



2003

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Recommended Citation

Matthew L. Myers, *Could Product Regulation Result in Less Hazardous Tobacco Products?*, 3 *YALE J. HEALTH POL'Y L. & ETHICS* (2003).
Available at: <https://digitalcommons.law.yale.edu/yjhple/vol3/iss1/9>

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Could Product Regulation Result in Less Hazardous Tobacco Products?

Matthew L. Myers*

In 1964, the first Report of the Surgeon General of the United States concluded that cigarette smoking caused, or contributed to, many serious diseases, including lung cancer. Public health efforts to reduce tobacco use have had substantial success, but today, almost one-quarter of all Americans smoke and more than four hundred thousand Americans die yearly from tobacco use. It is clear that current public health efforts must be expanded. Despite our best efforts, it is also likely that many Americans will continue to start smoking, while others will be unable or unwilling to quit. Therefore, it is appropriate to ask what, if anything, can be done to reduce the harm suffered by those who continue to use tobacco.

There is widespread agreement that cessation and prevention remain the best methods for reducing the toll of tobacco use. If some smokers cannot or will not quit, an additional strategy should at least be considered—one that focuses on whether tobacco products can be developed that significantly reduce the risk of disease. This seemingly simple strategy raises concerns that involve complex scientific, behavioral, ethical, and regulatory questions that fall into three broad categories:

1. *What is the impact on the individual?* Is it scientifically possible to develop a tobacco product that will significantly reduce the disease risk of smoking? Even if it is technically possible to produce less hazardous products, what must be done to promote the development of such products while protecting consumers against bogus or unproven health claims?
2. *What is the impact on the public?* If reduced-risk products can be developed, what will be the impact on efforts to discourage initial use or to encourage cessation? What if introducing a less hazardous tobacco product leads to a net negative impact on public health by removing a major motivation to quit smoking or by encouraging

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people to start? Is it possible to create a situation—either through regulation or economic incentives—that maximizes the positive impact of the introduction of a less hazardous product while minimizing its negative impact? If not, what should be done?

3. *What are the effects on the marketplace?* There are two important considerations. First, what should be done to insure that the greatest incentives are provided for the development of the least dangerous substitutes for current tobacco products, including pharmaceutical products containing nicotine? Second, if it is technically possible to produce a tobacco product that would be widely used and less hazardous than products currently on the market, why not require all tobacco products to meet what would be an ever-improving safety standard? Rarely has discussion of the potential benefits of reduced-risk products also included a debate about whether, or under what circumstances, major technological safety advances should be applied to all tobacco products. Yet, it makes little sense to encourage the development of less hazardous products without considering how to maximize the number of smokers benefiting from them.

These issues are not new. Almost immediately after the release of the first Report of the Surgeon General, scientists began examining whether changes in tobacco products themselves could reduce their harm. As early as 1966, the Public Health Service concluded that “the lower the tar and nicotine content of cigarette smoke, the less harmful would be the effect.”¹

The tobacco industry had already discovered that promoting filtered cigarettes and low-tar cigarettes reassured concerned smokers and was good for business. As early as the 1950s, major cigarette manufacturers began widespread advertising of filtered cigarettes, with a variety of explicit and implicit health claims.² Despite a series of cases in the last half of the 1950s in which the Federal Trade Commission (FTC) challenged many of these health claims, cigarette manufacturers continued to advertise tar numbers. This advertising practice lasted until 1960, when the FTC issued guidelines proscribing such implicit health claims absent a standardized testing method.

With the release of the 1964 Report of the Surgeon General, the

¹ SURGEON GENERAL, U.S. DEP’T OF HEALTH & HUM. SERVS., *THE HEALTH CONSEQUENCES OF SMOKING: THE CHANGING CIGARETTE* at v (1981).

² NAT’L CANCER INST., U.S. DEP’T OF HEALTH & HUM. SERVS., *SMOKING AND TOBACCO CONTROL MONOGRAPH 7: THE FTC CIGARETTE TESTING METHOD FOR DETERMINING TAR, NICOTINE, AND CARBON MONOXIDE YIELDS OF U.S. CIGARETTES* at iii (1996).

interest of both the public health community and tobacco manufacturers in lower-tar cigarettes—potentially less hazardous tobacco products—increased significantly. After lengthy negotiations between the tobacco industry and the FTC, in 1967, the FTC approved a machine testing method that it concluded would provide uniform, standardized data about the tar and nicotine yield of mainstream cigarette smoke. However, even the FTC recognized that machine testing did not replicate actual human smoking.

