October 2, 2007

Committee on Energy and Commerce
United States House of Representatives
Washington D.C. 20515

Re: **H.R. 1108-- Family Smoking Prevention and Tobacco Control Act**

Dear Representative:

We are writing to express our concerns about this bill, which is the subject of tomorrow's committee hearing. The bill is characterized as a public health measure. In fact, however, the bill could actually have several adverse health effects. It would restrict the advertising of smokeless tobacco as a safer alternative to cigarettes; it could hinder the development of other reduced-risk tobacco products; and it may well make it more difficult for the Food and Drug Administration to address deficiencies in its current health-related functions.

The last issue may well be the most important one. Government agencies are generally enthusiastic about expansions of their jurisdiction. Such expansions mean more power, more headlines, and a larger budget. In FDA's case, however, Commissioner Andrew C. von Eschenbach has expressed his misgivings about this bill, stating "repeatedly that FDA doesn't need more regulatory authority." USA Today, *FDA chief: Tobacco rules could backfire*, Mar. 6, 2007 (attached). The Commissioner's reluctance to see his agency's duties expanded in this manner indicates the questionable nature of this bill.

Moreover, FDA's handling of its basic food and drug safety responsibilities have received heavy criticism recently. In our view, the major problem with FDA's drug approval process is one of overregulation rather than under-regulation. A CEI survey of orthopedic surgeons conducted earlier this year found a strong majority taking the view that FDA is *too slow*, rather than too fast, in its approval of new drugs and devices. (See attached summary.) FDA's ability to improve this process would be impaired by any major expansion of its regulatory functions. Similarly, such an expansion would also impair the agency's ability to adjust its food inspection priorities regarding imported foods.

Section 204 of the bill requires that smokeless tobacco products carry a warning declaring that they are "not a safe alternative to cigarettes." This runs counter to a sizable body of scientific evidence, as summarized by the American Council on Science and Health (attached; see also G. Conko, *Running Away From Safety*, Washington Times, Sept. 25, 2003, attached).

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Section 101 sets forth extensive standards for the sale of reduced-risk tobacco products. In certain cases, FDA's approval of such products may add support for reduced-risk claims; in other cases, however, the standards may actually inhibit the development of reduced-risk products. A less draconian approach would be for FDA to certify those reduced-risk products that meet it standards. To the extent that the public views such certification as valuable, FDA-certified products would have a competitive advantage over uncertified products. FDA might even require uncertified products to carry disclaimers of FDA approval—an approach that would raise far fewer First Amendment issues than the bill's ban on uncertified claims. *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999).

Finally, as Commissioner von Eschenbach himself noted, the bill's approach of empowering FDA to reduce cigarette nicotine levels could itself easily backfire from a health standpoint. It could actually increase the consumption of cigarettes, and of the harmful tar they contain, by smokers determined to obtain the nicotine they crave.

We submit that these factors warrant a re-examination of this bill.

Respectfully submitted,

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