigarette. He also noted that, as far back as the early 1970s, a few scientists were questioning the legitimacy of claims about low yield filter cigarettes, but not many people were paying attention to them.

Gary Giovino, of the Roswell Park Cancer Institute, responded that he meant to say it was both marketing and product manipulation that played a role in the ascendancy of Marlboro and that to not regulate the product would be a terrible mistake.

Wael Al-Delaimy, of the University of California, San Diego, noted that an increase in risk at the population level can take a long time to become evident and that policy might not be able to wait for conclusive evidence. He also wondered why the tobacco industry is supporting the harm reduction strategy, saying that the tobacco industry is always one step ahead of the scientists. The public health community needs to investigate the aim of the tobacco industry in this regard and decide what the goal of the anti-tobacco movement should be as well.

Gary Giovino responded: "Marlboros are killing people. I'm especially opposed to the tobacco industry because they kill more people than any other industry I know of If we can promote products that get people off Marlboro, we should do it If people switch to medicinal nicotine instead of cigarettes, we wouldn't have as much lung cancer, assuming everything else was held constant." He then stated that the tobacco control movement must seek to harness, not tame, the tobacco industry, and to do everything possible to make their products less acceptable.

Mike Cummings, of the Roswell Park Cancer Institute, noted that the science indicates a continuum of risk from combustible cigarettes down to medicinal nicotine, and then asked whether the state should license the products or establish standards of exposure. If Omni has a demonstrated reduction in exposure, does the market need 44 versions of Marlboro? Why should Philip Morris be able to sell the most deadly products alongside the reduced exposure ones? Dr. Cummings proposed that cessation should be the goal for harm reduction; focusing on cancer-causing chemicals and carbon monoxide in tobacco is not enough.

Dorothy Hatsukami, of the University of Minnesota, responded that she believes we need a comprehensive panel of biomarkers to take a look at the toxicity of these reduced harm products, and determining those biomarkers poses a serious scientific challenge. Currently, states need to be looking at the legitimacy of the claims for reduced risk, for which the scientific evidence is lacking.

Gary Giovino added that, as far as cigarettes were concerned, the states should be doing everything they can to make them as unacceptable as possible.

Steve Hansen, a physician practicing in San Luis Obispo, shared his experience of helping over 2000 people quit smoking. He said reduced risk products have never aided his practice. His message: keep it simple. A majority of his patients want tobacco banned altogether. "They know it is bad, and a little less bad is still bad." States should be trying to incentivize doctors and make smoking cessation a part of health benefit packages.

Cynthia Hallett, of Americans for Nonsmokers' Rights, suggested that, in the absence of definitive science, it may be all right to fall back on "common sense" (i.e., an intuitive understanding of the harm smoking causes to smokers and to those around them), which was what drove most of the secondhand smoke initiatives in the 1970s.



Dorothy Hatsukami pointed out that while we do not have all the science some public health experts may want, enough scientific evidence exists now to refute many of the industry's implied health claims.

Mark Parascandola, of the National Cancer Institute, returned to the content of the draft paper. He said that TCS overstated the role of the Tobacco Working Group and that the recommendations put out by many public health agencies during the 1960s and 1970s were based upon the best evidence at the time. The basic principle that reduced exposure does not correlate with reduced risk is not entirely wrong, but the concept of exposure must be much more nuanced. It is more than simply asking smokers how many cigarettes they smoke per day. Many public health experts wrongly assumed that the tobacco industry would not try to circumvent the available means of measuring exposure, and the public health community is much wiser about that now. The best way for the public health community to keep up with the industry is to study the products.

Michael Thun, of the American Cancer Society, also offered some comments that relate to the draft report. He saw some things in the report as being very divisive. He said that the different kinds of products were blurred together, but a clear distinction should be made between the products. He hoped TCS would focus on the things that have a potential to unify the tobacco control movement, such as the position that federal laws not be permitted to preempt more strict state and local legislation. He expressed concern for the potential of harm reduction to negatively impact those actions that change the social norm: clean air laws, raising taxes, and other things that the industry cannot "spin." He also noted that when health agencies recommended to people who could not quit that they should at least switch to lighter cigarettes, the health agencies saw it as a complementary approach to quitting. For the industry, it became the whole approach. He asserted that controlling advertising was the key, and he also mentioned that he really liked Steve Hansen's comments about keeping it simple.

Jonathan Foulds, of the University of Medicine and Dentistry of New Jersey, suggested that one approach might be to say that, since the industry itself has shown it is capable of manufacturing reduced exposure products, the lowest level of toxins should become the new standard. There would be no need for Marlboro because it would have to comply with the same standard as the least harmful brand. That is how society regulates other things: lead in gasoline, for example. In that scenario, the government would also need to regulate cigarette advertising, and the measures of exposure would have to be based on actual use, not on machines.



Session 3

The Lure of Smokeless in Lieu of Smoking

The California Position on Smokeless Tobacco

Roberta Lawson of the California Department of Health Services, Tobacco Control Section (TCS), stated the TCS position with regard to smokeless tobacco:

- ◆ Federal tobacco policy should not allow smokeless tobacco manufacturers to market their products as safer than cigarettes, not even low nitrosamine snus [the Swedish word for snuff]. Unfortunately, according to the recommendations of the Institute of Medicine's recent report, snus could meet the criteria for reducing the exposure to one toxicant and for reducing the risk of one or more specific diseases, and therefore be marketed as reduced risk. However, recent claims that increased use of low nitrosamine smokeless tobacco products caused reduced smoking and substantial health benefits in Sweden have been scientifically challenged.
- ◆ TCS does not allow its funded programs to promote smokeless tobacco as a smoking cessation strategy. Promoting smokeless tobacco as a cessation strategy can give smokers who are concerned about their health a reason for not quitting tobacco use.
- ◆ Smokeless tobacco use causes oral and pharyngeal cancers, increases blood pressure and heart rate, increases LDL (bad) cholesterol, increases risk of heart arrhythmia, increases overall rates of death from cardiovascular disease, and increases the risk of insulin resistance in type 2 diabetes. There is also evidence that use of smokeless tobacco increases the risk of beginning cigarette smoking, especially among young people.
- ◆ Tobacco is tobacco is tobacco . . .

Is There a Public Health Benefit to Switching to Smokeless Tobacco?

Jonathan Foulds, PhD

*Associate Professor and Director of the Tobacco Dependence Program
University of Medicine and Dentistry of New Jersey, School of Public Health*

The focus of Dr. Foulds' talk was whether there is a health benefit to switching to smokeless tobacco. He acknowledged that he faced an uphill battle to convince the California Department of Health Services, Tobacco Control Section (TCS), that there is anything particularly good about smokeless tobacco, but his main aim was to give a rationale for nicotine maintenance and to show how, in one particular country, smokeless tobacco has had a potentially positive impact on tobacco-caused death and disease.

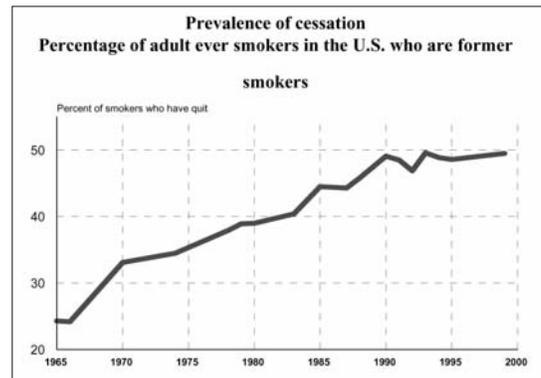


Before continuing, he mentioned that he has never had any financial or other links with the tobacco industry. In the past, he has received grants or honoraria from pharmaceutical companies involved in tobacco treatment, and he has provided testimony for plaintiffs in litigation against tobacco companies. His current support comes mainly from the New Jersey Department of Health and Senior Services.

Dr. Foulds agreed that the term “nicotine maintenance” is probably a more precise and preferable one than “harm reduction” as it describes the strategy rather than the desired outcome. While there is considerable doubt whether harm reduction is likely to be the end result of strategies often discussed under that heading, “nicotine maintenance” is a clear and accurate description of one strategy. The important context that one has to think about when talking about nicotine maintenance is that, right now, nicotine maintenance is the norm for tobacco users (i.e., in any one year, the vast majority of tobacco users continue to use nicotine on a regular basis). So, the real issue centers around whether we would improve health by switching some people from smoking to a form of nicotine maintenance that is markedly less likely to kill them or cause serious harm to their health.

Why not just stay with the dichotomy of cigarettes vs. quitting, with brief use of nicotine replacement therapy (NRT) if necessary?

1. Many people are not ready to give up nicotine use, and currently the most toxic form of nicotine delivery (cigarettes) is perceived as their only option. They consider smokeless tobacco, gum, and other NRT products as unappealing gimmicks. They believe that cigarettes are the preferred way to get nicotine.



2. Less than 10% of daily smokers in the U.S. are preparing to quit in the next month, and around 60% are not planning to try in the next six months. This percentage has remained stable throughout the 1990s.

Because that is not a particularly encouraging situation, should alternative strategies be considered? Perhaps, but these alternatives raise several problems. Dr. Foulds pointed to Interval, an existing nicotine maintenance product, as an example. Although certainly less harmful than cigarettes, its delivery of pure nicotine is very low; it probably would not satisfy a smoker. In addition, the public health community is correct to be concerned about how these products would be marketed; they may not have the desired impact. Yet, these products exist. The tobacco control community needs to be honest with the public as to their relative harmfulness versus the dominant nicotine delivery products, which are cigarettes.

Inhalation of the products of combustion is what distinguishes the most harmful products from other products that are markedly less harmful:

- ◆ Nothing that involves the inhalation of combustion products is likely to be markedly less harmful.
- ◆ Combustion creates an unavoidably toxic cocktail, so products such as Omni, Eclipse, and Advance would not be markedly less harmful. These products all carry the risks of decreasing cessation rates and giving people a false sense of safety with very little if any public health gain.



- ◆ Nicotine delivery products that do not require inhalation of combustion products or that do not deliver concentrations of toxic chemicals that could plausibly cause death and disease on the scale of cigarettes, such as nicotine replacement therapies and potentially low nitrosamine smokeless tobacco products, would be considered markedly less harmful.

There are three main options for nicotine maintenance:

- ◆ Encourage development of nicotine replacement therapies that are more acceptable to consumers, with higher nicotine delivery and more aggressive marketing in terms of cessation and nicotine maintenance. This would mean putting these products right next to tobacco and giving consumers a choice.
- ◆ Encourage marketing of low nitrosamine, high nicotine smokeless tobacco products such as snus for the purpose of nicotine maintenance.
- ◆ Both of the above

It is important to keep this discussion in the context of smoking-related morbidity and mortality: 442,000 people die from smoking-related diseases each year, and 12.7 million people suffer annually with serious smoking-related diseases, mainly chronic respiratory diseases.

With that in mind, Dr. Foulds posed a difficult question: Is there a public health benefit to switching to smokeless tobacco? He first looked at the benefit to the individual:

- ◆ There are no respiratory risks to the individual who uses smokeless tobacco.
- ◆ The cardiovascular risks are much less than smoking (much less than 50%).
- ◆ There are no or minimal cancer risks from some products with low nitrosamine concentrations.

So, for the individual, it is clear that switching to smokeless tobacco is likely to be much less harmful than continuing to smoke but with some excess risks (primarily cardiovascular) over complete nicotine abstinence. In some populations, such as pregnant women, there are much more serious risks, in which case any nicotine consumption should be strongly discouraged (although even in this population, which is extremely unlikely to be open to switching to smokeless, the health risks from smokeless are likely to be lower than from continued smoking). However, "given that smokeless eliminates all of the risks of lung disease caused by smoking, and has substantially lower risks of almost all other tobacco-caused disease," said Dr. Foulds, "I think it's what you call a no-brainer."

To discuss the use of smokeless tobacco at a population level, Dr. Foulds presented some data from Sweden, where they use a smokeless tobacco product known as snus (the Swedish word for snuff).

Swedish snus is characterized by the following:

- ◆ Moist fine-ground oral tobacco predominantly from air-cured dark tobacco
- ◆ Manufactured by a pasteurizing-like heating process (without any fermentation as is used in most manufacturing procedures for American snuff)
- ◆ Tobacco-specific nitrosamine (TSNA) content < 5 mg/kg (1/5 the content of American snuff)
- ◆ Benzo(a)pyrene (BaP) content < 10 µg/kg
- ◆ Its high pH (7.8-8.5) facilitates nicotine absorption; it can be purchased loose or portion-packed (similar to tea bags).

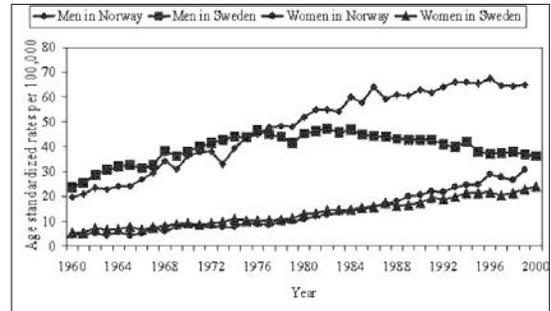


Swedish snus differs from smokeless tobacco used in the U.S. in the following ways:

- ◆ It is stored refrigerated.
- ◆ It adheres to well-established standards for toxin content.
- ◆ Its TSNA levels do not increase with length of time in storage.
- ◆ It shows low TSNA content and low mutagenic activity compared to smoked tobacco.

Dr. Foulds listed the following health effects of snus:

- ◆ It causes nicotine dependence (similar to cigarettes), which he sees as a necessary characteristic of a nicotine maintenance product in order for it to be capable of helping significant numbers of people switch from cigarettes.
- ◆ It causes oral lesions/gum recession (only some of which are reversible), but not oral, gastric, or head/neck cancer.
- ◆ It may increase cardiovascular risks but less than cigarettes. (Three studies find no increase; one finds increased myocardial infarction risk relative to non-tobacco users; all find a lower risk than cigarettes).
- ◆ It is certainly harmful to the unborn fetus (though less so than cigarettes).
- ◆ It does not cause respiratory disease or lung cancer.

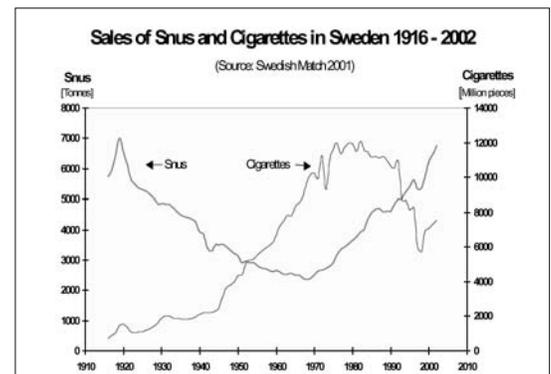


In looking at the health effects from snus use, one can look at the standardized lung cancer rates in Sweden as compared to its neighbor Norway. From 1960 to 1980, the lung cancer rates of men in Sweden and Norway were very similar. Beginning in 1980, however, the lung cancer rates of Swedish men began to drop, but not so for Norwegian men. That is not to say that snus is entirely responsible; decreased smoking is certainly the direct cause. But it is clear that smoking decreased and snus use increased among men over that time period. It is also clear that the reduction in lung cancer in men occurred despite stable tobacco use but with a growing proportion of tobacco use being attributable to snus use rather than smoking.

One can also look at the risk of myocardial infarction in men and women in Sweden from 1987 to 1995. The rate dropped significantly more for men than for women during the same period of time in which snus use was increasing. Sweden has a relatively low rate of oral cavity cancer, as well.

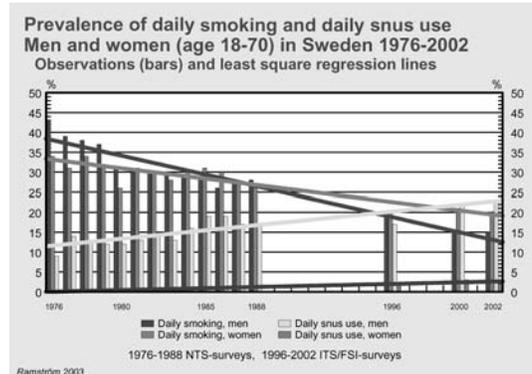
One can also look at data from the European MONICA study, which is a large study looking at heart disease, with cross-sectional surveys in many European countries. One of the study's centers is in northern Sweden. When researchers looked at the data there, it was consistent with the idea that men in particular were switching from cigarette smoking to snus use.

Data on cigarette consumption confirm that snus is used almost exclusively by men. In 1970, daily cigarette use was 42% among men, but as of 2003, the daily smoking prevalence rate was

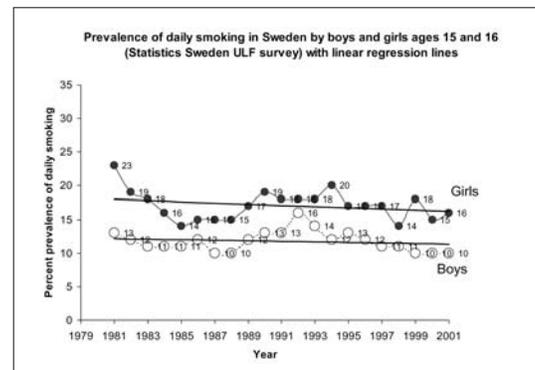


down to 14%. Smoking has come down in women as well, probably as a result of Sweden's very good tobacco control program. Their program focuses very much on reducing smoking among women, particularly pregnant women. Even so, Sweden is unique in that the smoking prevalence rate has fallen even more in men than in women, largely because of snus use.

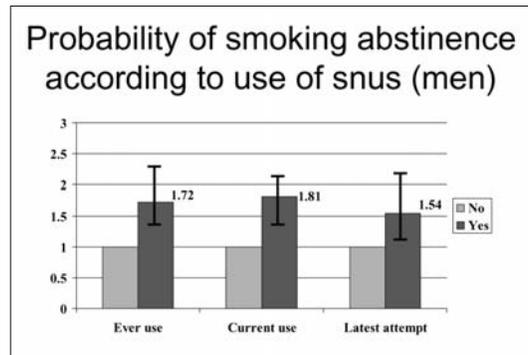
This is a key point in interpreting the Swedish data: Sweden is the only country in the European Union where snus is available legally; it is banned in the rest of the European Union. Furthermore, Sweden is the only country in the European Union (and possibly the world) in which male daily smoking prevalence has not only dropped faster than female smoking but has dropped far below the female smoking rates and continues to do so. While it is correct to applaud the excellent tobacco control work in Sweden, which discourages tobacco use in both sexes, the most likely explanation for the unusually positive trend in male smoking is that a significant proportion (around 30%) of Swedish men have given up smoking by using snus instead.



One of public health's greatest concerns is that many young people will take up snus or that it may be a gateway to cigarette smoking. Data indicate that the youth daily smoking prevalence rate has been very stable in Sweden over the past 20 years, at around 11% for boys age 16 and 16% for girls age 16, despite the fact that boys have had a much higher and increasing rate of snus use.



There is no evidence that snus is a gateway to smoking; if anything, it is just the opposite—snus use may be associated with quitting smoking. In a recent survey, 30% of men who had quit smoking had used snus to quit. Of those snus users, two-thirds of them continued to use snus after they quit smoking, thereby fitting into the definition of nicotine maintenance. Swedish men who have used snus are more likely to abstain from smoking.



Dr. Foulds stated these conclusions about snus use:

- ◆ Snus delivers much smaller quantities of toxins than smoked tobacco and smaller quantities than most other types of smokeless tobacco.
- ◆ Snus is not harmless but is markedly less harmful to health than smoked tobacco.
- ◆ Snus is almost as addictive as cigarettes, enabling a significant proportion of male smokers to transfer their dependence from smoking to smokeless.



- ◆ Swedish men who have quit smoking using snus have reaped the health benefits.
- ◆ The improvement in smoking prevalence and health status has been greater in Swedish men than in Swedish women, or men in other countries. At least part of this is attributable to widespread snus availability, marketing, and use by men in Sweden.
- ◆ Snus is therefore a concrete example of a reduced harm product that has been demonstrated to reduce net harm to health.
- ◆ It is possible (though not certain) that other similar products (NRT, Ariva) could have a similar beneficial effect, so long as they could compete with cigarettes on nicotine delivery, marketing, price, and other factors.

Dr. Foulds finished his presentation with some comments about the TCS draft document:

1. "First do no harm" is not a reasonable standard. Most healthcare policies or interventions involve a risk of doing some harm but are approved if it is perceived that the likely benefits will outweigh the likely harms. For example, most medicines have side effects, and many have potentially serious harmful effects, yet we don't refuse to use them in case some harm occurs. Rather, we try to ensure that clinicians and consumers are adequately and accurately informed about the potential benefits and possible dangers. The key is to give the public an informed choice on the risks and benefits. "Do no harm" is not a legitimate reason to make no changes or fail to look at alternatives to the status quo. The status quo gives cigarettes preferred status as the "norm" for nicotine maintenance and that in itself is causing enormous harm.
2. There is not necessarily a contradiction between smoking cessation strategies and nicotine maintenance strategies. It is all in the way the message is delivered and to whom. Tobacco control programs can still have as their main clear message, "The best thing you can do for your health is to stop smoking." However, when asked about the relative risks from nicotine maintenance (including low nitrosamine smokeless tobacco) versus continued smoking, we should be prepared to give an honest answer that reflects the scientific evidence. Low nitrosamine smokeless tobacco products should remain an alternative in the marketplace for those few who cannot or will not quit tobacco use right away, particularly as a preferable and less harmful alternative to the dominant product, cigarettes.
3. Contrary to what the draft paper says, snus use in Sweden is a concrete example of nicotine maintenance producing a net public health benefit.

To summarize, one way of accelerating the rate of smoking cessation and the consequent improvement in public health may be to create a regulatory framework that makes it much harder to market traditional cigarettes (or any product involving inhalation of combustion products) and easier to market markedly less harmful nicotine delivery products, including low nitrosamine smokeless tobacco.



Public Health Implications of Promoting Smokeless Tobacco Use

Scott Tomar, DMD, DrPH

Associate Professor

University of Florida College of Dentistry, Division of Public Health Services and Research

Note: Due to hurricane damage in Florida, Scott Tomar was unable to attend the summit. Alan Blum generously agreed to present Dr. Tomar's PowerPoint slides and commentary.

The term “smokeless tobacco” is an industry-coined umbrella term for a range of tobacco product types. Other than the fact they are all used in the mouth without lighting, many of these products have quite different nicotine dosing properties and quite different carcinogenic properties. Lately, a lot of attention has been given to moist snuff. American and Swedish tobacco manufacturers have been promoting smokeless tobacco as a harm reduction strategy to smokers who are unable or unwilling to give up nicotine delivery products. U.S. Smokeless Tobacco Co. has even petitioned the Federal Trade Commission for the right to include explicit health claims in advertising.



The latest marketing strategy for smokeless tobacco appears to position it as an adjunct to or complementary with smoking cigarettes, as is evident in the following advertising slogans:

- ◆ “Always there in a pinch: If your team’s smokin,’ but you can’t” Here, banning smoking in public places has turned into a marketing opportunity.
- ◆ “The more you want a cigarette, the longer he goes on and on and on” In this ad, workplace smoking restrictions are seen as a marketing opportunity.

One concern is that smokeless tobacco would keep smokers in the market who might otherwise quit. One of the benefits of clean indoor air policies is that, not only have they protected nonsmokers, but they have actually convinced quite a few people to stop smoking. So, the marketing of smokeless tobacco could have a negative effect by delaying or preventing cessation. It may also increase initiation among young people who previously had thought of smokeless tobacco as a highly harmful product.

Advocates of smokeless tobacco as a form of harm reduction often frame their arguments in terms of “the Swedish experience” and claim the following:

- ◆ Smokeless tobacco is substantially less harmful than smoking.
- ◆ Smokers are able to quit by switching to moist snuff, or snus, as it is called in Sweden.
- ◆ Snus has been responsible for a decline in smoking in Sweden since 1980.

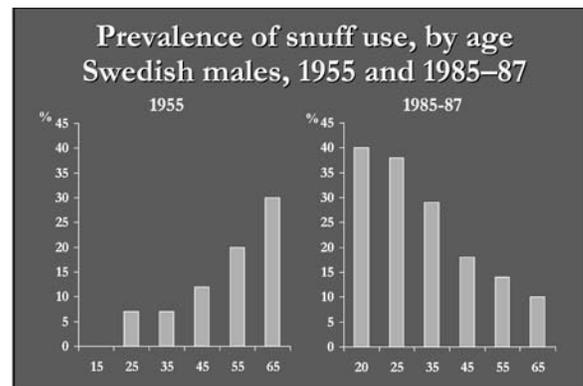


- ◆ Snus use explains lower smoking-related disease rates in Sweden.
- ◆ This approach can work in other countries.