Three years later, the FTC went one step further. In 1970, it started a rulemaking procedure to require tobacco companies to include machine-test ratings in their advertisements. The FTC subsequently dropped its rulemaking proceedings in favor of voluntary compliance by the major cigarette manufacturers. The introduction of the FTC testing method had an immediate effect. The sales-weighted average of tar and nicotine deliveries of cigarettes dropped dramatically in the following years. Additionally, the percentage of filter-tipped cigarettes rose and the percentage of smokers who used cigarettes with tar levels below 15 milligrams skyrocketed.

However, all these changes took place in the absence of any government regulation of tobacco products or their construction, and with minimal regulation of marketing. No public authority existed with the power to require that tobacco manufacturers disclose (1) the methods they used to alter their products to register lower test scores on the FTC machine, (2) what they added to their cigarettes, or (3) what they knew about consumer use of their products. There was no scientific or regulatory body with the authority to examine actual consumer exposure to the harmful substances in the newly designed tobacco products, or to monitor their health impact. Finally, no regulatory agency possessed the authority to restrain marketing claims that, though accurately reflecting FTC machine test scores, actually misled the public into thinking these products had been proven safer.

While the public health community was interested in newly designed products for their potential health benefit, internal tobacco industry documents indicate that the tobacco industry sold these products to keep people smoking.³ To accomplish this goal, the tobacco industry did not need to make products that were actually safer; it only needed to make products that would be perceived by the public as safer. According to its

³ M.E. Johnston, Philip Morris Companies, Inc., Special Report No. 248: Market Potential of a Health Cigarette 4, at <http://www.pmdocs.com/getallimg.asp?if=avpidx&DOCID=2040452500/2523> (June 1966).

own documents, that is exactly what it did.⁴

The results were not surprising. The introduction of the FTC testing method was a marketing bonanza for cigarette companies but an abysmal failure for those seeking to reduce the disease risks associated with smoking. Thirty-four years after the introduction of the FTC testing method, the National Cancer Institute (NCI) issued a report that was a devastating indictment of the effort to reduce the disease risks of tobacco products.⁵ The NCI reported that while cigarette design changed dramatically over the last fifty years in response to the FTC testing method, the disease risks of smoking did not.⁶ It also noted that many of the design changes made by tobacco manufacturers reduced tar and nicotine ratings on the FTC machine but did not alter the actual exposure of consumers to the harmful constituents of cigarette smoke.⁷ As a result, the NCI concluded:

[T]ar and nicotine measurements made by the FTC method for current cigarettes have little meaning for the smoker, either for how much he or she will receive from a given cigarette or for differences in the amount of tar and nicotine received when he or she smokes different brands of cigarettes.⁸

The NCI further concluded that the “[w]idespread adoption of lower yield cigarettes in the United States has not prevented the sustained increase in lung cancer among older smokers.”⁹ It added that “epidemiological and other scientific evidence . . . do[] not indicate a benefit to public health from changes in cigarette design and manufacturing over the last fifty years.”¹⁰ The NCI found that many smokers had switched to lower-yield cigarettes out of concern for their health, falsely believing the cigarettes to be less risky.¹¹ Some switched because they believed that lower-yield cigarettes would be a step towards quitting. The NCI report showed that those who switched instead of quitting paid a heavy price.

Recently, the NCI findings were reaffirmed by a report from the World

⁴ *Id.* at 2.

⁵ NAT'L CANCER INST., U.S. DEP'T OF HEALTH & HUM. SERVS., SMOKING AND TOBACCO CONTROL MONOGRAPH 13: RISKS ASSOCIATED WITH SMOKING CIGARETTES WITH LOW MACHINE-MEASURED YIELDS OF TAR AND NICOTINE (2001).

⁶ *Id.* at 1.

⁷ *See id.* at 1-11.

⁸ *Id.* at 1.

⁹ *Id.* at 10.

¹⁰ *Id.*

¹¹ *Id.* at 198.

