UC San Francisco/UC Hastings College of the Law
Consortium on Law, Science & Health Policy

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Division of Dockets Management (HFA–305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA-2009-N-0294, Regulation of Tobacco Products; Request for Comments

Dear Madam or Sir:

The UCSF/UC Hastings College of the Law Consortium on Law, Science, & Health Policy is pleased to submit comments in response to FDA's request for information and views on the implementation of the Family Smoking Prevention and Tobacco Control Act of 2009.

The UCSF/UC Hastings Consortium was created to support broad-based interdisciplinary collaboration between our two institutions on issues at the myriad intersections between law and science, with a focus on education, research, and service. In furtherance of the Consortium's commitment to service, and in recognition of the significant expertise at our institutions and in northern California on tobacco control, the Consortium sponsored a conference on August 28, 2009, entitled IMPLEMENTING THE TOBACCO CONTROL ACT: ADVICE TO FDA, to encourage discussion of the new law and share views with FDA. These comments are a distillation of the advice from the conference panelists. This document has been submitted electronically; this submission, however, includes DVDs of the entire conference as well as materials provided by the presenters at the conference. Our co-sponsor, the *Hastings Science and Technology Law Journal*, intends to publish conference proceedings, including revised and extended versions of presenters' views, later in the academic year. The names of the panelists whose views are incorporated in these comments may be found at www.uchastings.edu/academics/jd-program/law-science/docs/Schedule.pdf; short biographies of each are at www.uchastings.edu/academics/jd-program/law-science/docs/SpeakerBios.pdf.

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Federal, State, and Local Government Collaboration

Three major themes arose in the discussion of collaboration: (1) Take no action that would interfere with or preempt state and local laws regulating tobacco products, (2) encourage and assist state and local governments in acting in those regulatory areas in which FDA is not authorized to act, and (3) enlist enforcement assistance from state and local governments through cooperative agreements and other mechanisms available to FDA.

States have had over ten years of experience enforcing the advertising, promotion, marketing, and sales restrictions in the Master Settlement Agreement and many have been very effective in doing so. Enforcement of state and local laws directed at regulating tobacco advertising, promotion, marketing, and sales may be more effective and efficient than FDA enforcement of federal regulations. Therefore FDA should not regulate in such a way that would interfere with or preempt state and local laws, or divert resources from successful, evidence-based tobacco control activities at the state and local levels. It simultaneously should encourage and assist state and local governments in crafting effective statutory and regulatory schemes that maximize the public health impact of restrictions on the advertising, promotion, marketing, and sales of tobacco products. FDA should, to the full extent it is authorized to do so, enlist enforcement assistance from state and local governments to maximize the effectiveness of its own regulations.

The FDA should encourage and assist state and local governments to act in areas of tobacco regulation in which FDA is not authorized to act, such as:

- Banning the sale of selected tobacco products, like menthol-flavored tobacco products.
- Requiring prescriptions for the purchase of tobacco products.
- Banning tobacco product sales in particular types of retail outlets, such as pharmacies and those that admit persons under 18.
- Banning corporate sponsorship by tobacco manufacturers, distributors, and retailers of any athletic, musical, artistic, or other social or cultural event, or any team or entry.
- Banning the distribution of free samples of all tobacco products other than cigarettes and smokeless tobacco.

The offices of state attorneys general are charged with enforcing the Master Settlement Agreement. FDA should learn from the enforcement issues related to the MSA's prohibition on brand-name sponsorships, and should construe the sampling and sponsorship restrictions in the Tobacco Control Act broadly and adopt all-inclusive definitions of athletic and cultural events. FDA should act to maximize the effectiveness of the unique and overlapping provisions of the MSA and the new Tobacco Control Act.

FDA should also take the following actions to further effective collaboration:

- Create a website listing (and, ideally, ranking) state and local efforts to enforce tobacco control efforts, including information on the results of legal challenges by the tobacco industry.
- Designate a contact person to discuss proposed state and local legislation and regulation with state and local representatives.
- Convene an annual enforcement conference for governments to share information about enforcement of tobacco control initiatives.
- Ensure that states can continue to utilize available federal funding to enforce state youth access laws with maximum state penalties.
- Set standards for employee training programs on illegal sales to minors to help retailers minimize their liability for such illegal sales.
- To combat illicit tobacco sales, require that manufacturers and importers of tobacco products sell only to state-licensed distributors, and that state-licensed distributors sell only to state-licensed retailers.

Advertising, Marketing, Sale, and Distribution of Tobacco Products

Advertising, marketing, sale, and distribution issues with respect to tobacco products have become increasingly complex given the additional media – most notably the Internet and social media marketing – through which people, particularly young people, currently obtain information. The First Amendment imposes limits on restrictions that are deemed to be speech. FDA should impose the most stringent restrictions consistent with the First Amendment upon Internet and social media marketing; for these purposes it should measure the likelihood that such forms of marketing disproportionately reach persons under the age of 18.

