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Meeting with the OMB Office of Information and Regulatory Affairs
Thursday, January 2, 2013

Subject: RIN: 0910-AG38, FDA's Tobacco Products "Deeming Regulation"

Introduction

Thank you for this opportunity to meet with you.

Elaine Keller, President
Julie Woessner, Legislative Director

What is CASAA?

The Consumer Advocates for Smoke-free Alternatives Association (CASAA) is a non-profit 501(c)(4), all-volunteer organization with a grassroots membership of nearly 9,000 individuals from all walks of life. We are a consumer advocacy organization, not a trade association or industry representative. CASAA is dedicated to ensuring the availability of reduced harm alternatives to smoking and to providing smokers and non-smokers alike with honest information about those alternatives. Since CASAA's founding in 2009, we have educated the public and increased awareness about the benefits of reduced harm alternatives to smoking, including e-cigarettes. We also encourage responsible legislative policy designed to improve public health by recognizing that smoke-free nicotine-containing products are inherently far less dangerous than smoking.

Why we are here

We are the only major representative of the primary stakeholders in this regulation, the consumers. We are concerned that the proposed regulation of e-cigarettes will offer almost no benefits to consumers while imposing substantial costs. Note also that we understand that the proposed deeming regulation probably includes cigars and possibly other products; our comments here do not apply to those products, which are similar to cigarettes in most ways and thus could be sensibly and relatively easily brought into the cigarette regulatory regime.

CASAA's membership has many concerns about potential problems with FDA's proposed "deeming regulation" for electronic cigarettes (which are generally known as e-cigarettes). The FDA's submission states: "The proposed rule has two parts: one part deems all tobacco products to be subject to the FD&C Act; the other part proposes additional provisions that would apply to newly-deemed products as well as to other covered tobacco products."

We are working from a position of ignorance about the details, as you realize, and so may be addressing potential regulations that have not been proposed. But it is widely believed that those additional provisions that you are reviewing would impose an unreasonable regulatory burden that creates far more costs than benefits and would be beyond the capacity of the agency to administer. We are concerned that the regulations might effectively eliminate e-cigarettes from the legal market or at least restrict them to simple standardized mass-produced items which, in the opinion of most experienced users, are the lowest quality products.

We appreciate that it is not OIRA's role to delve into the specific science of a proposed regulation or to second-guess an agency's subject matter experts, and thus we will focus on what we believe are the points most relevant to OIRA decision-making. In particular, we want to emphasize that the FDA Center for Tobacco Products appears to be unable to fulfill its regulatory responsibilities for the products it already regulates. They have taken on a huge responsibility already, and adding e-cigarettes to the mix will dramatically increase that responsibility. While the names might imply that regulation of e-cigarettes and cigarettes is similar, in reality they are enormously different in terms of their physical and manufacturing characteristics, marketing and distribution, and health implications. Thus, there would be a substantial increase in the demands on a Center that is already straining to fulfill its current mission. Moreover, we worry that any mandatory approval process would act as a de facto ban; while an approval process might sound reasonable, the Center currently has a backlog of about 4000 applications from the cigarette sector and have only issued decisions on two dozen so far. We will revisit this point later.

We understand that you have already been briefed at some length on the public health benefits that the widespread availability of e-cigarettes have already brought about. We will not belabor that, but it is important for OIRA to keep these public health benefits in mind when considering the ramifications of the proposed regulations:

We all know that the preamble to Executive Order 12866 (signed 1993), describes a regulatory system that protects and improves the health, safety, environment, and well-being of the American people, and that improves the performance of the economy without imposing unacceptable or unreasonable costs on society. It also calls for regulations that are effective, consistent, sensible, and understandable.

We believe that FDA's proposed regulation fails to meet the standard of review established in Executive Order 13563 and, as such, we would urge OIRA to reject any part of the proposed regulation that does any of the following:

- stifles innovation in e-cigarettes, which are a dynamic technology, by requiring that all new products go through an approval process;
- even more so, forces a rollback of technology to what existed on some arbitrary point in the past, which would eliminate the highest quality products in favor of what was once a rather bad technology;
- imposes such stringent manufacturing standards that only a few manufacturers can meet them (note that, for what it is worth, those manufacturers would be almost exclusively the major tobacco companies)

- prohibits flavorings, except to the extent that specific flavorings appear to create a specific nontrivial health risk
- prohibits internet sales

While we do not support restrictions on advertising, we do not believe that these would impose a substantial burden, so long as they did not effectively prohibit internet sales by banning the websites necessary to conduct such business.

