Testimony of

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Regarding the Family Smoking Prevention

and Tobacco Control Act

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Mr. Chairman and Members of the Committee,

The public trusts the Food and Drug Administration (FDA) to safeguard the medicines and food products that contribute to good health and well-being. Having served as a member of an FDA advisory panel, I have great respect for this agency's work in assuring the safety of medications and medical devices used in the diagnosis and treatment of disease.

As we have known for decades, cigarettes are the nation's leading cause of cancers, heart disease, and emphysema. Placing our most lethal consumer product under the control of the Food and Drug Administration makes no sense. Asking this agency to promulgate "product safety standards" for this death-dealing device is an oxymoron and will perpetuate the myth that cigarettes can be made safer. Safer than what, one might ask, fresh air?

The championing of this bill by Philip Morris USA, America's top cigarette manufacturer with 50% of the market, should prompt skepticism about the measure and its alleged public health benefits. Reading the fine print bears this out. Consider these three points:

First, the bill would stringently regulate new and potentially less hazardous tobacco products but would not apply these same standards to the most harmful form of tobacco, namely Marlboro and other existing cigarettes which cause the deaths of nearly half a million Americans each year.

Second, although the bill will enable the FDA to prevent the introduction of new cigarette brands, it seems inappropriate for the protection of public health that the bill permits Marlboro and the other most popular existing cigarette brands to remain on the market, even though they are far and away the leading public health threat.

Third, although the bill specifically bans the use of strawberry, grape, chocolate, or similar flavoring additives in cigarettes, it does not require the FDA to eliminate (or even reduce the level of) toxic gases, including hydrogen cyanide or the more than 40 known cancer-causers in cigarette smoke such as benzene and radioactive polonium. The agency would be given the authority to take such action but there is no mandate to regulate these poisons.

The only sensible and ethical action for a health agency charged with regulating cigarettes could be to ban them, which is an unrealistic prohibition.

As Yogi Berra would say, this bill is déjà vu all over again. For more than 70 years, every newly published scientific report on the countless diseases caused by cigarette smoking was disputed by the tobacco industry, which claimed more research was needed and which promised to remove any constituents of smoke that might be found to cause disease. This led to a proliferation of marketing gimmicks to allay growing public anxiety about smoking, foremost among them filters that promised “Double-barrelled health protection,” or claimed to be “Just what the doctor ordered,” or in at least one instance was made of asbestos.

In spite of the fact that the cigarette filter does not confer any reduced health risk whatsoever, more than 95% of persons who smoke buy filtered brands in the false belief that they are safer. The second most sensible and ethical action for a health agency charged with regulating cigarettes would be to ban the filter, but this would hardly pass muster with Philip Morris.

When the Federal Trade Commission mandated that tar and nicotine levels be printed on cigarette packs and in advertisements, tobacco companies were only too happy to engage in a "tar derby." "Carlton is lowest," was a long-running ad campaign. "It's Official: US Government proves NOW is lowest," was another. Few consumers caught on that such numbers are meaningless. It's akin to advertising Wonder Bread as having "only one ounce of poison in every loaf" or Campbell's touting its soups as "low-arsenic." Hardly a week goes by when a patient doesn't proudly tell me, "But Doc, I smoke Carlton 'cause it's got only 1 milligram of tar." I try to tell these women they're being duped, but it's very difficult.

History has shown that the tobacco industry has outwitted us at every attempt to impose federal regulation on cigarette manufacture and marketing. The main goal of the Federal Cigarette Advertising and Labeling Act of 1970 was to remove cigarette ads from the broadcast media. Yet no sooner had cigarette commercials left the airwaves than televised sporting events such as NASCAR Winston Cup and The Virginia Slims Women's Tennis Circuit began airing for hours on end, providing even greater cigarette brand name exposure than ever before. Today we still see Marlboro logos on televised auto racing worldwide.

Tobacco companies have also outmaneuvered health advocates who believed they had found a way to utilize the industry's money to fund anti-smoking education. The Master Settlement Agreement of 1998 has resulted in a tiny fraction of settlement funding being directed toward smoking prevention and cessation programs. Only four states are currently allocating to tobacco prevention the minimum amount recommended by the Centers for Disease Control and Prevention; all told, only 2.6% of tobacco revenues are being spent on tobacco prevention and cessation.

Meanwhile, Philip Morris has not skipped a beat in cultivating financial relationships with dozens of career centers at universities across the country in an aggressive attempt to recruit college students as Marlboro sales interns and Marlboro territory sales managers. Thus these well-educated individuals who are least likely to smoke are being hired to promote cigarettes to the least educated and poorest sectors of our population. Bold ads in college newspapers brag about Philip Morris' innovative, redefined marketing strategies. When I asked one student why he was interviewing with Philip Morris, he told me "It's a great company. They don't just sell cigarettes. They help prevent smoking."

