PUBLIC HEALTH
LAW CENTER
at Mitchell Hamline School of Law

Commissioner Robert M. Califf
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

October 6, 2023

*Submitted Electronically*

Dear Commissioner Califf,
We are writing to provide comments on the Requirements for Tobacco Product Manufacturing Practice proposed rule, under the Agency Docket No. FDA-2013-N-0227. We appreciate the opportunity to express our input on this matter.

The FDA's responsibility is to the public health in its role in regulating the tobacco industry. This proposed rule presents an opportunity for the FDA to address existing gaps in the regulation of tobacco product manufacturing. By doing so, the FDA can ensure that the manufacturing of these products aligns with the public health standard.

We represent the Public Health Law Center, a non-profit organization dedicated to promoting equitable public health policies through the power of law. Our organization has been actively involved in efforts to regulate and eliminate commercial tobacco products, improve access to healthy food, support physical activity, promote equitable transportation, and enhance environmental health to reduce the burden of chronic diseases. We collaborate with various stakeholders, including Tribal leaders, federal agencies, health advocacy organizations, and state and local governments, to foster healthier communities nationwide and address systemic institutional racism.

The FDA has advanced versions of this proposed rule in the past. The focus of those rules appeared to be to simplify regulations to the benefit of the tobacco industry. We previously submitted comments on the Tobacco Product Manufacturing Rule in 2013 and 2017, and our position on those matters remains unchanged.

In our 2013 comment, we highlighted that the language recommended by tobacco companies relied on an individual risk standard, rather than the "public health standard" mandated by the Tobacco Control Act (TCA) for the FDA's use. We emphasized that the FDA's actions in regulating tobacco products must always be appropriate for the protection of public health. Additionally, we noted the absence of explanations regarding enforcement and penalties for violations in the regulations.

Our 2017 comment reiterated many of the deficiencies we identified in 2013. We emphasized the lack of enforcement from the FDA or any external body, as the proposed rule relied on the industry to self-regulate and report manufacturing defects to the FDA on their own timeline. We firmly believe that the FDA's permissiveness of industry self-

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regulation and requiring them to report defects to the FDA only when it becomes detrimental to their profits is not in the best interest of public health. The focus of the industry then and now is to reduce the reliance on a public health standard and reduce transparency to the public when it comes to regulating tobacco products. We have attached both comments for your reference, urging the FDA to reconsider these issues.

In our 2023 comment, we reiterate the positions set forth in 2013 and 2017 and add an additional layer in light of more information and evidence showing the harms of tobacco product manufacturing to the environment. We want to elevate awareness about the environmental harms of tobacco production and emphasize the FDA's role in preventing them.

The proposed rule as it is written, unfortunately, does not adequately address these concerns. It still appears to prioritize instances of individual harm over broader public health impacts, relies heavily on industry self-policing, and shows no regard for the environmental impact of tobacco product manufacturing. Instead, we believe that the FDA should focus on implementing public health standards related to tobacco products that will effectively reduce the number of smokers and mitigate the detrimental health outcomes associated with tobacco use for both people and the environment.

**I. Prioritize Public Health Protection over Industry Flexibility.**

The FDA should prioritize the protection of public health over industry flexibility and convenience. The FDA has a process to review tobacco products, particularly new products, for the marketplace. This is through the Pre-Market Tobacco Product Application (PMTA) process. The FDA should continue to prioritize that process rather than establishing additional rules that may make it easier for tobacco product manufacturers to put non-compliant products into commerce.

The proposed rules, according to the FDA, are "generally similar to many existing industry practices and are drafted to provide tobacco product manufacturers with flexibility in the manner they comply with the proposed requirements while assuring the protection of public health."[1] While the rules aim to provide flexibility for tobacco product manufacturers to comply with requirements, it is important to recognize that this flexibility may allow the tobacco industry to continue introducing non-compliant products into the market. This is happening under the current PMTA process. Hundreds of tobacco product manufacturers continue to ignore current FDA regulations and have non-compliant products in the marketplace. The FDA is committed to the review of all the PMTA applications and enforcing the law against those that receive Marketing Denial Orders, but the process is still in its early stages.

The FDA should prioritize the removal of unauthorized products and exercise caution in granting excessive flexibility to the tobacco industry, considering its history of non-compliance with regulations. By placing public health protection at the forefront, the FDA can ensure the well-being of both tobacco users and non-users.

**II. Minimize Reliance on Industry Self-Reporting and Risk Assessment.**

The proposed rule introduces various methods for the tobacco industry to report defects or improper products to the FDA. While this approach may seem beneficial in theory, there are concerns regarding the responsibility placed on the industry to determine whether such products should be reported to the FDA. According to the proposed rule, "In determining the significance of the risk, manufacturers should develop criteria against which the risk and its magnitude can be evaluated." The rule specifies that the industry must utilize a complaint mechanism that includes a risk assessment of their products, with the option for manufacturers to create their own tool as long as it meets the minimum requirements. However, the remaining aspects of the reporting process are left to the discretion of the industry.

This raises concerns because, although the FDA has outlined minimum standards for risk assessment and evaluation, the focus appears to be on what the tobacco industry deems unacceptable rather than what should be deemed unacceptable for the general public. While the rule does take into account the foreseeable misuse of tobacco products, it is likely that the industry is more willing to accept risks associated with defects in individual consumer products rather than consider the overall detrimental effects of tobacco products on society.

**III. Establish a Public Health Equity Standard in Tobacco Product Manufacturing**.

The proposed rule presents an opportunity for the FDA to establish a clear framework for what constitutes an equity-centered public health standard in tobacco manufacturing. It is evident from the language used throughout the rule that the FDA is committed to this objective. We urge the FDA to ensure that tobacco products are manufactured in a manner that safeguards the health of both tobacco users and non-users, reflecting its dedication to public health protection. This rule is an opportunity for the FDA to begin to codify what an equity-centered public health standard looks like in manufacturing.

**IV. Address Environmental Harms in Tobacco Product Manufacturing.**

Part of establishing an equity-centered public health standard in tobacco product manufacturing must involve considering the long-term effects of the environmental harms of the tobacco industry. In addition to prioritizing public health protection and minimizing consumer harms, it is crucial for the FDA to address the environmental harms associated with tobacco product production. The tobacco product manufacturing industry uses significant amounts of energy and resources. One of the major environmental hazards of tobacco production is the use of fossil fuels in transporting tobacco leaves long distances for processing. Additionally, other air pollutants come from tobacco manufacturing like greenhouse gas emissions from deforestation, manufacturing, and

transportation. For electronic devices, production can be even more environmentally taxing when manufacturing new plastics, metals, cartridges, batteries, and concentrated nicotine solutions/salts especially when they are created for single use. [2]
The larger environment affects public health and the FDA has authority to regulate factors, like manufacturing, that are harmful to people as a result. Another issue with tobacco product manufacturers is where manufacturing and distribution sites tend to be located. These are often in low-income communities or communities of color that are already contending with waste and chemical pollution in their ail, soil, and water.[3] FDA regulations related to the tobacco manufacturing process should consider how else the tobacco industry is harming the public health in its production processes. The health and wellbeing of the environment of users and non-users of tobacco products is also being harmed even before they use or are near a user of a tobacco product.

The FDA should recognize the importance of mitigating these environmental harms and incorporate measures within the proposed rules to promote sustainable practices in tobacco production. This could include encouraging manufacturers to promote the use of alternative materials in packaging, and implementing stricter regulations on waste management. The FDA should also make it standard practice to consider environmental assessments for new tobacco products to determine whether they would have an adverse effect on the environment and its impact on public health. Under the National Environmental Protection Act (NEPA), almost all agencies have a responsibility to assess the environmental impact of their actions. It is a procedural requirement that must be met when taking significant action. Adopting a good manufacturing processes standard could qualify as such an action. If so, the FDA should ensure that it is compliant with NEPA procedures in promulgating a new good manufacturing processes standard.[4]

By addressing the environmental impacts of tobacco production, the FDA can contribute to a more sustainable and environmentally conscious tobacco industry. This not only aligns with broader global efforts to combat climate change and protect natural resources but also supports the overall goal of public health protection by considering the long-term effects of tobacco production on both human health and the environment.