Health Organization's Scientific Advisory Committee on Tobacco Product Regulation. This committee found:

It is now clear that the combination of compensatory changes in smoking patterns by smokers and cigarette design changes (particularly ventilation holes in filters) which increased the yield of smoke can restore the smoke delivery of the so-called low-yield cigarettes to that of full flavor cigarettes with much higher machine measured yields. However, as a consequence of the conventional format for conveying tar and nicotine information, the consumer believes that "low yield" cigarettes provide an alternative to smoking cessation. This belief persists even though it is now accepted that "low yield" cigarettes do not offer any proven health benefit in comparison to higher yield cigarettes.¹²

The "tar derby"¹³ of the last half of the twentieth century was just a warm-up for the next act by the tobacco industry. Increasing consumer concern about the health effects of traditional tobacco products, combined with growing skepticism about low-tar products, has led to an entirely new generation of tobacco products—often with more specific and more sophisticated claims implying that these products have been proven safer. For example, Vector Tobacco, Inc. claims that its product, Omni, is the "only cigarette to significantly reduce carcinogens that are among the major causes of lung cancer."¹⁴ Brown & Williamson Tobacco Corporation claims its cigarette, Advance, provides "All of the taste . . . Less of the toxins™."¹⁵ In marketing Advance, Brown & Williamson claims its TRIONIC filter and patented curing process significantly inhibit the formation of tobacco-specific nitrosamines.

This is the low-tar derby all over again. In the absence of government regulation, the manufacturers of this new generation of potentially reduced-harm products do not have to pre-clear these claims and do not have to scientifically substantiate claims. They also do not have to disclose how they make their products, how they allegedly reduce the levels of the advertised toxic substances, or what they add to these products in the manufacturing process. Moreover, they do not have to produce any evidence regarding actual human exposure or any human data that would

¹² SCIENTIFIC ADVISORY COMM. ON TOBACCO PROD. REGULATION, WORLD HEALTH ORG., CONCLUSIONS ON HEALTH CLAIMS DERIVED FROM ISO / FTC METHOD TO MEASURE CIGARETTE YIELD 1 (2002).

¹³ NAT'L CANCER INST., *supra* note 2, at iii.

¹⁴ Vector Tobacco, Inc., <http://www.omnicig.com/prodBenefits.asp> (last visited Dec. 17, 2002).

¹⁵ Brown & Williamson Tobacco Corp., <http://www.bw.com/apps/pdf/advanceonserts.pdf> (last visited Dec. 17, 2002).

justify their conclusion that their products actually reduce risk by reducing exposure to one or more toxic substances.

Is there any evidence that this new generation of tobacco products will actually result in risk reduction? A committee of the Institute of Medicine (IOM) examined this precise question.¹⁶ Its conclusions demonstrate how little progress we have made in developing a science base to support the search for verifiably less hazardous tobacco products.

1. There is little direct evidence available to serve as a basis for judgment as to the potential for harm reduction of specific new tobacco and pharmaceutical products.¹⁷
2. Although many components of tobacco are known to be toxic, little is known of the specific dose-response relations of the individual toxins as they occur in cigarette smoke or of the interactions between the constituents of tobacco smoke. There is little direct evidence that removal of specific substances from tobacco smoke or from tobacco actually reduces risk or harm to human health.¹⁸
3. In considering the health effects of modified tobacco products, it is important to remember that the health consequences of the use of any such product are determined not by the toxic agents removed from the product but by the actual exposure to the toxins that remain. Harm reduction is the net difference in harm between the products as actually used.¹⁹
4. No one knows the dose-response relations of, the specific toxins in, the pathogenic mechanisms of, or the interrelationship between the many components of tobacco smoke with enough precision to make scientifically reliable quantitative judgments about the risk or actual harm reduction associated with use of any tobacco product.²⁰
5. Since even the availability of harm reduction products may deter some from following the healthier course of abstinence or cessation, assessment of health claims should be based on an estimate of the

¹⁶ COMM. TO ASSESS THE SCI. BASE FOR TOBACCO HARM REDUCTION, INST. OF MED., CLEARING THE SMOKE (Kathleen Stratton et al. eds., 2001).

¹⁷ *Id.* at ix.

¹⁸ *Id.* at viii.

¹⁹ *Id.*

²⁰ *Id.* at ix.

effect of the product on the prevalence of smoking in the population, as well as the effect on the health risk to the individual smoker.²¹

Based on the reports of the IOM and the NCI, the lesson that should be learned from our prior experience is that in the absence of effective government regulation, harm reduction, based on the voluntary action of tobacco manufacturers, has been a failure. Further, absent government oversight, harm reduction is virtually certain to continue to fail for at least two reasons. First, the interest of tobacco manufacturers in selling their products is served by products that are perceived to be safe, even if they are not. Second, the public health community, on its own, lacks the resources to develop the science needed to assess which products offer the greatest potential for risk reduction, the ability to monitor product changes or the health impact of these products, and the authority to restrain how these products are marketed.