When traveling in Sweden, however, one does not hear about “the Swedish experience.” It is a coinage that the Swedish Match Company invented. Just because snus consumption has increased and cigarette consumption has decreased does not mean that people who are quitting smoking are switching to snus. Undoubtedly, there is a decline in cigarette smoking and an increase in daily snus use among men, but right now, there is no scientific evidence of a causal relationship.

A careful ecological analysis of the Swedish data shows that most of the growth in snus use has not been among middle-aged smokers but among adolescent and young adult males. In 1955, virtually all snus users were older males; virtually no teenagers at all used snus during the 1950s. In 1985, there was a complete reversal in Sweden, and the same exact pattern occurred with smokeless tobacco in the U.S.

There are no randomized clinical trials showing that smokeless tobacco is effective in smoking cessation, nor is there any data about risk reduction for smokers who switched to smokeless. Actually, there are a number of prospective cohort and cross-sectional studies that found the majority of men and virtually all women who quit smoking did so without snus. Most of the growth in snus use was among young males, not among groups that were quitting their use of cigarettes.



To summarize: Is snuff really responsible for the smoking decline in Sweden?

- ◆ A large majority of men and nearly all women quit without ever using snus.
- ◆ Growth in snus use is primarily among adolescent and young adult males, not older smokers.
- ◆ There are small differences in use of snus at last quit attempt by men who quit (28.7%) and those who did not (23%).
- ◆ Cohort and cross-sectional studies of young people do not support a preventive effect on smoking.
- ◆ Between 1980 and 2001, the prevalence of daily smoking among 16–24-year-old males in Sweden declined by 49%. However, females in that age group experienced a virtually identical rate of decline during that period (50%) with virtually no snus use, suggesting factors other than snus likely accounted for the declining rate of smoking initiation among young people.
- ◆ The conclusions stated by Dr. Foulds (in the previous presentation) in favor of snus use ignore Swedish tobacco control efforts since the 1970s.



As a matter of fact, there is some evidence that snus use predicted cigarette smoking among some groups of young males. Unfortunately, assumptions supporting snus as a factor in cessation tend to underestimate the effects of Sweden's tobacco control program. For a small group of males, smokeless tobacco was an effective cessation tool, but the "Swedish experience" is largely an ecological fallacy.

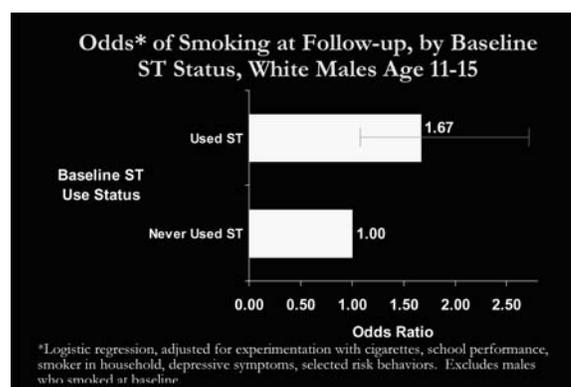
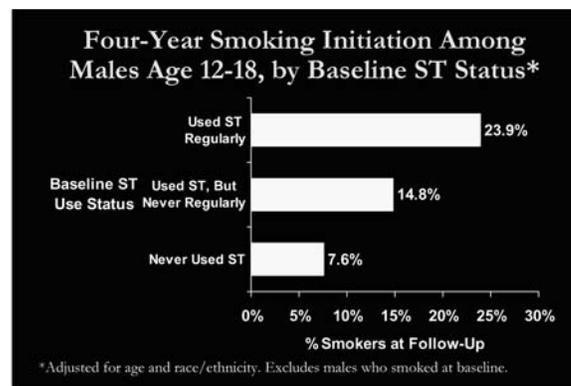
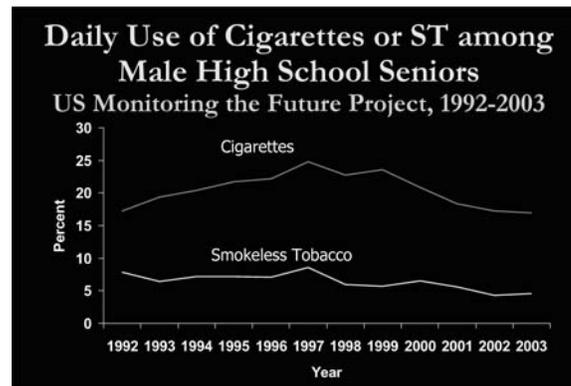
So, what about the "American experience?" One would expect the states with the highest prevalence of snuff use to have the lowest prevalence of smoking. Instead, there is a positive association; that is, states with a high prevalence of snuff use also tend to have a high prevalence of smoking. There is no meaningful evidence of product substitution. One quarter of states in the U.S. already have lower daily smoking rates than Sweden, with very little snuff use. Why would the U.S. want to adopt another strategy when what the states are doing now is working better?

The arguments in favor of smokeless tobacco as a preventive measure for smoking can be summarized as follows:

- ◆ Smokeless tobacco users are satisfied, and they do not initiate smoking.
- ◆ Common psychosocial factors likely explain the association between smokeless tobacco use and subsequent smoking.
- ◆ Most smokeless tobacco use does not precede smoking.
- ◆ Inverse ecological patterns of smokeless tobacco and smoking by age are seen in cross-sectional studies.
- ◆ Snus use is increasing and smoking is decreasing in Swedish males; daily smoking is lower for young males than young females.

The arguments against smokeless tobacco as a preventive measure for smoking can be summarized as follows:

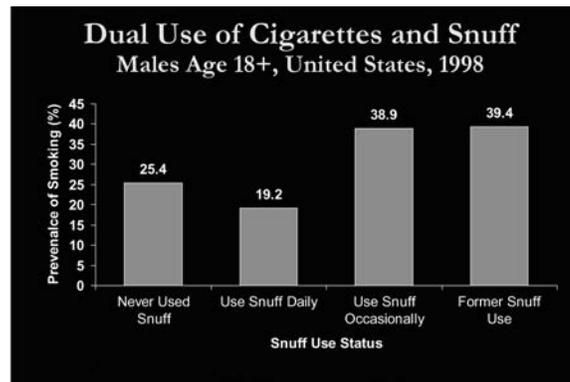
- ◆ There is a positive association between smokeless tobacco use and smoking, even after control for psychosocial factors.
- ◆ Historical trends in the U.S. do not support a preventive effect.



- ◆ The U.S. has seen growth in smokeless tobacco use among likely non-smokers, e.g., high school and college athletes (16% in a 1997 NCAA survey).
- ◆ There is a positive association between smokeless tobacco and smoking at the state population level.
- ◆ Smoking is declining rapidly among Swedish young women, who generally do not use snuff, suggesting that other factors are at work, namely the promotion of smoking cessation.
- ◆ Norway is the only European country other than Sweden where moist snuff can be legally sold. The prevalence of snuff use in Norway has more than doubled among 16–24-year-old males in Norway between 1985 and 2002, from 9% to 21%, but smoking remained relatively constant in that group.

The bottom line is that most data show a positive association between snuff use and cigarette smoking in the U.S. among young males. The net effects of smokeless tobacco use in the U.S. are as follows:

- ◆ Nearly all smokeless tobacco initiation occurs in young males.
- ◆ U.S. males are much more likely to switch from smokeless tobacco to cigarettes than vice versa.
- ◆ In 2000, 19% of U.S. male ever-smokers age 36–47 had a history of smokeless tobacco use.
- ◆ In 2000, just 1.2% of male former smokers age 36–47 reported using smokeless tobacco to quit smoking.
- ◆ Any role smokeless tobacco played in reducing smoking was eclipsed by recruiting adolescents to the course of tobacco addiction.



Dr. Tomar had these comments on the TCS draft position paper:

- ◆ He agrees that there is “insufficient evidence to conclude that the strategy can produce a public health benefit.”
- ◆ There is heavy financial and political influence by moist snuff manufacturers at all levels of the harm reduction (nicotine maintenance) debate.

Dr. Tomar’s presentation ended with these conclusions:

- ◆ Smokeless tobacco has unknown efficacy for quitting smoking.
- ◆ The so-called “Swedish experience” is largely ecological.
- ◆ Smokeless tobacco is widely accessible throughout the U.S., and its use is prevalent in some regions, but U.S. data suggest a very minor role of smokeless tobacco in cessation.
- ◆ There is no evidence of a preventive effect in the U.S. or Norway.
- ◆ Both smokeless tobacco use and smoking have been declining among U.S. youth since the 1990s, suggesting it is possible to reduce use of all forms of tobacco without promoting product substitution.
- ◆ 25% of U.S. states have achieved a prevalence of daily smoking lower than Sweden’s with little snuff use.



- ◆ There is no evidence smokeless tobacco marketing has had a positive public health effect in the U.S.
- ◆ Snuff use is neither necessary nor sufficient to reduce smoking.

One final comment: oral tobacco harm reduction proponents appear well-intentioned and espouse a strategy that makes theoretical sense. Unfortunately, the available evidence for their strategy is far weaker than they would like to believe, the risks greater than they think, and the likelihood of success is minimal because they completely ignore the behavioral component of smoking or the feasibility or acceptability of their approach in most populations.

Third Set of Questions and Comments from the Floor

Dian Kiser of the American Lung Association of the East Bay/BREATH mentioned that in her conversations with tobacco control advocates in Sweden, they speak of a “snus epidemic.” Usually, she noted, the word epidemic has a negative connotation.

Alan Blum of the University of Alabama mentioned that he appreciated Dr. Foulds’ presentation and noted that this debate will continue.

Dileep Bal of the California Department of Health Services spoke of his recent trip to India and noted that oral cancers are the number one type of cancer and use of snuff is very popular. He questioned Dr. Foulds’ assertion that oral tobacco does not cause cancer, saying, “The numbers in Sweden wouldn’t even qualify as a rounding error in India.”

Jonathan Foulds, UMDNJ School of Public Health, responded by saying that snus is not used in India; there, they use tobacco with higher levels of nitrosamines, making it much more carcinogenic. “I’m not promoting smokeless tobacco. I’m suggesting that there are forms of smokeless tobacco that are much less harmful than other forms of smokeless tobacco, and that probably all forms of smokeless tobacco are less harmful than cigarettes.” He then posed the question: Which will reduce the terrible toll of disease and death from tobacco in India, to impose a California-style norm change strategy in India, or to regulate tobacco in such a way that only low nitrosamine products are available?

Dileep Bal stood by his support for California’s norm change strategy and reiterated that there is no evidence to support the harm reduction claims for oral tobacco use.

Alan Blum recounted that every country has its own experience with smokeless tobacco. In the U.S., the use of smokeless tobacco used to be a habit of “little old ladies in the South” until the U.S. Smokeless Tobacco Co. set out to put “a pinch between the cheek and gum” of every young male in America. In terms of harm reduction, Dr. Blum asserted that the public health community can appeal to people’s intelligence and not just to their basic instincts.

Mike Cummings of the Roswell Park Cancer Institute noted that in one recent survey, 90% of smokers thought smokeless tobacco in the U.S. was as harmful as cigarettes, and that is not true. The public health community needs to be honest: there is a difference in the risks posed from combustible and non-combustible forms of tobacco. He said this debate is more about the regulation of marketing than anything else.

Alan Blum responded that oral tobacco is just as harmful as cigarettes to the person who gets oral cancer from it. As a physician, he would have a very hard time recommending that a patient switch from one form of tobacco to another form of tobacco to realize a lesser risk of a horribly mutilating condition.



Charles DiSogra, of the Tobacco-Related Disease Research Program at the University of California, said that he kept thinking of the Ralph Nader phrase “unsafe at any speed.” He appreciated the deconstruction of the Swedish experience with snus, but questioned the validity of the claim that snus use was the cause of a sudden drop in lung cancer, especially in light of Sweden’s tobacco control efforts beginning in the 1970s.

Jonathan Foulds noted that what he showed was the standardized lung cancer data from Sweden and that he understood Dr. DiSogra’s skepticism. The figures certainly should be looked at more carefully because these data may reflect changes in smoking from years before.

Charles DiSogra responded by saying that there were really two different issues here, and they kept getting blurred. One was the relative pathogenicity of smokeless versus smoked tobacco, and the other was the population impact of smokeless tobacco marketing. From a population perspective, what kind of regulation is required to prevent adverse impacts from marketing?

Alan Blum noted that there are already nicotine alternatives that physicians can prescribe; there is no need to prescribe smokeless tobacco as a safer alternative. The marketing of smokeless tobacco in this country is unconscionable, especially considering its effect on the young.

Steve Hansen, a physician practicing in San Luis Obispo, pleaded with the public health community not to give physicians any more power to prescribe something quickly and get patients out the door. “Make us do the hard work of helping [patients] quit.” He also reminded the audience that “smokeless tobacco” was a term coined by the industry, and what everyone really should be saying is either “spit tobacco” or “swallow tobacco.”



Session 4

Medicinal Nicotine— Short-Term and Long-Term Use

The California Position on Medicinal Nicotine

April Roeseler of the California Department of Health Services, Tobacco Control Section, stated the TCS position on federal and state policy regarding medicinal nicotine

- ◆ Federal Drug Administration (FDA) approval standards for medicinal nicotine (and tobacco industry nicotine products) that are promoted as having “reduced harm” must be consistent with those of other drugs and medical devices.
- ◆ Manufacturers of approved nicotine maintenance products must be required to monitor the health and nicotine behavior of a sample of users for 10 years.
- ◆ Direct marketing of medicinal nicotine maintenance products to the general public must be prohibited.
- ◆ All medicinal nicotine (cessation and maintenance) products must be available by physician prescription only.
- ◆ TCS-funded projects will be prohibited from promoting nicotine maintenance strategies.

How Much Should We Promote the Use of NRT?

Mike Cummings, PhD, MPH

*Senior Research Scientist and
Chairman of the Department of Health Behavior
Roswell Park Cancer Institute*

Dr. Cummings began by saying that he does not take any money from the pharmaceutical nicotine business and then stated that the public health community should promote nicotine replacement therapy (NRT) because of the following:

- ◆ NRT is proven effective in reducing symptoms of nicotine withdrawal and increasing the odds of quitting.
- ◆ NRT products are safe to use.
- ◆ Smokers are interested in using NRT.

To date, NRT has not had much impact on smoking rates in the population. He posed two hypotheses as to why not:

- ◆ Hypothesis A: NRT does not work outside the confines of a clinical trial.



- ◆ Hypothesis B: Not enough smokers are using NRT. Less than one in 10 quit attempts are being done using NRT, and a population effect probably would not be seen from such small numbers.

The truth may lie in some combination of these two hypotheses.

Dr. Cummings pointed out that data show NRT is efficacious in the following ways:

- ◆ Meta-analyses of NRT clinical trials show that the medications are safe and effective, boosting quit rates 50–100% compared to placebo.
- ◆ Based on these findings, the FDA has approved NRT as a treatment for tobacco dependence.
- ◆ The U.S. Public Health Service recommends that all patients attempting to quit should be encouraged to use effective pharmacotherapy, which includes NRT, for smoking cessation except in the presence of contraindications.

Population surveys show that about 30% of smokers have tried NRT in the past, but fewer than 10% of quit attempts involve NRT.

Results of a nationwide population survey of 1,040 smokers conducted in 2001 showed that there is widespread awareness of patches and gum, which are advertised heavily, with lower awareness of the inhaler and nasal spray. Most users use NRT as indicated. A low percentage of NRT users report using the products for over a year. There does not appear to be much abuse or long-term nicotine maintenance with these products. Quitting smoking is a tough thing to do; it is a chronic relapsing problem. Generally, when people relapse, they stop using the NRT.

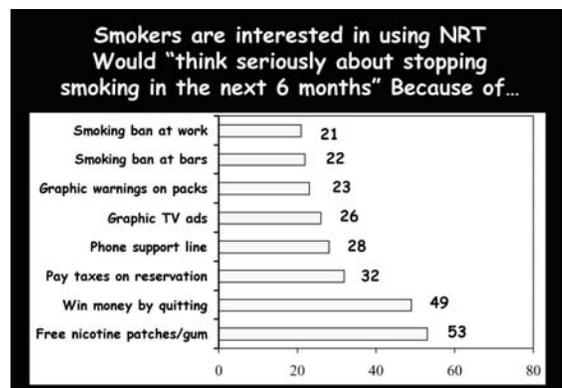
Why do so few smokers use NRT to quit? Here are some reasons:

- ◆ Low access (too expensive and much more difficult to get than a pack of Marlboros, for example)
- ◆ Misperceptions about nicotine and how NRT works
- ◆ Poor marketing
- ◆ Negative attributes of current NRT medications (taste, design, and nicotine delivery)

In terms of access, NRT usage changed after NRT became available over the counter:

- ◆ Use rates of patches and gum increased by a small percentage.
- ◆ The rate of multiple attempts increased.
- ◆ Insurance coverage of NRT medications decreased.
- ◆ The percent of attempts accompanied by cessation programs decreased.
- ◆ The NRT-assisted quit rate stayed about the same.

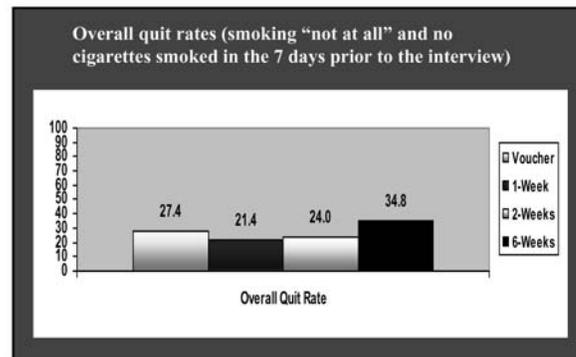
Because of the low percentage of smokers using NRT to quit since the medication became available over the counter, it is fair to ask if smokers are interested in using NRT. In the New York counties of Erie and Niagara, Dr. Cummings' organization surveyed smokers on what would make them think seriously about quitting smoking. Number one on the list was free nicotine patches or gum.



When the clean indoor air law went into effect in New York City, the Health Commissioner conducted a Free Patch Give Away Program with the help of the New York State Quit Line. People had to call the quit line to get a voucher for a free patch. The give away program was not advertised, only announced on the steps of City Hall, where it was picked up by the major media outlets. The quit line staff planned to hand out 34,000 units; it received 425,000 calls in the first three days. Free patch give away programs have now been conducted in several counties in New York State.

Dr. Cummings shared more information about New York's NRT give away programs:

- ◆ To be eligible, a smoker had to smoke at least 10 cigarettes per day; the quit line staff did the screening over the phone.
- ◆ The free give away programs appeal to slightly older, heavier smokers, who might be expected to be more interested in quitting.
- ◆ It is a very effective way to induce new users to call the quit line and get people into the service.
- ◆ Most people who received an NRT product said they used it. It is interesting to see that only 23% of the users who got the six-week supply ended up using the whole supply, compared to higher numbers for the one-week and two-week supplies.
- ◆ Users reported very few side effects associated with using NRT. Only 8% of users reported stopping their use due to side effects, and the side effects reported were dose-dependent: those with a six-week supply reported more side effects than those using it for two weeks.
- ◆ Overall quit rates were dose-dependent; those who received a six-week supply of NRT showed the highest quit rate.
- ◆ A substantial number of quitters were attributable to the give away programs; these programs are comparable or better in terms of cost-effectiveness to a lot of the other strategies out there.



Dr. Cummings stated that smokers are confused about nicotine; two-thirds of smokers either did not know or believed incorrectly that nicotine is the ingredient in cigarettes that causes cancer. Some smokers switch to low nicotine cigarettes believing that they are less dangerous and easier to quit. Of course, this is not true. Handing out free nicotine medications to smokers creates an opportunity to educate consumers about nicotine and is analogous to the way tobacco companies provided free cigarette samples to introduce people to their brands.

According to Dr. Cummings, marketing is the key to this whole issue of harm reduction.

The tobacco industry's approach to marketing

- ◆ Get 'em while they're young.
- ◆ Give the customer what they want.
- ◆ Offer lots of choices.



Public health's approach to marketing

- ◆ Cessation for the elderly
- ◆ We know what's best.
- ◆ It's okay to help people quit, but don't get rich doing it.

Who would benefit the most from harm reduction products?

- ◆ Younger smokers (<10 pack years)
- ◆ Heavy smokers
- ◆ Those not thinking about quitting
- ◆ Those smoking regular and light cigarettes

Who is the target market for the current array of reduction products?

- ◆ Older smokers (30+ pack years)
- ◆ Better educated
- ◆ Health-concerned
- ◆ Thinking of quitting
- ◆ Already cutting back on daily smoking
- ◆ Probably using an ultra-light cigarette

Thus, the current marketing approach creates the "Catch-22 of harm reduction":

- ◆ The health marketing claims of NRT and potential reduced exposure products (PREPs) appeal to older, more health-concerned smokers who are least likely to benefit from switching.
- ◆ The health marketing claims of NRT and PREPs as currently marketed are a turnoff to younger smokers who are most likely to benefit from switching.

The public health community needs to do a better job marketing NRT products, especially to young adult smokers. In other words, we need to do a better job making Marlboro, Newport, and Camel cigarettes less attractive and NRT products more attractive with young adult smokers. We need to fight fire with fire:

- ◆ Offer free samples of NRT through the quit line.
- ◆ Market NRT more aggressively.
- ◆ Support the development of better NRT products.
- ◆ Frame NRT marketing so it is "more fun and less medicine."
- ◆ Consider the possibilities of tastier gum and designer patches.

Dr. Cummings ended his presentation with this aside: "About the FDA, why are we waiting? If Philip Morris has a safer cigarette, they ought to come out with it now, and smokers ought to be demanding that they discontinue Marlboros and replace them with the safer alternative."



What is the potential impact of a public policy of harm reduction using medicinal nicotine on quitting and uptake of cigarette smoking?

John Pierce, PhD

Sam M. Walton Professor of Cancer Research

Director of the Cancer Prevention and Control Program, UCSD Cancer Center

University of California, San Diego

Note: Dr. Pierce requested that the following text be substituted for the presentation he made at the Harm Reduction Summit on September 8, 2004.

There has been an urgent call recently in North America for a major change in our public policy relating to tobacco use. Typically, such a case is built on an analysis indicating the abject failure of the current policy to achieve its goals, which in this area are to reduce the health consequences of smoking. No such analysis has been published.

Over the past decade, two of the major health consequences of smoking, lung cancer and heart disease, have experienced major declines. The scientific literature is clear that future health consequences of smoking can be predicted by knowledge of the duration of smoking and the intensity of smoking in the population.

Are these predictors of future health consequences going in the wrong direction? A broad-brush way of looking at this is to review the national per capita sales data for the past century. These have been compiled and reported by the United States Department of Agriculture. Per capita cigarette sales in the U.S. peaked in the early 1960s. Since then, sales have steadily declined; in 2003, the per capita consumption was 68% lower than it was in 1964. These data demonstrate that, for the past 40 years, the public health community has made a consistent and major impact on exposure to cigarette smoking, which is the major determinant of health consequences. It is important that this continuing major impact is not undermined by any sudden and not properly researched change in tobacco control policy.

There are five major questions that need to be addressed before we should seriously consider changing to a public policy of harm reduction using medicinal nicotine:

1. Are there some forms of nicotine consumption that have fewer health consequences than others?
2. Are there smokers who cannot or will not quit, despite knowing the health consequences?
3. Will these smokers change nicotine delivery systems if the public health community agrees to promote harm reduction (i.e., abandon the "quit or die" approach)?
4. Will the rate of quitting increase (or stay the same) if the public health community promotes harm reduction?
5. Will promotion of harm reduction not lead to an increased smoking uptake in teenagers or young adults?