We reiterate our previous positions on the good manufacturing practices that the FDA has promoted over the years. This one is similar in that despite the language to adhere to a public health standard, the proposed rule continues to give the tobacco industry unearned flexibility to self-report and self-police defects in tobacco products. We urge the FDA to take this opportunity to codify an equity-centered public health standard develop good manufacturing practices that regulate the tobacco products from a holistic perspective.

Thank you for considering our comments. We look forward to continued engagement on this important issue.

Sincerely,

*/s/ Esther Agbaje*
Esther Agbaje, Lead Staff Attorney, Federal Regulations Project

*/s/ Willow Anderson*
Willow Anderson, Staff Attorney

*/s/ Luke Haqq*
Luke Haqq, Staff Attorney

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.

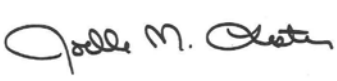
The tobacco product manufacturers submitted their initial proposal to the FDA on January 10, 2012. According to the cover letter to the proposal, the dialogue that led to the proposal began in 2011 and the letter also requests an in-person meeting

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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Tobacco Control Legal Consortium

Law. Health. Justice.

May 20, 2013

Division of Dockets Management
HFA-305
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Comment to FDA-2013-N-0227
Tobacco Product Manufacturing Practice; Establishment of a Public Docket

Dear Sir or Madam:

The Tobacco Control Legal Consortium is pleased to submit these comments to assist the U.S. Food and Drug Administration ("FDA") in analyzing the tobacco product good manufacturing practices proposal submitted by the tobacco industry. Specifically, we will address the fact that any such offering by the tobacco industry ought to be considered in light of the industry's history of avoiding meaningful regulation. We will discuss that this proposal in particular, is an attempt to advance the industry's agenda of subverting the public health purpose of the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act). We will also outline the FDA's broad authority to promulgate meaningful regulation that can improve public health.

Founded in 2003, the Tobacco Control Legal Consortium ("the Consortium") is the leading source of legal technical assistance on tobacco control policy in the United States. The Consortium promotes evidence-based and legally sound approaches to tobacco control policy, and provides legal technical assistance to federal, state, and local public health advocates, officials, and attorneys across the country. The Consortium's team of attorneys, based at the Public Health Law Center in St. Paul, Minnesota, provides legislative drafting and policy assistance, prepares educational materials, and files legal briefs as *amicus curiae* in key cases before the highest courts of the nation.

**I. Untrustworthy Racketeers**

The tobacco industry has a long history of deceitful behavior that is well-chronicled. The industry's behavior and tactics are documented by many sources, including a massive archive of internal industry documents housed at the University of California San Francisco, which this comment will frequently use as reference material. In addition, Judge Gladys Kessler's landmark 2006 opinion in *U.S. v. Philip Morris* provides a comprehensive compilation of the tobacco industry's deception.[1] In this case, the government charged the tobacco industry defendants[2] with violating the Racketeer Influenced and Corrupt Organizations Act (RICO).[3] Many of Judge Kessler's findings are directly relevant to the issue of whether the tobacco industry can be trusted to participate in good faith in the regulatory process, and therefore must inform the FDA's

consideration of this tobacco industry proposal.[4] That ruling should also serve as a guide, more generally, for the FDA's decision-making in its regulation of tobacco products. Any decisions made or regulations promulgated by the FDA should be consistent with the findings and the ruling in that case.

Among the deceitful acts recounted in Judge Kessler's opinion are the tobacco industry's long history of secretly conducting and hiding scientific research on the health effects of tobacco use,[5] the addictiveness of and the ability to manipulate nicotine,[6] the lack of any health benefit from light and low tar cigarettes,[7] and the hazard of secondhand smoke.[8] Judge Kessler also details the industry's efforts to ensure that none of its research would be seen by courts or the general public.[9] The tobacco industry has also been found to deliberately market its products to youth for decades,[10] and has been found to destroy and suppress damaging information.[11] Industry efforts to suppress evidence of the catastrophic health effects of tobacco products has included publicly disparaging any research finding a link between tobacco use and disease and death, as well as attempting to discredit the researchers who publish such findings.[12]

In the latter half of the twentieth century, when the mounting evidence of the health effects of tobacco use became undeniable and the public finally began to question the motives of the tobacco industry, the tobacco companies conspired to create front groups that appeared to be legitimate, independent third-parties and used them to continue to disseminate false information.[13] The tobacco industry has demonstrated a continued effort to avoid willfully availing itself of meaningful regulation. The industry has expended tremendous efforts to ensure that its public statements could not be used against it,[14] even when those statements were patently untrue. This strategy was summed up by one executive who said, "[o]ur basic position in the cigarette controversy is subject to the charge, and may be subject to a finding, that we are making false or misleading statements to promote the sale of cigarettes."[15]

If there is a single, clear message that one can take away from Judge Kessler's momentous opinion, it is this: the tobacco industry racketeers simply cannot be trusted. They have 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. When the tobacco industry puts forward a proposal such as the one at issue here, the FDA should question the industry's motivation. Its 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.

**II. Attempts to Escape Regulation by Racketeers**

If the tobacco industry has a single greatest skill (aside from manufacturing and marketing a highly addictive and deadly product), it is understanding the regulatory environment, fighting existing tobacco control regulations, and identifying every potential opportunity to prevent the adoption of new tobacco control regulations.

It is no secret that the tobacco industry has spent hundreds of millions of dollars over decades lobbying legislative branches at the state and federal levels.[16] The industry's manipulation of federal executive agencies is less visible, but just as critical to the industry's agenda. The tobacco

industry has spent tremendous resources to track the actions and potential actions of executive agencies for the purpose of preventing and challenging unfavorable agency actions.

For example, beginning in 1986, the Department of Health and Human Services (HHS) required cigarette manufacturers to submit lists of cigarette ingredients. In response, the tobacco companies prepared elaborate defensive measures in the event this information was made public. The six largest American tobacco companies collaborated on a strategy to respond to a potential leak of the ingredient list or a prepared report that HHS could submit to Congress. The tobacco industry was keenly aware that pooling its resources and presenting a unified front would minimize any potential reputation damage created by its ingredient lists becoming public. The tobacco industry lawyers knew that even though ingredient lists were confidential in the hands of HHS, once a list became a part of a report to Congress, HHS could publish the list without violating the law.[17] Anticipating the ingredient list becoming public, the industry and its lawyers developed complex strategies for every potential "leak" scenario, including a small leak of information, a formal report severely critical of industry practices, sustained critical media coverage or even congressional hearings.[18] The industry continued to update its strategy throughout the 1980s and into the early 1990s until its focus shifted to potential regulatory actions by the FDA.[19]

In 1994, Representative Henry Waxman chaired a congressional hearing at which the CEOs of each of the seven largest tobacco companies infamously testified that they believed that nicotine was not an addictive substance.[20] Internal documents indicate that the industry knew that nicotine was addictive as early as the 1960s.[21] This hearing and the subsequent public scrutiny of the industry mark the beginning of an even more concerted effort by the tobacco industry to monitor federal action and attempt to prevent future regulation. In July of 1994, the Tobacco Institute, a tobacco industry front group, prepared an extensive report assessing the potential of fourteen federal agencies and forty-two sub-agencies of the Department of Health and Human Services to regulate tobacco.[22] The report also identified 229 recipients of federal grants to study tobacco, the funding each organization received, and the specifics of what was being studied. Finally, the report identified thirty-one national, non-governmental tobacco control organizations and described their activities. The industry was preparing for potential federal action by researching any agency or group that might stand in the way of its goal of avoiding regulation.

