PUBLIC HEALTH
LAW CENTER
Tobacco Control Legal Consortium

December 21, 2017

Commissioner Scott Gottlieb, MD
c/o Division of Dockets Management
HFA-305
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20825

Re: Tobacco Product Manufacturing Practice

Docket No. FDA-2013-N-0227

Dear Commissioner Gottlieb:

The Public Health Law Center is pleased to submit these comments to the U.S. Food and Drug Administration (FDA) regarding the Good Manufacturing Practice (GMP) proposal submitted by a group of tobacco product manufacturers on June 7, 2017. The Public Health Law Center is the coordinating center of the Tobacco Control Legal Consortium, a national network of nonprofit legal centers providing legal technical assistance to public health professionals and advocates concerning legal issues related to tobacco and public health.[1] We submit these comments on behalf of these centers.

We have reviewed the June 7 letter from RAI Services Company to the FDA and note that it represents a wholesale adoption of the proposal submitted to the agency by R.J. Reynolds on January 10, 2012, with a short list of additional considerations related to e-cigarettes. Because there was no significant change in R.J. Reynold's proposal, we attach to this letter our May 20, 2013 comment on the previous proposal. All of the information contained in that comment is equally relevant to the minimally supplemented June 7, 2017 proposal.

[1] The Tobacco Control Legal Consortium's activities are coordinated by the Public Health Law Center, at Mitchell Hamline School of Law in St. Paul, Minnesota. The Consortium's affiliated legal centers include: ChangeLab Solutions, Oakland, California; Legal Resource Center for Tobacco Regulation, Litigation & Advocacy, at University of Maryland Francis King Carey School of Law, Baltimore, Maryland; Public Health Advocacy Institute and the Center for Public Health and Tobacco Policy, both at Northeastern University School of Law, Boston, Massachusetts; Smoke-Free Environments Law Project, at Center for Social Gerontology, Ann Arbor, Michigan; and Tobacco Control Policy and Legal Resource Center at New Jersey GASP, Summit, New Jersey.

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As a threshold matter, we would like to reiterate our view that the tobacco industry has demonstrated that they cannot be relied upon to participate in the creation of meaningful regulation or to comply in good faith with any regulations that do survive their attempts to block them. As we mentioned in our previous comment, when the tobacco industry puts forward a proposal, such as the one at issue here, the FDA should question the industry's motivation. The tobacco industry's agenda is not to help the FDA create meaningful regulation; it is to thwart strong regulations and preserve industry profits at the expense of public health. The original proposed practices and these e-cigarette-related addendums support that position.

In addition to our previous – and continuing – objections, we have two concerns specific to the most recent proposal. First, on page five of the 2017 proposal, the tobacco product manufacturers attempt to reassert that the purpose of GMP regulations is to "prevent[] the introduction of substances not ordinarily contained in tobacco products that would present a risk of injury to the consumer beyond that generally posed by the same category of tobacco products." This is false.

The letter recognizes that "Congress, the U.S. Surgeon General, and public health authorities have identified certain inherent risks associated with the use of different categories of tobacco products." While this premise is true, it does not logically follow that because tobacco products cause harm, the FDA's role in regulating the products is merely to protect the public from additional harm. As is discussed at length in the attached comment, this proposal is merely an attempt to persuade the FDA to reject the public health standard in favor of an individual risk standard which affords the industry more leeway to introduce new, harmful products.

Rather than accept the industry's entirely false premise, the FDA must promulgate GMP regulations in such a way as to protect public health from the disastrous health effects of tobacco products, not just from the incidental risk of exposure to materials not ordinarily found in tobacco products. In promulgating GMP regulations, the FDA must use the public health standard, a legal standard intended to *reduce* harm at the population level.

Second, while the FDA has taken some important steps to increase the transparency of various aspects of tobacco product regulation, for information and documentation submitted by the tobacco industry to the agency, in making decisions about disclosure, the FDA has often seemed to prioritize the industry's interest in confidentiality over the public's interest in transparency. The history of this proposal is only one example of this misplaced priority.

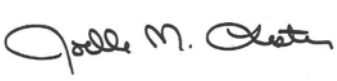
The tobacco product manufacturers submitted their initial proposal to the FDA on January 10, 2012. According to the cover letter to the proposal, the dialogue that led to the proposal began in 2011 and the letter also requests an in-person meeting

with agency staff. However, neither the prior nor subsequent correspondence between the FDA and any tobacco product manufacturers regarding the GMP proposal was placed into the docket for public inspection and comment. The agency did, in fact, have a meeting on May 20, 2012, regarding the GMP proposal and manufacturers corresponded with the FDA prior to that meeting. The agency and the industry also developed materials in advance of the meeting. All of these materials were in existence when the FDA published the GMP proposal for comment on March 19, 2013, and yet none of them were made available. The Consortium had to submit a request under the Freedom of Information Act in order to review these materials, which we attach to this letter.

It should be the FDA's standard practice to publish all relevant materials on a given subject so that the public can submit fully informed comments. We respectfully request that when the FDA's Center for Tobacco Products requests public comments on a tobacco industry proposal, the Center make it a standard practice publish all tobacco industry submitted materials and in-person meeting notes relevant to that particular docket. The industry's history of deceptive practices underscores the importance of prioritizing transparency in the FDA's interactions with the tobacco industry, especially in a situation where the FDA seeks public input on industry-submitted information.

We urge the FDA to promulgate GMP regulations designed to improve public health rather than working from an industry-drafted proposal. In addition, we request that the agency publish all information submitted by the tobacco industry when seeking comment on regulatory proposals submitted by tobacco product manufacturers.

Respectfully,



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Attachments

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