Nonetheless, neither the most recent report from the NCI nor the report from the IOM contradicts the original belief that a reduction in actual exposure to the harmful components of tobacco products will reduce risk. On the contrary, both agree that it is still reasonable to expect a relationship between the magnitude of exposure and the incidence of disease. Specifically, the IOM concludes that “[f]or many diseases attributable to tobacco use, reducing risk of disease by reducing exposure to tobacco toxicants is feasible.”²²

For nearly forty years, scientists have believed it feasible to reduce the death toll from tobacco use by altering tobacco products. However, we have made little progress in accomplishing that goal and in developing the scientific and regulatory tools to do so. Harm reduction, as a public health strategy, is worth pursuing only if it is preceded by the adoption of a meaningful regulatory system under the United States Food and Drug Administration (FDA). The IOM agrees with the need for regulation, concluding that the regulation of all tobacco products, both conventional and potentially reduced-risk products, is necessary to assure a scientific basis for judging the effects of these products and to assure that the health of the public is protected.²³

Indeed, the success of a proposed harm reduction strategy depends upon adequate FDA authority to oversee its development. The FDA’s authority must include the following:

²¹ *Id.*

²² *Id.* at 5.

²³ *Id.* at 6.

1. Tobacco companies must be required to disclose how they make their products and what they put into them. They must be required to test, and disclose to the FDA, substances in mainstream and side-stream smoke and the quantities in which they are received and metabolized. They must also be required to disclose all internal research relevant to health considerations.
2. When tobacco companies make any change in the design or composition of a tobacco product, they must be required to disclose that information to the FDA as well as any additional information required to evaluate the potential impact of the change.
3. The FDA must have the authority to set performance standards for all tobacco products for the purpose of reducing the harms they cause. This should include authority to require the reduction or removal of a component of the product, or its smoke, that the agency has identified as a harmful or potentially harmful substance, when technology exists to do so. The FDA's authority to require the removal of such a substance should be based on the conclusion that its removal is best for public health, considering the impact on both the individual smoker and the public as a whole. However, once a substance has been identified as potentially harmful, the FDA should not bear the burden of proof that the substance's removal will reduce disease risk.
4. The FDA must have broad authority to set standards for the promotion of less hazardous tobacco products, recognizing that its overall goal must be to reduce harm to both individual smokers and the population at large. The FDA's consideration of whether a product may be promoted as less hazardous must be based on the best available scientific assessment of actual risk and not just exposure, except where there is a scientific basis for correlating specific exposure with risk. The FDA's assessment of the product is just the starting point. The assessment must also examine actual exposure based on how the product will be used, who will use the product, and why. It should also consider the product's likely impact on smoking cessation and initiation. Therefore, the FDA's authority must extend to the marketing of these products and post-market surveillance, enabling the FDA to periodically reevaluate the actual impact of a product.
5. The FDA must have resources to develop the science base to effectively

evaluate different tobacco products and assess the behavioral impact of different marketing tools and claims. Harm reduction, as a strategy involving tobacco products, should not take place in isolation from either the FDA's consideration of the potential role of non-tobacco pharmaceutical products for smokers who cannot or choose not to quit, or its authority to set standards for all tobacco products. At present, pharmaceutical products containing nicotine have been approved for use exclusively as cessation tools. The potential for these products as long-term substitutes for tobacco users who cannot or will not quit has not been explored, despite the fact that these products have already met rigorous safety standards for short-term use. Similarly, if a harm reduction strategy leads to the introduction of less hazardous tobacco products that become widely used by consumers, the FDA should have the authority to require that all tobacco products meet its safety standards.

Until now, the debate about whether or not tobacco products can be made less hazardous and whether or not harm reduction is a legitimate public health strategy has taken place in an unregulated environment. If the goal is saving lives, harm reduction in the absence of regulation should be rejected as a public health strategy. Science continues to suggest that it is possible both to reduce the harm of tobacco products and to use harm reduction to reduce the death toll from tobacco use—if and only if the FDA is given broad, meaningful authority over both conventional and new tobacco products.