On August 11, 1995, the FDA published a notice that it intended to assert jurisdiction over cigarettes.[23] Internal documents show that the tobacco companies were already well prepared to take action. In fact, Philip Morris (now a division of Altria) had an "FDA Media Plan" devoted to thwarting any potential regulations initiated by the FDA. [24] This plan outlined strategies for several potential regulatory scenarios, including a notice of proposed rulemaking by the FDA, a leak of information from the FDA about a rule, or the issuance of a report that disparaged the industry. For each scenario, Philip Morris was prepared with press conference statements,[25] press releases,[26] radio and television advertising scripts,[27] newspaper op-ed pieces,[28] prepared speeches for industry-friendly congressional representatives,[29] grassroots campaign information,[30] and telephone contact lists for FDA employees.[31] This plan evolved into an "FDA Crisis Communication Plan," a minute-by-minute plan of the activities for a team of at least thirty-seven people who prepared for FDA action by running a "crisis simulation" on June 7, 1995.[32] This group was prepared for every step that FDA Commissioner David Kessler made, even disseminating rebuttals to speeches on the very day that Commissioner Kessler made them.[33]

All of these efforts were in addition to the formal channels that the tobacco industry used to challenge the FDA's proposed rule. From August 11, 1995 until January 2, 1996 and for an additional 30 days starting on March 18, 1996, the FDA's rule was open for public comment.[34] During the public comment period, the industry mobilized tobacco retailers by providing them with form letters to send to the FDA,[35] and by sending out an "Action Alert" describing the FDA's plan and outlining how retailers could get involved.[36] The tobacco industry also placed petitions inside tobacco retail stores so that customers could respond to the proposed rule.[37] Philip Morris solicited comments from its own employees by placing letter-writing booths outside employee cafeterias.[38] The tobacco industry also effectively motivated the advertising industry to respond negatively to the proposed rule by focusing on the rule's limitations on tobacco advertising and how it might affect advertising agency revenues.[39] This particular effort also included the provision of form letters.[40] In total, the massive mobilization campaign yielded the largest response to a proposed rule in FDA history.[41] The agency "received more than 700,000 individual pieces of mail, representing the views of nearly 1 million individuals."[42] This tremendous plan to overwhelm the FDA with comments represents how much effort the industry is willing to spend in order to utilize the formal legal processes to oppose regulation of its products. The notice-and-comment rulemaking process necessitates comments from the public but the tobacco industry's domination of the process demonstrates its capability and determination to avoid FDA regulation.

The industry mobilization did not block the FDA's efforts and the final rule was published on August 28, 1996.[43] While the tobacco industry identified possible tactics to thwart the FDA's efforts, such as lobbying Congress to limit FDA's enforcement ability by freezing its funding levels and/or forcing it to devote all of its employees to other tasks,[44] the industry ultimately resorted to the last tool in its toolbox: litigation. This was another strategy that the tobacco industry had been preparing for. Complaints had been drafted in advance and were prepared to be filed with the courts. Five tobacco companies and one advertising agency filed suit against the FDA and Commissioner Kessler on August 11, 1996, the same day the FDA published its final rule.[45] After a protracted legal battle that was eventually decided by the U.S. Supreme Court, the FDA's rule was struck down on March 21, 2000.[46] With the FDA rendered powerless to regulate tobacco, the industry returned its focus to Congress, monitoring and lobbying against any bill that could empower the FDA to regulate tobacco in the future.[47]

After numerous attempts, Congress passed the Family Smoking Prevention and Tobacco Control Act and President Obama signed the bill into law on June 22, 2009.[48] This Act finally granted the FDA the express authority to regulate tobacco products. However, this did not mark the end of the tobacco companies' attempts to evade regulation. Before the FDA had exercised any meaningful authority and even before most of the statutory provisions of the act had gone into effect, the tobacco industry challenged more than ten provisions within the Tobacco Control Act, including prohibitions on certain types of marketing activities directed toward youth and the Act's provision mandating graphic warnings on cigarette packages.[49] The industry later filed suit to challenge the FDA's final rule implementing graphic warnings.[50] The industry was unsuccessful in removing the FDA's authority to create graphic warnings, but has thus far blocked implementation of the graphic warning rule.[51] Additionally, the tobacco industry has tried, to forestall *potential* regulation of menthol cigarettes and dissolvable tobacco products by way of a lawsuit challenging the composition of the Tobacco Products Scientific Advisory

Committee (TPSAC), [52] which was formed pursuant to the Act to advise the FDA on safety and health issues, including those related to menthol cigarettes and dissolvable tobacco products. The industry has also attempted to use the Act's narrow preemption provision to stamp out novel tobacco control policies at the local level, twice in New York City[53] and once in Providence, RI.[54] Finally, the tobacco industry has also attempted to argue that the passage of the Tobacco Control Act extinguishes the court's jurisdiction in *U.S. v. Philip Morris* because it will be forced to comply with the Act's comprehensive regulation,[55] at the very same time that it was attempting to overturn the Act by arguing in another court that the Act was unconstitutional. All of these actions demonstrate the industry's dedication to avoiding regulation.

In short, the industry has the resources and motivation to block health-protective tobacco regulations at every stage of the regulatory process: both pre-rule (through public comment, mobilization, and Congressional influence) and post-rule (largely through litigation but also Congressional influence). This is not just a matter of history; the industry's recent responses to FDA actions made pursuant to the Tobacco Control Act show that the tobacco companies have not changed their ways. The proposal at issue in this comment is no exception. This history of underhanded tactics to avoid regulation provides context for the tobacco industry's current proposal. This industry has not demonstrated a willingness to participate in the creation of meaningful regulation and in examining the industry's current proposal, the FDA must account for the industry's continued attempts to avoid regulation. This next section will provide an overview of the industry's proposal and attempt to shed some light on its true intentions.

## III. The Racketeers' Meaningless Proposal

The tobacco industry's tobacco product good manufacturing practices proposal represents the industry's latest attempt to avoid meaningful regulation. Since the Tobacco Control Act was passed, the tobacco industry has not waited for the FDA to exercise all of its authority and instead has taken the initiative and petitioned the FDA, both formally and informally, to take actions that would be favorable to the industry rather than protective of public health. This industry proposal requests that the FDA codify a system of self-regulation. The FDA must be aware that allowing for self-regulation, for this industry in particular, will lead to disastrous consequences. It should be clear from the tobacco industry's behavior that this is an industry that cannot simply be left to regulate itself. When there is no oversight, there is no length that it will not go to in order to sell a product that it knows to be addictive and deadly. The FDA should not use its broad authority to simply mandate that the industry take actions that it ought to already be taking such as ensuring basic safety and sanitation in tobacco manufacturing facilities. This proposal is nothing more than a request for the least amount of FDA oversight that still gives the appearance of regulation. Instead, the FDA should implement stringent regulations that can reduce the harm of tobacco and improve public health.

This comment will attempt to identify some of the problems with the tobacco industry's proposal. Before detailing the specific failings with each subpart of the proposal, a few overarching problems must be addressed.

### A. Deliberate Inclusion of Meaningless Standards

Predictably, the tobacco industry's proposal would create no real binding requirements on the industry. Many of the proposed provisions would not require any safeguards, protection or testing procedures. Where requirements are established, no standards or criteria are set to measure the success or failure of the procedures. Instead, the regulations often refer to "adequate or appropriate standards" without making any attempt to define what is adequate or appropriate, presumably to afford deference to the manufacturer and make enforcement of the regulations very difficult.

These vague, undefined words appear so often in the proposal that even a quick glance can show the reader that the industry has no intention of providing meaningful guidance to regulators. Across the sixteen pages of proposed regulations the word "appropriate" appears eighteen times, "adequate" appears sixteen times, "suitable" appears six times and "proper" appears four times. In none of these cases are the words defined or provided in a context that makes it clear what they mean. The proposal also refers to "education and training" or similar language ten times without establishing what sort of education or training should be required for tobacco manufacturer employees.

The effect of this use of undefined terms is that the proposed regulations would have no real impact. For example, on page six of the regulations in Subpart B – Personnel, XXX.40(a), the proposal states: "each person engaged in manufacturing, testing, packaging, labeling, or holding, or in performing any quality control operations, *shall have the education, background, training, and/or experience to adequately perform the person's assigned functions*."

