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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

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Family Smoking Prevention and Tobacco Control Act

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Summary of Jack E. Henningfield's Testimony for October 3, 2007

FDA regulation of tobacco products is urgently needed to protect public health. More than 3 million Americans have died prematurely since the Supreme Court rejected the FDA's short-lived effort to regulate tobacco under the provisions of its 1996 Final Rule and assertion of jurisdiction. Although we have made progress in reducing tobacco use, I believe FDA regulation would have made the progress significantly greater.

The FDA regulation envisioned in H.R.1108 will strengthen efforts to prevent children as well as adults from initiation of tobacco use and escalation to daily use and addiction by restricting marketing and potentially reducing product innovations intended to appeal to children.

FDA regulation will support cessation of cigarette smoking and other types of tobacco product use by providing more effective communications about the risks of smoking and the ability to flexibly alter them as appropriate – a strategy demonstrated effective in Canada, Australia and other countries.

FDA regulation under H.R.1108 will substantially reduce the presently deceptive practices of the tobacco industry such as marketing "light" cigarettes with their implied health claims that the NCI, CDC, WHO, and other expert agencies have recognized offer no health benefit; yet today more than two thirds of all smoker smoke such cigarettes, many under the illusion that they are less harmful than so-called full-flavor cigarettes.

Tobacco products are complex drug delivery systems. FDA is uniquely qualified to evaluate drug delivery systems to determine actual dosing capacity and potential exposure to drugs, and other ingredients.

FDA is uniquely qualified to develop the performance standards provided for under H.R. 1108 for ingredients and designs that, over time, could lead to less addictive and less harmful products.

FDA is uniquely qualified to evaluate product claims under H.R. 1108 such as those related to harm reduction and to ensure that if such claims are approved that there will be safeguards to minimize unintended consequences, detect them in a timely fashion, and issue corrective actions as necessary.

New generations of tobacco products are already being unleashed unto consumers who are unsuspecting guinea pigs in experiments with results unknown for decades in the absence of regulation. FDA is uniquely qualified to evaluate new products and determine which should be allowed and what special constraints and allowances should be made.

Finally, nicotine is regulated in medicines to prevent dangerous and overly addictive exposure and it must be regulated in tobacco products where content and delivery are often much higher than is allowable in medicines. For example a typical "pinch" of some of the most popular snuff products contains 10-20 mg nicotine compared to 4 mg in the highest allowed dose of nicotine gum or lozenge.

Full written submitted testimony upon which my oral comments will be based.

Thank you for the opportunity to testify on H.R. 1108, the Family Smoking Prevention and Tobacco Control Act, that would provide "*the Food and Drug Administration with effective authority to regulate tobacco products.*" FDA regulation is not only the right thing to do, it is urgent. More than 4 million Americans have died prematurely since FDA asserted jurisdiction and issued its Final Rule to regulate cigarettes and smokeless tobacco in 1996. Although we have made modest progress in reducing tobacco use, I believe FDA regulation would have made the progress significantly greater. Furthermore, the tobacco industry is unleashing new products, new claims, and clandestinely modifying conventional products at a terrifying rate, with no plausibly-effective regulatory mechanism in sight, except for the approach embodied in the Bill. Even the FTC has thrown in the towel and apparently given up on its own widely criticized and deeply flawed method of cigarette testing.

Basis for Testimony

I am speaking on my own behalf and not as a representative of the organizations, of which I am a member, consult for, or voluntarily serve. I am an Adjunct 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. I was trained in behavioral science, pharmacology, and other disciplines relevant to understanding addictive substances. I have focused on tobacco-related issues for nearly three decades. From 1980 to 1996, I conducted and led tobacco and other drug research at the National Institute on Drug Abuse (NIDA). While at NIDA, I was liaison frequently to the FDA on tobacco products and tobacco addiction treatment. I contributed to numerous Surgeon General's reports as well as reports by other agencies. I presently serve on the World Health Organization (WHO) Tobacco Regulation Study Group (TobReg) which provides scientific guidance for implementation of several articles of the international tobacco treaty, the WHO Framework Convention on Tobacco Control (FCTC); a treaty (signed by not yet ratified by the United States) which includes many directives in harmony with the proposed FDA tobacco regulation.

