

Draft: 12 November 2007

Oral Statement of  
Jack E. Henningfield, Ph.D.

Vice President, Research and Health Policy  
Pinney Associates, Bethesda, Maryland  
and  
Professor of Behavioral Biology, Adjunct, and  
Director of the Innovators Awards Program  
Department of Psychiatry and Behavioral Science  
The Johns Hopkins University School of Medicine

Before the

The United States Senate  
Commerce, Science and  
Transportation Committee

Subcommittee on Consumer Affairs

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

Tuesday, November 13, 2007 @ 2:30pm  
Room 253, Russell Senate Office Building

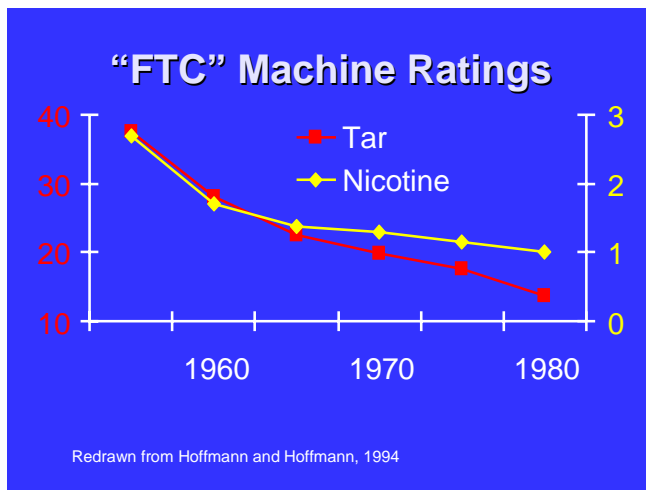
Senator Lautenberg, thank you for the opportunity to testify. For three decades, I have studied drug addiction and tobacco use at Johns Hopkins Medical School, the National Institute on Drug Abuse, and Pinney Associates, consulting to GlaxoSmithKline on smoking cessation medications. I provide additional detail in my submitted testimony.

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.

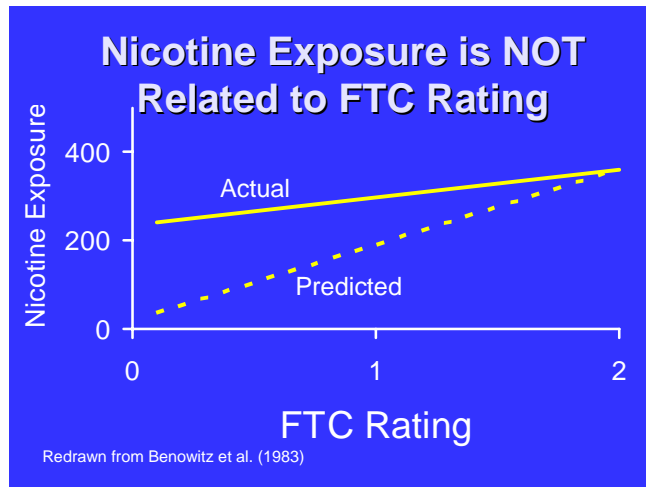
### THE PROBLEM

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. 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 published one of the seminal studies. His study showed that light cigarette did not deliver less nicotine. In fact, as shown by the solid line in this figure, actual nicotine exposure was not related to FTC rating. The dotted line shows what scientists had expected, what the companies advertised, and what consumers wanted: lower levels of exposure from cigarettes with lower ratings.



This problem was confirmed by FDA and acknowledged by FTC in the 1990s. In 2001, National Cancer Institute Monograph 13 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. 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.

### Cheating FTC: Vent Holes, Filter Overwrap, Burn Accelerants, Selective Filtration



### 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. 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., Hering, 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.

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.