Keynote Speech on the Application of Harm Reduction to Other Public Health Problems: What is Similar or Different About the Issue of Tobacco?

Cheryl Healton
KEYNOTE SPEECH ON THE APPLICATION OF HARM REDUCTION TO OTHER PUBLIC HEALTH PROBLEMS: WHAT IS SIMILAR OR DIFFERENT ABOUT THE ISSUE OF TOBACCO?

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Good afternoon everyone. Today our focus is on “reduced harm” tobacco products—the brands, old and new, that the industry brings to the market because these products allegedly cause less harm to consumers than traditional tobacco products. All of us who are dedicated to tobacco control and improving public health are automatically suspicious of these types of products. But, unfortunately, it appears that the general public does not share our suspicion, and therein lays the rub. Having been misled by the tobacco industry for decades, we come to this debate as what one could call “jaded” or just “historically informed.” I think Judge Gladys Kessler in her much-anticipated final opinion in United States v. Philip Morris USA, Inc. put it best:

[O]ver the course of more than 50 years, [d]efendants lied, misrepresented, and deceived the American public, including smokers and the young people they avidly sought as “replacement smokers,” about the devastating health effects of smoking and environmental tobacco smoke, they suppressed research, they destroyed documents, they manipulated the use of nicotine so as to increase and perpetuate addiction, they distorted the truth about low tar and light cigarettes so as to discourage smokers from quitting, and they abused the legal system in order to achieve their goal—to make money with little, if any, regard for individual illness and suffering, soaring health costs, or the integrity of the legal system.¹

It is a stinging indictment of the tobacco industry and one that surprised few of us.

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At the American Legacy Foundation, we know a great deal about the tobacco industry’s effort to distort and squelch the truth. We were finally—and unanimously—vindicated in the summer of 2006 by the Delaware Supreme Court in our long and costly five-year battle with Lorillard Tobacco, a company that had been aiming to shut down the Foundation and make it no longer possible for us to tell youth the truth about tobacco and the way it is marketed to them. While we produced ads using content directly from Lorillard Tobacco’s own documents, they argued that truth vilified and personally attacked them, a violation of the landmark 1998 Master Settlement Agreement (MSA).

The American Legacy Foundation was established as a public health foundation devoted to educating the nation about tobacco, with the intent of preventing young people from starting to smoke and helping those 45 million adult Americans who are still smoking by steering them to viable methods for cessation. Our truth campaign has been credited with 22% of the decline that has occurred in youth smoking during its first two years, and studies from 2002 to 2004 do not report an increase in tobacco use among youth. The campaign works and the tobacco industry has worked aggressively to silence it. Thankfully, the industry’s efforts have failed, and we intend to stay the course and save lives. To do so, we will continue to generate debate among youth about tobacco and how it is marketed to them. truth never tells kids not to smoke, but instead educates them to be wary, savvy consumers and lets them make their own choice about whether they want to take up this habit.

For adults, the debate gets more complicated because for the majority of adult smokers—and many of you know I was one—smoking is not about choice but very much about addiction. To a smoker addicted to nicotine, a reduced harm product in any form, whether it’s a new filter, whether it’s called “light,” “ultra light,” “mild,” or whether it’s one of the plethora of potential reduced exposure products (PREPs) in the offing, the response is: “Well, maybe this one isn’t so bad for me,” or “It must be safer.” In fact, in a study from a sample of about 700 individuals in the United Kingdom, approximately 70% of smokers, regardless of their position in the stages of change (including those just about ready to quit), wanted to try PREPs

3. Id. at 731.
and 90% believed that PREPs conferred less health risk.\footnote{Saul Shiffman et al., \textit{UK Smokers' and Ex-smokers' Reactions to Cigarettes Promising Reduced Risk}, 102 \textit{Addiction} 156, 157–58 (2006).} The truth is that even the tobacco industry concedes that there is "no such thing as a safe cigarette."\footnote{Philip Morris Int'l, \textit{Reduced Risk Products: “Safer” Cigarettes?}, \url{http://www.philipmorrisinternational.com/PMINTL/pages/eng/busenv/Reduced_risk.asp} (last visited Jan. 8, 2008).}

