

Submission of Alan Blum, MD

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Regarding "H.R. 1108, Family Smoking Prevention and Tobacco Control Act"

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The mission of the Food and Drug Administration (FDA) is to ensure product safety and to approve medications that treat disease, not substances that cause it. By all accounts, the FDA is struggling with the challenge of regulating an expanding universe of products and threats. It is the wrong agency at the wrong time to undertake oversight of tobacco products.

By having to promulgate health standards for cigarettes, the FDA will be communicating the perception that they are now safer to smoke. Thus HR 1108 will increase doubt among consumers that cigarette smoking is truly injurious and lethal.

The tobacco industry will most assuredly take advantage of this bill to remind consumers through the broadcast and print media and the internet that cigarettes are now regulated by the same agency that oversees the safety of our food and medicine.

Industry leader Philip Morris, maker of the world's top-selling cigarette, Marlboro, is already testing the waters. It's setting a new standard for chutzpah, by enlisting the nation's doctors in spreading the company's deceitful propaganda. For the first time in more than half a century, the cigarette giant is communicating directly to physicians by means of personal letters offering to supply their waiting rooms with unlimited quantities of *If you decide to quit smoking*---a 52-page booklet that avoids mention of the word "addiction," contains a total of three sentences that refer to diseases caused by smoking, and includes 17 color photographs, all of healthy, smiling 20-somethings and none of persons made ill from smoking or of their diseased hearts and lungs.

TV ads for Philip Morris' Youth Smoking Prevention campaign have been rightly condemned as cynical and ineffective by some of the very health organizations that have joined with Philip Morris in backing this bill. Yet the company touts this program in its recruitment of college students at career fairs on university campuses across the country (as well as on its website www.cantbeattheexperience.com), even though the only jobs it offers these students are in the Marlboro sales force, delivering fresh cigarettes to supermarkets, convenience stores, pharmacies, and bars.

Such tactics aimed at burnishing the company's nicotine-stained image among doctors, parents, college students, and university officials will flourish with the enactment of this bill. FDA regulation of tobacco products under HR 1108 would provide an unprecedented and unmerited legitimacy to cigarette makers and would send the misleading message to consumers that cigarettes, however problematic, are now government-sanctioned.

William Godshall, perhaps the most knowledgeable and effective tobacco control advocate ever to work for the American Cancer Society, sees a parallel between the countless medications and food products overseen by the FDA and the more than 400 cigarette brand variations on the US market, each with differing amounts of scores of chemical additives and thousands of poisons in the smoke. He rightly questions the feasibility of correlating smoking-related deaths and diseases with the brands of cigarettes consumed,

which the FDA would have to do if it is to make any valid assessments and recommendations about individual tobacco products.

The public is not generally aware that there are over 4000 poisons in cigarette smoke, including more than 40 cancer-causers. If a consumer is informed that one such poison or carcinogen has been reduced or removed from a cigarette brand, then he or she is going to infer that the problem is being taken care of or even solved. This ignores the dozens of other cancer-causers in that cigarette. In short, there is no evidence that tinkering with the levels of various constituents of tobacco smoke will result in a safer product.

Neither the technology to remove carcinogens from cigarette smoke nor the science to prove that the removal of any toxin from cigarette smoke reduces mortality yet exists. Such studies would take decades to detect any reduction of harm from tobacco use.

Moreover, it would be highly unethical to conduct such ongoing research on persons who smoke without providing constant cessation interventions. Having served as a member of the University of Alabama Institutional Review Board, which oversees research protocols to ensure the protection of human subjects, I cannot imagine that prospective comparison studies of different cigarettes would be approved by any legitimate scientific institution.

Yet this is precisely the strategy Philip Morris is counting on to perpetuate the myth that research can discover a safe cigarette. Assisted by the University of Virginia and Duke University, which have thus far accepted over \$40 million from the manufacturer of

Marlboro in the past year, Philip Morris is on track in its plan to turn back the clock half a century to the “Frank Statement to Smokers” issued by the tobacco industry (in reaction to the myriad scientific studies implicating smoking in a host of diseases), which pledged “aid and assistance to the research effort into all phases of tobacco use and health.”

In his remarks to shareholders at this year’s annual meeting of Philip Morris, Louis Camilleri, ceo of its parent company, boasted of his support of this bill and promised that the company’s new \$350 million research center in Richmond will seek to solve “societal problems raised by tobacco.” FDA regulation, the research center, and related grants to universities and medical schools make up Philip Morris’ formula for Marlboro’s continued sales success.

Does anyone with even a rudimentary knowledge of public health seriously believe in the wisdom of yet another quest for a safe cigarette? Philip Morris has played this game before with its earlier cigarette research centers in the 1950s and 1970s (“One of the most complete and fully integrated facilities for tobacco research in existence anywhere in the world. Its every detail has been designed for translating the scientific theories and findings of basic research into practicalities.”).

It is déjà vu all over again, and proponents of this bill are wittingly or unwittingly aiding and abetting the biggest member of Big Tobacco in institutionalizing junk science.

Philip Morris' endorsement of both the FDA bill and the Institute of Medicine report supporting FDA regulation is eerily reminiscent of the Tobacco Industry Research Committee's Frank Statement of 1954: "We accept an interest in people's health as a basic responsibility, paramount to every other consideration in our business... We always have and we always will cooperate closely with those whose task it is to safeguard the public health... In charge of the research activities of the Committee will be a scientist of unimpeachable integrity and national repute. In addition there will be an Advisory Board of scientists disinterested in the cigarette industry. A group of distinguished men from medicine, science, and education will be invited to serve on this Board. These scientists will advise the Committee on its research activities. This statement is being issued because we believe the people are entitled to know where we stand on this matter and what we intend to do about it."

And in 2007: "Philip Morris USA believes regulation of tobacco products by the FDA could potentially create a new framework within which manufacturers can refocus their efforts to pursue reduced harm products."

Since smoking prevalence is directly proportional to the degree of perceived harm from smoking, FDA sanction of cigarettes will lead to an increase in smoking prevalence compared to what would have occurred in the absence of this legislation.

Primary prevention---not taking up cigarettes in the first place---is universally agreed upon as the answer to end the devastating health toll caused by smoking. Reducing

demand through paid mass media education is the cornerstone of primary prevention. Nothing in this legislation addresses or encourages major multi-media anti-smoking campaigns. Indeed, by creating the impression that the cigarette pandemic is being addressed by the federal government, the bill could be a disincentive for state and local governments to devote additional resources.

We need to fight smoking with fire, not symbolic, tokenistic regulation. This bill is a godsend for Philip Morris. No one else will benefit.