By further way of disclosure and to provide you with some basis for my perspective, let me tell you that part of my role at Pinney Associates is to advise companies on how to minimize the risk of abuse, addiction, misuse and harmful effects of drugs with a known or suspected potential to cause addiction, including opioid analgesics, stimulants, sedatives, and many others. In many cases it is not only the chemical entity itself but the formulation and marketing of the drug that poses the challenge for risk minimization. This work includes advising GlaxoSmithKline Consumer Healthcare on its treatments to help people quit smoking. I also share two patents on a tobacco dependence treatment product under development which has given me additional perspectives on FDA regulation. On the tobacco side, I have reviewed thousands of pages of previously secret document and testified on behalf of the US Department of Justice (DOJ) and other plaintiffs against the tobacco industry concerning the many ways by which this industry has been able to manipulate its products to heighten their addiction risk under the cover of darkness left by the regulatory vacuum. I have gained first hand experience in understanding the challenges and benefits of FDA regulation of the tobacco industry and its products through these activities.

Tobacco products are sophisticated drug delivery systems – engineered and manufactured to increase their potential to cause and sustain addiction

Tobacco products are diverse and all are harmful and share the common feature of being designed to cause and sustain addiction to nicotine. The World Health Organization said in its 2006 World No Tobacco Day report, an effort to which I contributed: *all tobacco products are deadly and addictive in any form or disguise*. Products vary widely in their form and degree of sophistication in engineering. The most elaborately designed and manufactured product, the cigarette, accounts for the vast majority of the more than one thousand tobacco-attributable deaths that occur every day in the United States.

For most consumer products, extensive research and design expertise by manufacturers is often used to improve safety and reduce risk. However, this is not true for cigarettes: much of the research and engineering has been dedicated to increasing their risk of causing and sustaining addiction and high levels of use. In fact, many features are intended to make it easier to inhale the deadly poisons deep into the lungs where the damage is greatest. Why? Because this increases the addictive impact of nicotine by producing explosively fast absorption in the massive alveoli bed of the lung. This undoubtedly helps explain why lung cancer risk increased in the 1980s and 1990s even though machine measured tar levels declined. It also may help to explain the increasing proportion of the especially deadly deep airway small cell adenocarcinomas relative to squaemous cell lung cancer in the recent decade.

Cigarette design and manufacture is extensively researched and engineered to control features that contribute to deceiving smokers into thinking they are getting less harmful exposures, to make it easier to take up smoking, and to cause and sustain addiction. Much of this was summarized in the FDA's Final Tobacco Rule (1996) and more recently in the 1700-page findings by Judge Kessler in her ruling in the U.S. Department of Justice litigation against the tobacco industry. She wrote: "*Every aspect of a cigarette is precisely tailored to ensure that a cigarette smoker can pick up virtually any cigarette on the market and obtain an addictive dose of nicotine.*" (Paragraph 1368). Further, Judge Kessler concluded: "*Defendants have designed their cigarettes to precisely control nicotine delivery levels and provide doses of nicotine sufficient to create and sustain addiction*." (Paragraph 1366)

The remarkable range of features includes control over the following aspects of cigarette design, delivery, and addictive impact. Ignition propensity and burn rate are controlled with burn accelerants and paper porosity to help control nicotine dosing and make cigarettes convenient to use. Smoke particle size is engineered to facilitate efficient inhalation of smoke deep into the lung. Smoke temperature and harshness are controlled to make it easier to take up smoking, to inhale deeply and provide smoother smoke that fools the smoker into assuming it not as harmful. Smoke and ash color are controlled with chemicals in the tobacco and paper to make the process as neat and attractive-appearing as possible. Ingredients are further added to smooth, flavor and make the smoke more attractive to target populations, even if they yield additional carcinogens to the smoke (such as burned chocolate does). Still other chemicals are added that prolong shelf life and control humidity, which, in turn, helps control nicotine dosing and smoke sensations. The inclusion of some of these ingredients on FDA's Generally Recognized as Safe (GRAS) list is virtually meaningless when they are used in cigarettes. These ingredients have not been tested

and approved for use in burned products. They are "GRAS" for use in food, not for inhalation in combination with burned tobacco material.