If this language were adopted, the FDA would find enforcement impossible. How a manufacturer complies with this requirement and how it can be enforced is unclear based on this language. It leaves many questions and no answers:

- What sort of education is required? Level of education is an easy standard to measure. Must an employee be a high school or college graduate or earn a particular degree?
- What background is required? Is a certain amount of experience necessary for a particular task?
- What sort of training is required? How many hours of training are required?
- Most importantly, how do we know whether an individual's performance is adequate? What is the measure of adequacy?

Without a precise measure of adequacy, there is no way to enforce the standard. If this proposal became a regulation, how could the FDA seek enforcement against a manufacturer who employed personnel without the necessary "education, background and training" to adequately perform his or her assigned functions? The vagueness found throughout this proposal is just one reason the FDA should reject this proposal entirely.

### B. The Racketeers Attempt to Assert an Individual Risk Standard for Tobacco Regulation

The second large, overarching problem with the proposal is the standard that is applied to what the industry calls "contamination." This is the one and only defined standard found in this

proposal and almost the entire proposal centers around the concept of avoiding "contamination." The purpose of this proposal is to create a standard that is much more favorable to the tobacco industry and one that is not what Congress intended when it empowered the FDA to regulate tobacco.

The tobacco industry proposal's definition of contaminate, found at Subpart A, XXX.3 Definitions, includes, "any added substance not ordinarily contained in tobacco products that *presents a risk of injury beyond the risks generally posed* by the same category of tobacco products." This and other proposed provisions indicate that the tobacco industry is attempting to insert an "individual risk" standard into tobacco regulation. To understand why this is disingenuous, one must understand the standard, established by Congress, that the FDA is mandated to use when it exercises its authority to regulate tobacco. That standard, found throughout the Tobacco Control Act, including Section 906(e) – Good Manufacturing Practice Requirements, is known as the "Public Health Standard."

### 1. The Public Health Standard

The Food, Drug and Cosmetic Act (FDCA) provides established standards for the regulation of food, drugs, devices and other products over which the FDA has regulatory authority. The regulation of food and drugs focuses on ensuring that consumers receive the benefits of products without being exposed to unnecessary and unregulated risks. For food, the FDA must ensure that food is safe, wholesome, sanitary, and properly labeled.[56] For drugs, the FDA must ensure that drugs are safe and effective.[57] Tobacco is different than these other products in that it is an inherently dangerous and deadly product. It is only effective at killing more than half of its users.[58] Cigarette smoking kills over 440,000 Americans each year,[59] and is the single largest cause of preventable death and disease in the U.S.[60] Because tobacco is neither safe and effective nor safe, wholesome and sanitary, and because it has no health benefits, only risks, the food and drug standards are inappropriate for the regulation of tobacco products.

Thus, Congress had to develop a new standard for FDA regulation of tobacco products, the public health standard.[61] Rather than using a standard that focuses on the safety of the individual, Congress established a standard that focuses on tobacco's effect on the entire population. Under this standard, the FDA must consider three factors when regulating tobacco: 1) the risks and benefits to the population as a whole, including users and nonusers of tobacco products; 2) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and 3) the increased or decreased likelihood that those who do not use tobacco products will start using such products.[62] This aggregate, public health standard can be a very powerful tool for the FDA, permitting the FDA to not just mitigate the ongoing damage caused by tobacco use, but also to prevent future harm by implementing stringent product and manufacturing standards and ensuring that new products improve rather than harm public health. The FDA is empowered to promulgate regulations that prevent youth from starting smoking, to help tobacco users quit tobacco, and to protect non-users from health hazards like secondhand smoke.

Focusing on the health of the population as a whole rather than on an individual allows the FDA to take an action such as prohibiting menthol flavoring in cigarettes. To an individual user, smoking a menthol flavored cigarette may pose the same risks with respect to cancer, COPD and

coronary heart disease as smoking an unflavored cigarette. However at the population level, it is clear that menthol is a starter cigarette that addicts more youth than unflavored cigarettes,[63] and the unique properties of menthol make it more difficult for addicted smokers to quit.[64] Menthol cigarettes have also had a disparate impact on the health of African-Americans and other minority populations.[65] TPSAC published a report that found that a prohibition on menthol flavored cigarettes would improve the public health.[66] Unsurprisingly, the tobacco industry's rebuttal report focused on an individual risk standard rather than the public health standard.[67] With this proposal, the industry attempts the same tactic: to create a regulatory scheme that is weak and not what Congress intended.

**2. The Racketeers' Attempt to Assert an Individual Risk Standard**

The public health standard is so ubiquitous in the Tobacco Control Act and Congress was so deliberate as to how it ought to operate that it is glaringly obvious that the tobacco industry's omission of this standard is deliberate. In fact, the public health standard appears in the Tobacco Control Act more than thirty-three times,[68] and is mentioned every time Congress vests rulemaking authority with the FDA. There is only one place in the Tobacco Control Act that mandates the use of an individual risk standard: Section 908(c)(1) which governs mandatory tobacco product recalls.

The industry notes in its proposal that its concept of a contaminant is consistent with the mandatory recall language of Section 908(c)(1). For purposes of comparison, what follows is first, the tobacco industry proposal's definition of contaminant and then the relevant language of Section 908(c)(1). The overlapping language is italicized.

> "Contaminant means any added substance *not ordinarily contained in tobacco products* that presents a risk of injury beyond the risks generally posed by the same category of tobacco products. . ."
>
> "If the Secretary finds that there is a reasonable probability that a tobacco product contains a manufacturing or other defect *not ordinarily contained in tobacco products* on the market that would cause serious, adverse health consequences or death, the Secretary shall issue an order requiring the appropriate person (including the manufacturers, importers, distributors, or retailers of the tobacco product) to immediately cease distribution of such tobacco product. . ."

Clearly, concept of contaminant is far from consistent with the mandatory recall language. The only apparent overlap is that both concepts address a substance that is not ordinarily contained in a tobacco product. Each provision creates a standard based on the risk of harm to the individual but the tobacco industry's proposal misapplies the individual risk standard established by Congress.

The two most important distinctions between Section 908(c)(1) and the tobacco industry's proposal are that 1) the Act requires only a reasonable probability of a defect not ordinarily found in a tobacco product, not actual evidence of "contamination" and 2) the Act only applies this individual risk standard when there is a chance of "serious, adverse health consequences or death."

The first distinction speaks to the procedural requirements of the standard or when that standard is applied. The Tobacco Control Act is clear about when its standard applies: when there is a reasonable probability of a defect. The FDA defines a reasonable probability as more likely than not that an event will occur.[69] The industry's proposal provides a standard for contamination: when any added substance presents a risk of injury beyond the risk of similar products. However, it does not provide a mechanism for testing for contamination and thus provides no way to apply the standard. It makes several references related to preventing contamination and what should be done once a product is contaminated, but without a mechanism for determining which products are contaminated and which products are not contaminated, there is absolutely no way to determine when a product presents a risk greater than a similar product. Without this mechanism, the entire standard is rendered meaningless.

The second distinction is one of substance. The standard in Section 908(c)(1) only applies to a chance of "serious, adverse health consequences or death." While this language may seem slightly ambiguous, there is additional guidance on exactly what this means. "Serious, adverse health consequences means any significant adverse experience, including those that may be either life-threatening or involve permanent or long-term injuries, but excluding injuries that are nonlife-threatening and that are temporary and reasonably reversible."[70] The tobacco industry's proposed standard applies to a substance that "presents a risk of injury beyond the risks generally posed by the same category of tobacco products." This standard is far too vague for the FDA to apply and leaves too many unanswered questions:

- What type of risk is anticipated? Death, disease or some other injury?
- How far must a risk be beyond the ordinary risk in order to qualify as a contaminant?
- What are the categories of tobacco products that should be used for comparison? Other products from the same manufacturer? Other products from all tobacco manufacturers?

The tobacco industry has attempted to use Section 908(c)(1)'s product recall standard to lend credibility to its own empty, meaningless standard. It is clear, however, that in doing so, it has only borrowed a few words from the Act and that it hasn't actually incorporated the standard. Even if the tobacco industry had made a meaningful attempt to incorporate this individual risk standard, it would still be violating the spirit of the Act. As was mentioned previously, the proper standard to apply is the public health standard. The mere fact that the Tobacco Control Act includes an individual risk standard does not mean that it should be used in this context.

