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Full Statement of

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Subcommittee on Consumer Affairs

Hearing on the Accuracy of the FTC Tar and Nicotine Rating System

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Room 253, Russell Senate Office Building

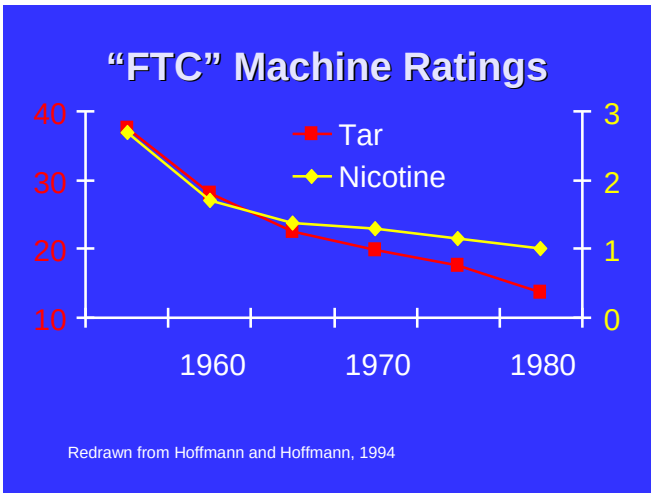
Mr. Chairman, Senator Lautenberg, and other members of the subcommittee, thank you for the opportunity to testify. For three decades, I have studied drug addiction and tobacco use at Johns Hopkins Medical School, the National Institute on Drug Abuse, and Pinney Associates. I serve on the World Health Organization Study Group on Tobacco Product Regulation and advise its Tobacco Laboratory Network and the Conference of Parties guiding implementation of the Framework Convention ("Treaty") on Tobacco Control on the measurement and communication of tobacco product contents and emissions. Through Pinney Associates I consult to GlaxoSmithKline on smoking cessation medications; I have a financial interest in a smoking cessation medicine that is under development; and, I have testified on these topics in litigation brought against the tobacco industry by the U.S. Department of Justice and other plaintiffs. My work is also supported by the Robert Wood Johnson Foundation Innovators Awards Program at The Johns Hopkins University School of Medicine. I speak on my own behalf and am not representing any of these organizations in my testimony today.

The FTC Cigarette Testing Method does not provide accurate information about tar and nicotine exposure to cigarette smokers and, in fact, greatly underestimates the inhaled amounts. Furthermore, the ratings support marketing that undermines our efforts to prevent young people from starting to smoke and to motivate smokers to quit.

This problem has persisted in part because of the absence of public health based regulatory oversight that would have been responsive to warning signs over the past two decades. How did it happen? What is the path towards resolution? I will start with the problem and how it was discovered.

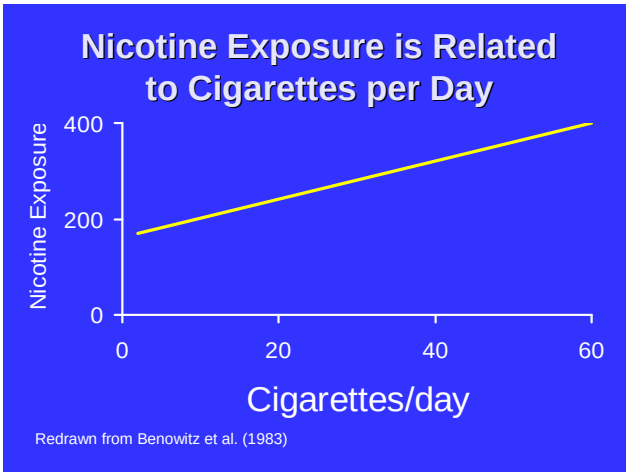
THE PROBLEM

I believe Americans trust product content ratings because our nation leads the world in setting standards for truthful ingredient information for foods and drugs. This information typically communicates maximum exposure from a product. When content or delivery ratings are found to misrepresent the product, established protocols can fix the problem. Every year, FDA acts on hundreds of products that are misrepresented or more technically – "misbranded". It isn't surprising that Americans believe the FTC rating bears some relationship to health effects and exposure. Consumers, such as my own sister, do not believe the government would allow a scam like this to go on.