A number of chemicals used in manufacturing process further alter the addictiveness of the product through manipulation of the chemical form of nicotine (e.g., ratio of free-base or unionized nicotine to ionized nicotine). These compounds increase the amount of free base nicotine, probably increasing the addictiveness of cigarettes because free-base nicotine is more readily released from the cigarette and absorbed in the mouth. For example, ammonia compounds can alter the free base fraction of the smoke while also making it easier to inhale. The practice of manipulating the free base fraction of nicotine is not unique to cigarettes: smokeless tobacco products marketed as "starter" products (an industry term) are mildly alkaline to yield a smaller proportion of free base nicotine than the more alkaline maintenance products such as Copenhagen. Why? Too much nicotine delivered too rapidly to the novice user can cause acute nausea and discourage further use. By contrast, highly tolerant smokeless users who have "graduated" (another industry term) to higher levels of daily use seek stronger and faster doses to satisfy their addictions.

Cigarette filter technology is also extremely sophisticated and reduces certain throat burning sensations but not necessarily the deadliest of the toxicants. Filters can help ensure that nicotine is readily delivered in a form that can be easily inhaled deep into the lung where addiction potential is maximized, and lung disease risk is increased by the inhalation of smoke particles that carry nicotine molecules into the lung. Filters also commonly include elaborate ventilation systems (described in greater detail below), which can increase the free-base fraction of nicotine and enable smokers to obtain addictive levels of nicotine regardless of its advertised yield.

It is time to rein in the addictiveness and harmfulness of tobacco products by giving FDA the authority to enact performance standards to regulate and restrict levels of ingredients (added or residual) that are toxic, and to reduce the ability of the industry to maximize the addictive potential of their products.

It is vital to give FDA the authority to regulate tobacco products and develop product performance standards as will be accomplished through H.R. 1108. FDA could develop performance standards that, over time, could lead to less addictive and less harmful products. One key feature of the legislation is that mere compliance with a performance standard cannot be used as the basis for product claims. This will help ensure that communications about the dangers are not weakened. After all, the products will still remain highly toxic and addictive by any ordinary standards and communications should not be used to imply anything contrary to these facts.

Performance standards can and should be developed for all smoke constituents including those that affect addictiveness and attractiveness as ammonia compounds, acetaldehyde, menthol, flavorings, as well as substances emitted in the normal course of use of the products, such as carbon monoxide gas and carcinogens. In addition, performance standards could cover substances that may not have been intended for the final product but are residual from tobacco growing, storage and processing, such as pesticide and herbicide residues, as well as contaminants including heavy metal residues, cyanide, insect parts and other materials.

Performance standards can also be developed for product emissions commonly known as tar but which include deadly carcinogens such as tobacco specific nitrosamines, and formaldehyde.

Nicotine content and dosing need to be regulated. Nicotine is regulated in medicines and it must be regulated in tobacco products where content and delivery are often much higher than is allowable in medicines. For example a typical "pinch" of some of the most popular snuff products contains 10-20 mg nicotine compared to 4 mg in the highest dose of nicotine gum or lozenge.

Tobacco delivered nicotine, particularly from cigarettes, is particularly addictive because of the various ingredients and design features that function to increase the addictiveness of the products. For example, the level of free base nicotine allowed in cigarette smoke needs to be examined and considered for performance standard development. Other ingredients that appear to synergistically increase the addictiveness of the product such as acetaldehyde need to be examined from this perspective in performance standard development.