In fact, when one puts the language of Section 908(c)(1) in context with the rest of the FDCA it becomes perfectly clear why Congress inserted this individual risk standard for tobacco product recalls. Substantially similar language is used in the FDCA to determine when food, drugs and devices must also be recalled. For the purposes of so drastic a measure as a product recall, an individual risk standard is appropriate. A product recall is costly and difficult and should only be undertaken when absolutely necessary. For a recall, Congress intends the FDA to take drastic steps only when there is a serious threat of harm. Below are excerpts of the relevant language relating to the recalls of tobacco products, drugs and devices, and food, with similar language italicized.

Tobacco Products Recalls – 21 U.S.C. § 387h(c)(1)

"*If the Secretary finds that there is a reasonable probability* that a tobacco product contains a manufacturing or other defect not ordinarily contained in tobacco products on the market that would *cause serious, adverse health consequences or death, the Secretary shall issue an order requiring the appropriate person (including the manufacturers, importers, distributors, or retailers of the tobacco product) to immediately cease distribution* of such tobacco product. . ."

Drug and Device Recalls – 21 U.S.C. § 360h(e)(1)(A) – (B)

"*If the Secretary finds that there is a reasonable probability* that a device intended for human use would *cause serious, adverse health consequences or death, the Secretary shall issue an order requiring the appropriate person (including the manufacturers, importers, distributors, or retailers of the device)--*
(A) *to immediately cease distribution* of such device, and
(B) to immediately notify health professionals and device user facilities of the order and to instruct such professionals and facilities to cease use of such device."

Food Recalls – 21 U.S.C. § 350l(a)

"*If the Secretary determines, based on information gathered* through the reportable food registry under section 350f of this title or through any other means, that there is a reasonable probability that an article of food (other than infant formula) is adulterated under section 342 of this title or misbranded under section 343(w) of this title and the use of or exposure to such article will *cause serious adverse health consequences or death to humans or animals, the Secretary shall provide the responsible party (as defined in section 350f of this title) with an opportunity to cease distribution* and recall such article."

Congress's intent is clear. In tobacco product regulation, the FDA must use this individual risk standard when considering a recall and *only* when it is considering a recall. By including this individual risk standard in the recall statute for tobacco products that is consistent with the recall language for other products, Congress has ensured that any FDA-enforced recalls should be based on the same sort of danger of harm to the public as for all the products it regulates. However, all other decision making by the FDA with regard to tobacco products *must* be evaluated under the public health standard.

Furthermore, this individual risk standard proffered by the tobacco industry and used only for product recalls is not found in the section that establishes the FDA authority over manufacturing regulations, Section 906(e). Instead, Section 906(e) instructs the FDA to use the public health standard found throughout the act. Thus, Congress's intent is clear: when establishing manufacturing practice regulations, the FDA *must* use the public health standard, not an individual risk standard. With this proposal, the tobacco industry attempts to undermine the

Congressional intent of the Tobacco Control Act and the FDA's authority to regulate its products.

### C. Additional Problems in the Racketeers' Proposal

#### 1. Background and Related Information

The tobacco industry provides a preamble to its proposal and it is in the first section of this preamble that it lays the groundwork for its attempt to insert an individual risk standard into tobacco product regulation. The industry argues here that many medical device recalls are the result of manufacturers not conforming to good manufacturing practices. It states the problem in this fashion because, as was noted above, it is under the FDA's recall authority that the individual risk standard is found.

In this section, the tobacco industry also establishes the three purposes of its proposal. The first stated purpose is to protect public health but it alleges that the proposal accomplishes this goal by preventing contamination, measured with an individual risk standard rather than the public health standard established by the Tobacco Control Act. This issue has been thoroughly discussed above and is the first of many examples throughout the proposal of a gross mischaracterization of the public health standard.

The second stated purpose of the proposal is preventing misbranded tobacco products. This inclusion is illogical when read in light of the rest of the document. Under the Tobacco Control Act, a product is misbranded if it does not comply with the FDA's established labeling procedures. The industry's proposed requirements governing labeling do not reference FDA labeling procedures or misbranding. In fact, the term, "misbrand" appears only in the preamble and not the text of the proposed regulations. It is included as an overarching goal in name only and not in substance.

The third stated purpose is to give manufacturers flexibility. Given the discussion of the public health standard above, clearly manufacturer flexibility should not be one of the FDA's considerations when regulating manufacturing practices. Furthermore, the tobacco industry asserts that this regulatory flexibility is rooted in the fact that tobacco is an agricultural product that has inherent variations across plants and seasons. Because of this inherent variability, the tobacco industry asserts that it must be given flexibility to manufacture, label, pack and store tobacco products. While agricultural variability may affect manufacturing and possibly storing, it would not, in any way, affect labeling or packaging. This goal also mischaracterizes the issues at hand.

In promulgating a manufacturing regulation or any regulation, the FDA must have only one goal: protecting public health and this goal is inconsistent with the tobacco industry's goal.

Following the tobacco industry's establishment of the purpose of its proposal, it lays out its argument for an individual risk standard. This specious argument is as follows:

> Underpinning the proposed cGMP regulation for tobacco products is an acknowledgement that the U.S. Surgeon General and other public health

> authorities have identified certain inherent risks associated with the use of different categories of such products. When Congress enacted the Tobacco Control Act, it acknowledged such inherent risks but did not ban such products, clearly stating that the intent of the act was "to continue to permit the sale of tobacco products to adults." FDCA § 907(d)(3)(A) (FDA is expressly "prohibited" from issuing a regulation "banning all cigarettes, all smokeless tobacco products, all little cigars, all cigars other than little cigars, all pipe tobacco, or all roll-your-own tobacco products.").
>
> Thus the cGMP regulation for tobacco product manufacturers must take into account that tobacco products have inherent risks and, given the purpose of the cGMPs, not require manufacturers to address those risks in this context.

Essentially, the tobacco industry's argument is that tobacco products are risky and thus manufacturing standards cannot address that risk. The chain of reasoning of this argument is, at best, deceptive. It is true that leading public health authorities have identified the inherent risks of tobacco products and that Congress recognized those risks in developing the Tobacco Control Act. Even the tobacco industry has begrudgingly admitted that smoking is harmful. It is true that Congress did not prohibit any tobacco products and it is also true that Congress did not give the FDA authority to prohibit any tobacco products. However, there is no connection between the acknowledged risk of tobacco products and the lack of a tobacco product prohibition in the Tobacco Control Act. At no point is there a suggestion that the inherent risks of tobacco use cannot or should not be addressed by manufacturing standards or any other regulations. Were this true, there would be no reason for Congress to give the FDA regulatory authority over tobacco products.

This argument also fails because Congress specifically mandated that the FDA address the inherent risk of using tobacco products in the context of manufacturing practices. We know this because Congress mandates that the FDA use the public health standard when promulgating regulations relating to manufacturing practices. To say that manufacturing practices should not address the inherent risk of tobacco products is untrue; they *can* and they *must*.

### 2. Subpart A – General Provisions: Missing Provisions and Vague Definitions

This subpart discusses the applicability of the regulations and also includes the definitions for the regulations. The first paragraph of this subpart once again attempts to assert that the individual risk standard is the appropriate standard to consider in establishing good manufacturing practices. However, there are additional problems with this subpart.

The first of several glaring omissions occurs in XXX.1 Applicability, subsection (d). This subsection notes that a manufacturer may apply for a variance to any of the established good manufacturing practices and that variance submissions should follow the procedures set forth in 21 C.F.R. § 10.30, which are the procedures for filing a citizen petition. At first glance, it is clear that the industry has deliberately omitted any criteria that the FDA should rely on when deciding whether to grant such a variance. However upon further inspection, the omission is much larger. What have been omitted are the extensive procedures for granting a variance established by the Tobacco Control Act.

