To: U.S. Food and Drug Administration

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VIA REGULATIONS.GOV

Re: CASAA comments on proposed deeming of e-cigarettes
    (Docket No. FDA-2014-N-0189,RIN 0910-AG38)

1. Introduction

This comment on Docket No. FDA-2014-N-0189 (RIN 0910-AG38), "Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products," is submitted on behalf of The Consumer Advocates for Smoke-free Alternatives Association (CASAA). CASAA is a public health and education NGO and is the leading representative of consumers who use or might in the future use smoke-free tobacco/nicotine products. CASAA is not an industry group and does not represent the interests of industry.

We are writing to comment on the proposed regulation of e-cigarettes, and all of our comments should be interpreted as referring to that product category unless explicitly noted otherwise. CASAA represents users of all smoke-free alternatives to combustible cigarettes, and thus is a stakeholder representative for users and potential users of the other smoke-free products covered under the proposed regulation. However, since other such products are largely speculative, and those that do exist have generated almost no interest from consumers, we do not address them in
our comments. CASAA does not take positions on the regulation of any combustible tobacco product.

In summary, it is our assessment that the proposed regulation is a de facto ban of more than 99.9% of the e-cigarette products currently on the market (something in the order of 100,000), creating an enormous cost to consumers. It would accomplish none of FDA’s stated goals, other than banning sales to minors, which is largely redundant with state laws and is easily enacted as a standalone that does not impose damaging restrictions (and even this is not purely beneficial, given that it denies minors access to harm reduction). The proposed regulation comes remarkably close to being all costs – very substantial ones – with no benefits.

FDA has repeatedly claimed it wants to do the right thing regarding regulation of e-cigarettes. However, The Family Smoking Prevention and Tobacco Control Act (TCA) effectively requires that FDA either enact devastatingly harmful regulations of e-cigarettes or none at all. In light of that, it is our recommendation that FDA forgo deeming e-cigarettes under the TCA and ask Congress for enabling legislation that would allow beneficial regulation, rather than the proposed scorched-earth regulation.

Failing that, we point out that the proposed regulation and accompanying publications by FDA are misleading, arbitrary and capricious for numerous reasons, and thus are not a legitimate basis for rulemaking. The stated scientific background and impact analysis are fraught with omissions, bias, and errors. The proposed regulation does not meet FDA’s own oft-repeated (including multiple times in the proposed regulation) standards for showing that there will be a net public health benefit, and, in fact, there is overwhelming reason to believe the net public health effects will be negative. Even if FDA does not genuinely want to do the right thing and forgo regulation until it can be done productively, what FDA has presented regarding the proposed regulation is unacceptable under the standards and requirements of federal regulation and must be withdrawn on that basis until the errors can be corrected.

2. How to do the right thing

FDA has sent strong signals that it genuinely wants to regulate e-cigarettes in a manner that is good for the public and for public health. For example, CTP Director Zeller has stated:

“Strategies should be pursued that encourage the use of the cleanest and safest form of nicotine delivery” [http://www.slideshare.net/lindsayfox/clive-bates-e-cigarette-summit, slide 17]
“Nicotine is the very same compound FDA has approved for over 30 years as a safe and effective medication. People are dying from the tobacco-related diseases from the smoke particles, not the nicotine. It's a challenge to all of us. Can we start to take a different look at this?” [http://www.cspnet.com/category-news/tobacco/articles/fda-must-have-open-mind-e-cig-benefits]

And from the proposed regulation, FDA emphasizes:

“The challenge for FDA, in considering currently regulated products and any additional products that would be deemed to be subject to the FD&C Act, is that regulatory policy under the Tobacco Control Act must account for the net public health impacts at the population level.”

The last quote is telling because it is clear that the proposed regulation, as it affects e-cigarettes, fails the test. It would have tremendous net negative public health impacts at the population level.

It appears to be FDA’s position that under the existing language of the TCA, it is not possible to assert jurisdiction over e-cigarettes without imposing particular regulations – most particularly, a substantial equivalence predicate date from 2007 – that would eliminate almost all currently available products from the market. This clearly will not be good for consumers or public health for reasons that we expand upon below. To summarize:

- The higher-quality e-cigarette products that are crucial for many smokers to permanently quit will be eliminated from the legal market.
- The only products that stand any chance of successfully navigating the premarket tobacco application (PMTA) process will be the cigarette-like (“cigalike”) products produced by a few large companies that are better suited to dual use than a complete transition away from smoking.
- A black market will emerge and thrive. Products in that market will not be subject to FDA regulation, and they will also no longer be subject to the current de facto regulation that comes from brand equity and the civil liability system.

Based on these observations, we believe that the only way for FDA to reconcile its own stated goals (which are mostly not objectionable in spirit) with regulation of e-cigarettes is to forgo deeming e-cigarettes under the current version of the TCA, and to request that Congress pass amendments or a new law that allows FDA to regulate e-cigarettes without the constraints that would effectively destroy the legal availability of these products. Thus, our foremost recommendation is that FDA remove e-cigarettes from the currently proposed deeming regulation and make the request to Congress.
The current regulatory regime, as created by the TCA, is designed primarily to make the marketing of cigarettes and other regulated products more difficult and to make it almost impossible for new products to gain regulatory approval (and, as applied by CTP, to make it almost impossible for changes in existing products to gain approval). In the case of e-cigarettes, applying the TCA as written would make it almost prohibitively expensive to produce and market these life-saving products. Of course, combustible cigarettes would remain widely available and affordable.