Other actions are critical to reduce the exposure of persons under the age of 18 to tobacco product marketing. FDA should require premarket testing of advertising by independent experts to assure their lack of "kid-appeal" and should prohibit tobacco use or tobacco product brand identification in motion pictures marketed to attract, or intended to be viewed by, persons under the age of 18. With respect to motion pictures, FDA should also encourage the Motion Picture Association of America to give movies in which there is tobacco use or tobacco product brand identification an "R" rating.

FDA should prohibit all sampling of tobacco products, and add additional sports to the sports marketing restrictions.

To support its regulatory actions in this area in the face of potential First Amendment challenges, FDA should solicit and obtain the best empirical data to demonstrate the validity and effectiveness of restrictive marketing provisions.

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Smoking Cessation and Tobacco Addiction

FDA should take a variety of actions to encourage smokers to attempt to quit smoking and then to assist them in reaching that goal. FDA should require graphic warnings on package inserts added to cigarette packs as well as graphic warning labels on packages. The package warning label should include a reference to the smoking cessation assistance hotline, 1-800-QUITNOW.

To encourage appropriate use of smoking cessation aids, FDA should clarify its guidance on the relative risks of using varenicline. It should update and correct its Center for Tobacco Products website to make it more consumer-friendly by labeling the nicotine replacement therapy (NRT) products as "Smoking Cessation Products to Help You Quit," and by removing from the listings products that are not commercially available in stores in the United States. It should require manufacturers of OTC NRT products to update their usage and warning labels to reflect current evidence and, for combination therapy, the Public Health Service Clinical Guidelines, *Treating Tobacco Use and Dependence: 2008 Update*. It should reclassify the NRT oral inhaler and nasal spray to allow their sale over-the-counter. It should eliminate any restrictions on packaging of NRT products to allow smaller quantities so consumers can try them with a smaller initial cash outlay. FDA should encourage private insurers and Medicare to cover all first-line smoking cessation medications, including combination therapy.

FDA should take into account special populations with respect to smoking cessation and addiction. The agency should seek guidance from professional and scientific organizations, as well as other government agencies, to assure that prevention and cessation regulations, and their implementation, recognize the special characteristics of populations in which there are high tobacco use rates. One important population to consider is smokers with psychiatric and substance abuse disorders. This population is disproportionately represented among smokers, but research has shown these people are just as eager to quit as other smokers and can successfully do so, but with greater difficulty than the general population of smokers.

FDA should prohibit the sale of tobacco products in any establishment in which health care is provided. Such a prohibition would have only indirect impact, but have important symbolic value. Very direct impact could be had by mandating the gradual reduction of nicotine in all tobacco products to <0.4mg per unit over ten years. That would likely eliminate nicotine dependence in all but the heaviest users (for example, >30 cigarettes per day).

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Prevention of Tobacco Use

FDA should set benchmarks to reduce youth smoking prevalence by 50 percent over five years and require that the benchmarks be met by industry (with sanctions for failure). This action is similar to agreements in the 1997 Global Settlement.

FDA should take a number of actions relating to the content of cigarettes. It should prohibit all flavorings, including menthol, and any alkaloids other than nicotine as additives in all tobacco products at the earliest possible date. It should require tobacco smoke to have a Ph above 8, to make the smoke not inhalable, as it was until the late 19th century when the tobacco industry developed the flue curing process to reduce the smoke Ph. It should also require the elimination of polonium 210 from all tobacco products.

To deal with the smoking environment, FDA should adopt minimum standards for state regulation of tobacco, including smoke-free workplaces and public places. It should also require state licensure for all manufacturers, distributors, and retailers of tobacco products to enable tobacco control. Price promotion in any form should be prohibited in the marketing of the top five brands of smoked and smokeless tobacco used by youths age 12 to 20, as determined by the National Survey on Drug Use and Health.

Additional Comments

One of the most effective activities FDA could engage in would be to vigorously promote the social unacceptability of tobacco use and of the tobacco industry. Such messages have to date been more effective in reducing tobacco use than discussions of tobacco's health risks. The agency should remain vigilant to condemn any attempts by the tobacco industry to portray tobacco use as now somehow safe or acceptable because the industry is regulated by the FDA.

FDA should encourage the FTC to continue to vigorously regulate tobacco marketing.

In collaboration with the federal Department of Justice, FDA should seek to obtain disaggregated tobacco marketing data. Together with DOJ attorneys, FDA should carefully consider the implications of the decision in *United States v. Philip Morris USA*, 477 F.Supp. 2d 191 (D.D.C. 2006), and its potential to support regulatory actions.

Very truly yours,

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