Within Section 906(e), subsection (1) outlines the FDA's authority to establish good manufacturing practices regulations and subsection (2) establishes the procedures for granting a variance. This subsection, in part, states that a variance application must identify the basis upon which the variance is based, the methods and controls to be used in place of the required practice and any other information that the FDA requires.[71] The Act also states that the FDA may refer the application to TPSAC,[72] that any variance granted requires a showing that the procedures used will maintain compliance with the Act,[73] and that the FDA can place additional conditions on any variance that it grants.[74]

By leaving these procedures out of its proposal and replacing them with meaningless procedures, the tobacco industry has attempted to create a much weaker variance process that will make it difficult – if not impossible – for the FDA to enforce regulations to protect public health.

Subpart A also includes the definitions section of the tobacco industry's proposal. It is in this section that the industry includes the definition of contaminant, which is thoroughly discussed above. Another important definition found in this section is "tobacco product." Although the proposal language mostly tracks the language in the Tobacco Control Act, the tobacco industry added some language to the end of the definition that limits tobacco products to only those over which the FDA has asserted jurisdiction under Section 901(b). Nowhere in the Tobacco Control Act is the definition of tobacco product limited in this fashion. This limitation would prevent the FDA from regulating the manufacturing facilities of new and novel tobacco products that might fall outside the definition of tobacco product. Including this limitation is likely an attempt to limit FDA authority to regulate some manufacturing facilities.

### 3. Subpart B – Personnel: Lack of Dedicated Quality Control

As was indicated above, this subpart dealing with personnel, is rife with vagueness. Where there should be standards related to education and training, the tobacco industry's proposal has indicated at XXX.40(a) that an employee's background must only be sufficient to "*adequately perform the person's assigned functions.*" This section would be difficult for the FDA to enforce and invites pointless, costly litigation.

This section, which purports to create requirements for quality control staff, does not mandate that the tobacco industry have staff dedicated to quality control. According to XXX.31, it is merely sufficient to have staff members who are assigned quality control tasks but do not have to dedicate their time to such tasks. Because of this lack of dedicated staff, it is very easy to foresee a situation where a manufacturing facility employs personnel who are quality control personnel in name only and do not actually perform quality control tasks or only perform them when there is an FDA inspection. It is particularly easy for the industry to accomplish this given the lack of education and training standards for such staff.

This subpart also contains the most instructive language on how a manufacturer should ensure that its employees can prevent contamination. Because this proposal is centered on preventing contamination which is measured by the individual risk standard proffered by the industry, one would expect this extremely important provision to be very extensive and detailed. XXX.35 reads as follows:

> You shall establish and maintain requirements for the health, cleanliness, personal practices, and clothing of personnel if contact between such personnel and tobacco product, packaging, or materials could reasonably be expected to result in contamination.

This provision contains no standards, no way to measure success or failure, and therefore is utterly unenforceable. The absolute deference to the tobacco product manufacturer contemplated by this proposal is unacceptable. The tobacco industry cannot and should not be allowed to regulate itself. In establishing manufacturing regulations, the FDA cannot simply ask the tobacco industry to do the bare minimum, as this proposal would have it do. The FDA must promulgate meaningful regulations that save lives and protect public health.

### 4. Subpart C – Physical Plant and Grounds: Individual Risk Standard Mischaracterization of Federal Law

A regulation governing the physical plant and grounds must be thorough and outline regulations relating to the physical environment and the methods that should be used to prevent contamination. The industry's proposed language does neither of those things. This section, much like the rest of the proposal, includes no real standards that can be applied to allow for effective regulation. Rather than rigorous standards relating to cleanliness, the proposal states at XXX.50(b) that the physical plant should be in a "clean and sanitary condition." No definition for clean or sanitary is provided in the proposed regulations. The tobacco industry's preamble, at Subpart C, suggests that clean and sanitary indicates that "a manufacturer's physical plant shall be kept clean to the extent necessary to protect against contamination, taking into account the inherent risks of tobacco products and an analysis of the risks of contamination." The preamble at Subpart C also states that the term "sanitary" is "not intended to require sanitization, sterilization, or any other specific form of cleaning beyond what the risk analysis determines is necessary."

Predictably, this section makes another big push toward an improper individual risk standard. The tobacco industry applies this standard toward cleanliness. Because the standard is based on the risk of harm to an individual rather than a population, a manufacturer could significantly reduce the resources that it puts towards cleaning its facility as long as each individual cigarette is not rendered more harmful. Using an individual risk standard for cleanliness creates an impermissible amount of flexibility that ultimately imposes no standards at all.

This subpart also allows manufacturers complete freedom to use "insecticides, fumigants, fungicides or rodenticides." The only qualifier on the use is that it must be done, "when monitoring indicates the need for the use." Unsurprisingly, there are no monitoring requirements established nor are there any established thresholds for when the products should be used and so it seems that "when monitoring indicates the need," means that the manufacturer can use its own discretion.

While this section indicates that these products should be used to protect against contamination, the language in no way anticipates that the pesticide products themselves might be contaminants even though these products could potentially be toxic and/or carcinogenic. The only attempt to

establish regulations on the use of pesticides is a passing reference to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The purpose of FIFRA is to regulate pesticide manufacturers by imposing regulations related to registration, labeling, recordkeeping and the import and export of various pesticides. FIFRA makes almost no references to the use of pesticides and none of the use regulations would apply in this context.[75]

Finally, the FDA is given the specific authority, by the Tobacco Control Act, to create regulations that, "provide for the testing of raw tobacco for pesticide chemical residues regardless of whether a tolerance for such chemical residues has been established."[76] Any meaningful regulation of tobacco product manufacturing practices must use all of the FDA's authority including testing of pesticide chemical residues.

### 5. Subpart I – Evaluation and Acceptance Activities: No Testing Necessary

This section purports to impose regulations relating to the receipt of tobacco products by manufacturers. Unfortunately, this section establishes no meaningful standards and does not actually mandate any kind of regulation. In fact, the tobacco industry notes in its preamble that, "[b]ecause of the unique nature of tobacco products,. . . in-process or finished tobacco product testing is not required." This section makes no attempt to impose any kind of regulation.

### 6. Subpart J – Nonconforming Tobacco Product: Contaminated Products Can Be Reworked But Don't Need To Be Tested

This section establishes the procedures relating to what a manufacturer may do with a contaminated product. The industry's proposed regulation would not require that a contaminated product be discarded as harmful, but instead would allow a manufacturer to "rework" the contaminated product.

Because of the potential risk of harm, the process of reworking a product should be thoroughly and stringently regulated. This is not the case in the industry's proposal. A manufacturer would only need to establish a plan for ensuring that the reworked tobacco product meets specifications. A manufacturer would not be obligated to test the product to ensure that the contaminant was removed. As long as a plan is in place and followed, the manufacturer has fulfilled its obligations. It need not actually determine whether or not the reworking process was successful, which could result in contaminated products being introduced into the marketplace.

### 7. Subpart M – Complaints: Far From Enforcement

This section of the proposal provides language that is the closest that the tobacco industry's proposal comes to creating a compliance and enforcement mechanism. Unfortunately, the only thing that this section actually does is suggest that the industry investigate complaints that it receives. The complaints would presumably come from tobacco product consumers, although there is no language that instructs the industry to make information on the process of submitting a complaint available nor are there any procedures for receiving complaints. Most egregiously, the proposal does not actually mandate an investigation, it only suggests that complaints be investigated, "[w]here appropriate." Consistent with the rest of the proposal, there is no indication as to what must be measured to determine the appropriateness of an investigation. The

proposal also includes specific language that allows the tobacco industry to only conduct a single investigation for a group of similar complaints. One would expect that many similar complaints would indicate that a full and thorough investigation is necessary due to the risk of some large-scale, catastrophic contamination, but according to the tobacco industry's proposal – no such investigation would be required.

#### 8. Effective Date: Large Manufacturers vs. Small Manufacturers

One final problem with the racketeers' proposal is found in the very last sentence of the industry's proposal. While the tobacco industry suggests that the proposal cannot take effect for two years after the final rule is published, no such delay is required by the Tobacco Control Act. What the Act does mandate is that the FDA must give small tobacco product manufacturers four years before they are required to follow any established manufacturing practices. The large tobacco companies have used this last sentence of the proposal to weaken their smaller competitors, showing not just their contempt for public health but also for healthy competition.