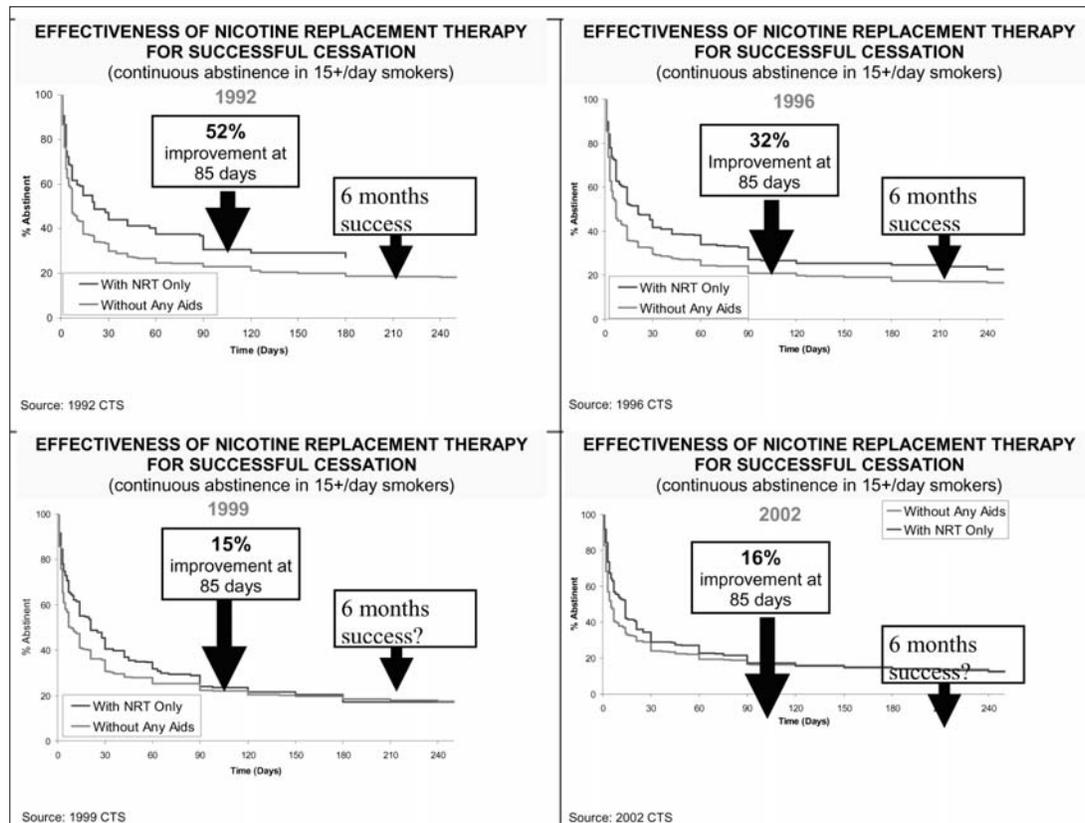
There is little question among most scientists that some forms of nicotine consumption have fewer health consequences than others, particularly nicotine replacement therapy (NRT), which became available by prescription in the latter part of the twentieth century.

Are people using nicotine patches to replace cigarettes? A large number of nicotine patches were sold by prescription in 1992, their first year on the market. However, sales dropped in subsequent years, when the product was approved for over-the-counter sales in 1996. Since then, sales



volume increased slightly and then stabilized. This has not been a booming success story for the pharmaceutical industry.

During this time, nicotine replacement products have had a significant advertising budget. According to the Nielson data, from 1999 to 2002, adults were exposed to an average of 10 advertisements for NRT each month. It is interesting to consider the messages in these advertisements. From my observations, the messages initially focused on the usefulness of the product for successful quitting and encouraged smokers to talk to their doctor. After 1996, the messages appeared to change to associate the product with the act of quitting itself rather than as a means to achieve success. It is important to note that once the NRT products were available over the counter, their effectiveness as an aid to quit smoking disappeared.



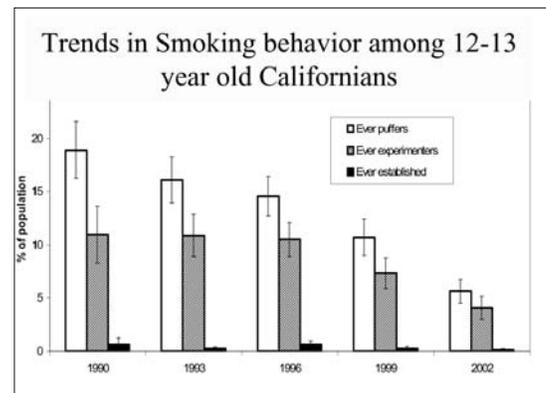
In 2002, only 17% of quitters used NRT to assist them on their last quit attempt. A total of 30% of all smokers reported that they had previously used NRT; this proportion was 50% among heavier smokers. This was expected, since NRT has never been shown to be effective for lighter smokers. Thus, there are many smokers who have previously used NRT but have decided not to use it on a new attempt.

The pattern of NRT use is also important to our considerations. Smokers reported using NRT only until the point that they relapsed to smoking. Thus, there is no evidence that current dependent cigarette smokers will change their nicotine delivery product.

Another vital question is whether promotion of a harm reduction policy could lead to an increased probability of smoking initiation. We first need to address the current trends in smoking initiation, particularly as it relates to the ongoing California Tobacco Control Program (CTCP). Since the start



of the CTCP, there has been a significant reduction in “ever puffing” and tobacco experimentation rates among 12- and 13-year-olds. Among 14- and 15-year-olds, and again with 16- and 17-year-olds, a similar decline has occurred. Thus, significant progress has been made in reducing adolescent smoking in California. Any major change in public policy towards smoking must be addressed as to how it might impact the ongoing success of the current policy.



It is critical to look at other examples of promoting harm reduction to determine if there is any risk that the recent success in reducing smoking initiation in California might be reversed by a change in public policy. Alcohol and marijuana are two relevant examples of substance use with documented health behavior that can inform us of likely effects of a harm reduction approach.

For alcohol use, there is a case-control study currently in progress that compares patterns of alcohol use in Australia and the U.S. The International Youth Development Project is a large longitudinal study of adolescent behavior in two countries. It is a joint undertaking by Dr. Richard Catalano from the University of Washington and Dr. John Toumbourou from the University of Melbourne; I need to thank them for their willingness to let me discuss some of their unpublished data.

Australia and the U.S. have taken very different approaches to limiting alcohol use in young people. In Australia, the legal drinking age is the same as the legal driving age: 18 years. Public health messages focus on drinking in moderation and staying under the 0.05 blood alcohol driving limit. In the U.S., a much different approach has been taken. The legal age of drinking is 21 years, many years later than the legal driving age. Driver licenses are used to protect against sales to minors; under-aged drivers caught with any detectable blood alcohol level face stiff penalties, including loss of license.

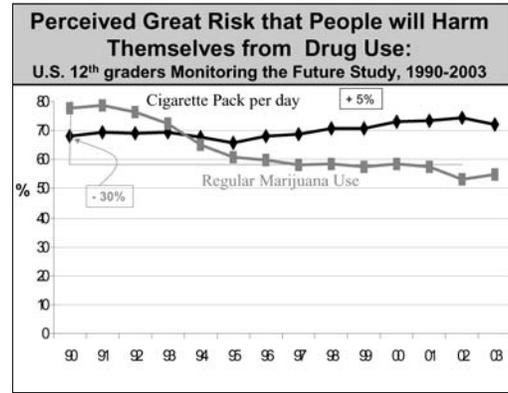
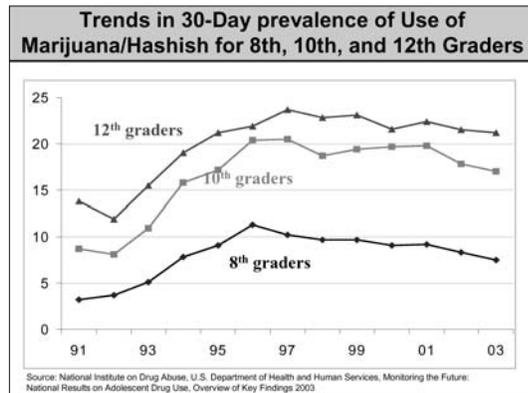
The early results from the International Youth Development Survey show a dramatic difference in adolescent alcohol use between the U.S. and Australia. Youth in the 7th and 9th grades in Australia are twice as likely as youth in the U.S. to have used alcohol both recently and regularly. Reported binge drinking occasions as well as other occasions when adolescents felt that they couldn't stop drinking were three times more likely to occur in Australian 9th graders than in their U.S. counterparts. Most worrying was the accompanying threefold difference in 9th graders who reported injury/accidents that were alcohol related. Even at this early stage of the study, these dramatic results are leading to a reconsideration of the public policy approach of harm reduction for alcohol use in young people in Australia (Toumbourou, personal communication).

The public health community in the U.S., particularly in California, has tacitly approved a harm reduction public policy for marijuana. Over the past 10 years, smoking marijuana is widely believed to have important medicinal properties, including relief of pain associated with cancer, even though there are much more effective pharmaceuticals for pain management. What effect has this harm reduction message had on the perception of harm from marijuana? We can use the perception of harm from cigarettes for our comparison. The *Monitoring the Future* study of high school seniors allows us to review trends in relevant 12th graders' perceptions. The perceived severity of risk from smoking a pack of cigarettes per day remained largely unchanged in U.S. high



school seniors from 1990 through 2003 (70% perceived great harm). However, this was not the case with the perceived severity of risk from regular smoking of marijuana. In 1990, almost 80% of high school seniors thought regular marijuana smoking posed a great health risk. However, between 1990 and 1995, possibly because of the public debate on whether marijuana should be legalized for medical use, there was a major 30% decline in the perceived severity of risk among high school seniors.

At the same time that there was a decrease in the perceived severity of risk from marijuana use, there was a major increase (80%) in reported use of marijuana in the past month among students of all grades surveyed (8th, 10th, and 12th grades). This increased use coincidentally balanced out with the stabilization of the perceived health risk.



These are two recent examples that a public policy of harm reduction may lead to an increased use by adolescents. This provides credible evidence that similar results could occur with adolescent smoking if we were to change to a public policy of harm reduction.

Is there any evidence that NRT advertising may have influenced the probability that teens will start smoking? Data already indicate that teens believe that, if they start smoking, they will be able to quit anytime before there are any health consequences. They get this idea from their peers (including peer smokers) and from NRT advertising.

Nielson Media Research shows that teens are exposed to three nicotine-related TV commercials per month from the pharmaceutical industry. Assuming that the message is that NRT is an effective way to quit smoking, it can be informative to review the evidence showing who among teens believes this message. In the California surveys, only about 20% of teens who are established smokers believed that NRT is an effective way to quit. However, twice as many susceptible never-smokers (those most likely to start smoking in the near future) believed that NRT is effective. This suggests that the message on the effectiveness of NRT is not coming from their friends who smoke but instead from the mass-media advertising. Thus, this message from the pharmaceutical industry could also be undermining California's Tobacco Control Program efforts to reduce cigarette smoking.



Returning to the questions previously mentioned that need to be addressed prior to any change in public policy to support a harm reduction approach:

Questions	Quality of the Evidence
1. Are there forms of nicotine use that have fewer health consequences than others?	Good evidence to support this
2. Is there a significant number of smokers who cannot or will not quit, despite knowing the risks?	Insufficient evidence that this is a substantial population
3. Will these smokers be willing to change their nicotine delivery system?	Insufficient evidence
4. Will the rate of population quitting increase or stay the same if the policy is changed to harm reduction?	Evidence suggests that it is unlikely that it will increase and may decrease
5. Will a policy of harm reduction increase smoking initiation in teens and young adults?	Evidence suggests that it is very likely that adolescent smoking will increase.

For these reasons, I believe that a public health policy of promoting harm reduction in general, and medicinal nicotine in particular, is unjustified at the present time.

The Promotion of NRT: Population Implications

Shu-Hong Zhu, PhD

Principal Investigator for the California Smokers' Helpline

Associate Professor, Department of Family and Preventive Medicine

University of California, San Diego

Dr. Zhu's presentation focused on two issues: first, the relationship between a quitter's motivation and the use of medicinal nicotine as a cessation aid, and second, what effect the promotion of cessation aids might have on the rate of quitting in the smoking population in the long run.

Dr. Zhu presented four basic questions:

1. Why do smokers need help?
2. How much help do they need?
3. How much can we help?
4. How then should we promote cessation aids?

First question: Why do smokers need help?

- ◆ They do not want to quit smoking, or they are ambivalent about quitting.
- ◆ They do not feel they can quit even if they want to.
- ◆ They are not desperate enough to expend the effort needed to succeed.



A large part of the challenge seems to come from the last bullet, expending the effort. Of people who call the California Smokers' Helpline and say they would like to try quitting by using the patch, 45% actually go get a supply of patches when it is not free, and 60% go get a supply of patches when given a voucher for free patches. A large percentage of the people who say they want to quit, and even have a method in mind, still fail to follow through to even go get a supply of patches.

Second question: How much help do they need?

- ◆ They need a lot of help finding the inspiration to want to quit.
- ◆ They need a lot of help being convinced that they can quit.
- ◆ They need a lot of help in finding the will to invest a lot of effort to quit.
- ◆ How much they want to quit significantly affects whether they think they can quit and the amount of effort they are willing to put forth.

Dr. Zhu presented a clinical example: With patients who say they cannot quit, the clinician plays a game. He or she says to the patient, "Imagine you are about to light up that first cigarette of the day, and I show up at the door with a \$1000 bill in exchange for that cigarette. Would you be able to give up that cigarette?" Most patients say they probably could. They realize it is not a matter of "can't" but a matter of "don't want."

In an article by Viswesvaran & Schmidt in the *Journal of Applied Psychology* in 1992, in which 633 studies were analyzed, the authors concluded that motivation plays a huge role in successful smoking cessation. For control groups, the quit rate was 6%, and for groups receiving a physician's advice, the quit rate increased to 7%. However, when physicians advised pulmonary patients to quit smoking, 34% of them did, and when physicians advised cardiac patients to quit, 42% did. Cardiac patients are much more highly motivated to quit than the other groups and are therefore more successful at it.

Dr. Zhu presented another clinical example, that of quitting among women of child-bearing age vs. pregnant women—11% vs. 47%. He noted that pregnancy is a state, not a trait, and that these could be the same women at different times. This example shows that having a strong motivating factor boosts the successful cessation rate significantly.

Third question: How much help can be provided?

- ◆ A lot can be done on the population level to influence the amount of "want."
- ◆ Some things can be done on the part of "can."
- ◆ No data is available on what can be done to affect effort.

Dr. Zhu said that a comparison between Chinese smokers in China and Chinese smokers in the U.S. demonstrated how environmental changes can be instituted to affect motivation at the population level. About 12% of Chinese smokers in China make a serious quit attempt in any given year, whereas 47% of Chinese in the U.S. make a serious quit attempt in any given year. Demographically they are the same group, but in one environment they are much more motivated to quit smoking.

Policies can motivate people to quit, along with social and cultural norm changes, such as a smoking ban in the home. In the group of pregnant smokers, the public health community made a very serious effort to convince them not to smoke, and the population quit rate for pregnant smokers significantly increased from 1993 to 1999. Note that very little medication is used in this group because medication is usually contraindicated.



Fourth question: How should cessation aids be promoted?

First, it must be determined to what extent NRT can help smokers quit; the answer appears to be that it helps some, but not a lot. The absolute quit rate for people who do not use any aids is about 7%, and for people who use aids of one sort or another, the quit rate is about 15%. This is what the smokers actually experience. They use the quitting aids, and they see other people use the quitting aids, and they see that it works only 15% of the time. A lot of the advertising is based on clinical trials of highly motivated smokers, and the quit rates quoted there can be as high as 40%. That kind of success rate is simply not true “out there in the real world.”

So, what is the population impact of NRT?

- ◆ There is probably some population impact, but it has been difficult to find.
- ◆ There are many projections, but little actual data.
- ◆ Coverage alone is not sufficient. (See Boyle, *Health Affairs*, 2003.)
- ◆ From a study design perspective, NRT use in a given population needs to be dramatically increased in order to examine if there is an impact, and this is a very expensive proposition.
- ◆ A price reduction is probably necessary before trying a harm reduction strategy.

As to helping smokers understand that they have to put in some effort, it is hard to find any systematic data, except anecdotal clinical experience. Generally speaking, people do not like to hear that they need to put in a lot of effort to succeed, because they are already fearful of what it will cost them if they quit smoking. But, like it or not, they need to hear what is true:

- ◆ Although cessation aids can help, at least half of the success comes from the smokers themselves, whether by might or by luck, by virtue of their actually making a quit attempt.
- ◆ To look at it more positively, smokers need to hear that just because they have not succeeded yet, it does not mean that they have to wait for some magic cure to arrive.

How then should cessation aids be promoted? Theoretically, if smokers attempting to quit want to maximize their chance of success, then all of them should use cessation aids, because it appears to double the chance of success (from 7% to 15%).

The fact that they do not want to use cessation aids to quit means one or more of the following:

- ◆ They do not really want to quit.
- ◆ They do not know about cessation aids.
- ◆ They do not think that cessation aids work.
- ◆ They do not have the money to pay for it.
- ◆ They are not desperate enough to put in the effort.

Dr. Zhu puts the emphasis on the first bullet, “They do not really want to quit.” Unless smokers are really motivated to quit, simply delivering the cessation aids to every smoker will lead to waste. It can be an even bigger issue if such a distribution uses a big portion of the public funds for tobacco control. Stronger experimental evidence is needed to help us find the balance point on cost-effectiveness of distributing cessation aids on a large scale.



Smokers need to know that any one quit attempt is likely not to succeed, whether aided or unaided. Over-promotion of cessation aids may lead to the following self-fulfilling prophecy:

- ◆ Smokers receive the marketing message, “You can’t quit smoking without cessation aids; you will quit smoking with the aids, with little effort.”
- ◆ Smokers get hit with the reality that most of the time they still cannot quit smoking with the cessation aids. It might be represented like this: Smoke → NRT → Relapse → NRT . . . (up to seven times before success.)
- ◆ Therefore, harm reduction is the most logical next step.
- ◆ Is this the message we want to send?

Here is what the public health community knows for certain: marketers should not promote NRT with messages that say cessation aids are necessary for successful quitting. Most quitters quit without aids.

Promotion of NRT also should not give the impression that quitting is an all or nothing proposition—most quit attempts lead to relapse, and it certainly should not give the impression that quitting will be easy with aids. It may be easier, but it will not be easy.

In summary, what should cessation aid promotion do?

- ◆ It should increase the desire of smokers to make a serious quit attempt.
- ◆ It should generate the impression that quitting is the norm among current smokers, including quitting multiple times, and lifetime quitting success is the goal.
- ◆ It should increase confidence in the smokers’ ability to quit on their own or with aids.
- ◆ In short, promotion of cessation aids should be in the service of promoting quit attempts in the general smoking population.

The public health community needs to watch for any trends that suggest promotion of cessation aids is leading to a decrease in the quit attempt rate; that is the danger we must avoid.



Fourth Set of Questions and Comments from the Floor

Jonathan Foulds, of the University of Medicine and Dentistry of New Jersey, said he did not hear anything in any of the day’s presentations supporting the idea that NRT products should be placed back under prescription only, which struck him as strange since that was the main controversial point in this section of the draft paper. He said he did not see any convincing evidence that NRT marketing leads kids to smoke. In fact, he noted that Dr. Pierce presented data showing that during a time when there was a lot of NRT advertising, there was also a significant decrease in smoking among adolescents. That is inconsistent with the idea that NRT advertising was inducing kids to smoke.



Jonathan Foulds also asserted that there is a group of people who can be defined as those who cannot or will not quit. “What would you call the millions of people who began smoking in adolescence and die in middle age of a smoking-related disease? Aren’t they people who didn’t or couldn’t quit?”

Jonathan Foulds also challenged the idea that smokers who do not quit lack sufficient motivation, pointing to participants in clinical trials who say they are highly motivated, have to jump through many administrative hoops, answer extensive questionnaires, complete several physicals, and get the best treatment money can buy, yet only 25% of them are successful in their quit attempts six months out. He suggested John Pierce might be neglecting the “teensy weensy factor of nicotine addiction.”

John Pierce, University of California, San Diego, responded in this way: “We have to distinguish between the physiological dependence on nicotine and the psychological dependence. NRTs can help with the physiological symptoms, but motivation comes into play with the psychological dependence. Look at people who have been abstinent for nine months, pregnant women, prisoners, etc., who have no physiological effects from nicotine in their bodies, and they relapse as soon as environmental conditions change. Their personal identities are so wrapped up in being ‘smokers’ that they go back to smoking. Those people will not change to a less harmful product because it’s not the physical addiction that’s at work here, it’s the psychological factors.”

Mike Cummings of the Roswell Park Cancer Institute added that he thought most smokers do not like smoking, and that New York’s patch give away programs show there is a demand for NRT medication.

John Pierce suggested that what smokers demand is a “magic cure.” He has found that smokers who make behavioral changes such as smoking bans in the home are much more successful when they use NRT than people who do not make any behavioral or environmental changes.

Shu-Hong Zhu of the University of California, San Diego, added that just because a person says he or she cannot quit does not mean that physical nicotine dependence is the cause.

Paul Bloom of the University of North Carolina wondered if there are data about the sales of NRT products for purposes other than cessation and asked Mike Cummings if he worried about young adults using “cool” nicotine patches for non-cessation purposes.

Mike Cummings replied that he was more fearful of young people using flavored Camels than he was about them using patches in unintended ways. NRTs must be part of a comprehensive tobacco control program.

Mitch Zeller, of Pinney Associates, Inc., asked April Roeseler of TCS if the State of California agreed with the four problems Mike Cummings listed for NRT products, and, if so, would it not be better to address those problems first before placing the products back under prescription status.

April Roeseler responded that TCS always tries to let data drive the program, and NRTs have become less effective since they went OTC. If NRT medications went back under prescription status, the State would have more control in the attempt to regain that effectiveness. She added that prescription status might not preclude taking a lot of the actions Mike Cummings suggested.

John Pierce interjected: “You are assuming it [NRT] works, but smokers appear to think it doesn’t work. People are associating it with quit attempts rather than cessation.”



Mitch Zeller responded that he was assuming that increased access and improved utilization would increase its effectiveness and help more people quit.

John Pierce offered his hypothesis that, when the patch first came out, the most motivated people used it, and as time went on, less motivated people began trying it without doing the ancillary behavioral changes that increase quit success. That would account for its lessened effectiveness.

Shu-Hong Zhu offered that one of the benefits of returning NRTs to the purview of doctors is that doctors can play an important role in motivating their patients to use the products properly.

Steven Schroeder of the University of California, San Francisco, noted that there was clearly a split among the members of the panel about whether NRT works. The study showing an increase of 7% to 15% does show a positive effect, so the state needs to decide whether it thinks these products work. If the state does decide they work, then taking them into prescription status ignores the evidence that doctors do not do a very good job of helping smokers quit and that there may be other health care professionals who could also motivate patients to quit smoking. The public health community will have to do a lot of work to help doctors be more effective if the medication is put back under prescription status.

Steven Schroeder continued with another point: 44% of cigarettes are consumed by people with serious psychiatric and substance abuse problems. The assumption in all the presentations has been of the rational smoker. But, many smokers are not rational; they are self-medicating. He asked the panel what their recommendations were for that population.

John Pierce did not accept Steven Schroeder's figure of 44%, saying he did not think it was a huge problem.

Mike Cummings said that when New York's psychiatric facilities became smoke-free, having NRT products available helped, and that most of the problems came from the staff, not the patients.

Steve Hansen, a physician practicing in San Luis Obispo, promoted raising the tobacco age to 21, noting that this is the position of the Preventing Tobacco Addiction Foundation, of which he is a board member. He observed that it was a lot easier motivating his heart and lung patients to quit smoking after they came out of the ICU. He referred to an article in the *Journal of the American Medical Association* that recommended talking to every patient as if they were a heart or lung patient; people need to be shocked into behavioral changes.

Cynthia Hallett, of Americans for Nonsmokers' Rights, noted that, in California, the tobacco control movement created an environment that was conducive to quitting, and that the public health community should look into ways to create environments more conducive to quitting than to switching. She also stated that she was going to drop the term "harm reduction" in favor of "nicotine maintenance," similar to the choice of using "secondhand smoke" over the industry-favored "environmental tobacco smoke (ETS)."

Dileep Bal of the California Department of Health Services asked Shu-Hong Zhu to address the issue of cost, and directed a comment to Mike Cummings referring to the limited public health budget in California and elsewhere as the reason for thinking in terms of an either/or choice between harm reduction and norm change strategies.

Mike Cummings responded that, clearly, NRT medication is too expensive, yet denied it was an either/or situation. NRT should be a part of a comprehensive tobacco control program. There are



probably creative things that governments could be doing to lower the price and increase access. When cessation is part of the overall tobacco control program, it involves building relationships with smokers like the tobacco companies do. Quitting is a long-term relapse problem, and tobacco control programs can use techniques similar to those used by the tobacco companies in order to help smokers in their quit attempts.

John Pierce framed it as an ethical issue when a program is faced with limited public funds, dubious effect, and a potentially huge market with large profit margins for the tobacco companies.