We believe that only a short list of regulations would pass a cost-benefit test. These include:

- requiring child-resistant packaging;
- requiring accurate ingredients labeling;
- requiring clean manufacturing facilities and consistent manufacturing practices;

Principle 1: Propose or adopt a regulation only upon a reasoned determination that its benefits justify its costs.

This is a hurdle that seems almost impossible for any regulation of e-cigarettes, other than a very light touch, to clear. Proposed regulations of e-cigarettes are largely a classic case of a "solution" in search of a problem. There are few apparent benefits, except from the reasonable and not-burdensome rules we suggested. The costs, however, are potentially huge:

-As a satisfying substitute for smoking that is estimated be approximately 99% less harmful, e-cigarettes are a public health boon. They have allowed many people to quit smoking who did not feel like they could otherwise do so. Our and others' research suggests that the innovative product characteristics, including the hardware and the flavorings, play a large role in helping people quit smoking. Burdensome regulation, including prohibitions and expensive and inefficient approval processes, would effectively eliminate these products. Restrictions on internet sales would dramatically reduce their availability to most smokers. While some smokers might be satisfied by the mass-produced low-end products that might survive such regulation, many will not, and thus will keep smoking.

-Moreover, using e-cigarettes also make them enormously happier than they would have been with complete abstinence (doing so with little health cost). While FDA typically ignores happiness when making policy, implicitly acting as if longevity trumps all other economic concerns, in a case like this where the health costs are apparently minimal and the other benefits are enormous, this simplification cannot be justified. Enormous welfare costs cannot be justified by health benefits that are both small and purely speculative.

-To the extent that a regulatory approval process did not simple eliminate entire sectors of this valuable market, the costs would be enormous. Current regulation of cigarettes follows a pattern similar to pharmaceutical approval, with every detail -- down to the printing on the product or what adhesive is used on the paper -- requires approval to change. Even though cigarettes are a relatively simple and static product, this is a huge burden for the manufacturers and, as we noted, one that the FDA has not been able to handle its end of this process. E-cigarettes are far more complicated, and rather more like computers than cigarettes. Imagine if Dell Computers had to get regulatory pre-approval for every

configuration of its products before it could sell them, or if a restaurant had to get approval every time it changed who was supplying its vegetables. That is the level of burden that cigarette-like regulation would impose on e-cigarette manufacturers.

What are the ostensible benefits of the proposed regulations? For the most part the harms that regulation is supposed to combat are non-existent, are purely speculative, and it is not clear that to the extent that they do exist that the expected regulation would actually address them.

-Claims of health harms from e-cigarettes are purely speculative, and if any risk exists it is small. Based on extensive evidence from smokeless tobacco and NRT products, there is no measurable health risk from nicotine, when it is not delivered via smoke. There has been substantial research on the other chemicals found in e-cigarette vapor, and a recent review of all that information -- sponsored by us and conducted independently by a professor at Drexel University -- showed that none come anywhere close to levels that post a risk. (Any risk from "second-hand exposure" is thus enormously less than the already very small and speculative risk to the user, though restricting use in public places is more a matter of local regulation, so is not a legitimate concern in the FDA process in any case.) Thus, there is no urgency to regulate rapidly and no justification for imposing great burdens.

-Moreover, to the extent that there is a small health cost from e-cigarettes, it is not clear how any regulation would reduce it. Regulations that simply drove people away from using e-cigarettes would eliminate any such trivial health cost, of course. But only at the expense of eliminating the public health benefits -- since many of those would-be e-cigarette users will just smoke instead -- and the non-health benefits that we noted.

-One specific health concern that is sometimes cited is the lack of control of the manufacturing process and problems that could result from that. There is much rhetoric about the process being like the "wild west." And yet there is not a single documented case of a contaminated or adulterated product causing a health problem or even being found in the market. If there were such problems, it is not clear that most possible regulations would do anything to keep it from happening except by simply eliminating manufacturing. In particular, it is just as likely to occur -- quite possibly more likely -- with a product whose design has grandfathered approval as compared to a improved innovative product that might not be approved. (There have been a few cases of batteries causing fires, though no more so than with most battery-operated devices, and far fewer than are caused by cigarette lighters. But it is not clear that FDA regulations could even address battery technology.)