Perhaps most controversial is whether performance standards should be developed with the intent of phasing nicotine out of cigarettes. I have published papers on the potential benefits (e.g., making tobacco products less addictive) and obstacles (e.g., precipitating increased use, mass withdrawal, and inadequate treatment infrastructure for tobacco dependence) for such an effort. However, I am in agreement with the World Health Organization, that at present it would be premature to attempt to drastically alter levels through regulation. The bill will give FDA the flexibility and authority to develop the additional science, as necessary, to set performance standards for nicotine content and delivery.

Regulatory flexibility to address emerging science and evolving products is part of FDA's strength that will be enabled by the Bill. If we think of tobacco products as analogous to deadly globally spread viruses, then we must also think of them as constantly evolving, requiring vigilant oversight and the sort of authority to regulate that FDA exerts over foods and drugs. This means that performance standard setting and evaluation will be a continuous process as long as tobacco products are marketed. This is also important because we need to assume that in any science-based regulatory process, new science will emerge that requires an agency like FDA to reconsider and, if needed, modify previously issued regulations. By contrast, as described below, the light cigarette fraud emerged and persisted over several decades and was not even irrefutably unmasked until the 2001 publication of National Cancer Institute Monograph 13. But yet the fraud continues unabated in the regulatory vacuum!

Product misrepresentation, health and harm reduction related claims need to be regulated
With the recognition by the Surgeon General in 1964, that cancer risk was related to overall tobacco exposure, cigarette smokers were encouraged to quit. Those who did not quit were encouraged to reduce their exposure. The focus was on "tar" because this conglomerate smoke condensate contained many substances that separately and together were clearly implicated in cancer and lung disease. This gave birth to the Federal Trade Commission's method for tar and nicotine assessment and communications. Nicotine was included in part because of its presumed role (probably over estimated at the time) in heart disease. The intentions of the FTC were good but it is not a science and health agency, and it adopted a method that was well understood and

easily defeated by the tobacco industry. Armed with a flawed method and little expertise in understanding drug delivery systems, assessing drug delivery, or monitoring and evaluating health effects, the FTC was no match for the tobacco industry. The industry co-opted the FTC's ratings of tar and nicotine as marketing tools to reduce smokers concerns about smoking. By designing cigarettes that generated lower tar and nicotine ratings, labeling those below certain levels "light" and "reduced tar and nicotine" the industry had a powerful force to prevent or at least delay life-saving smoking cessation by many people.

After reviewing evidence and listening to various experts, Judge Kessler, in the *Findings* from the DOJ trial concluded as follows: *"they [tobacco company defendants] also knew that the [FTC] Method was totally unreliable for measuring actual nicotine and tar any real life smoker would absorb"* (Paragraph 2627). Further, *"By engaging in this deception, Defendants dramatically increased their sales of low tar/light cigarettes, assuaging fears of smokers about the health risks of smoking…"* (Paragraph 2629)

The light cigarette fraud continues: Regulation is needed to prevent deceptive designs that are killing Americans

Today, more than two thirds of cigarette smokers smoke light cigarettes. My sister was one of them. As she told me: "You can tell Reds (Marlboro Regular Cigarettes) are worse: they felt stronger and left my throat raw compared to Lights. Let me tell you a few things she didn't know and that angered her when she found out. She assumed that there were government standards for light cigarettes and that the FTC testing method intended to measure tar and nicotine yield reflected health effects or at least actual intake as is the case for food labeling. She assumed that cooler, smoother smoke meant that it was weaker and less harmful. She had no idea that a hidden ventilation system was diluting the poisons for smoking ventilation by allowing fresh air to be "inhaled" by smoking machines, whereas she and other smokers were probably taking in two to three times as much tar and nicotine than indicated by the ratings. She couldn't believe "the government" would allow such a scam.