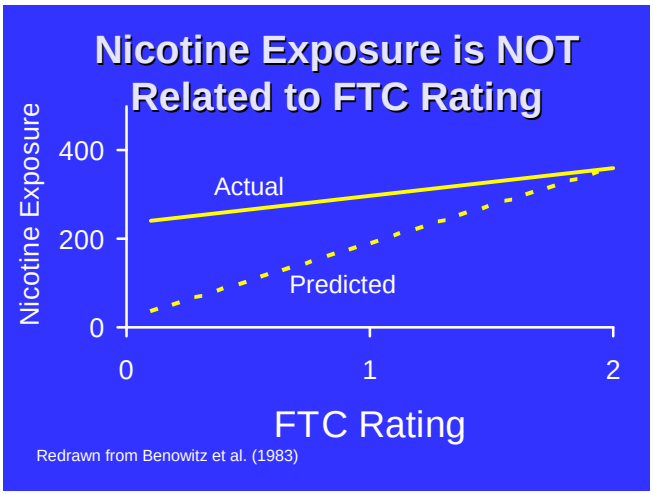


This figure shows what many of us thought was a major success story in public health: the 1960s to 1980s plummeting of tar and nicotine levels in cigarettes as rated by the FTC method (figure modified from Hoffman and Hoffman, 1994). As intended, consumers flocked to cigarettes with lower ratings. Even scientists like me thought we could take advantage of what appeared to be the broad range of nicotine dosing systems for biological research. Of course, we knew the ratings did not precisely predict exposure but we expected that the ratings were meaningfully related to human exposure.

The warning bells sounded in the 1980s by NIH researchers. In 1983, Dr. Neal Benowitz and his colleagues (1983) published one of the seminal studies. His study showed that light cigarettes did not deliver less nicotine. This figure (estimated from plasma cotinine levels) shows that nicotine exposure is directly related to number of cigarettes smoked.



The second figure from the Benowitz study revealed the problem. The dotted line shows what scientists had expected based on FTC testing: namely that there would be lower levels of exposure from cigarettes with lower ratings. However, the solid line reveals that actual exposure was NOT related to FTC rating.



Unfortunately, consumers not only reasonably believe that their exposure to tar and nicotine will be less from cigarettes with lower FTC method deliveries, they believe that health risks of cigarettes are lower in proportion to tar and nicotine reductions. For example, Kozlowski and Pillitteri (2001) reported the results of a national telephone survey which showed that for many cigarettes smokers an important factor in smoking light cigarettes was the belief that they could reduce the risks of smoking without having to quit. They also cited previously secret tobacco industry documents which revealed that this was the intent of the industry in their design and marketing approach that enabled them to "reassure smokers, to keep them in the franchise as long as possible." Responses to survey questions about the number of light cigarettes that would need to be smoked to get the same amount of tar as from a regular cigarette indicated that about 90% of the respondents held "mistaken beliefs regarding the distinctions between machine based *yields* of tar and actual tar *intake*."

These consumer misperceptions were further explored by Cummings and colleagues (2004) in a telephone survey of cigarette smokers. They found that only 12% of smokers correctly understood that you could get as much tar from a single light cigarette as from a regular cigarette, and a third or more smokers believed that high tar cigarettes were twice as likely to cause disease as low tar cigarettes.

A further complication in the accuracy and potential misapplication of FTC method testing is that as meaningless as the results are for widely marketed "conventional" cigarettes, FTC has never even developed testing protocols for modified cigarettes and novel cigarette substitutes that are under development and in early stages of marketing. For example, Shiffman and colleagues (2003) found that one cigarette substitute, marketed with tar and claims based on the tobacco companies own modification of the FTC method has led to serious misperceptions among smokers such as one in four believing that Eclipse is a completely safe alternative to conventional cigarettes, with highest levels of interest in people who had been contemplating quitting smokers. Even more startling was that 15% of young adults who had quit smoking for at least two years were interested in using Eclipse. There are many other modified tobacco products in various stages of marketing and development, as described by Hatsukami and

colleagues (2004, 2005), and these pose emerging problems of even greater complexity to testing and communications than conventional cigarettes.

These problems were confirmed by FDA and acknowledged by FTC in the 1990s. In 2001, National Cancer Institute Monograph13 came to the most devastating conclusion of all: there is no health benefit to cigarettes marketed as “light” and “low tar”.

HOW DID IT HAPPEN?

FTC’s intentions were good and it was probably not unreasonable for the agency to expect that the rating system would help smokers reduce their tar and nicotine exposures as advocated by the Surgeon General, AND would provide incentives for companies to develop lower-yielding cigarettes (Wilkenfeld et al., 2000). FTC did not anticipate the extent to which the tobacco industry would go to design cigarettes to undermine the test and render the rating system meaningless with respect to actual intake and health effects. Also underappreciated at the time was the power of the addictive process that motivated cigarette smokers to more intensively smoke cigarettes that delivered lower yields per puff (“compensatory smoking”).