-Concern about children using e-cigarettes are overblown and, in any case, are unlikely to be addressed by the regulation. In order to rationalize this regulation, there has been a spate of artificially engineered concern about underage use of e-cigarettes. But the numbers are actually quite small, and the supposed doubling of use that has been widely touted was actually a doubling of the number who had ever tried a single puff from an e-cigarette. We are sure it is obvious to you why this "ever tried" number will inevitably increase over time for a new product. The number actually using e-cigarettes appears to be extremely small. Most important, it appears to be mostly as a substitute for smoking and

other high-risk behaviors. Of all the forbidden activities that children could engage in, this is one that appears to about the least risky. It is also important to realize -- though we understand that this drills down into the subtleties of the science -- that the rhetoric about children getting hooked for life because of e-cigarette use has no scientific basis: The evidence suggests that nicotine alone does not have that effect even though cigarettes do.

-But even if underage use were a serious concern, regulation of the products -- short of a complete de facto ban -- is unlikely to affect it. If only a few products remain available, they might have limited appeal to adult smokers, eliminating most of the benefits, but kids would still experiment with them as they do with any number of things. While there is much rhetoric about non-traditional flavors appealing to children, there is no evidence that children actually favor such flavors (while there is evidence that many adults do), let alone any reason to believe that eliminating them will reduce children experimenting with e-cigarettes.

In sum: The costs from restrictive e-cigarette regulation to health and welfare, as well as compliance costs themselves, are huge. The maximum potential benefits are comparatively trivial, and the actual portion of those benefits that would actually be achieved by the regulation is smaller still, and quite possibly none at all.

Principle 2: Tailor its regulations to impose the least burden on society

It is not clear that there are any problems with the current marketplace that impose substantial cost to society. To the extent that there are genuine concerns that can be addressed by regulation, most can be addressed with minimally burdensome regulations.

Principle 3: Select, in choosing among alternative regulatory approaches, those approaches that maximize net benefits

-Sales to children can be prohibited by state or federal law without regulating the products themselves. About half the states already prohibit such sales. While such restrictions are obviously porous, as proven by children's easy access to cigarettes in spite of heavy regulation of those products, they will have as much effect at reducing underage use as any regulatory action other than a complete ban.

-The observation that there has been no harm from manufacturing failures does not mean it will never happen, of course. Thus, a light-touch "good manufacturing process" regulation would reduce that risk at minimal cost.

-Concerns about consumers "not know what is in them" could be addressed by imposing and enforcing accurate labeling of nicotine content and other ingredients.

<u>The burden of inefficient regulation</u>

A critical concern, from the perspective of minimizing burden is the fact that the Center for Tobacco Products' resources are already overtaxed, and thus burden that might appear minimal on paper might translate into de facto bans due to inefficiencies.

When considering any regulation of tobacco products, it is necessary to understand the following: While the FDA process seems, on paper, to offer reasonable options for product manufacturers, it is actually a functional complete failure. It is the classic picture of virtually banning the regulated activity via red tape.

The regulation of cigarettes and smokeless tobacco forbids the changing of existing products or the introduction of new products unless they are explicitly judged to meet one of a few standards. One such standard is "substantial equivalence" or SE, in which a product is judged to be basically the same -- particularly in terms of health impacts -- as a product that was grandfathered or previously approved. By the time the FDA first acted on any of these applications, in 2013, over 3,700 applications had been submitted over the course of years, and the total is presumably over 4000 now. Only two dozen have been acted upon to date.

An alternative pathway for a new product is the "modified risk tobacco product" or MRTP approval. This ostensibly allows a tobacco product that is substantially less riskier than an alternative to enter the market and to make claims about the lower risk. But the details of the process are so burdensome and so unclear that there have been no serious applications to date. Manufacturers have repeatedly asked FDA to clarify some of the requirements and what science would be needed to meet them, and FDA has pointedly refused to do so. Thus, the entire process is only theoretical until some of these applications are submitted -- at great cost -- and acted upon. One small manufacturer of specialty smokeless tobacco products submitted applications soon after the process was opened, several years ago, and FDA avoided acting or committing to the process in any way by declaring (contrary to the obvious reality) that these products were not tobacco products and thus the application was void. As far as the public knows, no other applications have been submitted. One major manufacturer of smokeless tobacco has been announcing, for most of a year, that they are going to submit an MRTP application, but the process is so burdensome that they have not yet completed it.