Since the light and low-tar scam began with a vengeance in the late 1960s America has lost tens of millions of its citizens prematurely as they smoked light cigarettes to their graves, all the time not knowing that tobacco industry marketing of "light" and "low" cigarettes was completely misleading and that these products were not any less harmful than other cigarettes. In 2001, the National Cancer Institute in Monograph 13 finally concluded definitively: "Epidemiological and other scientific evidence… does not indicate a benefit to public health from changes in cigarette design and manufacturing over the past 50 years."

How did it happen? What can we learn? Looking into lights – through their holes.

Most aspects of cigarette design that contribute to harm and addiction require sophisticated equipment and procedures to detect, such as CDC's approach to measuring free-base nicotine. However, cigarette ventilation is one deadly scam you can see for yourself. If you tear the filter paper from a cigarette filter and hold it up to the light, you can see bands of tiny vent holes about 3/8 to 1/2 inch out from the filter end. This is right where they can be easily covered with lips or fingers. Unbeknownst to most cigarette smokers, blocking of the holes with lips or fingers can easily double or triple delivered tar and nicotine. On most cigarettes they are difficult to see because the designs that are intended to hide them. When the cigarettes are smoked according to

the FTC method, the holes leak anywhere from about 20-90% air into the testing apparatus, thereby contributing to the deceptively low advertised rating. I did this demonstration a few years ago for my son Vincent's third grade class and his classmates reacted with clarity and passion. Their comments included: "that's cheating!" and "they [the companies] can't do that".

By analogy, this is like punching holes in a fruit drink container, allowing some of the beverage to leak out, *then* testing the residual beverage for calorie and sugar content and listing those figures on the box even though consumers may consume several times more sugar than was listed on the package or in advertisements. That would be cheating, and there is a means of stopping and preventing it with food products, but not for tobacco products – not until tobacco is regulated by FDA, which routinely addresses such issues with food and drug products. In fact, for any food or beverage in America, including Kraft cheese, Miller Lite beer, Oreo cookies, and potato chips made by tobacco company affiliates, such fraudulent misrepresentation of products can result in the products being pulled from shelves and/or penalties. Manufacturers can't even claim dog food is low fat if it is not true. Companies that market addictive drugs for therapeutic use must formulate and market them to reduce risk of addiction and other adverse side-effects, or the drugs can be refused approval, pulled from the market, or be subject to new limitations on marketing, as has happened to several potentially addictive medications in recent years. Tobacco products are not therapeutic but many of the same principles apply.

"Light" and "low tar" cigarettes can be considered the first generation of putative but fraudulent "harm reduction" products designed to address smokers concerns about health but not really to reduce their health risks. Light cigarettes may just be the tip of the iceberg though.

New generations of products appear to be following the commercially effective model of light cigarettes, which is to ensure that new products are highly addictive to sustain use, with designs and marketing efforts to assuage fears about tobacco. There is the theoretical potential to reduce actual toxin exposure and an Institute of Medicine Report released in 2001 acknowledged this, giving the potential product category a new name: Potential Reduced Exposure Products or PREPS. It urged, however, regulation by FDA to provide a framework for evaluation of the products, determine what communications would be appropriate, and monitor their use and impact. Absent with such regulation, products termed PREPS by an unfettered industry could be the next generation of lights, further undermining prevention and cessation, and killing many of their users.

Fortunately, we have learned a lot in the past decade that will arm FDA in its regulation of PREPS, lights, and all other tobacco products. Much of this information emerged thanks to the 1990s investigation by FDA as part of its Tobacco Rule development. More information emerged through litigation against tobacco companies that made public millions of pages of previously secret internal tobacco industry documents, giving birth to a new research discipline called "tobacco document research," which involves increasingly sophisticated analysis to determine what the industry knew about health effects and addiction engineering, as well as many of its actual practices. We also have empirically derived knowledge from NIH and CDC research relevant to tobacco product design and effects. Perhaps most importantly, we have learned, through the tobacco industry documents, how much more the industry knows than it discloses, how much it knows about designs and ingredients to heighten addiction risk, and how

much more we need to learn if we are to more effectively prevent continued product manipulation. I believe that an empowered FDA could demand and evaluate such information, and put it to use to serve public health.