Shu-Hong Zhu suggested that in Asia the push should be for secondhand smoke policies to take advantage of the cultural values of protecting children and family. It does not cost a lot of money, and no one can argue in favor of harming children with secondhand smoke. In the face of this kind of community norm change, many people will quit smoking on their own without aids just as people did here in California.

Mark Parascandola of the National Cancer Institute observed that there is a tension between what is an acceptable level of risk in the public health approach as opposed to the clinical approach. The draft paper sets a very high bar for evidence that a new nicotine maintenance product not cause any harm at the population level. This standard exceeds current standards, and these kinds of data are extremely difficult to gather before a medication goes on the market. He wondered what kind of evidence the state was looking for.

Mike Cummings responded that companies' product claims ought to be supportable, and their safety data has to be reported to consumers. Today, marketing of NRTs is bad; consumers are clueless about how they work, their efficacy, and their toxicity compared to the cigarettes they are replacing. We also need to look into the possible adverse unintended consequences from the marketing of these products. Post-marketing surveillance is needed. That should be enough.

Shu-Hong Zhu saw the question in terms of cost-benefit analysis: The trend is that smoking is going down. The cost of supplying NRTs to the smoking public is potentially huge. That is the reason the public health community needs to understand these products very well.

John Pierce thinks there is definite evidence suggesting that NRTs decrease the quit rate and have an adverse effect on uptake in kids, and that it could have a negative effect on the norm change successes in California. The state needs to be convinced that those things are not going to happen before it goes down the harm reduction path.

Gary Giovino of the Roswell Park Cancer Institute stated that advertising should make clear that quitting takes effort and that smokers who are quitting have to put up with discomfort. Consumers also need to be informed that NRTs take the edge off the cravings, and they do not cause cancer or heart attacks. He was very concerned that, as a result of NRT marketing, people may get the idea that it is okay to start smoking because they can always quit with these cessation aids. He also suggested that one needs to be careful about drawing conclusions from John Pierce's alcohol and marijuana data because of other factors there.

John Pierce agreed, saying it is not necessarily proof, but the data may serve as a warning nonetheless.

Tom Glynn of the American Cancer Society asked whether the public health community is in danger of waiting too long to get good data before making policy decisions.

John Pierce stated, "If something isn't working, we should pull the plug, and I think we're right at that point now."





Reflections on Day 1 of the Harm Reduction Summit

David Altman, PhD

*Vice President of Research and Innovation
The Center for Creative Leadership*

Dr. Altman began by joking that he had counted 675 slides presented and that he had been able to integrate about 400 of them, apologizing for those 275 that he had missed.

Putting all jokes aside, he noted that it had been a long day, and people were tired. He told the audience that he originally had intended to present three perspectives on the summit: (1) his observations on the innovation and creativity being stimulated by the people that were brought together and the process that was being used, (2) a summary of the key substantive points that were made on the issue of harm reduction, and (3) a piece of creative writing that summarized the day.

He decided to jump right to the creative writing piece, called *Down on J Street*.

Down on J Street

The air was hot and dry on J Street. It was just a few days on the fall side of summer, and palpable tension was in the air. Seventy-five people from around the country descended on J Street for a gathering with high stakes, high anxiety, and high uncertainty about the outcome. At its root, the tension in the air was over the fact that more than 1,000 Americans would die this day from tobacco-induced disease. Many thousands of others had another miserable day living with the ravages of tobacco. Worldwide, the number of deaths was manyfold higher. In New York, in Richmond, in Winston-Salem, and in Greensboro, the tobacco companies were making yet another large deposit in their robust bank accounts. Stock options and bonuses were back in vogue. The Chamber of Commerce in Winston-Salem was lauding the jobs created by Brown and Williamsons' move from Louisville.

The J Street crowd knew that this was insane. Something had to be done. We were at a crossroads. The future of tobacco control was on the table, but a vision of that future was not all together clear. This was too much harm to accept day in and day out. Despite huge differences in philosophy and approach, there was a clarion call for reducing this harm. Christ, it had been 40 years since the Surgeon General told us that tobacco killed and maimed. Yet, we were still losing 1,000 souls each day. The gains we have made in the past 40 years, and they have been significant gains, had to be maintained and improved upon. Some of the best and brightest were



brought to J Street to tackle this dilemma, perhaps with new approaches. Some felt tackled by harm. Others felt shackled by harm. Nerves were touched. Buzz was created. Poppycock was in the air. This was not a public health love-in, though it seemed quite tame at times, at least until the final few hours on day one. The tobacco industry would love to have a ticket to this J Street gathering, to watch those tobacco control fanatics go after each other—to witness firsthand the ongoing civil war in the tobacco control community. They licked their chops at the thought of the press getting wind of the dissension in the room.

The tobacco companies did not get a ticket to J Street, but at times, some folks who did get a ticket had as much trust in one another as they had in the tobacco companies. The stakes were indeed high. Santayana was evoked as the resident philosopher: “Endeavor to understand each other.” Calls for dialogue, not consensus, for issue analysis, *not* personal attack, were made. However, these calls for appreciative inquiry did not diminish the concern that by the end of the second day, positions would be more polarized, and that centripetal rather than centrifugal forces would ultimately rule the day. In the minds of some J Street participants, recombinant innovation was still possible, but it would take considerable effort the following day, and the days after that, to achieve new understanding and more effective approaches at multiple levels. The April 20th release date of the report loomed large.

The J Street participants were presented with a position paper and asked to comment on whether they were pro or con; to decide which camp they could call their own (the “quit or die” camp or the “unintended consequences” camp). Positions of pro and con, of camp one or camp two, of either-or, of nicotine maintenance vs. comprehensive tobacco control, however, did not adequately describe the texture and depth of conversations that occurred on J Street. We were told that “in every con job, there is a willing participant.” But it seemed that for most J Street participants, the issues were not as easy as choosing between dichotomies. The space between dichotomies is where the interesting conversations took place and where conversations need to take place in the future. Some thought that the harm horse was out of the barn; others did not. All agreed, however, that there was a horse in or near a barn and that the horse needed to be more carefully studied. People were less certain about whether the horse had a rider controlling it or whether the horse was on its own. Likewise, some people posited that the *devils* were in the details. Others posited that the *angels* were in the details. On J Street, angels and devils were dancing around each other all day. But details, hard details, carefully examined and vetted, matter. J Street participants wanted to discuss the details so that the angels and devils could be more easily differentiated.

J Street could simply be a street named after the letter J. At least for today, the J was a marker for justice, judgment, judiciousness, and jeopardy.

The room on J Street was like a meeting room in any large hotel: cold, dark, and bland. The dialogue, however, was anything but cold and bland. No, it was sharp and passionate, at both the microphone and in whispers permeating the room. Conversations were dressed in strong clothes with vibrant colors:

- ◆ This was tried before and it failed.
- ◆ The science behind this is solid.
- ◆ The science is unequivocal.
- ◆ This was a disastrous episode in public health.
- ◆ Seduction vs. a reasoned approach
- ◆ We have made great progress in tobacco control and even greater progress is possible.



- ◆ Cancer, heart disease, addiction, diabetes; that's our focus.
- ◆ Drugs and money drive quit attempts.
- ◆ Innocence by association
- ◆ Safe harbors
- ◆ Public health fraud
- ◆ Toxicant exposure vs. disease effects
- ◆ Reduced exposure vs. reduced effects
- ◆ Low yield; safe
- ◆ Dismantling and crippling the current approach
- ◆ Denormalization vs. use
- ◆ Cigarette-like; smokeless; medicinal
- ◆ Individual vs. population impact
- ◆ Do no harm; relative harm; reduced harm; reduced risk
- ◆ Either-or vs. both-and
- ◆ Bull-shit; ruses; arsenic
- ◆ Will not! Will too! Will not!!! Will too!!!
- ◆ Do no harm. Do no harm. That seemed to get people's attention.

The instruments of intervention were hotly debated. State and local rights were key drivers in the discussion. Tradeoffs of risks and benefits were always on the table.

That night, after dinner, most J Street attendees returned to their room for more front and center debate . . . this time on their TV at 10 PM Pacific time. You couldn't get away from it. Peter Jennings was the object of their attention now. A Jennings special, "From the Tobacco File: Untold Stories of Betrayal and Neglect," was on the air. A press release billed the show as follows: "How the public health advocates who fought the tobacco industry for years turned their backs on a landmark deal that, for the first time, would have regulated the manufacturing and sale of cigarettes and put billions of dollars into anti-smoking campaigns. This is the untold story of how two icons in the public health industry—former Surgeon General C. Everett Koop and former Food and Drug Administration Commissioner David Kessler—failed to support the most comprehensive anti-tobacco legislation in the country's history. In the second story, Mr. Jennings reports on the failure of the states to sustain the fight against smoking. When the tobacco companies settled the first lawsuits brought by states on behalf of taxpayers, the states promised to use much of the \$246 billion from settlements for public health measures and tobacco control. Time and again, the states have broken that pledge. Mr. Jennings reveals that Florida, which spent millions of dollars on one of the most effective anti-smoking campaigns in the country, recently gutted funding for these programs. Mr. Jennings explains the tragic results of such neglect. Finally, irony of ironies, today Philip Morris, which led the fight against governmental regulation for decades, is now urging government to regulate tobacco products. At Philip Morris headquarters in Virginia, a senior executive acknowledges to Mr. Jennings that, during the height of the tobacco wars, when these companies operated in complete secrecy, a reporter would not have been allowed on the property. Philip Morris now believes government regulation is in their best interest and will lead to official recognition of a new 'safer' cigarette. Mr. Jennings tells the intriguing story of this turnaround."



This was more than some J Street participants could handle in one day. Conspiracy theorists now had their evidence. Attacks on Koop and Kessler? Like the conference organizers had predicted, this symposium had gotten completely out of hand. But that's the path to innovation, so a little out-of-handedness is not a bad thing. Now, however, J Street participants wanted to sleep. By the end of the Jennings show, it was 2 AM Eastern time. It was time to roll up the sidewalks of J Street, spend some closed eye time contemplating a rather remarkable day, and prepare for what will likely be a roller coaster ride tomorrow . . . Down on J Street.



Looking Back on Day 1— Looking Forward to Day 2

The Seduction of Harm Reduction: Innovation, Turbulence, and Recombination

David Altman, PhD

*Vice President of Research and Innovation
The Center for Creative Leadership*

Dr. Altman explained that one of the reasons he agreed to participate in this meeting was that he believed the diversity of the participants as well as the meeting's format might lead to something unique. He wanted to share with the participants some information about creativity and innovation as they relate to the tobacco control issues being discussed.

He recommended two books, *How Breakthroughs Happen* by Andrew Hargadon and *The Highest Role* by Michael Ray.

Dr. Altman began with a unique look at Shakespeare, terrorism, and leadership. An interesting op-ed article in the New York Times recently looked at President Bush's leadership through the eyes of Shakespeare: "The paramount lesson from Shakespeare's plays is that the world is full of nuances and uncertainties, and that leaders self-destruct when they are too rigid, too sure of themselves, or . . . too intoxicated by moral clarity." It seemed to Dr. Altman that this statement applied to some of the content of the summit.

Another lesson from Shakespeare is the inevitability of intelligence failure. In almost every play, characters place their faith in information that turns out to be catastrophically untrue. Indeed, in many of Shakespeare's plays, the only person who seems to provide the king with sound advice is the court fool. Dr. Altman couldn't resist saying that there were plenty of court fools present in the room, the result of which was a positive energy. According to Dr. Altman, Shakespeare provides a warning for the public health community not to act rashly on the basis of flawed intelligence.

For people wrestling with the ideas of harm reduction, these are the lessons to be taken from Shakespeare: be cautious; do not suffer from too much moral clarity; be wary of the absence of



nuance or humility or the presence of too much rigidity; consider the quality and durability of the data; and look for unintended consequences.

Dr. Altman noted that risk perception was a huge topic at the summit. In order to make health decisions wisely, people need to understand risks and benefits. They need to understand the limits of the scientific knowledge when weighing advice from the experts. People can be hurt by inaccuracies. There are benefits and risks to the kinds of communications broadcast by the public health community; those reports and decisions will impact the general public.

Researchers are struck by the ability of people to manage risk solely on the basis of observation and intuition. On the other hand, overconfidence in the quality and quantity of data can mislead people into making ill-informed risk-benefit decisions.

One of the goals of this meeting was to create what Stanley S. Gryskiewicz's book by the same name calls "positive turbulence." Positive turbulence is a chaotic energy that can be used to challenge assumptions and established positions. The hypothesis is that as a result of such turbulence, creativity and innovation result; yet, leaders often seek order, organization, and focus. Too much order stifles innovation. Dr. Altman encouraged the summit participants to entertain the ambiguity, incorporate the peripheral perspectives, suspend judgment, and "empty [their] vessels so that they [might] be filled up again with new constituents" that would allow them to see things in different ways.

Dr. Altman defined innovation as the synthesizing or bridging of ideas from different domains, simultaneously thinking in multiple boxes—not thinking outside the box, but thinking in multiple boxes. Innovation comes from recombinant processes: recombinant invention and building new communities around the recombinant results.

Innovation involves building on past knowledge through this process of recombination. Innovation is usually not the result of individual creativity but rather is fostered by structures that promote this recombinant process, structures that bring people together who have traveled to different worlds. And while innovators need to draw from a wide variety of disciplines, they also need strong communities to support them.

Dr. Altman suggested that innovation in tobacco control may come by searching for recombinations of existing knowledge. The tobacco control community might consider stopping research for a time and sitting down to think about ways to recombine the knowledge that already exists.

Finally, Dr. Altman encouraged the summit participants to stir up a bit more positive turbulence during the second day's discussions in order to increase the chances for new insights and creative solutions.



Session 5

The Impact of Harm Reduction and Regulation on Tobacco Control Efforts —Past and Present

Harm Reduction and Local Regulation

Marice Ashe, JD, MPH

Project Director

Public Health Institute

Technical Assistance Legal Center

Ms. Ashe gave the audience some background information on the Technical Assistance Legal Center (TALC) and its role in the drafting of local ordinances governing tobacco control. TALC is funded entirely by TCS.

About a year ago, TALC convened a meeting of tobacco control experts and attorneys general from around the country to look at these new tobacco industry products. The original intent of the meeting was to look at what state food and drug agencies could do in the absence of federal regulation. The discussion soon turned to consumer fraud theories. The meeting prompted quite a bit of activity around the country, with several state attorneys general looking at these products through a consumer fraud prism.

Following the meeting, California tobacco control representatives met to discuss the next steps. At the time, the focus was on tobacco industry products only. Taking into account population science, as well as lessons learned from the light cigarette fiasco, these experts worked to determine what should be done to prevent a repeat of that scenario in the future.

TALC's job was to take the information gathered at that meeting and shape a local response, not necessarily a statewide response.

Similarly, TALC staff members are here at this summit to learn how to translate what has been discussed here into the most effective local action in order to protect public health. TALC will examine the legal and political aspects of these issues and explore whether local communities will embrace moratoria or other policy actions.



Ms. Ashe finished her presentation by stating the TCS position on harm reduction and tobacco control efforts:

- ◆ Harm reduction (nicotine maintenance) products direct attention away from proven strategies (comprehensive programs).
- ◆ Tobacco/pharmaceutical manufacturers should not be allowed to make reduced harm claims unless their products meet existing FDA standards for product safety.
- ◆ There needs to be a fully-funded comprehensive national tobacco control program based on the California model.

Bullst and Ruses: Historical Glimpses of Marketing Seemingly Harm Reduced Cigarettes**

Rick Pollay, MBA, PhD

Professor Emeritus of Marketing

Sauder School of Business, University of British Columbia

Dr. Pollay began by explaining that he had gathered much of this information in preparation for his experience testifying for two weeks in a 2002 trial against the tobacco industry in Canada. In his presentation, he went over the history of tobacco marketing in the U.S. and also described the Canadian experience in the 1990s with a seemingly reduced harm product.

It is well established that smokers believe lower tar and nicotine cigarettes are healthier, and the prime motivation in smoking a low tar cigarette appears to be health related.

In the 1950s, filtered cigarettes were introduced with some fairly explicit health assurances. Ads referred to scientific breakthroughs and discoveries using modern, pure materials. The terms used suggested a benign quality to the resulting smoke: mild, gentle, smooth. Endorsements from the American Medical Association (AMA) and the U.S. government were implied in the advertising. Ad slogans included phrases such as “Just what the doctor ordered” and “Inhale to your heart’s content.”

Tobacco companies used images of technology and modernity to imply scientific innovation and improved safety. For example, Parliament “Hi-Fi” Filter cigarettes were introduced in 1958 at a big press conference in Manhattan against a backdrop of bubbling test tubes and glassed-in smoking machines. Men and women in long white lab coats bustled about; the cigarette’s filter was described as “hospital white.”

Menthol cigarettes took advantage of the medicinal history of menthol familiar to consumers, such as mentholated lozenges for coughs. The industry knew that people who were concerned about their health took solace in menthol. The “smoother” experience of smoking menthol cigarettes made smokers conclude it was a less harsh product.

Tobacco industry documents reveal the companies’ motivation to introduce another “innovation”: charcoal filters. “The public had



been conditioned to accept the filtering effects of charcoal in other fields, and when charcoal was added to cigarette filters, it proved to be an effective advertising gimmick.”

When Kent cigarettes came out, an ad said in bold print that AMA tests proved Kent used the most effective filter. Although the AMA called it “outrageous, reprehensible hucksterism” in its professional journal, the public saw the Kent ad, not the journal editorial. It later became evident that filters were for cosmetic purposes only.

Parliament ads implied endorsement by the U.S. government: “The first filter cigarette in the world that meets the standards of the United States Testing Co.” Actually, the United States Testing Co. was a private firm unaffiliated with the government.

Other kinds of advertising were also employed, such as one of Viceroy’s “Intelligent Smoking for Intelligent People” ads that showed an astronomer, literally a “rocket scientist,” thoughtfully choosing to smoke this particular brand.

So, who responded to this kind of advertising and why? They fell into two groups.

In the first group were concerned smokers (“pre-quitters”), who were generally older, college educated, and female; and in the second group were smokers seeking to avoid both real risks and cosmetic social risks. In other words, they sought to avoid disease and death and also to avoid appearing indifferent to having an immoral or unclean habit.

Tobacco industry documents indicate the industry’s understanding of smoker psychology:

- ◆ “Most smokers see themselves as addicts . . . the typical smoker feels guilty and anxious about smoking but impotent to control it.”
- ◆ “Psychologically, most smokers feel trapped. They are concerned about health and addiction. . . Advertising may help to reduce anxiety and guilt.”
- ◆ “[Smokers are] receptive to advertising, which helps them escape from their inner conflicts about smoking.”

The tobacco control community often focuses on the role of advertising as a recruitment tool for new smokers, but advertising also plays an important role in reassuring and reinforcing existing smokers to continue smoking.

In the 1960s, the tobacco industry continued its misleading and cynical emphasis on filtration as the means to reassure smokers who were concerned about their health. “The illusion of filtration is as important as the fact of filtration . . . Therefore, any entry [into the market] should be by a radically different method of filtration but need not be any more effective,” stated a 1966 Philip Morris document. To sell well, a product had to look better, but not necessarily be better.

In the 1970s, light cigarettes were developed and marketed. The tobacco industry realized that these low yield products were perceived as less satisfying, somewhat effeminate, and risked weaning smokers from smoking. The ad campaigns for these products featured bold headlines that implied scientific validity and government endorsement.



The success of light cigarettes was due to the following:

- ◆ Technologically improved products
- ◆ Consumer desire for a reasonable compromise between continuing to smoke high yield cigarettes and quitting altogether (i.e., “healthier” cigarettes)
- ◆ Massive advertising dollars spent on these products

Many ads for light cigarettes imply that “if you smoke this brand of light cigarettes, you do not have to quit.” In fact, tobacco companies know that consumers still have little knowledge about the products they are smoking and continue to rely on nomenclature such as “light” and “low tar” as if it were meaningful. People concerned about their health respond to the idea of “light” in all sorts of products, including food (Kraft Light peanut butter), beverages (Miller Light), and so forth.

Dr. Pollay concluded that light cigarettes turned out to be the savior of the industry, and to that end, he shared this Christmas carol (sung to the tune of “Hark! The Herald Angels Sing”):

*Hark! The herald angels sing
 Glory to the low-tar king
 Best on earth, and oh so mild
 Health and pleasure reconciled.
 Joy! The brand we sanctify.
 Joy! The triumph of our lie.
 Joy! Angelic ads proclaim.
 Smoke in peace—no fear, no phlegm.
 Hark! The herald angels sing
 For God’s sake,
 Smoke the low-tar king.*

In the 2002 Canadian trial in which Dr. Pollay testified, the tobacco company Imperial Tobacco Ltd. (ITL) argued that federal (Canadian) regulation on tobacco advertising had caused a new product, Player’s Premiere, to fail.

The tobacco company claimed the following:

- ◆ ITL developed the product, then the promise, i.e., the advertising.
- ◆ ITL had “actually solved” the irritation problem found in other brands.
- ◆ The ads informed consumers about product differences.
- ◆ Player’s Premiere failed due to federal (Canadian) Tobacco Act restraints.

ITL documents showed that product development consisted largely of crafting a high tech image rather than a high tech product. Their efforts focused on the following:

- ◆ Finding the right words
- ◆ Finding the right packaging
- ◆ Finding the right “device” for “tangible credibility”
- ◆ Finding the right image
- ◆ Finding the right marketing mix



Did they actually solve the irritation problem? Dr. Pollay discovered company documents that suggested not. Consider, for example, the following quotes:

- ◆ “What remains to be done . . . is to develop the product that fully delivers on the promise that we are about to make to consumers.”
- ◆ “What is still less complete, however, is the product.”

But, did that stop them? No. Sales “can be driven by imagery rather than significant product differences,” according to one company memo.

The company proceeded to market this “new discovery” in a clever campaign that conveyed the idea Player’s Premiere was innovative and “high tech.” These ads featured

- ◆ A cut-away drawing of the filter and its constituents
- ◆ A blueprint background to bring in the notion of technology and engineering
- ◆ Windows and an arrow like an icon on a computer screen
- ◆ Descriptions of a unique filter with an “effective natural filtering agent”
- ◆ A product name, “Premiere,” that implied a “first” or a breakthrough in both English and French

They also used images that conveyed tastefulness:

- ◆ Colors were fairly dark and rich.
- ◆ The images embodied the “self-reliance required to live this very rugged life at sea.”
- ◆ The Player’s brand represented “tradition, heritage, and master craftsmanship.”

Did Player’s Premiere actually deliver less irritation? Consumer data show that in blindfolded tests, only 10% of smokers who tried the product found it less irritating, whereas 29% of smokers found it more irritating, and 47% found no difference in irritation.

However, when smokers who were aware of the Premiere filter concept tried the cigarette, 40% found them less irritating, 33% found them more irritating, and 21% found no difference. The company’s advertising certainly worked on consumers’ perceptions; yet there was no avoiding the conclusion that the company failed to deliver on its advertised promise.

Additional expert opinion revealed that the Player’s Premiere cigarette produced smoke containing even greater quantities of irritating substances than the smoke of the company’s other brands.

In the final analysis

- ◆ Did the product precede the promise? No.
- ◆ Did the company actually solve the irritation problem? No.
- ◆ Were the ads informative?
 - They did not explain what causes irritation.
 - They did not explain what the company did about that.
 - They did not explain what to expect with this product.
 - They did not make comparisons to other products.



- ◆ Did the product fail due to regulation? No.
- ◆ Was there a loss of public benefit? No.

As a result, Dr. Pollay concluded that the company conducted false and misleading advertising and gave false and misleading sworn testimony during the trial.

Dr. Pollay shared these final thoughts:

- ◆ "Reduced risk" products and ads were designed to reassure "pre-quitters" to keep them smoking.
- ◆ Filters and "lights" were successful at keeping pre-quitters from quitting.
- ◆ Industry documents show the tobacco companies' awareness that consumers' faith in the virtue of new products was misplaced and unwarranted.
- ◆ The industry attempted to deceive the courts and regulators, just as they deceived consumers.

A Safer Form of Arsenic?

Alan Blum, MD

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It is regrettable that the public health community has been drawn into an increasingly rancorous and divisive debate over whether certain forms of tobacco can be substituted for others and thus reduce harm. Smokeless tobacco, a marketing term for moist snuff products coined in the 1970s by the United States Tobacco Company (since changed to United States Smokeless Tobacco Company or USST), has a deceptive connotation, i.e., the consumer will "smoke less" and, unlike the cigarettes it is intended to replace, the product is "smoke-less."