The cigarette designs that circumvented the method were elaborate, but several are easily pointed out. Vent holes dilute the smoke in FTC machines, but do not do so when covered by the fingers and lips of smokers. There are many other tricks employed in the deception and these include the use of various chemicals to alter burning properties and nicotine delivery as well as other physical design features that are discussed in National Cancer Institute Monographs 7 and 13. For example, the machine stops smoking 3mm before reaching the overwrap connecting the filter to the tobacco column and so does not test all the tobacco. Not surprising, this overwrap became larger when FTC testing started. Accelerant chemicals are added so that the cigarette would burn faster and, therefore, the relatively slow-puffing machines would measure lower tar and nicotine. The mix of design features used to cheat the FTC test method varies across cigarettes and appear to be continuing to evolve. Until the testing is in place under authority of an agency with the experience to evaluate drug and toxin delivery and empowered to demand information about the designs and their consequences, scientists and consumers alike will remain in the dark with respect actual deliveries and associated health effects.

The recent and emerging problems with respect to emerging generations of modified cigarette products, such as those involving carbon heating systems, electronic ignition, and novel filtration, is occurring because there is presently no regulatory oversight mechanism in place with expertise to develop and validate new testing methods. In the vacuum, the tobacco companies are adopting their own variations on the existing FTC method.

PATH TOWARDS RESOLUTION

There is no simple fix that we could provide to FTC, in part, because, cigarette designs continue to evolve. But there is a path toward resolution and that is to charge FDA to set standards for cigarette testing and labeling and oversee the validity of the testing, as proposed in current legislation intended to give FDA authority over tobacco products.

FDA is the world authority in measuring dosing capacity and exposures produced by a broad range of products, including ever-changing drug delivery systems. It would be capable of developing and validating accurate methods for testing and communicating the results for current cigarette products as well as for the emerging generations of modified cigarettes and cigarette substitutes. For FDA, this scientific challenge is well understood. It has the capacity to not only fix the problem with respect to currently marketed cigarettes but also to prevent such a colossal and long-lasting deception of consumers and impediment to public health from ever occurring again.

Supporting References

Benowitz, N.L., Hall, S.M., Herning, R.I, Jacob, P., Jones, R.T., Osman, A.L. Smokers of low-yield cigarettes do not consume less nicotine. *New England Journal of Medicine*, 300: 139-142, 1983.

Cummings, K.M., Hyland, A., Giovino, G.A., Hastrup, J.L., Bauer, J.E. Bansal, M.A. Are smokers adequately informed about the health risks of smoking and medicinal nicotine? *Nicotine and Tobacco Research*, 6: S333-S340, 2004.

Hatsukami, D.K., Henningfield, J.E., Kotlyar, M. Harm reduction approaches to reducing tobacco-related mortality. *Annual Review of Public Health*, 25: 377-395, 2004.

Hatsukami, D.K., Hecht, S. *Hope or hazard: what research tells us about potentially reduced exposure tobacco products.* University of Minnesota Transdisciplinary Tobacco Use Research Center, Minneapolis, 2005.

Kozlowski, L.T., Pillitteri, J.L. Beliefs about “light” and “ultra light” cigarettes and efforts to change those beliefs: an overview of early efforts and published research. *Tobacco Control*, 10: i12-i16, 2001.

Shiffman, S., Pillitteri, J.L., Burton, S.L., Di Marino, M.E. Smoker and ex-smoker reactions to cigarettes claiming reduce risk. *Tobacco Control*, 13: 78-84, 2003.

Hoffman, D., Hoffman, I. The changing cigarette, 1950-1995. *Journal of Toxicology and Environmental Health*, 50-307-364, 1997.

National Cancer Institute, *Smoking and Tobacco Control Monograph No. 13. Risks associated with smoking cigarettes with low-machine measured yields of tar and nicotine.* National Institutes of Health, NIH Pub. No. 02-5074, 2001.

National Cancer Institute, *Smoking and Tobacco Control Monograph No. 7. The FTC Cigarette Test Method for Determining Tar, Nicotine, and Carbon Monoxide Yields of U.S. Cigarettes, Report of the NCI Expert Committee*, National Institutes of Health, NIH Publication No. 96-4028, 1996.

Wilkenfeld, J., Henningfield, J., Slade, J., Burns, D., Pinney, J. It’s time for a change: Cigarette smokers deserve meaningful information about their cigarettes. *Journal of the National Cancer Institute*, 92(2): 90-92, 2000.

Wilkenfeld, J., Henningfield, J., Slade, J., Burns, D., Pinney, J. Response to FTC’s Response to: It’s time for a change: Cigarette smokers deserve meaningful information about their cigarettes. *Journal of the National Cancer Institute*, 92(10): 842-843, 2000.