For example, as you have learned, the State of Massachusetts cigarette testing program shows nicotine levels had gradually increased in many brands since the late 1990s. There has been considerable debate as to why this was done. My opinion is that this was done to make it easier for cigarette smokers to get their daily addictive fix of nicotine when faced with restrictions on smoking and higher costs that drive their daily cigarette intake down. To tobacco companies, keeping their customers addicted and satisfied is better than allowing cigarette smokers to reach that point that sustaining nicotine is such a hassle that they are more driven to quit. However, that is my opinion, and in the absence of regulatory oversight there is no way to find out the basics: the how, what, why and when. You see, regulation would give FDA the authority to demand an explanation and even to ban the manipulation if it deemed that it was contrary to the interests of public health. FDA could freeze levels; it could even require reduction of various toxicants and nicotine over time.

It is time that the American public be truthfully told what the tobacco industry knows about the ingredients, delivery, and effects of the products, and that the products they buy and use are honestly labeled regarding ingredients and maximum possible exposure levels. We would not tolerate such deception with food manufacturers or the makers of any other products consumed by Americans. It is time to stop protecting the tobacco companies and start making them play by the same rules as the manufactures of other products consumed by Americans. The deception continues and is poised to worsen: tobacco products are mutating undeterred by regulatory oversight. Learning the truth and developing appropriate communications for consumers for existing products and the pipeline of new drugs or consumed products, is central to FDA's mission.

Absent regulation, the deadly deception I have described continues. Cigarettes and smokeless tobacco products are designed to addict, designed to go beyond the addiction risk of their relatively crudely manufactured ancestors. Cigarettes are designed to taste smooth and garner misleadingly-low tar and nicotine ratings because consumers react to such information as meaning substantially-less harmful. Tobacco products are researched, designed, manufactured and marketed to maximize the likelihood of trial, the graduation from trial to addiction, and to retain their addicted users despite efforts to quit. Products are fine tuned to attract various populations, including the young, with flavors, designs, and dosing characteristics. This is far beyond simply satisfying existing needs and desires of adults.

And the problem appears to be worsening: More Americans than ever before are concerned about smoking, and want to quit. But without regulation these individuals will turn to light cigarettes or new tobacco products that falsely claim (at least implicitly) to be less harmful. These products have been shown to reduce the motivation to quit smoking because of the false reassurance that the smoker is "doing something" that represents a healthier step in the right direction. But delaying tobacco cessation is deadly: disease risk is more strongly related to years of smoking than to the number of cigarettes smoked per day.

Worse still, the pipeline of new products and claims is growing. Some of you may have seen advertisements in widely-circulated magazines such as Parade, trumpeting cigarettes such as Omni and Eclipse that are "lower in carcinogens" and "may present less risk of cancer, chronic bronchitis and possibly emphysema." Eclipse, delivers very high levels of the deadly odorless gas carbon monoxide. Marketed versions were also reported to deliver glass fibers from its aluminum and glass inner chamber that can penetrate the lung.

Philip Morris is now test marketing what many smokers might be truly waiting for, a Marlboro with reduced risk claims: Marlboro Ultra Smooth. Philip Morris has admitted that it is premature to make harm reduction claims for the product though they tout the product's potential to reduce exposure to harmful substances. In the void of regulation, however, Philip Morris is test marketing the product and creating the illusion of reduced harm with through its clever name and descriptions of the potential of the product to reduce certain substances. Furthermore, it is using messaging such as "Filter Select" and "new carbon filter" which might be reasonably construed by a consumer to indicate advances in filtration of harmful elements.