### D. Strategic Missing Elements

In addition to the problems found in the text of the industry's proposal, there is also a significant problem with what has been left out of the proposal. Nowhere in this proposal is there any indication as to what might happen to a tobacco manufacturer who violates these regulations. It has been noted how weak and difficult to enforce these regulations are. However, assuming that a manufacturer did violate some established principal, there is no suggestion as to what procedures the FDA must follow in pursuing an enforcement action or what penalty might apply to a violating manufacturer. This omission is likely a deliberate one.

Further clouding the issue of enforcement is a strange quirk that is found throughout the proposal. Many but not all sections of the regulations refer to "you" and what "you" must do in regard to manufacturing standards. The use of second person language is very uncommon in statutes and regulations. Rather, precise regulations refer to the party that is being regulated – in this case, tobacco product manufacturers. Complex corporate relationships could potentially complicate enforcement of these regulations unless the regulations clearly indicate the party to be held responsible. This proposal fails utterly in this respect.

## IV. The Full Extent of FDA Authority

Any action taken to regulate manufacturing practices must maximize the authority granted to the FDA by Congress. The Tobacco Control Act devotes all of Section 906(e) to discussion of the FDA's broad authority to regulate tobacco product manufacturing. Congress has allowed the FDA to create different regulations for different types of products where such regulation is appropriate.[77] The FDA can mandate the testing of pesticide chemical residue.[78] The FDA can implement a stringent variance process that allows TPSAC to review all variance applications.[79] The FDA can also implement strong enforcement mechanisms including large civil monetary penalties for violations. The FDA is also required to have an oral hearing before promulgating any manufacturing regulations,[80] and the FDA must allow TPSAC to review any proposed regulation.[81]

## V. Conclusion

The tobacco industry's history of avoiding and fighting meaningful regulation shows that it cannot be trusted to be a good-faith participant in the regulatory process. When the FDA exercises its authority to regulate tobacco product manufacturing, it cannot rely on this meaningless and deceptive proposal proffered by the tobacco industry.

The Tobacco Control Legal Consortium urges the FDA to consider the past actions of the tobacco industry when weighing the industry's proposed tobacco product manufacturing regulations.

Respectfully,

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[1] United States. v. Philip Morris USA, Inc., 449 F.Supp.2d 1 (D.D.C. 2006). For an overview of industry practices from the findings section of the case, *see* TOBACCO CONTROL LEGAL CONSORTIUM, THE VERDICT IS IN: FINDINGS FROM UNITED STATES V. PHILIP MORRIS (2006) *available at* http://publichealthlawcenter.org/sites/default/files/resources/tclc-verdict-is-in.pdf.

[2] Philip Morris, Inc., now Philip Morris USA, Inc. (a division of Altria), R.J. Reynolds Tobacco Co., now Reynolds American, Brown & Williamson Tobacco Co., now part of Reynolds American, Lorillard Tobacco Company, The Liggett Group, now part of Vector Group Ltd., American Tobacco Co., which merged with Brown & Williamson, now part of Reynolds American, Philip Morris Cos., now Altria, British American Tobacco Investments Ltd., The Council for Tobacco Research U.S.A., Inc., and The Tobacco Institute, Inc.

[3] This decision has led many in the tobacco control community to label the tobacco industry defendants, "racketeers."

[4] This proposal has been put forth by R.J. Reynolds Tobacco Company, a division of Reynolds American; along with Santa Fe Natural Tobacco Company, Inc. and American Snuff Company, LLC, also divisions of Reynolds American; Altria Client Services on behalf of Philip Morris USA Inc. and U.S. Smokeless Tobacco Company; Lorillard, Inc.; Commonwealth Brands, Inc., a division of Imperial Tobacco plc; Swedish Match North America, the SMARTT Coalition; Liggett Group LLC, Vector Tobacco Inc.; National Tobacco Company, L.P.; and Hail & Cotton, Inc. Not all of these companies and groups were defendants in *United States v. Philip Morris* and thus any references in this comment to the tobacco industry generally, unless otherwise noted, should be understood to reference the tobacco industry defendants in *United States v. Philip Morris*, and not necessarily all of the companies that have offered this proposal.

[5] 449 F.Supp.at 146-208.

[6] 449 F.Supp.at 208-384.

[7] 449 F.Supp.at 430-561.

[8] 449 F.Supp.at 694-801.

[9] 449 F.Supp.at 801-839.

[10] 449 F.Supp.at 561-694.

[11] 449 F.Supp.at 801-839.
[12] 449 F.Supp.at 35-143.
[13] 449 F.Supp.at 35-143; *id.* at 723-788
[14] 449 F.Supp.2d at 208.
[15] 449 F.Supp.at 801-839.
[16] $846,321,676.00 represents the aggregate campaign and lobbying spending by the tobacco industry from 1989-2012. *See* INFLUENCE EXPLORER, http://influenceexplorer.com (last visited May 20, 2013).
[17] Memorandum from Clausen Ely on Strategy for Responding to Inquiries Following the Release of a Report by the Department of Health and Human Services on Cigarette Ingredients to James L. Charles et al. (Apr. 12, 1989) *available at* http://legacy.library.ucsf.edu/tid/fqg62b00/pdf.
[18] Memorandum from Clausen Ely on Strategy for Responding to Inquiries in Connection with the Release of a Cigarette Ingredients List, a Report by the Department of Health and Human Services, on Cigarette Ingredients or a Congressional Hearing on Ingredients Matters (Jan. 16, 1994) *available at* http://legacy.library.ucsf.edu/tid/bmi96b00/pdf.
[19] Memorandum from Stanley L. Temko & Clausen Ely on Strategy for Responding to Inquiries in Connection with the Release of a Cigarette Ingredient List, A Report By the Department of Health and Human Services on Cigarette Ingredients or a Congressional Hearing on Ingredient Matters (Jan. 26, 1994) *available at* http://legacy.library.ucsf.edu/tid/zze35a00/pdf.
[20] *Nicotine and Cigarettes: Hearing Before the Subcomm. on Health & the Env't, of the Comm. on Energy & Commerce*, 103rd Cong. (1994).
[21] *United States v. Philip Morris USA Inc.*, 449 F. Supp. 2d 1, 1454 (D.D.C. 2006).
[22] *Federal Tobacco Control Effort*, LEGACY TOBACCO DOCUMENTS LIBRARY, http://legacy.library.ucsf.edu/tid/vol33d00/pdf (last visited Apr. 3, 2013).
[23] Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco Products to Protect Children and Adolescents, 60 Fed. Reg. 41,314 (Aug. 11, 1995).
[24] *Introduction (Mar. 1, 1995)*, LEGACY TOBACCO DOCUMENTS LIBRARY, http://legacy.library.ucsf.edu/tid/ref36e00/pdf .
[25] *Steve Parrish Statement For Press Conference Announcing Suit*, LEGACY TOBACCO DOCUMENTS LIBRARY, http://legacy.library.ucsf.edu/tid/rav72e00/pdf .
[26] *Philip Morris Files Suit Against FDA, Commissioner Kessler*, LEGACY TOBACCO DOCUMENTS LIBRARY, http://legacy.library.ucsf.edu/tid/rav72e00/pdf.
[27] *Reuter TV/FDA Primer 2nd Draft 3/7/95*, LEGACY TOBACCO DOCUMENTS LIBRARY, http://legacy.library.ucsf.edu/tid/cef36e00/pdf.
[28] *Fixing Fundamentals, Instead of Treating Symptoms, Key to FDA Reform*, LEGACY TOBACCO DOCUMENTS LIBRARY, http://legacy.library.ucsf.edu/tid/wdf36e00/pdf.
[29] *FDA Media Plan, Confidential*, LEGACY TOBACCO DOCUMENTS LIBRARY, http://legacy.library.ucsf.edu/tid/mdf36e00/pdf.
[30] *Audience Message*, LEGACY TOBACCO DOCUMENTS LIBRARY, http://legacy.library.ucsf.edu/tid/gef36e00/pdf.
[31] *FDA Contact List*, LEGACY TOBACCO DOCUMENTS LIBRARY, http://legacy.library.ucsf.edu/tid/vbv72e00/pdf.
[32] *FDA Crisis Communication Plan*, LEGACY TOBACCO DOCUMENTS LIBRARY, http://legacy.library.ucsf.edu/tid/mef36e00/pdf.
[33] *Preparations for Kessler Speech*, LEGACY TOBACCO DOCUMENTS LIBRARY, http://legacy.library.ucsf.edu/tid/hyi87e00/pdf.
[34] Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco Products to Protect Children and Adolescents; Extension of Comment Period, 60 Fed. Reg. 199, 53560 (Oct. 16, 1995) *available at* www.gpo.gov/fdsys/pkg/FR-1995-10-16/pdf/95-25670.pdf.
[35] *Form Letter to Dockets Management Branch (HFA-305)*, LEGACY TOBACCO DOCUMENTS LIBRARY, http://legacy.library.ucsf.edu/tid/rqa11d00/pdf .
[36] *Action Alert from Smokers' Advocate on Message Points (Oct. 1995)*, LEGACY TOBACCO DOCUMENTS LIBRARY, http://legacy.library.ucsf.edu/tid/mgm18d00/pdf.
[37] *Fax from L.W. Clayton on FDA Action Plan Update to J. J. Ellegate (Oct. 16, 1995)*, LEGACY TOBACCO DOCUMENTS LIBRARY, http://legacy.library.ucsf.edu/tid/vjw72d00/pdf (last visited Apr. 19, 2013).
[38] *On Monday, October 16, Take a Few Minutes to Let the FDA Know What You Think About Its Plan to Regulate Cigarettes*, LEGACY TOBACCO DOCUMENTS LIBRARY, http://legacy.library.ucsf.edu/tid/xiq77d00/pdf.