But American consumers are now seeing the tobacco industry's marketing expertise rise up once again as the industry works to promote supposed reduced harm products, while smoking remains the nation's number one cause of preventable death and the leading cause of cancer—of course lung cancer is the number one cancer killer—not to mention heart disease.\footnote{Am. Lung Ass'n., \textit{Facts About Lung Cancer}, \url{http://www.lungusa.org/site/pp.asp?c=dvLUK900E&b=35427} (follow "What Causes Lung Cancer?" hyperlink) (last visited Jan. 8, 2008); Am. Heart Ass'n, \textit{Cigarette Smoking and Cardiovascular Diseases}, \url{http://www.americanheart.org/presenter.jhtml?identifier=4545} (last visited Jan. 8, 2008).} The American Legacy Foundation is restricted from lobbying. Therefore, in the language of the MSA it is not possible for me to comment, in any substantive form, about the current bill in Congress proposing Food & Drug Administration (FDA) regulation of tobacco.\footnote{Family Smoking Prevention and Tobacco Control Act, S. 625, 110th Cong. (2007); H.R. 1108, 110th Cong. (2007).}

The Foundation does, however, hope to play a role in allowing the drumbeat of controversy and discussion to go on. Regardless of the fate of that particular bill, whatever would come of it would inevitably be changed over time and so the law would be only the beginning of a very long process, in the same way regulation has evolved in other areas.

I would now like to give an operational definition of harm reduction. It refers to policies or practices that lower risk along a continuum.\footnote{See generally John S. Baer & Heather Brady Murch, \textit{Harm Reduction, Nicotine, and Smoking}, \textit{in HARM REDUCTION} 122, 127–37 (G. Alan Marlatt ed., 1998).} They can be interventions that society puts in place or they can be individually derived. They can be medical, such as vaccines; they can be engineered, such as seatbelts. They can also be activities that are substitutional, such as: soy instead of whole milk; healthy oil instead of fat; non-alcoholic beverages instead of alcohol. If you're in the public health community and you're looking at this problem, you absolutely must consider harm reduction as a major focus because you understand that universal cessation—absent some very unusual set of circumstances we may see decades from now—is not likely to come about.

Before joining the American Legacy Foundation, I spent about twenty years of my career working in the area of HIV/AIDS, particularly in the areas of women's health and adolescent health. The field of HIV/AIDS was, and to a certain extent still is, marked by very similar and very heated debates where sometimes it's clear that some positions are purely political, but more often than not it's active...
scientific debate about what will work best. Most of the time, the actual effect of the policies that are being considered and put in place cannot be a priori predicted. People seem to fall into the purist and pragmatist side of the equation and that affects how they frame the issues. They also have to deal with whatever available information they have to frame a risk-benefit equation; and very smart people can frame that risk-benefit equation differently, particularly if part of the equation is predicting what is, essentially, the unpredictable. I’m going to give one example where it made sense that a certain action was going to have positive results from a public health perspective, but it did not turn out that way.

Another example includes teen pregnancy, abstinence programs versus birth control. I have my own opinion on those issues and I’m sure others do too. The one I’m going to make a particular example of is called the Hierarchical Method of HIV Risk Reduction. In New York State, a number of people in the scientific community were looking at the data on the use of spermicides and the impact on the transmission of sexually transmitted diseases (STDs). There was a large body of evidence that associated not only condom use, but the use of gels, foam, and spermicides, and diaphragms in combination with gels and spermicides, with a markedly decreased risk of acquiring syphilis, Chlamydia, and a whole range of sexually transmitted diseases. We all came together and said that the message that we are putting out about HIV—that the only way to protect yourself is the male condom—is probably problematic in the view of those data.