Until the late 19th century, when concerns about the spread of tuberculosis led to the passage of anti-spitting ordinances, oral tobacco was more widely consumed than cigars, cigarettes, or pipes. The invention of the mass production cigarette machine to replace the labor-intensive hand-rolled product, combined with the promotion of cigarettes as a safer alternative to chewing tobacco, put cigarette sales well ahead of all other forms of tobacco by the turn of the century.

Oral tobacco use declined and remained a custom primarily confined to the South and West. In the 1970s, USST fomented a national resurgence of moist snuff by means of an aggressive TV and print advertising campaign that featured former rodeo and football star Walt Garrison offering free samples by mail of the company's Copenhagen and SKOAL brands. Garrison's catchy slogan was "A pinch is all it takes," and in illustrated booklets distributed with the product, he instructed new users in "the art of dipping."



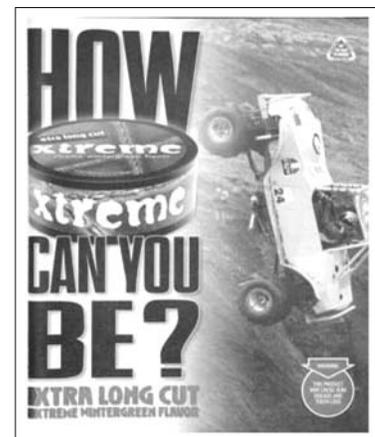
Garrison, who became president of the company, was joined in advertising for Copenhagen and SKOAL by fellow football legends Earl Campbell, Nick Buoniconti, and Lawrence Taylor, all-star baseball player Bobby Murcer, world champion rodeo cowboy Ty Murray, racecar driver Harry Gant, and country music star Charlie Daniels.

Throughout the 1980s and 1990s, USST actively recruited new users by means of free distribution on college campuses across the country and year-round sponsorships of rock and country music concerts, the professional and college rodeo circuits, bull-riding championships, and various motor sports including stock cars, dragsters, Indy cars, tractor pulls, sprint cars, and monster trucks. The company also aggressively targeted the Hispanic population by means of sponsorship of *Cinco de Mayo* celebrations and "low-riders" competitions. T-shirts, caps, music videos, and tote bags were given away as prizes for playing simple carnival games at promotional booths set up by the company. As late as 2000, USST was still hosting concerts and promoting and distributing its products on college campuses. A mail order catalogue featured a wide variety of clothing and utensils with tobacco brand logos.

Rodeos remain popular in the West and Southwestern U.S. USST maintains a highly visible presence at these events, to which children are admitted free, and many of these events are nationally televised on The Nashville Network (TNN) and other cable channels. The 1986 ban on TV ads for smokeless tobacco thus did not deter the manufacturer from sponsoring events that would in turn be televised.

USST mails out a glossy bimonthly publication called *Heartland*, the "magazine of the American outdoor lifestyle," which features current and past professional athletes and associates its tobacco products with vigorous activities. Since the airline smoking ban of 1988, the company has promoted its products for use "when you can't smoke." Similarly, USST has glommed onto institutions which have restricted smoking, such as fire departments and the military. A national advertising campaign touting SKOAL as "the solution" for maintaining dependence on tobacco when situations do not permit smoking has been running in numerous publications, including *TIME*, *Newsweek*, *US News & World Report*, *Sports Illustrated*, and *USA Today*.

Currently, each issue of the most popular young men's magazines such as *FHM* and *Maxim* features several full-page ads for SKOAL and other brands of smokeless tobacco, often with risk-taking themes such as extreme sports. In spite of a ban in 1991 on smokeless tobacco in minor league baseball, a disheartening 25% of players still report using this product. With the harm reduction movement all too willing to endorse smokeless as a safer alternative to cigarettes, and the manufacturers promoting the product as aggressively as ever, the morbidity from smokeless tobacco seems destined to increase among the next generation.



Implications of Harm Reduction for Comprehensive Tobacco Control

Corinne Husten, MD, MPH

*Acting Director of the Office on Smoking and Health
Centers for Disease Control and Prevention*

Dr. Husten began her presentation by stating that potential reduced exposure products (PREPs), along with the broader issue of harm reduction, have generated considerable debate. What are the implications of PREPs from a population perspective, a policy perspective, and a program perspective? Any consideration of the potential effect of PREPs has to be considered against the background of these three perspectives.

PREPs have the potential to be widely adopted by smokers. A JP Morgan report stated that “Overwhelming smoker demand for reduced risk options suggests PREPs could become the next transforming tobacco market innovation We expect successful innovation around a safer cigarette to reduce the likelihood of any acceleration in the 2–3% consumption rate decline.”

In order to show that a product has achieved harm reduction, three things must occur:

- ◆ Reduced exposure
- ◆ Reduced individual risk
- ◆ Reduced population risk

In addition, the product must not cause greater harm or different kinds of harm than at present.

In order to say that reduced population risk has occurred, these assumptions must be made:

- ◆ Measured exposure translates into actual exposure.
- ◆ Reduced exposure translates into reduced individual risk.
- ◆ Reduced individual risk translates into reduced population risk.

None of these assumptions is necessarily correct, and it has to be tested on a case by case basis.

Dr. Husten pointed out that two other facts must be kept in mind: harm comes from all kinds of tobacco products, not just cigarettes; and the population level effects will be determined not just by the characteristics of the products, but also by how they are promoted and perceived by the population.

How did past harm reduction efforts fare in reducing population risk? Three such strategies involved the following:

- ◆ Reducing the amount of tobacco smoked
- ◆ Using nicotine replacement therapy (NRT) to reduce tobacco intake
- ◆ Switching to low tar cigarettes

Reducing the amount of tobacco smoked: At first glance, reducing the harm by reducing the amount smoked seems to make sense. It is logical to think that lighter smokers are at less risk than heavier smokers. However, cohort studies suggest that reducing daily tobacco intake by as much as 50% may not result in tobacco-related mortality and disease reduction. This may be because people who reduce the number of cigarettes they smoke may smoke those remaining cigarettes differently. To preserve a constant nicotine intake, they may inhale more deeply, take more puffs, or smoke more rapidly.



Similarly, when people switch from one type of tobacco product to another, they may use the new product differently. For example, cigar smokers who previously smoked cigarettes inhale more than cigar smokers who have always smoked cigars.

Using NRT to reduce tobacco intake: Using NRT would seem to make sense, because it helps avoid the compensation of nicotine seen in the previous example. Does smoking reduction result in a reduction of biomarkers associated with harm? Studies suggest that smokers cannot reduce the amount smoked by very much, cannot maintain such a reduction, or even if they do maintain it, the reduction in smoking does not translate into a reduction of biomarkers.

Switching to low yield cigarettes: It seemed to make sense biologically; smokers who switched to low-tar cigarettes would reduce the level of tar they were exposed to. Early studies seemed to suggest that individuals were reducing their risk. Public health officials endorsed this strategy for those smokers who could not quit. The 1981 Surgeon General's report said that "smoking cigarettes with lower yields of tar and nicotine reduces the risk of lung cancer and, to some extent, improves the smoker's chance for longer life, provided there is no compensatory increase in the amount smoked."

The Public Health Service even ran public service announcements for several years encouraging smokers to switch to low-tar cigarettes. Low-tar brands soon dominated the U.S. market. However, the way smokers actually used these cigarettes resulted in something quite different than the anticipated effect. It soon became apparent that people smoked these cigarettes differently than the machines used to measure the tar and nicotine yields. To compensate for the lower doses of nicotine in these cigarettes, they inhaled more deeply, resulting in more risk than before they switched. In other words, reductions in measured exposure did not translate into reduced actual exposure. The switch to low tar cigarettes may account for the shift in tumor histology of lung cancer to adenocarcinoma, which was once relatively rare. This could be because smokers inhaled these cigarettes more deeply; it could also be because they were exposed to greater doses of tobacco-specific nitrosamines.

On a population level, smokers who might have already quit smoking switched to low tar cigarettes instead, resulting in a decrease or at least a delay in cessation. As a result of these unforeseen effects, low tar cigarettes conferred at best a minimal benefit at the individual level, and possibly harm at the population level. At a 2003 congressional hearing on harm reduction, Surgeon General Richard Carmona stated, "We now know that low-tar cigarettes not only did not provide a public health benefit, but they also may have contributed to an actual increase in death and disease among smokers." It should be noted that the results did not become evident until years after the introduction of the products.

Several lessons can be drawn from the low tar cigarette experience:

- ◆ Measure the right thing. In this case, machine measured yields failed to translate into actual exposure.
- ◆ Consider population risk.
- ◆ Be careful! Public health officials were wrong in their predictions of the effects of low tar cigarettes. Given the complexity of the effect, and the magnitude of the unintended adverse consequences, it is imperative that future harm reduction proposals be thoroughly scrutinized before being implemented.



Even a product with documented reduced exposure may not reduce individual risk:

- ◆ Cigarette smoke contains numerous carcinogens and toxins. It remains to be seen whether reducing a few of these substances reduces risk.
- ◆ There may be offsetting effects: processes that reduce the level of one toxin may result in the increase in the level of other toxins.
- ◆ The dose-response relationship between exposure and disease risk may not be linear. For example, lung cancer is more directly related to the duration of smoking than to the amount of smoke exposure. And the risk of heart disease increases rapidly with exposure to very small doses of tobacco smoke.
- ◆ Any attempt to measure the impact or probable impact of PREPs needs to look at multiple effects and outcomes because tobacco smoke affects nearly every organ in the body.
- ◆ People may use PREPs concurrently with cigarettes. This may expose them to multiple risk factors as the products may interact in multiple and complex ways.

The possibility that reduced exposure may not reduce risk is even truer at the population level:

- ◆ The population may experience an increase in initiation resulting from the perception that PREPs are safer; these people may later switch to cigarettes, resulting in greater prevalence of disease.
- ◆ These products may cause a decrease or delay in cessation. Smokers are highly ambivalent about quitting. If they believe they are taking a positive step to reduce their risk, it allows them to rationalize their decision to postpone quitting.
- ◆ Former smokers may relapse.
- ◆ PREPs may introduce new disease risks, as happened when low tar cigarettes took over the market.

Unintended consequences may occur at the program level:

- ◆ People might perceive that the problem is solved and there is no need to further address efforts to fight this problem.
- ◆ Communities may see an increase in initiation, especially if young people misinterpret endorsements of these products as meaning they are safe and therefore okay to use. How PREPs are promoted could contribute to this effect.
- ◆ These products may undermine cessation programs because smokers can rationalize their decision to postpone quitting.
- ◆ PREPs may have an adverse impact on smokefree policies and rules. They may undercut smokefree policies' power to encourage smokers to quit by allowing smokers to continue their nicotine addiction in a way that does not violate the smoking ban. Products that are marketed as eliminating secondhand smoke take away from the urgency to have smokefree policies.
- ◆ These products may undercut changes in social norms by increasing the acceptability of tobacco use. PREPs undermine the argument that all tobacco products are unsafe.
- ◆ PREPs may undermine efforts to reduce smokeless tobacco use if these products are marketed as being safer than cigarettes.
- ◆ The existence of these products permits tobacco control opponents to portray tobacco control advocates as uncaring extremists who present smokers with a cruel and unnecessary choice to "quit or die."



It is critically important that PREPs be considered within the broader context of comprehensive tobacco control. The case for harm reduction may rest on a false premise: that the public health community has done everything it can to help smokers quit, and despite these best efforts, there are still 46 million Americans who cannot or will not quit. But we do not know yet whether those 46 million Americans cannot quit or do not want to quit, just that they have not quit yet. It can be argued that we have yet to implement a national-scale comprehensive tobacco control program of the nature that has been shown to work. It is too early to concede defeat and write off the remaining smokers.

With respect to cessation, much work remains to be done. Cessation treatments need to be made more widely available and affordable.

Comprehensive tobacco control programs must be established. The synergy between all the parts of such a program makes each component more effective. Comprehensive tobacco control programs need to continue to focus on the following:

- ◆ Promoting cessation
- ◆ Preventing initiation
- ◆ Eliminating secondhand smoke exposure
- ◆ Identifying and eliminating disparities

What issues must be analyzed with respect to implementation of PREPs and harm reduction from a policy perspective? This is one of the most complex and unpredictable aspects of the topic. It is certainly worth asking these policy-related questions:

- ◆ Will PREPs contribute to the perception that the tobacco use problem is “solved?”
- ◆ Will it cause elected officials and policy makers to feel a decreased sense of urgency to take on policy initiatives that address tobacco-related problems?
- ◆ Will the need to research PREPs divert attention and funding away from proven interventions to reduce tobacco use?
- ◆ What are the implications for the long-term use of NRT?
- ◆ And what are the implications of NRT products that offer smokers increased “impact?”

Any serious attempt to assess the impact of PREPs requires multiple perspectives:

- ◆ Individual
- ◆ Population
- ◆ Program
- ◆ Policy

Any analysis that fails to include all of these perspectives runs the risk of overlooking important potential outcomes.

Clearly there is much the public health community does not know about PREPs and harm reduction. What is known is far outweighed by the unknowns. Public health should not completely shut the door on new harm reduction opportunities, but any steps taken should be solidly grounded in clear scientific findings. More research is needed to build the depth of knowledge. While waiting for the results of that research, public health must be guided by past lessons of harm reduction, especially by the experience with low tar cigarettes.



As Surgeon General Carmona has stated, "Until we have this science base, we must convey a consistent and uncompromised message: There is no safe form of tobacco use."

Two harm reduction strategies are already available that have been proven to be safe and effective. One is comprehensive tobacco control programs; the other is nicotine replacement therapy. It offers a relatively clean, pharmacologically controlled source of nicotine for smokers who are serious about quitting. Even the long-term use of NRT is preferred to the relapse use of tobacco products. It is not perfect, and it should be improved, but it is much better than the new PREPs now entering the market.

As the Surgeon General has stated, "The best quitting strategy is not to trade one carcinogenic product for another, but to use FDA-approved methods like nicotine replacement therapy."

Dr. Husten concluded with two final points: "First, a note of caution: considering the great complexity and uncertainty of this field, and its high potential for error and unintended consequences, we must be careful. We must be cautious that in our intentions to do good, we do not end up inadvertently doing harm. Second, because of the number of PREPs already in the marketplace, and the potential for these products to be widely adopted by smokers, we need to quickly increase our knowledge base in this area and develop a proactive, well-organized, carefully thought-out response."

Fifth Set of Questions and Comments from the Floor

Michael Thun of the American Cancer Society wanted the panel to discuss the gradation of products from combustible cigarette-like products to medicinal nicotine. He assumed there would be wide consensus that cigarette-like products would not be the way to reduce risk. Next would be spit tobacco products, with a high level of caution there. Next would be the promotion of non-tobacco nicotine products that are not intended for cessation that pose a regulatory problem for states like California. Lastly, there is medicinal nicotine that is tested and marketed for cessation. The current way the statement in the draft report is written, it tackles all four of those, and it does not reflect the gradient of the problem. He wondered how the report should be modified to reflect these categories, perhaps splitting out the products or grouping them in different ways, to reflect the gradations in the products and perhaps foster consensus about how they should be regulated.

Corinne Husten of the CDC acknowledged that there certainly is debate over whether the California program should focus on medication or focus on counseling, environmental change and the like. Is long term use of medication preferable to long term use of tobacco products? She cautioned against any disagreement around that issue causing the public health community to lose the focus on these new PREPs that have the potential to set tobacco control programs back a long way. To some extent, it comes down to a philosophical difference about not wanting to provide someone with an addictive substance versus a focus on disease and death. It is important not to lose sight of the bigger picture that these products are going to be marketed in extremely savvy ways just like their predecessors and they have the potential to do great harm to tobacco control programs.



Alan Blum, of the University of Alabama, said he would part company with Dr. Husten on that last comment because he lived through the cigar craze of the 1990s, and there were dire reports on cigars as the next great menace. That fad faded. He does not necessarily see these new PREPs as fads, but he does not see them gaining any market, either. Omni was a gimmick that came and went. "The elephant in the room is Marlboro. The number one cause of disease and death in our society isn't smoking, isn't tobacco, isn't nicotine; it's Marlboro."

Alan Blum also suggested that cessation therapies not be limited to NRT products. Non-nicotine approaches, cognitive approaches, and linguistic approaches are equally viable approaches.

Paul Bloom, of the University of North Carolina, asked the panel, and Rick Pollay in particular, if any cases were being pursued as deceptive advertising claims. He wondered if implied claim cases had been pursued anywhere.

Rick Pollay, of the University of British Columbia, answered that the deceptive advertising issue came up within the context of the constitutionality of the advertising regulations in the case in which he testified. In general, implications of imagery are very difficult to argue under the law.

Jonathan Foulds, of the University of Medicine and Dentistry of New Jersey, commented that the discussion has made it clear that regulation must extend not just to the product but also to the marketing of the product. However, one of the important things about advertising is making sure that what is said is accurate. The same standard must apply to the public health community—information disseminated must be accurate and based on the best scientific evidence. The California draft paper claims that nicotine in its purest form poses health risks including heart disease and the development of cancer, and he questioned the validity of those claims.

Jonathan Foulds went on to say that epidemiological studies have found that low nitrosamine smokeless tobacco does not contribute significantly to heart disease or acute cardiovascular events. In Sweden, the use of low nitrosamine snus has not been associated with oral cavity cancer. "As you know, the Surgeon General made a statement that said smokeless tobacco is just as dangerous as cigarettes, which based upon the scientific data, I would regard as inaccurate. What are the panel's thoughts on whether it would be accurate for a smokeless tobacco company selling low nitrosamine smokeless tobacco to put on the box, 'does not cause lung cancer,' 'does not cause emphysema,' 'less harmful than cigarettes?'"

Corinne Husten responded that she thought one would have to take into account the potential population impact. Will people distinguish between various smokeless tobacco products? Will they use them in the way they are intended to be used? Will they switch from cigarettes or use them concurrently with cigarettes? The population impact of these products is simply unknown.

Alan Blum noted that spit tobacco products have not been marketed responsibly in the past, and that fact gives him pause when thinking about them being marketed in the future as an alternative to cigarettes. Pharmacological products that have been tested and that are appropriate for cessation or nicotine maintenance already exist.

Mitch Zeller, of Pinney Associates, Inc., said that he did not think TCS has responded to Dr. Thun's comments. The report equates the risk of harm from nicotine with the risk of harm from tobacco. Therefore, all products get lumped together. He repeated his earlier question: "If the state has the science wrong, what implications does that have for the rest of the report?"



Dian Kiser, of the American Lung Association of the East Bay/BREATH, spoke from the field perspective. She said, "We still have groups that we have not touched with traditional cessation. They are, in this order, low SES, non-Hispanic white males, non-Hispanic white females, African American males, African American females, Asian immigrants, and LGBT. That's something we need to do before we move into the realm of NRT. We need innovative, creative programs for these particular groups. In these dwindling resource days, are we going to come back here in five or 10 years to put together cessation programs for nicotine maintenance?"

Alan Blum added that he would argue that average in-office clinicians are a disadvantaged group in terms of their knowledge.

Wayne Hagen of the organization BUILT said he wanted to speak from a real-man-on-the-street perspective. BUILT is a program funded by TCS that delivers tobacco education to unionized construction workers. He said, "I have a hard time getting my mind around the idea that spit tobacco can be some kind of harm reduction. This particular population perceives it to be a big problem. They don't want to reach down and grab a piece of rebar with spit on it. More workers are starting to use spit tobacco at work sites where they can't smoke. And a lot of people who are using spit tobacco as a means to quit smoking are using it in conjunction with smoking. These workers don't live in a vacuum; they are already exposed to a lot of toxins. This is a population that does not use NRT to quit. They want to quit cold turkey. They don't trust NRT. This is a population that's not going to bother with other kinds of tobacco products. They don't see the sense of using nicotine to quit nicotine."



Session 6

To Regulate or Not To Regulate?

Greg Oliva of the California Department of Health Services, Tobacco Control Section, restated the California position on tobacco product regulation:

- ◆ The nicotine maintenance strategy threatens proven efforts.
- ◆ New criteria are needed to determine if products should be allowed on the market.
- ◆ Federal regulation of nicotine delivery products requires greater scrutiny.

The Current Environment and Tobacco Regulation: What Can We Get and What Should We Accept?

Matthew Myers, JD

President and CEO

Campaign for Tobacco-Free Kids

Mr. Myers began with the statement, "Effective FDA authority over tobacco products will enhance public health efforts to reduce the toll from tobacco."

The tobacco industry is not waiting for the public health community to decide its views about harm reduction. The industry continues to introduce new products and dish out the same old deception:

- ◆ Tobacco companies are introducing many so-called "reduced risk" products.
- ◆ Tobacco companies are making health claims for these products.
- ◆ No government agency has the authority to verify tobacco companies' health claims.
- ◆ No evidence exists that any of these products will reduce the risk of disease in individuals.

Is history repeating itself? Tobacco product ads continue to make or imply health claims. The old ad for True said, "Considering all I'd heard, I decided to either quit or smoke True. I smoke True." A recent advertisement for Eclipse cigarettes said, "The best choice for smokers who worry about their health is to quit. But for those who choose to smoke, the next best choice is Eclipse." A recent advertisement for Omni cigarettes said, "If you smoke, please consider Omni," and another said, "Introducing the first cigarette to significantly reduce carcinogenic PAH's (polycyclic aromatic hydrocarbons), nitrosamines, and catechols, which are the major causes of lung cancer in smokers." A recent advertisement for Advance said, "Star's processing methods greatly reduce SOME (emphasis added) cancer causing chemicals (nitrosamines) and a special filter reduces



SOME (emphasis added) toxic gases in cigarette smoke." Finally, the ad for Quest, which is virtually an unregulated drug advertisement, said, "Step Your Way to Nicotine Free!"

While the public health community worries about these health claims and debates the concept of harm reduction, the tobacco companies demonstrate once again that there is no end to the innovations they will put on the market to make their products attractive to non-smokers, such as the new flavored cigarettes in strawberry, blueberry, "Beach Breezer," "Margarita Mixer," and "Twista Lime."

New products are combined with themes and marketing campaigns designed to attract young people, and mainstream products are marketed to the young hip hop generation, such as KOOL packages with illustrations of hip hop musicians.

Why is all of this relevant? The discussion about harm reduction is not occurring in a vacuum; harm reduction marketing is going on now and is controlled entirely by the tobacco companies. Until now, the public health community has been lucky; these products have not been very popular with consumers, but our luck will run out if they introduce so-called reduced harm products that the public likes.

Without government regulation, our ability to counter their unregulated claims or limit what products can be introduced is very slight. In order to prevent products the tobacco companies claim are reduced harm products from gaining acceptance and to limit what products are introduced, enacting meaningful government regulation by the Food and Drug Administration (FDA) over tobacco products is a public health priority.

Mr. Myers next turned his attention to the low tar cigarette debacle because of its relevance to the current discussion: Lights can be seen as evidence that harm reduction does not work or as a case example of the need for regulation. What people do not know or control can kill them.

Lights and low tar cigarettes were introduced by the tobacco industry to address smokers' health concerns and to give them an alternative to quitting or not starting, and the American public responded. There is no doubt that there is a demand for lower risk products. When light cigarettes came on the market and the tobacco companies convinced consumers that they were a reasonable alternative to quitting, smokers switched in droves.

But in the absence of government regulation, low-tar cigarettes did not reduce the risk of disease. Why?

- ◆ The government falsely assumed that cigarettes were simple products whose relative toxicity could be easily measured by machine.
- ◆ The government underestimated the complexity of the product and the ability of the manufacturer to change the product in ways not reflected in the machine tests.
- ◆ The government underestimated the power of addiction and the ability of manufacturers to increase the addictive nature of its products in ways that were not easily discovered.
- ◆ The government did nothing to control how these products were marketed.



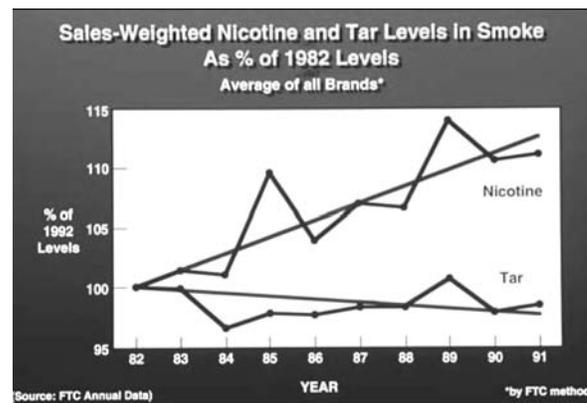
Yet, almost from the beginning, the tobacco companies knew that low tar cigarettes were a deception: "In most cases, however, the smoker of a filter cigarette was getting as much or more nicotine and tar as he would have gotten from a regular cigarette. He abandoned the regular cigarette, however, on the ground of reduced risk to health," according to tobacco industry documents quoting Ernest Pebbles, Senior Vice President and General Counsel for Brown & Williamson, in 1976.