[39] *Action Alert on Urgent Message: FDA Plans to Regulate Tobacco Advertising*, LEGACY TOBACCO DOCUMENTS LIBRARY, http://legacy.library.ucsf.edu/tid/fem18d00/pdf.
[40] *Id.*
[41] Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco Products to Protect Children and Adolescents, 61 Fed. Reg. 168, 44398 (Aug. 28, 1996) *available at* http://www.gpo.gov/fdsys/pkg/FR-1996-08-28/pdf/X96-10828.pdf.
[42] *Id.* at 44418.
[43] *Id.* at 44615.
[44] *Proposed Provisions for Chairman's Mark of FDA Appropriations Bill*, LEGACY TOBACCO DOCUMENTS LIBRARY, http://legacy.library.ucsf.edu/tid/zhx80d00/pdf.
[45] *Coyne Beahm, Inc. v. United States Food & Drug Admin*, 966 F.Supp. 1374 (M.D.N.C. 1997).
[46] *United States Food & Drug Admin. v. Brown & Williamson Tobacco Corp*., 529 U.S. 120 (2000).
[47] *FDA Tobacco Jurisdiction Legislation in the 107th Congress Senate Bills*, LEGACY TOBACCO DOCUMENTS LIBRARY, http://legacy.library.ucsf.edu/tid/dth77a00/pdf.
[48] Family Smoking Prevention and Tobacco Control Act, Pub. L. 11-31, 123 Stat. 1776 (2009).
[49] *Discount Tobacco City & Lottery, Inc. v. United States Food & Drug Admin*., 674 F.3d 509 (6th Cir. 2011).
[50] *R.J. Reynolds Tobacco Co. v. United States Food & Drug Admin.*, 845 F.Supp.2d 266 (D.C. Cir. 2012).
[51] *Id.*
[52] *Lorillard, Inc. vs. United States Food & Drug Admin.*, No. 11-440 (RJL), 2012 WL 3542228 (D.C. Cir. 2012).
[53] *23-34 94th St. Grocery v. N.Y.C. Board of Health*, 685 F.3d 174 (2d Cir. 2012); *U.S. Smokeless Tobacco Manufacturing Company, LLC v. City of New York*, 703 F.Supp.2d 329 (S.D.N.Y. 2010).
[54] *Nat'l Assoc. of Tobacco Outlets, Inc. v. City of Providence*, No. 12-96-ML., 2012 WL 6128707 (D.R.I. 2012).
[55] *United States v. Philip Morris USA, Inc.*, 686 F.3d 832 (D.C. Cir. 2012).
[56] 21 U.S.C. § 393(b)(2)(A).
[57] 21 U.S.C. § 393(b)(2)(B).
[58] WORLD HEALTH ORG. TECHNICAL REPORT SERIES, THE SCIENTIFIC BASIS OF TOBACCO PRODUCT REGULATION 3 (World Health Org. Press 2007), *available at* http://www.who.int/tobacco/global_interaction/tobreg/who_tsr.pdf.
[59] Centers for Disease Control and Prevention, *Smoking-Attributable Mortality, Years of Potential Life Lost, and Productivity Losses – United States, 2000-2004*, 57 MORBIDITY & MORTALITY WKLY. REP. 1226, 1226-28 (2008), *available at* http://www.cdc.gov/mmwr/PDF/wk/mm5745.pdf.
[60] *Id.*
[61] H.R. REP. NO. 111-58, pt. 1, at 39 (2009), *reprinted in* 2009 U.S.C.C.A.N. 468, 488.
[62] 21 U.S.C. § 387g(a)(3)(B)(i).
[63] TOBACCO CONTROL LEGAL CONSORTIUM ET AL., CITIZEN PETITION TO FOOD & DRUG ADMIN., PROHIBIT MENTHOL AS A CHARACTERIZING FLAVOR OF CIGARETTES AND CIGARETTE SMOKE 16 (Apr. 12, 2013) FDA-2013-P-0435, *available at* http://www.regulations.gov/#!docketDetail;D=FDA-2013-P-0435.
[64] *Id.* at 16, 17.
[65] *Id.* at 24-28.
[66]Tobacco Products Sci. Advisory Comm., *Menthol Cigarettes and Public Health: Review of the Scientific Evidence and Recommendations*, U.S. FOOD & DRUG ADMIN., 225 (July 21, 2011), *available at* http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM269697.pdf.
[67] Lorillard Tobacco Co. et al., *The Industry Menthol Report: Menthol Cigarettes: No Disproportionate Impact on Public Health*, U.S. FOOD & DRUG ADMIN. (Mar. 23, 2011), *available at* http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM249320.pdf.
[68] 21 U.S.C. § 387(21)(C); § 387c(a)(8)(B)(ii); § 387e(j)(3)(A)(ii); § 387f(d)(1); § 387f(d)(3)(B); § 387f(e)(1)(A); § 387g(a)(3)(A); § 387g(a)(3)(B)(ii); § 387g(a)(4)(A); § 387g(a)(4)(B); § 387g(c)(2)(A); § 387g(c)(3); § 387g(d)(1)(A); § 387g(d)(2); § 387g(e)(1); § 387g(f)(1); 387h(a)(1); 387i(a), (a)(3); § 387i(a)(6); 387j(3)(A)(ii); § 387j(c)(2)(A); § 387j(c)(4); § 387j(c)(5)(A); § 387j(d)(1)(A); § 387k(g)(2)(A)(i); § 387k(i)(2); § 387k(j)(3)(C); 387o(b)(1); §387o(b)(2); 387r(b)(1).
[69] 21 C.F.R. § 810.2(h).
[70] 21 C.F.R. 810.2(i).
[71] 21 U.S.C. § 387f(e)(2)(A)(i)-(iii).
[72] 21 U.S.C. § 387f (e)(2)(B).

[73] 21 U.S.C. § 387f (e)(2)(C).
[74] 21 U.S.C. § 387f (e)(2)(D).
[75] 7 U.S.C. § 136 et seq.
[76] 21 U.S.C. § 387f(e)(1)(A).
[77] *Id.*
[78] *Id.*
[79] 21 U.S.C. § 387f(e)(2).
[80] 21 U.S.C. § 387f(e)(1)(B)(ii).
[81] 21 U.S.C. § 387f(e)(1)(B)(iii).