What developed is something called the Hierarchical Method of HIV Prevention where there was basically a pyramid. The top of the pyramid was the male condom, the second element in the pyramid was the female condom, below that a diaphragm with additional gel, and finally gels and spermicides alone as a last resort. The theory behind this hierarchy was based on the presumption that, early-on in the epidemic, most sex acts that occurred around the world went unprotected, and this, of course, was the driving force fueling the AIDS epidemic.


Eventually, after much debate and queasiness, the state health department bought into this pyramid, which then became a disseminated model of education.\(^\text{16}\)

What were the arguments against it? One argument against it was very similar to the smoking versus smokeless argument: “Goodness, if we do this, people who would otherwise use the male condom in their sex acts are going to shift to this easier thing; they’re going to misunderstand it and think spermicides are just as good as a male condom.” There was a great deal of debate about it, but nonetheless it became policy, practice, and public education before solid proof existed because it seemed like an urgent health problem. What happened, as shown by a large scale international study that was undertaken on the effects of spermicides on HIV acquisition, was that not only were spermicides proven not to protect against HIV, they actually \textit{increased} the probability of HIV transmission.\(^\text{17}\) This is a classic public health story where everyone felt that the mechanisms for the acquisition of other STDs could be fungible to HIV and it turned out that they were wrong.

There are other examples: the whole issue of needle exchange and how our nation has approached it in terms of our international HIV work, or how our nation has approached condom use and abstinence. You have a large camp of individuals from many different walks of life on both sides. Though the science may be clear, when you apply it to public policy, different things happen—in terms of the U.S. and the countries in which the U.S. spends its public health monies. Some favor abstinence-only as a method of sexually transmitted disease prevention. Others favor a combination of abstinence, monogamy, and condom use. We know that abstinence-only does not work. As Alan Rosenfield, the Dean of the School of Public Health at Columbia University, likes to say, “Abstinence is fine, as long as you use it in moderation.”\(^\text{18}\) This debate is not new to public health. In essence, we come down to the question: how do we balance human health with human nature? We are a country that loves our freedoms. If you say, “Gee, maybe tobacco should be banned,” you are immediately labeled as “crazy.” But the fact of the matter is that if tobacco were a newly introduced product, it probably would never make it to the market.

The American Legacy Foundation did a wonderful series of ads called “Crazyworld,” where it basically drew analogies between all sorts of other consumer products that were found to lead to the deaths of three or four children

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and the aggressive steps that were followed to take these products off the market.\textsuperscript{19} We all remember the spinach problem, and how it dominated the headlines. While the spinach problem dominated the headlines, 1,200 people were dying every day from tobacco-related deaths.\textsuperscript{20} So I said to myself, and I’ve said this to Philip Morris also, “Keep making your product, just don’t have a combustible version of it.” I don’t think it’s wrong, if you are thinking as a public health person, to try to get as close as you can to a cigarette that does not combust and, thereby, markedly reduces that risk yet delivers nicotine.

I am not only a former smoker, but a former nicotine gum addict, and a former patch addict, and I used nicotine as a substitute, although substitution is not technically a legitimate use. It took me a very long time until I could finally get off the gum as well. I think the way we have handled medicinal nicotine, which does provide an appropriate substitution for cigarettes, really does need to change because it is too inaccessible for a variety of reasons. It doesn’t have to be the only product. I think the point has been made that the incentives are not in place to get another product out to the market; for that matter, the incentives aren’t in place for the tobacco industry itself to try to aggressively move away from combustion.

One of the reasons that we do not see enlightened public health policy with regard to tobacco, one of the primary reasons that the battle has been so long and the efforts have been so arduous to have the right thing happen, as Christine Gregoire (who served as the Attorney General during the MSA negotiations) noted: The states and their politicians are addicted to the money.\textsuperscript{21} Most analyses have shown that 50% of state legislators accept money from the tobacco industry.\textsuperscript{22} There probably is an even higher percentage in Congress\textsuperscript{23} because these checks are often automatically created. This is a major public policy problem. It is very difficult to have enlightened public policy if the majority of our state legislators and federal legislators—and they’re not all doing it—are receiving tobacco industry donations.