And, from the verdict in *Miles vs. Philip Morris*: "The evidence at trial demonstrates not only that Marlboro Lights and Cambridge Lights are just as harmful as their regular counterparts, but that these products are actually more harmful and more hazardous than their regular counterparts. The Court finds that Philip Morris was aware of the increased harm from these Light cigarettes based upon their own scientific testing."

The tobacco industry knew what it was doing. As long as light cigarettes appeared safer to the consumer, the tobacco companies accomplished their marketing goals. They did not have to actually make the cigarettes less hazardous or less attractive.

While changes in tobacco blends and types led to a decrease in the tar levels in smoke, unbeknownst to the public health community, these changes were accompanied by higher levels of the carcinogenic nitrosamines and nicotine.

In addition, companies were secretly adding a whole host of ingredients to tobacco, including ammonia to "liberate free nicotine from the blend, which is associated with increases in impact and satisfaction reported by smokers," according to one company's tobacco-blending handbook.



The tobacco companies' manipulations of their products were far more sophisticated than we realized at the time. As early as the 1950s, Philip Morris was studying the particle size of smoke. A Philip Morris document from 1957 stated, "Increasing the size of smoke particles to get them to a size range which will go into the buccal cavity but not into the lungs would allow the smoker to taste the smoke but not get a large mass of smoke into the lungs." Philip Morris appeared to understand that it could decrease the amount of harmful substances that were lodged in the lung where they could do the most damage. Using that same research and knowledge, the industry instead figured out the right size of particle to lodge in the lungs and deliver the maximum dose of nicotine. In other words, presented with a choice between reducing harm and maximizing the potential impact of nicotine, in the absence of government awareness of this choice or government oversight, the industry chose the latter.

The harm from cigarettes comes from many potential sources, and the only way to know the true impact of product changes and associated claims of harm reduction is to know the impact of product changes on all of the toxins in tobacco products, the effect of these changes on the behavior of smokers, and the resulting effects on tobacco-related diseases.



In the absence of regulation, harm reduction comes down to trusting the word of the tobacco industry. In the absence of government regulation, harm reduction as it has been practiced has been perhaps summed up best by the words of the CEO of Vector tobacco company, the manufacturer of Omni, who said, "It will not kill them as quick or as much as other brands."

Mr. Myers then turned to the draft position paper. He characterized the California position as thoughtful but flawed. He indicated that California opposes government regulation unless three preconditions unrelated to regulation itself are satisfied. Apparently, that is true even if regulation could lead to the satisfaction of the seven criteria California set out for assessing the public health value of nicotine maintenance.

He characterized the California position as concluding that regulation of tobacco

- ◆ Is tied inextricably to the promotion of a harm reduction agenda
- ◆ Has a high probability of legitimizing tobacco and tobacco use
- ◆ Will divert, partially if not fully, resources and attention away from comprehensive population prevention programs like California's
- ◆ Is inconsistent with the FDA's mission

The premises for California's position on regulation are flawed or uncertain:

- ◆ A harm reduction agenda is not the inevitable result of regulation.
 - Regulation can provide the information needed to make decisions based on science and not speculation.
 - Regulation can set ground rules that seek to protect the public health, not maximize industry profits. In fact, it is probably the only way that the criteria for assessing the impact of harm reduction on public health that California believes should be applied will be applied.
- ◆ Regulation need not lead to further legitimization of tobacco products.
 - Despite California's fine work, tobacco products are already perceived as legitimate and authorized by the government—every pack carries a government seal in the form of a tax stamp.
 - The public already believes the government oversees tobacco.
 - The concern about legitimization is fair; steps must be taken to avoid this problem.
- ◆ There is no factual basis to conclude that the addition of regulation to the tobacco control arsenal will undermine or divert focus from prevention.
 - No supporter of regulation sees it as an alternative to prevention or as the sole harm reduction strategy.
 - Regulation can aid prevention efforts by curtailing marketing and adding to our information base.



- ◆ Regulation of tobacco products is consistent with the FDA's mission.
 - FDA's mission is to protect the public health and to reduce the harm and maximize the potential benefit of the products it regulates. Unlike drugs, unsafe tobacco products are on the market and don't require FDA approval to stay on the market. Today, no one has the authority to keep the most unsafe products off the market. If health protection by the FDA is measured in terms of lives saved, regulation of tobacco is right on target.
 - By replacing the safety and efficacy standard used for food and drugs with a "protect the public health" standard, FDA can measure its action by lives saved.
 - FDA is the only federal agency with the appropriate scientific expertise and regulatory authority to regulate tobacco products.

Mr. Myers then turned to a discussion of what is meant by FDA regulation. FDA regulation means regulating how products are manufactured, marketed, and sold. In the simplest of terms, it would

- ◆ Require disclosure of what is in the products and when the products are changed in any way
- ◆ Require existing and new products to meet toxicant exposure standards and other standards that might make them less hazardous
- ◆ Ensure that claims made about products are truthful
- ◆ Prevent marketing that is deceptive, encourages tobacco use, or makes tobacco appealing to children.

FDA regulation could mean

- ◆ Limiting marketing and sales of tobacco products
 - Imposing limits on industry marketing, sales, and promotions
 - Restricting sales to children by limiting self-service displays and requiring age verification
 - Enabling states to restrict intrastate forms of tobacco marketing
- ◆ Disclosure of ingredients and additives and other substances found in tobacco products and tobacco smoke, even if they occur naturally or as the result of the combustion process
 - Public access to all information about the naturally occurring ingredients and non-natural additives, as well as constituents of tobacco smoke that result from burning the product
 - Requiring tobacco companies to notify the FDA whenever it changes a product
- ◆ Access to the tobacco industry's information on the health effects of tobacco products, on nicotine and its addictiveness, on marketing, along with other information needed to protect the public health
- ◆ Requiring manufacturers to change the language, content, and format of warning labels in order to make them more effective, science-based, and realistic
- ◆ Protecting public health by reducing risks where technologically feasible by setting toxicant standards
 - Requiring manufacturers to adopt technologies that are feasible and proven to reduce the harm of the product (e.g., reduce or eliminate naturally occurring constituents and/or controllable byproducts of combustion)
 - Authority to remove harmful substances without having to prove that the specific substance is the cause of harm or that its removal will reduce the risk of harm
 - The ability to prohibit claims based on product standards



- ◆ Protecting public health by overseeing introduction of new “reduced risk” products
 - Prohibiting claims without proof of health benefit
 - Consideration of population impact of products and marketing on potential starters, quitting, and relapses as well as on other tobacco prevention efforts
- ◆ Requiring that any claims must be evaluated for scientific accuracy and their impact on public health—the FDA would have the authority to require tobacco manufacturers to prove any claims about the health risks (or alleged benefits) posed by their products (e.g., statements that suggest lower risks of cancer, etc.), both in terms of their scientific accuracy and their impact on public health.

What is the harm of no regulation (the status quo)? It is the absence of regulation that undermines comprehensive efforts, not vice versa:

- ◆ There is no way whatsoever to know if products are actually less harmful or to what degree. The tobacco industry controls what consumers know.
- ◆ Claims mislead consumers.
- ◆ False claims keep people from quitting who otherwise would—lights and low tars all over again.
- ◆ Product manipulation contributes to maintenance of addiction and discourages quit attempts.
- ◆ Marketing attracts new smokers who see it as less harmful or still enticing.

The bottom line is that tobacco companies are marketing products with reduced risk claims, and products like Camel are out there right now marketing candy-flavored cigarettes. It is highly doubtful that Twista Lime cigarettes are aimed at current smokers; rather, they are just another ploy to make cigarettes attractive to youthful non-smokers. These are among the reasons why FDA regulation is needed.

Mr. Myers concluded:

- ◆ Harm reduction will fail as a public health strategy in the absence of regulation.
- ◆ Science has not reached the point where the impact of product changes on the individual can be reliably predicted, especially for combusted products.
- ◆ Without regulation, the tools or measurement systems are not in place to control or measure the impact of harm reduction on the population. Extensive post-market surveillance of these products is needed.
- ◆ Science should lead policy, not vice versa.
- ◆ Regulation is a tool that can spur science, set standards, arbitrate scientific disputes, and complement other tobacco control efforts.

Mr. Myers finished his presentation by saying, “I take seriously the potential intended and unintended consequences of regulation. At the same time, I think we make a fundamental mistake if we take regulation off the table as one of our tools. If we fear that harm reduction will detract from prevention and cessation and prolong the tobacco epidemic, we should see government regulation by an agency like the FDA as our ally, not our enemy. Only then will decisions about the viability and relative risk-benefits of harm reduction be made based on sound science with public health rather than industry profits as the prime motive.”



A Risk Benefit Review of Tobacco Regulation

Steven Schroeder, MD

*Distinguished Professor of Health and Health Care,
Division of General Internal Medicine, Department of Medicine
UC San Francisco*

Dr. Schroeder began his presentation by responding to Dr. Bal's request for disclosing conflicts of interest by reminding the audience just how complicated this notion of monetary conflict of interest can be: "I don't take tobacco or pharmaceutical money, but it's not as simple as that. I'm the chair of Legacy Foundation. Legacy gets its money from the tobacco settlement. They don't pay for me to be the chair, but they pay for my transportation, and I've had some nice meals in Washington. I'm funded at the Smoking Cessation Leadership Center by the Robert Wood Johnson Foundation. Fifty-five percent of the assets from the Robert Wood Johnson Foundation are in Johnson & Johnson stock. Probably half of its sales and two-thirds of its profits are pharmaceutical in nature. The Smoking Cessation Leadership Center has as one of its partners Pfizer. We don't get any money from Pfizer, but in fact the state does, because Pfizer paid for 30,000 of these little cards ["Gold Cards," which feature information about the California Smokers' Helpline] to put them in the offices of dental hygienists and family physicians. I hope more people will call the quit line because of those cards and more people will quit. It's easy to think about the issue of funding as a dichotomy, but it's more complicated than that."

Dr. Schroeder's interest in tobacco control dates back to 1976, when a conversation with the dean of the School of Pharmacy at the University of California, San Francisco, prompted him and a colleague to survey 100 pharmacies in San Francisco to see how many of them sold cigarettes; 89% of them did. In 2003, he duplicated the survey, and found that the proportion selling cigarettes was much lower, but the ones who had stopped selling tobacco were the independents. The chain stores and the supermarkets continue to sell cigarettes.

Dr. Schroeder then declared, "I have been seduced. I believe in harm reduction when it is done well." He reviewed the current situation:

- ◆ Tobacco products are unregulated.
- ◆ Treatment for smoking cessation is tightly regulated.
- ◆ 169 countries are signatory to the Framework Convention on Tobacco Control, which uses global regulation as a weapon of tobacco control.
- ◆ Lack of regulation permits unverified claims ("light," "low tar") that hint at safety.
- ◆ Tobacco ingredients are kept secret.

Dr. Schroeder next reviewed the potential benefits of tobacco regulation, with the U.S. Food and Drug Administration (FDA) as the prototype regulator:

- ◆ Manufacturers would have to disclose the ingredients of tobacco products.
- ◆ Disclosure would aid in the understanding of the link between smoking and disease. Scientists might also learn about other areas of carcinogenicity through this research.
- ◆ Nicotine content could be controlled. The dose response to heart disease might be very low, which might explain why cutting down on smoking does not seem to reduce the risk of heart disease. The amount of nicotine available in cigarettes could be ratcheted down, making them less addicting.



- ◆ Stronger warning labels could be required.
- ◆ Misleading advertising could be prevented.
- ◆ The entry of new products could be controlled.
- ◆ The elimination of dangerous ingredients could be required.

Dr. Schroeder then reviewed the potential harm from regulation:

- ◆ There is potential for the political capture or muzzling of the regulatory body. (The president might not appoint an activist commissioner, and Congress might try to pass legislation circumscribing the FDA's ability to regulate tobacco.)
- ◆ False assumptions of safety by the public might discourage smokers from quitting and/or encourage people to start smoking.
- ◆ Regulation may reduce the urgency of tobacco control (probably not in California so much, but a definite danger in other parts of the country), resulting in less legislation, less funding, and less public advocacy.
- ◆ Regulation may shield the industry from future lawsuits. (The defense in a legal case would be able to argue that the FDA says it is a "safe" product authorized by the government.)
- ◆ Regulation may discourage more fundamental tobacco control.

Dr. Schroeder then shared his views on the draft position paper.

He agrees with the three preconditions to federal regulation of nicotine, noting that in this political climate the tax increase is highly unlikely.

On the regulatory provisions for medicinal nicotine products

- ◆ He agrees that medicinal nicotine products should meet current FDA requirements.
- ◆ On the issue of making them available under a prescription, he said doctors do not do very well in getting people to stop smoking. Most physicians do not know about quit lines and other aspects of cessation. "I would think twice before saying that nicotine replacement therapy (NRT) has to be prescribed by a doctor. Dentists can do it; nurses can do it; pharmacists can do it . . . All medical care professionals should be encouraged to become familiar with the quit line; they can fulfill their professional obligation to their patients and clients by referring them to the quit line without becoming an expert on the difference between the patch, the inhaler, and other forms of nicotine replacement. "
- ◆ NRT products should not have to pass a higher bar than any other medicines; they should be regulated the same as other medicinal products. "My sense is that NRT is a pretty marvelous drug, and I'm wondering why you want to make it so tough."
- ◆ Restriction of advertising is fine.
- ◆ To add further to the discussion about California's proposal to restrict NRT products to prescription-only status, Dr. Schroeder understands the concern that it may seem less effective now than it was when it was by prescription only, but the fact is that most doctors will not prescribe it and are not good at counseling patients about smoking. In addition, OTC is the trend for many other drugs. "I'm not convinced this is a good idea."
- ◆ He is not aware of evidence that NRT increases the risk for cancer.



Dr. Schroeder suggested that California's Tobacco Control Section has a different interpretation of the NRT data than many other people in the tobacco control community and a different philosophical approach to it. He said that he thinks there is a consensus that it does increase cessation success to some extent. For every person who quits successfully with NRT, that is another life saved, and it also moves society toward denormalization of tobacco use.

Dr. Schroeder concluded by saying, "I am just not as worried about NRT. Yes, some people may take it long term for nicotine maintenance, but not a lot. I don't think kids are going to go out and get it. I don't equate the perils of NRT as synonymous with the perils of smoking Marlboro. I'm willing to accept the risk of a little bit of harm because I think that risk is outweighed by the potential good it can do."

Sixth Set of Questions and Comments from the Floor

Steve Hansen, a physician practicing in San Luis Obispo, made a number of points:

- ◆ Tobacco is a political disease, and political forces prevent adequate leadership from the medical schools.
- ◆ Medical students need a cessation curriculum; it is time to up the ante on the doctor's role in cessation.
- ◆ What can we do to avoid the politicization of regulation?
- ◆ California should leverage its experience in the initiative process to help other states.

Steven Schroeder, of the University of California, San Francisco, responded that tobacco control advocates will have to "keep the heat on" after regulation goes into effect.

Matt Myers, of the Campaign for Tobacco Free Kids, said, "You'll never be able to take politics out of tobacco. Advocates will have to keep pushing the tobacco control agenda."

Mike Cummings, of the Roswell Park Cancer Institute, added, "No matter how good Philip Morris may look on Peter Jennings' specials and no matter what policy initiatives they may endorse, they still sell more cigarettes more cheaply than anybody else, and they still make the most toxic product of anyone else."

Steven Schroeder admitted that it "makes me very nervous that Philip Morris is supporting FDA regulation."

Alyonik Hrushow, of the San Francisco Department of Public Health, raised several questions:

- ◆ Should federal regulation be consistent with or stronger than the framework convention on tobacco control?
- ◆ How do the draft recommendations pertaining to advertising take into account the First Amendment?
- ◆ Will making NRT available only by prescription create a barrier to access for low income and uninsured people?

Dennis Eckhart, of the California Department of Justice, said the Master Settlement Agreement (MSA) is the closest thing we have to national regulation of tobacco advertising, and it is better than the complete lack of regulation that existed before the MSA. He continued, "As an attorney



working for the state for 28 years, I believe in the essential good from governmental regulation of the tobacco industry. Along with the three 'preconditions,' regulation is part of a national comprehensive tobacco control strategy. Think of the four items all together, with regulation being the fourth. Any regulatory agency [regulating tobacco] must be adequately funded in order to do the science and the population studies necessary, and that takes it back to the political realm."

Cynthia Hallett, of Americans for Nonsmokers' Rights, said to remember that compromise is acceptable as long as it does not prevent future action. She worries that with federal regulation, the perception would exist that the problem is solved. We need to make sure that federal regulation does not preempt local and state regulation that is more innovative.

Alan Blum, of the University of Alabama, said the proposals seem to be more concerned with the newer less toxic products than with the most toxic products, which are Marlboro, Newport, etc. He said Steven Schroeder might have overrated medicinal nicotine products. He noted that there has never been a single direct observational study of clinicians talking to patients about smoking. "Have we given up on the physician as the front-line agent of change?"

April Roeseler of TCS questioned Matt Myers about the FDA having regulatory authority. She asked how the regulation of harmful products such as cigarette-like products or smokeless tobacco could be consistent with the mission of the FDA. "How does that not undermine the good work of the FDA?" she asked.

Matt Myers responded that he agreed with former FDA Commissioner David Kessler, who said it was well within the mission of the FDA to regulate tobacco products.

Dileep Bal of the California Department of Health Services characterized the discussion on the science in the previous two days as good, but a little naïve, and noted that coming up with an operational consensus based on the science is a very difficult thing. He said the secret is not in the science, it is in the translation of the science. "Immanuel Kant said we often make a decision on the basis of information sufficient for action but insufficient to satisfy the intellect. What makes TCS strong is that they take the information and then they follow the Nike adage and 'just do it.' If it's wrong, they figure it out and do something else."

Matt Myers said having the FDA as the regulatory body is something of a compromise. Having a separate and independent agency is an ideal "that probably won't happen in our lifetime," but having someone regulate it, in this case, the FDA, is better than no regulation.

Steven Schroeder said of a new federal regulatory body, "I worry about the seduction of a new agency. What's to say that this new thing isn't going to have any of the deficits of the existing agency? The FDA does regulate the content of advertising, and if you want another agency to regulate some of these other issues, that's terrific. I don't know that it has to be an either/or issue.



Session 7

Rising Above the Static— Effective Communication Strategies

The California Position on Communication Strategies

Colleen Stevens, MSW

Chief, Media Campaign Unit

California Department of Health Services, Tobacco Control Section

Ms. Stevens began her presentation by stating the California position on communication strategies:

- ◆ Federal tobacco policy should not allow marketing of any product that maintains nicotine addiction.
- ◆ Federal tobacco policy should not allow marketing of products as “safer” than cigarettes unless or until the product is proven to be “safe.”
- ◆ TCS will embark on a campaign to delegitimize proposed harm reduction products as an alternative to quitting, comprehensive programs and other proven harm reduction interventions such as higher taxes and secondhand smoke policies.
- ◆ The term “harm reduction” is too broad and misleading, and TCS will work to clarify and limit its use.

Ms. Stevens said that, up to this point, most of the discussion about harm reduction or nicotine maintenance has occurred at a pretty high level, and she thought that there was still time to frame this issue for the general public. The tobacco control community has a responsibility to clarify the terminology surrounding this issue; again, how can anyone be against “harm reduction?”

Ms. Stevens said she believed that everyone in the tobacco control community is interested in the same outcome—decreased health impacts (disease and death). The argument is over the methods to achieve the desired outcomes. The danger is that a harm reduction strategy may divert energy and resources from proven interventions.

California’s norm change strategy works:

- ◆ More than 60% of California smokers are light or non-daily smokers.
- ◆ More than 60% have made at least one serious quit attempt.
- ◆ These numbers are both going up.



- ◆ 60% of California smokers (representing 2.8 million people) are poised to quit.
- ◆ California cannot afford to give them an excuse for continuing their addiction.
- ◆ Nationally, momentum for social change is growing. "Give states a chance!"

Ms. Stevens proposed the following agreement on terminology:

- ◆ Avoid using the term "harm reduction" unless and until the strategy is proven to substantially reduce harm.
- ◆ Do not use the term "safer cigarette" unless the product is proven safe.
- ◆ Do not use the term "potentially less harmful."
- ◆ "Nicotine maintenance" means ongoing use.
- ◆ "Cessation aids" are intended to be used for a limited amount of time.

Many people in attendance used the term "unintended consequences." Instead of that term, Ms. Stevens said, "We should be talking about collateral damage. We need to be careful about the terminology we use; don't use words favored by the tobacco industry like 'safer,' 'reduced risk,' and 'harm reduction' when we really mean other things."

Ms. Stevens urged continued support for proven methods:

- ◆ Encourage prevention and cessation.
- ◆ Support comprehensive programs.
- ◆ Implement policies that support norm change.
- ◆ Increase tobacco taxes.

Ms. Stevens reminded the audience that ex-smokers talk about smoking like most people talk about comfort foods, in very loving, affectionate terms. There is a very real danger of large numbers of ex-smokers relapsing if they believe that there is a much safer form of cigarette on the market.

Are the Remedies the Actual Problem?

Paul Bloom, PhD

*Professor of Marketing
Kenan-Flagler Business School
University of North Carolina*

Dr. Bloom began his presentation by describing his interest in tobacco advertising. "As a marketing professor, most of my life I have focused on antitrust, consumer protection, and social marketing. In the last few years, I have begun to focus more on tobacco marketing, but tobacco marketing has always been there in my studies."

Dr. Bloom said he never worked for a tobacco company, and he testified for the justice department in a case against the industry. He did some consulting for Glaxo before they acquired SmithKline, but was never involved in cessation or nicotine products. He has been supported by some National Cancer Institute grants.



Dr. Bloom introduced his topic with what he called problematic tobacco marketing practices:

- ◆ Heavy promotion of nicotine replacement therapy (NRT) products
- ◆ Heavy promotion of existing “light” cigarettes
- ◆ Heavy promotion of smokeless tobacco products
- ◆ Heavy promotion of so-called “safer” cigarettes (now and in the future).

He reminded the audience that promotion is much more than advertising; it includes sampling, deals, displays, slotting, Internet presence, public relations, direct advertising, sponsorships, and other activities. Tobacco companies, who are very sophisticated marketers, have known for a long time that advertising by itself is not as powerful a tool as it once was.

Next, Dr. Bloom presented the possible positive and negative outcomes of promoting various nicotine products. See the table below.

Promotion of...	Positive Outcomes	Negative Outcomes
NRT products	Can lower the perception of effort required for quitting	Can lower the perceived costs of quitting in the future
	May motivate people to quit now	Can lower the perceived risks associated with smoking
	Can increase nonsmokers' perceptions of risk associated with smoking	May encourage initiation or heavier usage
	May deter initiation	
Smokeless tobacco	May reduce harm	Creates misperceptions about the benefits of smokeless
	Eliminates secondhand smoke	May encourage initiation or heavier usage of tobacco
		May become a gateway drug or addiction starter
		Has known detrimental side effects
Cigarettes and cigarette-like products	May reduce harm	May have unforeseen health effects
		May be seen as an easy remedy for nicotine addiction
		Might result in delayed quitting
		Might result in heavier usage of traditional cigarettes
		Might result in heavier usage of these “safer” products
		May become gateway drugs or addiction starters
	May have unforeseen health effects	

Given what is known about the promotion of these products, where does the public health community go from here?

- ◆ Assuming (1) these products will remain legal and (2) promotion of them will be protected somewhat by the First Amendment, how can the promotion of them be “shaped,” regulated, and/or countermarketed so as to achieve the previously-cited good outcomes while mitigating the bad outcomes?
- ◆ Understanding the behavioral mechanisms through which these promotions influence individual behavior could help to formulate better public policy responses to this promotional onslaught.



Dr. Bloom presented a simple model of remedy message effects: messages tell people that the costs of using the products are not so high; in other words, they are easy to use. In this model, costs include things such as effort, energy, time, and even social embarrassment. The messages also tell people that the products reduce risk, which in this model is the likelihood and severity of harm. Such messages result in future use of the product and potentially less harmful behaviors.

Generally, promotion of these “reduced harm” products will attempt to make the “costs” of using them look lower and the benefits in terms of lower risks look greater (i.e., reduced perceived risks), leading to use of the products and potentially “harm-reduced” behaviors. But it may not be the same for all audiences and/or products.

