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September 24, 2009

Division of Dockets Management (HFA-305)
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket Number FDA-2009-N-0294

To Whom It May Concern:

The Public Health Advocacy Institute ("PHAI"), initially established in 1979, has thirty years of experience focused on legal policy approaches to reduce the public health toll caused by tobacco products. PHAI is a non-profit public health law research organization based on the campus of Northeastern University in Boston, Massachusetts.

PHAI has collaborated with Northeastern University School of Law as consortium partners on three National Institutes of Health R01 studies, including a competitive renewal, addressing legal approaches to tobacco control; discerning tobacco industry attorneys' roles on smoking and health issues as revealed in internal document archives; and identifying the use of personal responsibility argumentation to impede public health interventions. PHAI has worked under contract to the U.S. Department of Justice conducting research related to *U.S. v. Philip Morris, Inc.* and has performed tobacco control research funded by grants from the Robert Wood Johnson Foundation and the American Legacy Foundation and contracts with Massachusetts Department of Public Health, The American Cancer Society, and the American Academy of Pediatrics.

PHAI offers the following comments and recommendations regarding the development and implementation of the FDA Tobacco Product Regulations, in furtherance of the public health goal of significantly reducing smoking related mortality and morbidity under the FDA's grant of regulatory authority pursuant to the Family Smoking Prevention and Tobacco Control Act of 2009 ("the Act").

Research designed to identify and evaluate the threshold range of nicotine yields that produce tobacco dependence in smokers should be actively commissioned and considered by the FDA and its Tobacco Products Scientific Advisory Committee. Prioritizing such research to inform the promulgation of tobacco product regulations is consistent with the Act's stated purposes to empower the FDA "to set national standards controlling the manufacture of tobacco products and the identity, public disclosure and amount of ingredients used in such products"[1] and "to vest the Food and Drug Administration with

[1] Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, Division A, 123 Stat.1775 (2009). *See* Sec. 3 Purpose, subsection (3).

the authority to regulate the levels of tar, *nicotine*, and other harmful components of tobacco products."[2]

Research regarding the legal and policy framework supporting nicotine reduction regulation must also be conducted. For example, an analysis of the experiences of prior legislative or regulatory harm reduction public health efforts would inform nicotine yield rulemaking, along with an analysis of how to apply the new "appropriate for the protection of public health"[3] standard to the nicotine yield rulemaking process.[4] In addition, research and analysis of the range of objections and evidence that may be produced by parties opposed to nicotine yield findings or standards should be undertaken. Legal and policy research regarding enforcement of possible regulations to reduce nicotine yields would also be valuable.

Reducing nicotine levels - potentially below the threshold levels required to produce and maintain addiction - is clearly contemplated by the Act, notwithstanding an express denial of the Secretary's authority to ban all tobacco products or reduce nicotine yields to zero.[5] Legislative history clarifies that the statutory language empowering the Secretary to set nicotine yields "does not prohibit any positive number above zero," including for example, a level such as ".0000001."[6]

The FDA, through its Tobacco Products Scientific Advisory Committee, is explicitly authorized and expected to evaluate the impact of nicotine yield standards for the purpose of protecting public health.[7] For example, the Tobacco Products Scientific Advisory Committee is specifically charged with *inter alia*, providing "advice, information and recommendations to the Secretary- …

> (2) on the effects of alteration of the nicotine yields from tobacco products;
> (3) on whether there is a threshold level below which nicotine yields do not produce dependence on the tobacco product involved;…."[8]

Identifying such a threshold or range of thresholds presents certain challenges.[9] Research suggests that some non-daily smokers, perceived as non-addicted, actually show evidence of dependence. Moreover, a single threshold may not apply to the entire population. Analysis of whether phased nicotine reduction mitigates smokers' withdrawal symptoms as well as of compensatory smoking behaviors associated with nicotine reductions should also be investigated.

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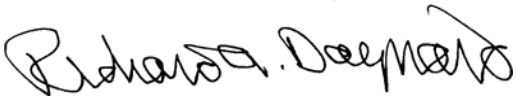
[2] *Id*. at Sec. 3 Purpose, subsection (5)(emphasis added).
[3] *Id.* at Sec. 907(a)(4)(A).
[4] *Id*. at Sec. 907(a)(4)(A)(i).
[5] *Id.* at Sec. 907(d)(3).
[6] Mark-up of H.R. 1256, House of Representatives, Committee on Energy and Commerce, Washington, D.C. at 132, March 4, 2009.
[7] *See* n.1 at Sec. 907(c) (4).
[8] *Id.* at Sec. 917(c).
[9] Benowitz, NL, Hall, SM, Dempsey, D. et al., Safety of a Nicotine Reduction Strategy. Paper presented to the Annual Meeting of the Society for Nicotine and Tobacco Research, 2004.

The FDA now has a mandate and the necessary legal authority to set nicotine levels for current and future tobacco products as part of a national harm reduction policy. Lowering nicotine yields for smoked tobacco products below levels triggering and sustaining dependence among most or all of the population could be the single most effective harm reduction measure currently available to the FDA, providing smokers with an unprecedented opportunity to exercise free choice and reducing the possibility of young nonsmokers becoming inadvertently addicted. Such an approach could result in dramatic reductions in tobacco-caused morbidity and mortality including that of non-smokers. Smoking is the "dirty needle" of nicotine delivery; and consistent with section 907(a)(6) of the Act the Secretary should consult with other agencies and informed persons to develop tobacco product standards that limit nicotine yields.

PHAI urges the FDA to prioritize smoked tobacco nicotine reduction as a potentially highly effective tool to mitigate the public health cost of smoking. We look forward to continuing to offer advice and recommendations regarding how to achieve this key goal.

Sincerely,



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