As public health professionals, we are here today to examine reduced harm cigarettes or smokeless tobacco to see if they are truly viable steps along the continuum for reducing risk. We know the toll that smoking takes on our nation is


\textsuperscript{20} Am. Cancer Soc’y, Youth & Tobacco, Youth & Tobacco, http://www.cancer.org/docroot/COM/content/div_Northwest/COM_5_1x_Youth__Tobacco.asp (last visited Feb. 14, 2008).


\textsuperscript{22} Jill Abramson, Tobacco Industry Gave Big Where it Faced Attack, N.Y. TIMES, June 8, 1998, at A16 (“Since Jan. 1, 1995, the tobacco industry donated about $1.8 million to state party central committees in 26 states.”).

high when 21% of the U.S. population currently smokes, leading to over 400,000 deaths every year.  

We know that smokeless tobacco is addictive and is strongly associated with an increased risk of oral cancer, but I just learned that the estimated numbers of those oral cancers are really far less than I originally understood. Of the 168,000 cancer deaths caused by tobacco, about 7,500 of those deaths were from oral cancers, but the majority of those deaths were related to smoking and drinking as opposed to smokeless tobacco. 

We do know that smokeless tobacco carries with it a fairly small risk of heart disease.

The American Cancer Society recently released a report announcing that cancer deaths continue to fall, but there is enormous cause for concern due to the fact that while both youth smoking for eighth and tenth graders and adult smoking have stalled, they are no longer falling as of last year.

We must stop and ask ourselves, are these products promising reduced harm or are they really offering a different harm? Or are they offering something that takes us along that continuum of reduced harm that is a hallmark of public health practice? There are three issues that we are addressing when looking at the net public health benefit, and these were highlighted in the Institute of Medicine (IOM) report. First, will young people be induced to start (i.e., initiated into) using tobacco when they otherwise would not have? Second, will people who would otherwise quit tobacco, not quit? This certainly happened in the case of "light" cigarettes to a substantial extent, and it was a fraud that allowed it to happen. Here, the issue is whether such people would nonetheless be engaged in a behavior that carries

30. AM. CANCER SOC'Y, supra note 27, at passim.
substantially less risk than the combustible cigarette. Third, will people who have successfully quit smoking return to using a tobacco-related product?\textsuperscript{32}

Just to be a little of a provocateur, I would say that if I had 100 of my public health colleagues in the room with me who did not work at all in the tobacco field, and they reviewed the evidence, probably 80 of the 100 would say smokeless tobacco is a viable alternative to combustible tobacco. I know, in a sense, that is unacceptable in many circles, but I think the reality is—and this has come up many times when public health problems are being analyzed in terms of their net public health benefit—many times we overestimate the probability of certain risks occurring. There are ways, in theory, to try to estimate those risks, and I know there are papers out there that have tried to look at this issue, but at the end of the day, it’s all about risk-benefit ratios.

I will just take a brief moment to discuss the concept of a ban. Some of you may know one of the leading national health associations in the country—I won’t name which, because it decided not to do it—was going to announce its belief that tobacco should be banned. A number of people talked the association out of it. In fact, consumer products that cause harm generally are banned. And this is a product that kills 50% of the people who use it as directed over the course of their lives. I just want to share some thoughts that you might hear in public policy health circles, but not in tobacco circles. When I’m on the road speaking to groups where there are many young people, the most common question I am asked by adolescents is “If it’s so bad, why isn’t it banned?” That is also one of the top five questions I am asked by adults.