Adding prior usage of tobacco as an influencing variable leads to hypothesizing that past users’ bad habits would be exacerbated by these promotions. For one thing, they are more likely to be exposed to the messages because the companies that are marketing these products know who their target market is. Smokers are likely to perceive lower costs to risky behavior than nonsmokers. In one of Dr. Bloom’s studies, after seeing a message about NRTs, a randomly-assigned group of smokers perceived less risk from continuing to smoke than a control group of smokers that was exposed to a smoking cessation message from the American Cancer Society. On the other hand, nonsmokers who saw the NRT message were even less inclined to smoke than smokers who saw the cessation message.

The effects of age can be hypothesized to be similar. The more youthful the audience, the more messages they see and hear. Young people believe they are capable of quitting. The remedy messages reinforce the “ease” of quitting, and young smokers end up perceiving less likelihood of harm (not necessarily less severity of harm). “I’ll be able to quit before anything bad happens to me.” Individual risk tolerance also plays a role, and young people may be more risk tolerant than older people.

Different products may work on these mechanisms in different ways. NRT promotion may increase perceived self-efficacy at reducing risk and reduce the perceived costs of the remedy, both of which in turn lower the perceived likelihood of harm. This may result in future risky behavior for a longer period of time or in the form of smoking more cigarettes.

Light and smokeless promotions work mostly on perceived likelihood of harm and perceived severity of harm, whereas promotions for “safer” cigarettes and potential reduced exposure products (PREPs) may have influence on perceived self-efficacy of reducing risk as well as perceived likelihood of harm and perceived severity of harm. The result is future risky behaviors.

Using the “remedy message effects” model, Dr. Bloom presented example policy approaches for different markets and products:

Youth nonsmokers

- ◆ NRT: use addiction as the ad theme.
- ◆ “Light” and smokeless: use industry manipulation ad themes and restrict access.
- ◆ “Safer”: use engaging, interesting science education about addiction and nicotine effects.



Youth smokers

- ◆ NRT: perhaps develop teen products; disclose realistic costs.
- ◆ “Light” and smokeless: require true disclosure; restrict access.
- ◆ “Safer”: use unknown dangers as an ad theme.

Adult smokers

- ◆ NRT: monitor “ease of quitting” claims; disclose realistic costs.
- ◆ “Light” and smokeless: urge use of lower nicotine products.
- ◆ “Safer”: make comparisons to other products; create the same mindset about “safer” cigarettes that Europeans have about genetically modified foods, for example.

Dr. Bloom concluded with some final thoughts. He noted that there are unintended consequences to every policy action. Was banning broadcast advertising a financial windfall for the tobacco industry? Did the ban on billboards encourage more trade deals and lower prices?

Much more research is needed on consumer reactions to these products, marketing practices, and potential policy actions, but it is very difficult for most consumer researchers.

Finally, he urged the audience to explore the world of sponsorships as a financing mechanism for tobacco control efforts, pointing to what the Komen Foundation has accomplished with breast cancer as an example. He suggested finding a company, maybe an athletic shoe company, that would be interested in adopting tobacco control as its signature cause. Companies are finding that adopting social causes is a great way to differentiate themselves from their competitors in the eyes of consumers.

Harm Reduction: A Communication Challenge

Matthew LeVeque

*Senior Vice President
Rogers & Associates*

Mr. LeVeque began his presentation with information about the firm for which he works, Rogers & Associates, which is the major public relations firm for the California Department of Health Services, Tobacco Control Section (TCS), the County of Los Angeles, Oregon’s tobacco control program, and other agencies. It specializes in social marketing campaigns, public health campaigns, and school-based programs. Other parts of the company do global consumer marketing.

Mr. LeVeque observed that he does not like the term PREPs. He said it sounds like a candy: cherry preps, lemon-lime preps

Harm reduction presents a complex and troubling communication challenge for the public health community. In order to explore its complexities and challenges, Mr. LeVeque’s presentation looked at the issue in terms of a strategic communication planning model that the firm uses to develop communication campaigns.



Mr. LeVeque presented five of the components in the strategic planning model. As he presented each one, he explained its applicability to the challenge of communicating the issue of harm reduction.

1. Organization's Goal

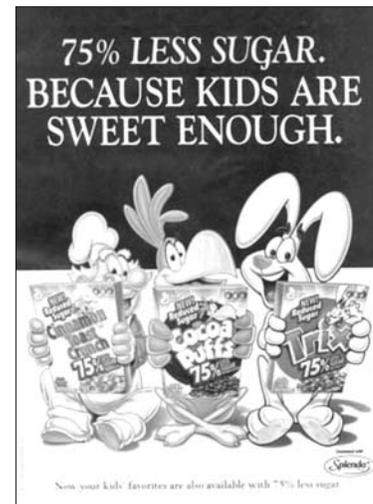
- The goal of public health is to save lives, prevent disease, and improve the quality of life.
- The goal of the tobacco and pharmaceutical industries is to make money and maximize shareholder value.

2. Statement of Problem/Opportunity

- The entire summit has covered this point for public health (risk vs. benefit, individual vs. population impacts).
- About 48 million smokers in the U.S. represent a huge potential market ("opportunity").

3. Research/Situation Analysis

- Media clutter and message confusion reign in American society.
- The average person is overwhelmed by information and pays attention to few details. In filtering and processing information, people use
 - Selective attention—what they pay attention to
 - Selective perception—what they see and hear
 - Selective retention—what they remember
- People consume messages with a "what's in it for me?" perspective.
- Tobacco and pharmaceutical industry marketing budgets are potentially enormous:
 - The tobacco industry spent \$11.22 billion on advertising in 2001.
 - The pharmaceutical industry spent \$12.7 billion on advertising in 1998.
- Public health versus industry marketing budgets: these industrial giants have far larger budgets than any health department.
- The marketing of these products is likely to consist of saturating the media with oversimplified imagery and slogans, not scientific discourse.
- The industries will review and model other successful campaigns.
- Harm reduction could become like obesity "solutions": all about the easy way out and very little about real health solutions.
- Companies are likely to send the message that "reduced risk" products can be part of a healthy lifestyle—similar to certain food items (e.g., snack crackers and soda).



Much can be learned from previous experience, so Mr. LeVeque showed some familiar advertising for regulated pharmaceutical products.

- Lamisil: Cartoon characters tell viewers about nail fungus. How is this helping the consumer make an informed choice? It directs viewers to go to a website or call a toll-free number and get a coupon for a discount on a prescription. Remember, the organization's goal is not public health. It is to create demand for the product and make money.
- Prevacid: John Elway demonstrates the power of celebrity endorsements. Imagine a race car driver endorsing a nicotine product because it gives him alertness and clarity or because he is not able to smoke behind the wheel.
- Claritin: Images of people riding bicycles in the park give the perception that viewers can have the life they want if they take this drug.
- Celebrex: Imagine a nicotine product in place of this arthritis pain reliever. "With [nicotine product], you can live the life you want." "With [nicotine product], I will not give in." "If you're having trouble managing [quitting] on your own, ask your doctor about [nicotine product]." "Take control with the proven strength of [nicotine product]."
- Viagra: Advertising can have unintended consequences, as in the Viagra campaign, in which young men with no physical problems are asking their doctors for prescriptions to help them conquer anxiety or for performance enhancement.

Mr. LeVeque reminded the audience that advertising is just part of the bigger marketing mix for pharmaceutical products. Other promotional activities include sampling, in-office pitching, in-hospital pitching, and promotions/public relations.

How the news media treats harm reduction is of great concern. Examples of media coverage of health news are often sensationalized. In their selective perceptions, consumers often hear only the headlines about the newest "wonder drug" and not the fine print or details found many paragraphs down in the articles.

4. Audiences

These are the people whom the tobacco industry, the pharmaceutical industry, and the public health community are competing with each other to reach:

- Potential and former smokers (at-risk youth and adults)
- Current smokers
- Key opinion leaders/media
- Policy makers
- General public not in the above categories



5. Key Message

Mr. LeVeque concluded his presentation with this final thought: If public health cannot arrive at a consensus on what terms to use (and not use) and how to frame the issue in a fashion that the average person understands, consumer confusion and unintended consequences will reign, and public health messages will be drowned out by a tobacco and pharmaceutical marketing tsunami.

Seventh Set of Questions and Comments from the Floor

Alan Blum, of the University of Alabama, said he thought that health professionals misunderstood the issues surrounding marketing in three ways:

1. They worry about the cleverness of content, rather than the frequency of and impressions left by the messages.
2. They do not appreciate the fact that the public health community needs to find a better way to fund its campaigns. He said that in Australia, a cancer organization sold sunscreen, bathing suits, and other products to fund their skin cancer awareness campaigns. If American agencies could be more creative and do similar things here, they would not constantly be asking for corporate handouts and worrying about where the money is coming from.
3. They do not understand that social marketing is not designed with the same function as conventional advertising, which is to sell products. He continued, "I'm the first person that I know of to purchase advertising space—this was on bus benches—about smoking. We wanted to serve as a model to inspire the major public health organizations, the Cancer Society and others, but we weren't successful. I believe they (the Cancer Society and Legacy and others) should be spending more money on advertising. ACS shouldn't be endorsing products."

Michael Thun of the American Cancer Society responded: "ACS chooses to endorse products that further the mission of the ACS, which is to reduce cancer. That's the main thing, rather than income development. No matter what you do, some people are going to attack you. For example, in Australia, there were critics who attacked the cancer society's sale of sunscreen because they said it makes people think you can expose yourself to more sun. You're never going to make everyone happy." He continued, "We need to get together on this issue so that it works for public health. Look how even we get sucked into using the industry's terminology. Instead of saying 'less lethal' cigarettes, we say 'safer' cigarettes. I don't have a good phrase for the issue surrounding these supposedly miraculous products, but I think ridicule and humor are very effective weapons."

Alan Blum noted that "What we need is a national strategy. Coca-Cola doesn't market differently in 1800 separate markets. You showed us ads that we've all seen no matter where we come from. We need consistency in our message."

Mitch Zeller, of Pinney Associates, Inc., addressed his comments to Matthew LeVeque: "Your presentation bordered on the irresponsible. Sure, corporations are in the business to sell products and make money, but to fail to distinguish the purpose of the product in lumping the pharmaceutical industry and the tobacco industry together bordered on irresponsible. Your budget figures were for the entire pharmaceutical industry, and a lot of the discussion is about NRT, which is practically a stepchild when it comes to sales and marketing. To leave this audience with the impression that the industry spends \$11 billion on advertising NRT is wrong. The figure is much lower than that."



Matthew LeVeque (of Rogers and Associates) responded that, of course, he would be much more specific in a full strategic analysis. “I wanted to point out that the industry taken as a whole is an incredibly large and powerful force with far more resources than we have in the public health field.”

Steve Hansen, a physician practicing in San Luis Obispo, reiterated his earlier theme of “keep it simple.” “There was only one instance of spontaneous applause during this whole conference, which was when Corinne Husten cited the Surgeon General. The message needs to be ‘keep it simple! Tobacco is the worst consumer substance on the planet. The tobacco industry is the deadliest [industry] on the planet.”

John Pierce, of the University of California, San Diego, offered the observation that “profit maximization is always paramount when talking about corporations.”

Jonathan Foulds, of the University of Medicine and Dentistry of New Jersey, returned to the issue of clarity: “We have to be clear with our terms. Terms like harm reduction, nicotine maintenance products, cessation—we need to define our terms or they’re meaningless. Are we against tobacco-related disease or are we against nicotine addiction? Sometimes our thinking is muddled because we’re not clear about that. Despite all our differences, I think we can agree that there’s no such thing as a safe cigarette. Anything combustible is bad; the best thing to do is stop smoking. We also need to be aware of the blatant conflict of interest in terms of states that rely so heavily on tobacco taxes to balance their budgets.”

The final word from the floor came from an unidentified audience member who said that “inoculation” was imperative: “We need to create a skeptical public that is inoculated against the industry’s campaigns. Teach people about the marketing tricks of tobacco companies and pharmaceutical companies so that the public has the tools with which to judge these claims.”





Further Reflections and Closing Thoughts

Day 2: What Have We Learned?

David Altman, PhD

*Vice President of Research and Innovation
The Center for Creative Leadership*

Dr. Altman began this final presentation by sharing a few of the one million Google “hits” for the term “harm reduction.” Such a large number of hits indicates this topic is obviously gaining a lot of attention.

In thinking about what had occurred the previous two days, he said that he noticed quite a bit of mistrust of various institutions and individuals, including tobacco companies, pharmaceutical companies, government agencies, policy makers, scientists, tobacco users, and others.

Dr. Altman then launched into the main body of his presentation, which was organized as a series of PowerPoint slides encapsulating his thoughts and observations in lists of words and phrases.

Phrases revolving around the issue of risks versus benefits arose frequently:

- ◆ Level of confidence in estimates of benefits and risks
- ◆ Identifying and quantifying unintended consequences
- ◆ Dichotomies in a multivariate world (either-or; pro-con; for-against; camp 1 or camp 2)
- ◆ Getting into an inescapable hole
- ◆ It’s déjà vu all over again
- ◆ Paralysis through analysis . . . take action when possible
- ◆ And the band played on . . .
 - The tobacco industry is not waiting for us to figure out our position. The industry is introducing products, making health claims, and there is no government agency charged with regulation.
 - What are we going to do about it?

There were many points on which most people in the room were in agreement. They fell into the general areas of promoting public health, funding comprehensive tobacco control programs, the feeling that the tobacco control movement was at an important juncture, the need for high quality data, suspicion about the tobacco industry, and the need for assurances that participation in the harm reduction summit would not be construed or portrayed as endorsement of its outcomes.



Points of Agreement

- ◆ Promote public health:
 - Reduce tobacco-induced disease, disability, mortality.
 - Get 'em before they become regular users; help 'em when they become regular users.
 - Counter tobacco company pro-disease efforts.
 - Make tobacco products less desirable among users/non-users.
 - Keep your eye on the consumer. They are being targeted . . . now!
 - Prohibit claims on "risk" of new products until the science is completed (and the translation of science to practice is considered).
 - Tobacco advocacy groups need to keep the heat on.
- ◆ Fund sustained, comprehensive programs:
 - Increase the price of tobacco.
 - Protect non-smokers (secondhand smoke).
 - Employ evidence-based treatment.
 - Mount counter-marketing campaigns.
- ◆ We are at a juncture in tobacco control with no strong consensus on where to go from here. Is there consensus to get beyond "either-or" framing and toward recombinant innovation?
- ◆ Data is needed:
 - We need high quality, scientific data, from multi-, inter-, and trans-disciplinary perspectives to help inform decision making. There are many topics for which there is insufficient research.
 - The translation of the science is extremely important but often overlooked.
 - Keep things simple whenever you can and take action whenever evidence supports taking action. There are many issues on which we don't need any more data to support action.
- ◆ Industry position: There is concern about tobacco industry support of harm reduction. What are we missing? What trap are we potentially falling into?
- ◆ Attribution of involvement in this meeting and the report that is disseminated after the meeting need to be handled carefully.

There were other points upon which there was considerable disagreement. These fell into three general categories: the ultimate objectives, the overarching strategy, and the tactics.

Points of Disagreement

- ◆ The Ultimate Objectives
 - Setting realistic, achievable objectives vs. idealist objectives that push the envelope, set a high bar (but create insurmountable hurdles)
 - Clarifying and agreeing on definitions: harm reduction, avoidance, minimization, NRT, nicotine maintenance; tobacco dependence/disease; need more nuanced/precise definitions; what terms to use and not use; framing; consumer understanding of our language
 - Effectiveness of tobacco control interventions (overall and NRT)



- Death and disease tradeoffs/risk-benefit calculations
 - The “floor” of use and disease we’re willing to accept (at what level above zero could we or should we claim success?)
 - The generalizability of the California experience? What components are generalizable and what components are not? It’s not a dichotomy.
- ◆ The Overarching Strategy
- Efficacy of federal government policy and regulatory instruments overall (FDA in particular) and their effects (positive and negative) on state and local efforts, particularly in states where success has been achieved (like California)
 - Having a tool does not equate with the tool being used in the right settings with the right force.
 - There are advantages and disadvantages of working with and through new and existing agencies.
 - Harm reduction is not the inevitable result of regulation. Regulation need not further the legitimization of tobacco products. Addition of regulation will not divert focus from prevention (it may be just another tool in the arsenal). Regulation of tobacco products is consistent with the FDA’s mission.
 - Effects on other tobacco control interventions (negative counter-effects vs. synergistic effects). Have we done all that we could to reduce tobacco use? It’s too early to conclude that we have reached our full intervention potential (decreased sense of urgency).
 - Potential unintended consequences/collateral damage (increase initiation, decrease cessation, relapse, new disease risks; perception that tobacco problem has been solved, change norms, undercut smoke-free policies, other approaches perceived as uncaring)
 - Nicotine maintenance as a distraction or as counterproductive to implementing comprehensive programs vs. as a component of comprehensive programs (Quit or die vs. unintended consequences)
 - Relative risk vs. population attributable risk; clinical vs. public health approaches; exposure, individual risk, population risk
 - Population(s) targeted (e.g., youth vs. non-youth)
 - Revolutionary vs. incremental change
 - The evidence regarding the efficacy of nicotine replacement/maintenance. Effects of long-term use? Gradient of toxicity risks of different types of nicotine products (medicinal, spit, new PREPs). The report lumps all products together, regardless of risk.
 - Estimates about future market penetration of PREPs
 - The health effects of nicotine and the quality and quantity of scientific evidence. Science of nicotine safety . . . Did TCS get it right or wrong? If wrong, fundamental recommendations made in the report may be ill-informed.
 - How do you address the population of individuals who have mental illness or substance abuse problems? What is the size of this population?
 - Role of smokeless (spit, swallowed) tobacco in tackling tobacco-induced disease. Health effects of different forms of smokeless tobacco. “Cleaner” nicotine.
 - Is “first do no harm” a reasonable objective, given the harm caused by a variety of other accepted products and technologies (e.g., prescription drugs one of the top killers)?



◆ The Tactics

- How do you effectively market the stuff? What are the risks and benefits of different marketing approaches? What is the role of motivation? How much demand is there for NRT? Can and should demand be stimulated?
- Be more aggressive promoting NRT. Stop promoting it. Increase availability. Limit availability.
- The role of health professionals in promoting, overseeing, marketing, and advising users needs more discussion; efficacy of prescription vs. over-the-counter approaches; outreach and involvement of the clinician on the street.
- Cost of nicotine maintenance; cost-effectiveness of alternative approaches; overall resources available

Now that the summit has concluded, the Tobacco Control Section must proceed with the following tasks of leadership: set direction, create alignment, and gain commitment. In doing so, TCS must ask itself, “Where do we stand on these tasks within TCS, within California, and beyond California?”

Closing Thoughts, or Some Non-Random Reflections, Ruminations, and Rumbblings of an Old Indian

Dileep Bal, MD, MS, MPH

Chief, Cancer Control Branch

California Department of Health Services

Dr. Bal closed the summit with some of his favorite quotes, along with a bit of commentary:

Dr. Seuss: “Be who you are and say what you feel because those who mind don’t matter and those who matter don’t mind.”

Dr. Bal: This should be TCS’s mantra. We’re going to sit down after this meeting and figure out what we’re going to do.

Edmund Burke: “Government is a contrivance of human wisdom to provide for human wants. Men have a right that these wants should be provided for by this wisdom.”

Dr. Bal: This is what TCS does. We take the best of science and translate it into the people’s will to the best of our abilities and with the best of intentions.

Jomo Kenyatta: “When spider webs unite, you can bind a lion.”

Rabindranath Tagore: “If you shut your door to all errors, truth will be shut out.”

Dr. Bal: TCS screws up more than anyone else. We’ll probably screw up harm reduction a few times. But we do what most people don’t—we take a stand on controversial issues.

The Talmud: “You may not be required to finish the work but you may not desist.”

Rev. Martin Luther King, Jr.: “He who accepts evil without protesting against it is really cooperating with it.”



Dr. Bal: Sometimes you can't define things away The tobacco companies are the embodiment of evil, responsible for enormous suffering and death every year, all in the name of the almighty dollar. Doing nothing is not an option; when you see evil, you must act.

Unknown: "Justice will not return to Athens 'til those who are not injured are as indignant as those who are."

Abraham Lincoln: "I am not bound to win, but I am bound to be true. I must stand with anybody who stands right, stand with him while he is right, and part with him when he goes wrong."

Dr. Bal: Civil disagreement, emphasis on the word "civil," is essential.

Winston Churchill: "Appeasement reflects the hope the crocodile will eat you last."

Dr. Bal: Another TCS mantra . . .

Rev. Martin Luther King, Jr.: "Our scientific power has outrun our spiritual power. We have guided missiles and misguided men."

Dr. Bal: Science has become our golden shackles.

Dan Walsh: "Placing regulatory authority for tobacco and nicotine products within the FDA is inherently in conflict with their mission."

Dr. Bal: Dan Walsh is a state enforcement guy who knows what he's talking about . . .

Common knowledge: "'Mural dyslexia' is a regrettably common complaint."

Dr. Bal: This is what you have when you can't see the writing on the wall.

Mahatma Gandhi: "If you want to change the world, be that change."

Dr. Bal: Still another mantra

In closing, Dr. Bal thanked the staff of the Tobacco Control Section for their profoundly important work, thanked David Altman for his off-the-cuff observations, and thanked everyone else, especially out-of-towners, for coming.





Email Correspondence

Some invitees to the harm reduction summit who were not able to attend nevertheless responded generously with comments about the draft position paper. TCS considered these comments carefully while revising the paper.

In addition, a number of summit participants sent email messages to TCS in the days following the conference. These extended electronic conversations, whether composed in airline terminals or back at the office, covered a lot of ground in terms of content and intent. The emails included messages that neatly summarized the issues (sometimes with a certain “spin”), clarified some of the more opaque discussion points, made fervent attempts to assert strongly held opinions, and pleaded with TCS to be cautious in its contemplation of radical policy changes.

Because the pre-summit and post-summit email correspondence formed an important part of the summit dialogue, excerpts from many of those email messages, edited for clarity and brevity, are presented below.

The following writers expressed the view that harm reduction (at least in some form and under some conditions) is compatible with denormalization strategies and/or has a place in the tobacco control toolbox:

Jonathan Foulds

Over 95% of the harms to health caused by tobacco are caused by smoking cigarettes. We can continue to be very clear and aggressive in our opposition to cigarettes, and in trying to reduce cigarette smoking, without throwing out the potential of a non-smoked nicotine delivery system as an aid to smoking cessation.

Mike Cummings

A strategy focused on smoking cessation and treatment of nicotine dependence is not in competition with a strategy focused on tobacco product denormalization. In fact, these strategies are complementary and synergistic.

Russ Sciandra

Fundamentally, TCS is concerned that a harm reduction strategy, even implemented with adequate regulatory safeguards, undermines the social denormalization approach that we all believe is the most effective approach to eradicating tobacco-caused disease. I share this concern, and that is clearly why the tobacco industry is pursuing “harm reduction.”



Certainly, the public health community's complicity contributed to the light cigarette debacle, and we should avoid repeating history. But I doubt that our complicity was the only, or even most important, factor in the tobacco industry's success, and I doubt that our opposition will stop the industry this time, particularly if they develop a consumer-acceptable "reduced harm" product.

So "harm reduction" is going to happen no matter what we think. We can try to run counter-marketing/PR campaigns against it, but we will lose this fight. We are simply outgunned by Big Tobacco's money and the consumer's desire to believe in such a panacea. Or we can introduce regulations to control "harm reduced" products, which does not necessarily rule out campaigning against those that are then marketed, since none will be truly safe. Of course, while regulation may eventually ensure that reduced harm products really do reduce population harm, there is a risk that, by implying that population harm reduction is at some point possible, regulation will undercut denormalization.

But I am willing to consider regulated harm reduction as a concurrent approach along with denormalization for two reasons. First, because during the time it takes to eradicate tobacco use through denormalization, millions of Americans will die. Do not be fooled by policy (e.g., tax and clean indoor air) advances around the country. Our experience in New York State shows that without a robust tobacco control program, the effect of policy change on prevalence (which is the goal, after all) is minimal. Right now, only California has a tobacco control program worth talking about. California is far ahead of the rest of the United States, which is far ahead of the most of the world in this regard. And, even in California, progress is only incremental.

Second, I am not sure that harm reduction is necessarily antithetical to denormalization. Accepting that there is "an inherent contradiction between strategies to motivate tobacco users to quit and strategies to motivate tobacco users to switch to a reduced harm product," we need to recognize that, at best, both are going to be out there, one pursued by public health and one by the tobacco industry. I think we should do some deep thinking about how we can continue to push abstinence while acceding to (not promoting) harm reduction as a partial step. We can convey the idea that smoking a reduced harm product is "like playing Russian Roulette with two bullets in the gun instead of three."