One widely-advertised cigarette, Quest from Vector, even claimed to be "nicotine free" supporting the claim by asserting it met the "standard" of Benowitz and Henningfield. Now, without detracting from my own work with Dr. Benowitz, we are not FDA, and we never intended a recommendation for reducing the addictiveness of cigarettes to stand in place of FDA evaluation and regulation. This would be laughable if it were not deadly and still being perpetuated.

I am not here to testify, that products such as Quest and Marlboro Ultra Smooth are in fact as deadly as conventional products. The problem is there is no way to know if they are potential steps in the right direction or as fraudulent and deadly as light cigarettes. And there will be no way to tell until we have an authorized and empowered FDA to find out.

There is also an increase in widely advertised smokeless tobacco products from "for when you can't smoke," implying you don't need to quit smoking because you can use their products when you can't smoke. The lure is increased by touting new products and implied benefits. One product is packaged to resemble a medicinal cessation product with its label reading "for when you can't smoke." These manufacturers are using Americans as guinea pigs without informed consent. They are introducing new products; modifying products with new designs and ingredients; and making claims, implicit and explicit, without regulatory oversight from the one agency, FDA, that is charged with the oversight of consumable products that have health effects, and require consumer communications that are honest and do not mislead. These efforts not only are deceptive, they help the industry thwart tobacco prevention and cessation efforts.

Regulation is overdue and urgent

For several decades, the tobacco industry anticipated but fought FDA regulation, as illustrated by Philip Morris scientist William Dunn's warning to his superiors in 1969: *"I would be more cautious in using the pharmic-medical model – do we really want to tout cigarette smoke as a drug? It is of course, but there are dangerous FDA implications to have such a conceptualization go beyond these walls."* Dr. Dunn was right in his apparent assumption that FDA authority could have reined in many deceptive practices of the tobacco companies.

FDA is the right agency and the only agency with appropriate experience to develop and enforce product performance standards.

I have heard the entire range of arguments about why FDA should not be granted regulatory authority, including that FDA was not designed to evaluate cigarettes. The fact is that FDA was designed to assess safety, ingredients, and resultant exposure to a broad range of drugs and foods. Tobacco products are drug delivery systems at heart. They are sophisticated and complicated with many ingredients, just as many drugs are. Even the tobacco industry admits this in their documents. Moreover, they are designed to deceive, and designed to heighten addiction risk.

Foods and drugs that are designed and/or marketed to deceive, whether by intent or not, can be judged as misbranded or recalled, and lead to various correctional actions ordered. This happens frequently and routinely many times each year for foods and drugs. FDA has more experience and sophistication in the regulation of drugs and drug delivery systems than any agency in the world. This is the same expertise that needs to be applied to tobacco.

For any product, whether food, drug or dog food, FDA can ask and must be given answers to the basic questions that many consumers of those products undoubtedly believe are being addressed for tobacco products: WHO is the product for? WHAT is in it? WHY is it designed and manufactured as proposed or done? HOW is it manufactured? WHEN were changes made? FDA can require surveillance to detect unintended consequences of products already marketed or proposed for marketing approval if it has residual concerns.

Finally, what is communicated to consumers about product content will be vital, so that eventually tobacco products, like other consumable products, are labeled in meaningful ways that do not confuse or obscure the truth, do not inappropriately make or imply claims, and do not unintentionally undermine efforts to prevent tobacco use from beginning and tobacco users from quitting.

FDA's authority will not make tobacco products safe, and should not be seen as a substitute for comprehensive tobacco control efforts to reduce all forms of tobacco use and disease. In fact, FDA regulation should be viewed as a partner in these efforts and be positioned to serve these efforts because it will restrict the ability of the industry to modify products and descriptors to undermine prevention and cessation. For all of these reasons and more, FDA regulation of all tobacco products is vital in setting our nation on a healthier path. Directing the FDA to develop its regulatory system with urgency, empowering it to rise to the challenge of tobacco regulation, and providing it with the support to get the job done can be accomplished through H.R. 1108.. I therefore urge its most expeditious passage and implementation.