The scientific requirements from the process are so strenuous and burdensome that the CTP itself cannot rise to them. In a recent comment about the FDA's analysis of menthol in cigarettes (possibly a step on the path toward banning it), the manufacturer Lorillard very effectively pointed out that FDA's analysis did not come close to meeting its own stated standards, as defined in their MRTP Guidance and elsewhere. Indeed, we are somewhat surprised that this process has not generated a spate of lawsuits. The only reason that it has not been a major public relations problem for government regulation in general, and the administration, is that few people -- not even most smokers -- are inclined to speak up about burdensome regulation of cigarettes. That will be rather different if e-cigarettes -- which are appreciated and even beloved by millions of people -- are added to the process.

Clearly, making any product go through either of these dysfunctional processes fails the "least burden" test even when it is a relatively uniform, standardized, technologically-static, and mass-produced product. If e-cigarettes were subject to similar approval rules they would effectively be banned or restricted to whatever products were grandfathered because these application processes are simply not functional. Every minor change, quite possibly down to package art and undoubtedly including improvements in flavoring or hardware,

would be prohibited. This would be fatal for the innovation that improves the products, literally month-to-month.

As we noted, imposing regulations similar to the existing ones governing cigarettes would be similar to asking a computer merchant to get pre-approval for every variation on their configurations, every new software update, and even a change in which color wires they used. The FDA's Guidance for Substantial Equivalency applications specifies detailed comparisons between the predicate product and the subject product, down to the nanogram level in such things as the chemical make-up of ingredients or parts supplied by outside companies. If there were some compelling benefit from effectively eliminating the variety and innovation in the e-cigarette market, perhaps this could be justified, but there is not.

It should also be emphasized that if a grandfathering date in the past was specified, even many current innovations would be eliminated.

If the CTP were to try to act on such applications, they would face the burden of evaluating these products which are nothing like the basically agricultural products that they regulate now. They would need to acquire new capacity to deal with different liquids and solids chemistry, electronic hardware, and countless other complications. It is difficult to imagine they would be an position to act on any regulatory application for years.

There are some additional technical points about application deadlines that have passed already. E-cigarette manufacturers, not yet subject to FDA regulation, did not have the option of making such applications, and if subject to them have no way to comply.

Principle 4: Specify performance objectives, rather than specifying the behavior or manner of compliance that regulated entities must adopt

At this point, performance rather than procedural regulations are probably not a realistic option. As we have already noted, the applications processes which are focused on outcomes rather than process have been dysfunctional. This is why we currently recommend good manufacturing process regulations rather than product testing. However, production-line testing should be considered as part of any eventual beneficial regulation regime.

Testing of batches to ensure that the liquid (the nicotine solution) is pure and consistent with the labeling seems like a reasonable requirement, so long as it is implemented gradually enough that the infrastructure can be built to do it. If there were any history of contamination problems, there might be some urgency to this despite the cost of haste, but absent any such problems, a gradual evolution of such a process is called for.

Conclusions

To summarize:

- The status quo shows no compelling reason to rush to further regulation of e-cigarettes. The current marketplace is functioning well.

- Many possible regulations that do not appear to be a ban on paper would serve as a de facto ban of the entire category, or at least of the higher-quality products and the innovative improvements that happen every month.
- This is especially true in light of the paralysis currently observed in the CTP applications approval process.
- The more onerous regulations that we believe might be proposed do little or nothing to address the ostensible problems they supposedly address, other than perhaps effectively eliminating the market, along with all of its benefits.
- Relatively low-burden regulations could solve those problems that are most often cited as warranting FDA regulation, and probably do so better than burdensome alternatives.
- The Center for Tobacco Products has demonstrated that it does not have the capacity to fulfill its existing mandate, must less take on a new set of regulations for a very different category of products.

In 2010, the U.S. District Court for the District of Columbia ruled that the FDA could not ban e-cigarettes and suggested that it could regulate them as tobacco products. This has proven to be a miracle for hundreds of thousands of American smokers who have quit smoking by using e-cigarettes as an alternative. Imposing any regulatory regime that basically banned most e-cigarettes by imposing a pointlessly costly and currently non-functional regulatory system on them would violate the spirit of that ruling and dramatically hurt the health and well-being of those consumers.

> Excessive government intervention not only limits individual freedoms, it stifles entrepreneurial creativity and job creation.
> *--Edwin Feulner*