I think we have time to do this. After all, the debate is not over whether the tobacco industry will introduce "reduced harm" products—it will. The question is whether the public health community will in any way endorse these products. Despite the differences evident at the harm reduction summit, no serious member of the tobacco control community supports the introduction of "reduced harm" products without adequate regulatory review. If FDA legislation were ever to be enacted, the completion of regulatory review for any product would still be years in the future. The public health community will be unanimous in condemning any products introduced without such review, including the forthcoming Philip Morris cigarette, and certainly TCS can "tee off against them."

Given that TCS has the luxury of time before making definitive statements about whether the benefits of government-regulated population harm reduction will ever outweigh the concerns about the impact on denormalization, why stake out a position now with possibly unforeseen adverse consequences? These possible consequences include (1) exacerbating divisions within the tobacco control community, (2) fostering mixed messages that confuse the public and benefit only the tobacco industry, (3) entrenching positions that are difficult to retreat from if the science changes, and (4) marginalizing tobacco control in the eyes of policy makers.



Instead, issue a paper that does the following:

- ◆ Opposes the introduction of any alleged PREPs without adequate regulatory review
- ◆ Sets out standards for “reduced harm” products that incorporate all your concerns
- ◆ Sets out your standard for the regulatory agency and discusses the need for related initiatives, but not as a precondition to regulation. (Your “preconditions” to regulation are so politically unrealistic as to approach nihilism.)

Such a paper would serve tobacco control advocates throughout the country by giving us talking points in the face of the forthcoming tsunami of alleged reduced harm products.

These writers expressed the view that the tobacco control community should not endorse the concept of harm reduction as a tobacco control strategy:

Charles DiSogra

- ◆ The phrase “*primum non nocere*” should set the policy. Harm reduction implies some harm and thus is not acceptable.
- ◆ Harm reduction is analogous to “same gun, smaller bullet.” It is akin to military arguments in favor of smaller, tactical nuclear weapons, which try to make inherently abhorrent devices appear “nicer” or more “acceptable” because they are smaller and somehow better contained.
- ◆ TCS’s draft position paper did not emphasize sufficiently the problem of addiction. Clinicians should not classify patients as smokers but instead should diagnose them as addicted to nicotine. Addiction then becomes a treatable diagnosis and carries the negative social stigma associated with the term, “addiction.” The expression “nicotine maintenance” should be expanded to “nicotine addiction maintenance.”
- ◆ Harm reduction is a ploy to keep smokers from quitting under the guise of creating healthier products. The best counter-communication strategy is to expose this ploy and raise the volume on all tobacco products.
- ◆ “Quit or die” is a polarizing cliché that discredits the true meaning—quit to stay healthy. The tobacco control community should not co-opt this expression.

Jon Lloyd

It is interesting that no one at the summit questioned the assertion that the evidence is insufficient and the risk of unintended consequences is too great to go forward with these various nicotine maintenance/harm reduction strategies. They conceded this main point. Nevertheless, they want to go forward, at least with research.

Stanton Glantz

In the draft position paper, TCS acknowledges that at the beginning of the California tobacco control program, there was a lot of guesswork and “shooting in the dark.” While this is true, I think it misses the point. In fact, back when the program started, there had never been such a large intervention, and so there was very little direct empirical data upon which to build a program. That is no longer the case. Today, there is a large body of evidence about what works and does not work in tobacco control. We know that large-scale media campaigns, clean indoor air policies, and community norm change strategies work. We also have evidence based on our earlier experience



with filtered and low-delivery cigarettes, as well as some evidence with over-the-counter nicotine replacement products, that these types of interventions tend to keep people smoking. That experience constitutes strong empirical evidence that the harm reduction approach will fail.

While everyone agrees that comprehensive programs are good, this assertion is often used to justify doing things when there is no good evidence that they work (such as youth access and school-based programs.) “Comprehensive” should not mean ineffective or, in the case of reduced risk products, counterproductive actions.

Jonathan Foulds

On page six of the draft, there is a statement that “a review of the data used to make these claims concluded that the reduction in smoking by Swedish males was more likely caused by public health and tobacco control efforts in Sweden than by the promotion and use of snus as an alternative to smoking.” The reference cited here was not a “review of the data” but rather was an invited (non-peer-reviewed) commentary on two other articles published in the journal. Replies to that commentary by the authors of both the original articles (published in the electronic version of the journal) found serious faults with the points made in that commentary. It was pointed out that the commentary failed to account for the important fact that male smoking prevalence has fallen much more, and far below, female smoking prevalence and no plausible explanation for this has been offered other than that many of the men switched to snus, while very few of the women did.

We are also preparing an article with more recent data which refutes the claim (also made at the meeting) that the uptake of snus in Sweden was in different age cohorts from the downturn in smoking. A key point here is that many of the younger men are using snus temporarily to stop smoking. Thus, among the cohort of men who were aged 25–34 in 1996, 28% were ever snus users and 19% were daily smokers in 1996. By 2003, when this cohort was aged 32–41, their ever snus use had increased to 45% whereas their current daily cigarette smoking had dropped to 9%. Without going into all the details at this stage, it is sufficient comment that the paragraph at the bottom of page six gives a rather skewed summary of reviews and commentaries on this topic.

John Pierce

With reference to the statement on page 13 of the draft, “We in California’s Tobacco Control Program submit that the public health community should strongly and unequivocally oppose the marketing of any proposed nicotine maintenance product until there is sufficient scientific evidence that its use will . . . not increase youth initiation of smoking or use of smokeless tobacco products,” I think you want this to include “will not slow the rate of decrease in youth uptake.” This is what appeared to happen with the safe cigarette controversy in 1978. The number of ever smokers had been declining with each new birth cohort; then it stopped declining with the birth cohort that was 12–14 in 1978.

Russ Sciandra

It is not useful to say that pharmaceutical companies are only in it for the money and therefore are morally equal to the tobacco companies. As a lobbyist, I learned long ago not to question people’s motivations, only the effect of their actions.

The ad hominem attacks on individuals, even if unnamed, undermine the credibility of the document, as does the cavalier way in which positions (frequently *prevailing* positions) are dismissed without substantive, science-based counterargument.



Jon Lloyd

One or more of the speakers at the summit expressed these thoughts:

- ◆ The tone of the report was divisive.
- ◆ The paper dismissed every opponent as biased.
- ◆ The paper's treatment of the IOM report was unfair.
- ◆ The paper oversimplified the issue into "either/or" or "all or nothing" types of arguments.
- ◆ The two approaches (harm reduction and denormalization) are not contradictory.

What, if anything, should TCS do about these charges? TCS should, of course, avoid *needlessly* raising hackles, and if there is a way to take out offensive language or statements without diminishing TCS's position, then by all means, it should be done.

These writers commented on what they perceived as the paper's "lumping together" of various types of nicotine products.

Jonathan Foulds

I stated at the meeting that there appeared to be confusion as to whether the main aim was to reduce tobacco-caused death and disease, to reduce tobacco use, to oppose the tobacco industry as a whole, to reduce nicotine use, or some other goal. The optimal strategies will be different according to the overall goal, and these goals are not synonymous. Cigarettes of all types do much more harm to health than high carcinogen smokeless tobacco, which does much more harm than low carcinogen smokeless tobacco, which does more harm than nicotine replacement, which does a net good even under the most pessimistic assumptions.

My recommendation is therefore that the draft proposal address these different types of products differently, based on the massively different harms to health that these products cause. By lumping many different products together, and by making recommendations that effectively make it harder for the public to get the least harmful (actually beneficial) products (NRT by prescription only) than the most harmful (cigarettes—widely available OTC from government shops), the draft is unlikely to benefit public health and runs a serious risk of having harmful unintended consequences.

Mike Cummings

Evidence on health risks can be confidentially arrayed as follows from most toxic to least toxic:

- ◆ Highest: combustion tobacco products (cigarettes, cigars, pipe, PREPS)
- ◆ Medium: non-regulated smokeless tobacco products (spit and chew tobacco, tablets)
- ◆ Probably low (but unknown): unregulated nicotine products (nicotine water)
- ◆ Low: regulated nicotine medications (patch, gum, lozenge, inhaler, nasal spray)

Russ Sciandra

It is wrong to link NRT and tobacco industry products. Discussing tobacco products and NRT in the same document as if they are equivalent will only confuse policy makers and the tobacco control community.



Jon Lloyd

Just about everyone who opposed the TCS position complained that the draft paper lumped the three categories of harm reduction products (cigarette/cigarette-like, smokeless tobacco, and medicinal nicotine) together and thus misleadingly ignored any sense of the “continuum of harm” across the three types. This can probably be sufficiently addressed with the addition of just a few sentences of clarification.

Marice Ashe

Beyond differentiating between the various types of so-called harm reduction products, the paper should also distinguish between the degree of skepticism and/or regulatory control appropriate for the different products. So, for example, unless TCS currently is convinced that the pharmaceutical products are on par with the tobacco industry products in terms of their potential harm to decrease cessation attempts, etc., TCS may want to announce deep skepticism and call for research on specific hard-hitting questions (e.g., are these products being used by smokers as nicotine maintenance products?).

After considering the issues raised by the pharmaceutical products, I was moved by Steven Schroeder’s analogy to a needle exchange program. Needle exchange will not solve the AIDS problem, but it is a valuable, if flawed, tool that should be preserved. If this is an apt analogy, then these products should be treated differently from tobacco industry products. The place where the analogy certainly breaks down, however, is the amount of money the industry can put into the promotion of the products. The advertising is likely to inflate the value of these products in the minds of the public and even health professionals, and that is a problem in itself that is not present with needle exchange campaigns.

TALC [the Technical Assistance Legal Center] would like to work with TCS to take the next steps for local programs. We are imagining a range or spectrum of opportunities for local programs from amending their licensing ordinances to be sure to include new tobacco industry products (easy) to the total ban on sales (the merit of which still needs to be determined).

Stanton Glantz

The implicit assumption that has underlined all of “harm reduction” in the past was that it was impossible to dramatically reduce cigarette consumption and that a substantial number of people would continue to smoke no matter what the public health community did. The experience in California, Massachusetts, and elsewhere has shown that this is not the case. A well-conceived and adequately funded (and, in the larger scheme of things, not all that expensive) tobacco control program is capable of rapidly reducing smoking to the point that it is not only reflected in reduced cigarette consumption, but also reduced heart disease and cancer. These effects are orders of magnitude greater than even the most optimistic “harm reduction” enthusiast would ever claim. In other words, the real harm reduction is done through creating an environment that supports smoking cessation and prevents smoking initiation. TCS obliquely touched on this point in the draft; it should be made strong and explicit in the introduction.



These writers were concerned about this statement on page six of the draft paper: “There is a great deal of scientific evidence indicating that the ingestion of nicotine, even its “cleanest,” purest form, poses very serious health risks, can cause heart disease, and, based on growing evidence, may contribute significantly to the development of cancer.”

Jonathan Foulds

A major flaw with the document was that it was not based on a balanced review of the available science on the harmfulness of nicotine to health—particularly the third paragraph on page six of the long version of the draft. There are numerous studies and reviews by experts on this subject that come to different conclusions from those stated in the document. If clean nicotine was widely accepted to be a major cause of mortality from heart attacks, strokes, and cancer, then I would have greater agreement with a number of the recommendations. However, that is simply not what the science suggests.

Among the best evidence on this at a population level comes from studies of smokeless tobacco use in Sweden. Here we have very large numbers of people taking nicotine along with a number of other carcinogens (but without smoke) for decades, and the epidemiology suggests no increased risk of myocardial infarction or stroke (with one study finding an intermediate risk of MI, lower than that from smoking). TCS should consult with those who specialize on this topic (e.g., Benowitz, et al).

Mike Cummings

Evidence on the health risks of nicotine exposure needs to be more carefully considered. The draft document overstates the health risks of nicotine-only exposure.

Russ Sciandra

The claims about the adverse health effects of nicotine are very weak and certainly open to dispute from unimpeachable experts. These allegations sound like a red herring to back up TCS’s real concern about widely available NRT—that it may undermine the denormalization strategy while doing little or nothing to reduce tobacco use. It is wrong to so quickly accept John Pierce’s findings while dismissing all the countervailing evidence of its effectiveness.

Jon Lloyd

Several people said they thought there were problems in the summary of the science on the harm caused by these various products, especially the assertion that pure nicotine may cause or contribute to cancer. It would be wise to go back over the citations and make sure TCS is not overstating the harm or erroneously reporting study results. In Benowitz’s book on nicotine, the chapter that focuses on nicotine and cancer seems to support the paper’s claims, although in his conclusion to that chapter, Benowitz did, somewhat arbitrarily and without much explanation, dismiss the results of the studies, which he characterized as being insufficient to prove the connection. TCS could call Benowitz and ask him how to report those findings fairly, along with more recent ones not in his book that suggest a connection. It would not be a big loss if TCS had to back off from the nicotine–cancer connection. The important thing is that nicotine does beyond any doubt cause harm to the cardiovascular system and is extremely addictive (which creates the risk of the unintended consequences listed in the paper.)

The Alan Blum/Scott Tomar response more than countered Jonathan Foulds’ arguments in favor of the benefits of Swedish snus. The current statement in the paper on this may be sufficient, or TCS could add more of the reasons (as presented in Scott Tomar’s presentation) for doubting the claim that snus caused the prevalence of smoking among men to decline precipitously in Sweden.



One point made in favor of smokeless tobacco as a nicotine maintenance product—Dorothy Hatsukami and maybe one or two others said this—was that it is best to be honest with the public and tell them the “truth” that use of smokeless tobacco, especially low-nitrosamine smokeless tobacco, poses a significantly lower risk to the user compared to cigarettes. However, there is reason to doubt that this has really been established scientifically. New risks are being identified, such as pancreatic cancer. Corinne Husten’s presentation, which agreed with Surgeon General Carmona’s position on smokeless tobacco, defined a position which seems most reasonable (and met with spontaneous applause at the summit). To make a reduced harm claim, the smokeless tobacco advocates are going to have to demonstrate the benefit to the FDA, and they have not done that. This is in accordance with the recommendation by Steve Hansen and Michael Thun to keep the message simple. And then there is the problem Alan Blum referred to: how can a physician or public health practitioner recommend a product which is undoubtedly so dangerous to use? First, do no harm!

These comments focused on the proposal to place NRT products back under prescription-only status:

Jonathan Foulds

- ◆ TCS’s understanding of the health risks posed by nicotine was not based on the best available science.
- ◆ John Pierce has data showing that NRT has a significant long-term effect of increasing cessation among individuals living in a household with a smoking ban, which appears to be an interesting synergistic effect between a social support/denormalization effect and a treatment effect.
- ◆ TCS appears skeptical about comments from people whose work is funded by pharmaceutical companies, so it would be helpful for researchers with no pharmaceutical funding to weigh in on the discussion.
- ◆ Perhaps soliciting the views of ATTUD, the Association for the Treatment of Tobacco Use and Dependence (which does not accept pharmaceutical funding) would be useful.

It is extremely unlikely that the claimed reduction in effectiveness of NRT in California after 1996 was caused by its switch to OTC status. There are a number of both retrospective and prospective studies showing that NRT increases quit rates—even in an OTC setting. There are also a number of studies (including one that I published) based on proper prescription-like settings, in which NRT had disappointing effects at medium long-term follow-up. The quality of the scientific evidence suggesting that NRT only works in a prescription setting is not adequate to make a policy change of this nature. I noticed that Table 8.2 of the October 2003 California TCS report shows that “No NRT” quit rates took a significant dip in 2002 as compared with previous years (e.g., at six months from 20% in 1999 to 15% in 2002.) Should we therefore change policy to say that quitting without NRT is no longer effective unless under the guidance of a doctor? No, of course not—there are clearly some very interesting phenomena being recorded in the California evaluation data, but it is important that policy change is based on a thorough review of the evidence and potential interpretations and not a knee-jerk reaction.



Mike Cummings

- ◆ NRT should be expanded, not reduced.
- ◆ The proposal to make NRT by prescription only is based upon misinformation about the safety profile of nicotine.
- ◆ Data from our prospective study of COMMIT participants refuted John Pierce's suggestion that the efficacy of NRT is lacking.
- ◆ NRT has not had a huge impact on population level indicators of smoking behavior because of underutilization, not zero efficacy.
- ◆ The idea that the efficacy of NRT is low and limited tobacco control resources could be better spent elsewhere might be a reasonable position and worthy of debate, but it is not a justification for a prescription-only policy recommendation.

Access to regulated nicotine medications can assist smokers in quitting, both by motivating a cessation attempt and increasing the odds of quitting. Price and misperceptions about the safety and efficacy of nicotine medications are barriers that have kept usage rates low. TCS should promote policies that increase access by smokers to regulated forms of nicotine medication (this means both OTC and prescription only).

John Hughes

- ◆ TCS should solicit outside expert opinion on NRT.
- ◆ Evidence shows that switching to prescription-only status is a bad idea.
- ◆ A recent analysis by Saul Shiffman showed that OTC NRT users are a self-selected group biased toward worse outcomes in ways the Pierce analysis did not correct for and thus raises questions about Pierce's conclusions.

Charles DiSogra

The action or treatment for smokers should be to proscribe smoking and prescribe NRT and a cessation support program or whatever else is proven to work in conjunction with NRT. Thus, I agree with your policy recommendation that all NRT products should be removed from the OTC realm—patches, gum, lozenges, etc. This would certainly get attention, but may be difficult to achieve given Internet purchasing channels.

Edward Anselm

- ◆ Nicotine is an antidepressant and is used for mood modification and cognitive enhancement in a broad range of treatable psychiatric conditions. To offer nicotine to the general smoking population is to mask a large number of treatable psychiatric conditions. The exclusive focus on nicotine is unfortunate as there are other agents shown to be effective in smoking cessation. Depressed patients now get lifelong treatment with anti-depressants; that is not harm reduction, that is appropriate and effective medical treatment.
- ◆ A psychiatric condition can only be diagnosed by its phenomenology. When the patient is taking medications, depression, OCD, ADDS, and even anxiety-related conditions are difficult to diagnose. Remove the cigarettes, caffeine, and all other drugs and you can make a good diagnosis. When I offer this insight at conferences, the head bobbing by the clinicians who treat smokers begins.
- ◆ As you seek insights about harm reduction, listen most to those who treat patients, not scientists, not advocates, but clinicians. They are the ones with legitimate opinions on this matter.



Russ Sciandra

I have been raising questions about New York State's rush to make NRT more available through the Quit Line, etc., on a cost-effectiveness basis, but I am not at all convinced that restricting access through doctors who will write prescriptions just to shut up their patients will accomplish anything. We know how good the pharmaceutical industry is at creating demand among patients for all kinds of drugs. What makes you think this will be any different?

Jon Lloyd

TCS should drop the recommendation to put NRT back on a by-prescription-only basis (although it is still a worthwhile move.) It is off-topic and a diversion and it leads to confusion. With this change, TCS can stand by its very reasonable, widely supported recommendations regarding medicinal nicotine.

These comments pertained to the regulatory issues and "preconditions" presented in the position paper:

Charles DiSogra

- ◆ I think we are a long way from the "tabac" shops à la France, and a national tobacco control agency may be tough to sell in the current political environment.
- ◆ On page 19 of the draft paper, TCS should add that tobacco should not be smoked in "any confined space shared with children and non-smokers" and also that there should be no "outdoor smoking on public property shared by children and nonsmokers except in designated areas."

Jonathan Foulds

The suggestions here are probably all helpful in themselves (if unlikely to ever happen or be under our direct control), but there is no convincing rationale for why they should be preconditions for regulation. They are good suggestions (excepting the implication that the national model should be modeled on California, rather than taking the best from around the country—with much of the best being in California) but should not be preconditions for regulation.

Mike Cummings

Evidence is lacking to support a change in FDA regulation that would promote long-term maintenance of nicotine medications. On the contrary, recent data from New York State suggests that smokers may benefit from a shorter duration of use than even recommended by current practice guidelines.

Stanton Glantz

While I do not disagree that many of the other tobacco control strategies outlined in the paper are desirable, even TCS admits that in the current environment, they are pie-in-the-sky. Spending so much time on them and linking them so closely to the arguments around harm reduction detracts from the central argument and weakens TCS's case.

Every criticism of harm reduction the paper makes is true quite independent of whether or not the tobacco tax is increased by \$2.50. At the very least, TCS needs to pry apart the discussion about the characteristics of an optimal tobacco control program from the discussion of reduced harm products.



Appendix A

Agenda

Wednesday, September 8, 2004

8:30 Welcome and Opening Remarks

Dileep G. Bal, MD, MS, MPH

Chief, Cancer Control Branch

California Department of Health Services

8:45 Summit Purpose

April Roeseler, MSPH

California Department of Health Services

**9:15 The California Position on Harm Reduction
and Tobacco Regulation**

Greg Oliva, MPH

California Department of Health Services

10:00 BREAK

Discussion Panels

Objective: Discuss the California Position as it relates to tobacco and nicotine products

10:15 Cigarette and Cigarette-like Products: It's Still a Cigarette

- **Review California Position**

David Cowling, PhD

California Department of Health Services



Discussants

- **Issues and Challenges Associated with Modified Cigarettes and Cigarette-like products**
Dorothy Hatsukami, PhD
University of Minnesota
- **Cigarette Harm Reduction—Is it Possible?**
Gary Giovino, PhD
Roswell Cancer Institute

Facilitated Discussion

11:45 LUNCH

12:45 The Lure of Smokeless in Lieu of Smoking

- **Review California Position**
Roberta Lawson, RDH, MPH
California Department of Health Services

Discussants

- **Is there a Public Health Benefit to Switching to Smokeless Tobacco?**
Jonathan Foulds, PhD
*Tobacco Dependence Program
UMDNJ School of Public Health*
- **Public Health Implications of Promoting Smokeless Tobacco Use**
Scott Tomar, DMD, DrPH
*Division of Public Health Services and Research
University of Florida College of Dentistry*

Facilitated Discussion

2:15 BREAK

2:30 Medicinal Nicotine—Short and Long Term Use

- **Review California Position**
April Roeseler, MSPH
California Department of Health Services



Discussants

- **How Much Should We Promote the Use of NRT?**
Mike Cummings, PhD, MPH
Roswell Cancer Institute
- **The Science Behind NRT**
John Pierce, PhD
University of California, San Diego
- **The Promotion of NRT: Population Implications**
Shu-Hong Zhu, PhD
University of California, San Diego and California Smokers' Helpline

Facilitated Discussion

- 4:45 Reflections**
David Altman, PhD
The Center for Creative Leadership

Thursday, September 9, 2004

- 8:30 Welcome Back**
- **Day 1 Recap and Day 2 Objectives**
April Roeseler, MSPH
California Department of Health Services
- 8:45 The Impact of Harm Reduction and Regulation on Tobacco Control Efforts—Past and Present**
- **Review California Position**
Marice Ashe, JD, MPH
Technical Assistance Legal Center

Discussants

- **Bulls**t and Ruses: Marketing Light and Less Irritating Cigarettes**
Richard Pollay, MBA, PhD
*Sauder School of Business
University of British Columbia*



- **A Safer Form of Arsenic?**
Alan Blum, MD
Center for the Study of Tobacco and Society
University of Alabama
- **Implications for Comprehensive Tobacco Control**
Corinne Husten, MD
Office on Smoking and Health
Centers for Disease Control and Prevention

Facilitated Discussion

10:25 BREAK

10:40 To Regulate or Not to Regulate?

- **Review California Position**
Greg Oliva, MPH
California Department of Health Services

Discussants

- **Current Environment and Tobacco Regulation—
What Can We Get and What Should We Accept?**
Matthew Myers, JD
Campaign for Tobacco-Free Kids
- **A Risk/Benefit Review of Tobacco Regulation**
Steven Schroeder, MD
School of Medicine
University of California, San Francisco

Facilitated Discussion



12:20 LUNCH

1:30 Rising Above the Static: Effective Communication Messages

- **Review California Position**
Colleen Stevens, MSW
California Department of Health Services

Discussants

- **Are the Remedies the Actual Problem?**
Paul Bloom
*Kenan-Flagler Business School
University of North Carolina*
- **Battling the Industry Behemoth: Communicating the Tobacco Control Message to the Public**
Matthew LeVeque
Rogers & Associates

Facilitated Discussion

3:00 What Have We Learned?

David Altman, PhD
The Center for Creative Leadership

3:30 Closing

Dileep G. Bal, MD, MS, MPH
*Chief, Cancer Control Branch
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Appendix B

Participant Directory

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