Instead of concentrating on regulation, we should be putting most of our efforts into reducing demand, especially major multimedia paid counter-advertising campaigns that young people will see daily and remember. In other words, we need to fight smoke with fire.

Research has documented that the kinds of marketing restrictions imposed by this bill are not effective in reducing youth exposure to cigarette advertising. There are simply too many venues for tobacco companies to market their products, and anything short of a near-total ban on advertising and promotion of tobacco products (which could violate the First Amendment) is unlikely to have a substantial effect on youth smoking.

There is no evidence that the system of product safety standards set up by the bill would result in a safer product. Essentially, the bill gives the FDA a mandate which it cannot carry out. The only way to know whether any reductions in specific constituents of tobacco smoke would result in a safer product would be to conduct long-term studies, using smokers as guinea pigs. Perhaps some would view that as acceptable because the product is dangerous anyway. However, the problem is that smokers are going to assume that these reduced exposure products are safer.

There are an estimated 40 compounds in tobacco smoke that cause cancer. What sense does it make to require the manufacturers to take out two or three of them or even 25? What if smokers then believe that this is a safer product and start smoking more? This approach will kill people, not save lives.

The bill would make it virtually impossible for modified risk products to enter the market, while at the same time permitting reduced exposure products to be falsely marketed as reduced risk products. At least that's how consumers are going to perceive them. How else would someone interpret a claim of reduced exposure?

The bill will diminish the public's appreciation of the inherent, irredeemable harmfulness of cigarettes. By promulgating health standards, the FDA will be fostering the perception that cigarettes are now safer to smoke. Few of my patients who still smoke realize that there are 4000 poisons and 40 cancer-causers in cigarette smoke. If they are told that the nitrosamines have been reduced or removed, they are going to assume that a problem has been taken care of. Since we know that smoking prevalence is directly proportional to the degree of perceived harm from smoking, this will

lead to an increase in smoking prevalence, compared to what would have occurred without this bill.

In her opinion in the Department of Justice lawsuit against the tobacco companies, Judge Gladys Kessler ruled last year that decade after decade the defendants had engaged in fraud by marketing cigarettes that rated lower tar and nicotine yields via machine testing in a way that misled consumers to believe that these product offered a health benefit over higher machine-yield products. The basis of her decision was the body of literature demonstrating that machine-yields of nicotine and other tobacco smoke constituents have no direct relationship with actual human exposure, and thus with actual health risk, either on an individual or a population level.

The bill implies that reductions in nicotine yields would be a good thing. But the reality is that reduced nicotine yields could be harmful to public health because they would likely increase cigarette consumption due to the smoker compensating by inhaling more deeply leading to increased exposure to poisons (tar and toxic gases) and resulting in higher rates of lung cancer and emphysema.

The proposed FDA bill will simply change who is committing consumer fraud. Currently, it's still the cigarette companies, marketing reduced tar and nicotine cigarettes in a way that deceives consumers into believing that these products are known to be safer. If the FDA bill is enacted, then the government will be doing the dirty work. Small wonder why Philip Morris embraces this legislation. It completely removes the risk of litigation for fraud, yet allows the tobacco companies to tell consumers that they are complying with stringent product safety standards, assuring a safer product produced under the nose of the FDA.

In summary, I regret that there is no evidence to suggest that this bill will save any lives at all. To the contrary, there is well-documented evidence to suggest that the legislation will not reduce the risks of cigarette smoking. The bill is likely to cause harm through its grandfathering of high-risk products; its hindering of the introduction of reduced risk products; its eliminating litigation for fraud; and its inhibiting tougher state and local legislative tobacco control efforts.

However well-intended, the Family Smoking Prevention and Tobacco Control Act is misguided. While setting up an impossible standard for new

products, it gives the most harmful (and most consumed) existing product a free ride. This bill could well become known as the Marlboro Protection Act. At the very least, it should come with its own Surgeon General's warning: "This legislation is harmful to public health."

This submission is an extension of a commentary in the medical journal, *The Lancet*, co-authored with Michael Siegel, MD, Professor of Social and Behavioral Sciences, Boston University School of Public Health. (Siegel M, Blum A. FDA regulation of tobacco: reprieve for the Marlboro man? *Lancet* 2006; 368: 266-68.) I also relied on additional critical analysis of the Family Smoking Prevention and Tobacco Control Act by Dr. Siegel (mbsiegel@bu.edu).

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