There is a disconnect for the man or woman on the street with the policy we have pursued. For example (although it’s politically nonviable), I think if there was an effort to ban the combustible cigarettes, it would get a lot of momentum. It would certainly get a lot of legs in the public health community. Maybe not in the tobacco community\textit{ per se}, but politically, given the strength of the industry that I described earlier (economically and psychosocially) it is very unlikely that a ban will happen in this country. The issue with a ban—and I’m not promoting a ban, but doing an intellectual exercise—is the example that’s always raised: prohibition. There is a big difference between a drug that is substantially mind altering and confers a set of reactions in a person and a substance that largely relieves your withdrawal symptoms. Most people say smoking calms their nerves because as soon as they finish a cigarette, they start again on a cycle of withdrawal. Essentially, there is a disconnect in terms of how we handle consumer products, and there is a disconnect in the reasons we dredge up for why we don’t move toward much more aggressive regulation of this particular product.

\textsuperscript{32} See INST. OF MED., CLEARING THE SMOKE 31–34 (Kathleen Stratton et al. eds., 2001).
To me, it's largely the political context that is the driving force, because it's shifting our expectations. If you don't think it can be done, then you don't spend much time doing it. I am in the camp that you need to start somewhere and you need to do something. At the end of the day, I do embrace the bottom line that came out in the IOM report: we do not have the evidence before us now that PREPs, as opposed to smokeless tobacco products, represent any kind of reduced harm. The report also weighed in on regulation and said that the time is now. The IOM made the very important point that the net public health impact of reduced harm products is unknown. The IOM's path is going to be a very time consuming and scientifically rigorous path to follow. While we're on that path, it would be a good idea for us to be on another path considering the steps that would bring us closer to harm reduction for everyone, not only in this country, but around the world, given the fact that the United States is one of the lead (if not the lead) exporters of the most deadly drug known to man. It is now causing and will continue to cause enormous death and disability.

For argument's sake, what could be done with the acquisition of no new knowledge, just by implementing the policies that we now know work? More importantly, what is the price for not doing so? These questions should drive our discussions about PREPs and, frankly, about smokeless tobacco, and our discussions about the current regulatory environment that does not allow innovative nicotine delivery devices to get out there. The reality is that, in the United States, the overwhelming majority of these 45 million Americans who still smoke are lower-middle-income and low-income. Their health plans do not cover nicotine gum, and it's frequently priced at the point of purchase at $70 a box. Depending on how much you smoke, that may last you two weeks, or it might last you a week, or in some crazy cases, maybe three days. So I think we really need to consider, just in terms of harm reduction, making that product more accessible to individuals so that they may choose to use that product in lieu of smoking. Now, I know that evidence suggests that cutting back on smoking after many years of smoking has a very negligible impact on risk, and I am not arguing that nicotine therapy should be used in lieu of smoking while you are still smoking. I do, however, think that it is

33. Id. at 5.
34. Id. at 6.
35. Id.
38. Even if tobacco-dependence treatments are offered by a state’s Medicaid plans, many Medicaid beneficiaries do not seek such treatment because they are not aware of the coverage options. Sara B. McMenamin et al., Physician and Enrollee Knowledge of Medicaid Coverage for Tobacco Dependence Treatments, 26 AM. J. PREVENTIVE MED. 99, 99 (2004).
insufficiently available and that's a very important harm-reduction issue that needs to be taken up—not only the price, but the packaging of the product itself.

In closing, I am delighted to be here and share some of my thoughts with you. I am also just delighted that the Health and Human Service's Healthy People 2010 goals related to smoking, which are the reduction of adult smoking to 12% and youth smoking to 16%, were put in place in the year 2000 and are moving at the most rapid pace. Although we've had a recent stall, the reduction in smoking in the United States since 1964 is by all accounts and in the views of the broad public health community outside of tobacco control, one of the greatest public health victories that has ever occurred. I just hope that we altogether redouble our efforts to continue such a public health victory and drive us all the way home to the eradication of tobacco use, the eradication of an epidemic. Thank you.