We understand FDA’s fear and cultural frustration about not being able to inspect or shut down manufacturing facilities in the event of a problem, or even demand information from manufacturers. It appears that acquiring the ability to do so is a major motivation for rushing the regulation. However, as discussed below in the context of the black market, the proposed regulation will almost certainly do exactly the opposite: migrate manufacturers to operate in ways that the CTP will never be able to regulate.

FDA has acted on e-cigarettes precipitously and before the CTP had the capacity to regulate or even understand them properly and effectively. The proposed regulations, as they relate to e-cigarettes, read more like an advanced notice of proposed rulemaking (ANPR) than an actual draft regulation: There is no substantive regulation of e-cigarettes (other than banning sales to minors) that would be implemented or is even proposed, and the regulations contain more questions than answers. The proposed regulations do, however, contain paperwork and filing requirements that CTP would be unable to handle except by effectively refusing to do any regulating, by making it too onerous or fruitless for manufacturers to even submit applications. CTP already has a crippling backlog of applications from manufacturers of the simple products that it already regulates and understands; it has failed badly to fulfill its obligation to act on those applications. CTP would be overwhelmed by the complexity of adding e-cigarettes – which are fundamentally different in many ways, and far more complicated – to its already unmanageable workload.

The precipitous actions appear to be, to a large part, due to pressure to act from some members of congress as well as state-level elected officials. Thus, it is reasonable to expect that Congress will act to provide the necessary new legislation to allow rational and productive regulation of e-cigarettes, rather than the irrational, arbitrary, and destructive regulation that is currently proposed.
3. The proposed regulation fails to further any of its ostensible goals

The arbitrary and capricious nature of the proposed regulation, and the hinted-at follow-up plans, is best exemplified by considering the possible goals it pursues. These are not easy to discern, since they have never been stated clearly (which goes to the arbitrariness, and to this apparently being regulation merely for the sake of regulation), but they can be inferred from the content of the proposal and surrounding rhetoric. Details supporting the points summarized in this section appear below.

3.1 The regulations will harm, rather than help, public health
The officially stated goal of these regulations is to protect public health. But there is simply nothing in them that seems to accomplish that. There are no substantive claims about benefits the regulation will provide. Claims that are ostensibly about benefits are merely observations that the FDA will have increased power, with no indication of any problems that would be addressed nor worldly improvements that would result from applications of that power. Meanwhile, the regulations would make e-cigarettes far less available and attractive compared to smoking, and the resulting higher rate in smoking would be a major public health loss. To the extent that FDA is able to regulate products, technological improvements that are beneficial to public health would be frozen. To the greater extent that the regulations will drive products into black and shadow markets, the current ability and incentives manufacturers have to ensure their products are beneficial to public health would be greatly weakened.

3.2 Nothing would be done to reduce access to e-cigarettes to minors, or their alleged appeal to minors
The proposed regulations would deny the realistic possibility of FDA approval to any e-cigarette products other than the mass-production cigalikes that are widely available in convenience stores and similar outlets. However, unless there is a secret plan to never grant any approvals at all, this means that the products most likely to be tried by minors – because they require minimal financial or knowledge investment, are widely available from the same sources that supply the cigarettes that minors have little difficulty obtaining, and are easy to conceal – will remain on the market. Meanwhile, black and shadow markets for other e-cigarette products will exist and be less regulated than they are now, almost certainly lowering barriers to access by minors. FDA touts a ban on free samples as stopping access by minors, but there is no reason to believe that e-cigarettes are being provided as free samples to minors or ever will (unlike individual cigarettes, they are too expensive to be handing out to people who are not likely customers). There are clear signals in the regulation that FDA is looking for an excuse to ban most e-cigarette flavors based on denying minors access to these, but flavored products will be readily available in the black and shadow markets. Thus, even setting aside the question of whether adult choices should be limited by overblown and unsubstantiated worries about children being attracted by e-cigarette flavors, there is nothing in these regulations that would serve that goal.
3.3 Nothing in the regulations would make consumers better informed

Another vaguely cited justification for the regulations is to ensure consumers are adequately informed about e-cigarettes. If the regulations included mandatory disclosure of ingredients to the consumer, even for the very few products FDA will be able to regulate, this goal would be served to some extent. But there is no indication that FDA plans to institute such rules (such information would be collected, but there are no apparent plans to disseminate it). Instead, the claims of better information seem to be based on the FDA having more authority in the space, and thus being able to broadcast more information. FDA offers no indication of what information it will provide, let alone an explanation for how it will be useful. Specifically, FDA claims the regulation “would reduce the use of misleading claims on the products to allow for better-informed decision-making by consumers and would prohibit these products from being targeted to youth populations.” Perhaps this is true for cigar regulation, but because only a few companies – who are already highly scrutinized – would seek FDA approval for e-cigarettes and the rest of the market would go underground, FDA would have even less influence than they do now. Moreover, there is no evidence that e-cigarette manufacturers are targeting children (to the extent that a few small rogue merchants might be doing so, they will obviously not subject themselves to FDA scrutiny), and misleading claims are rare and inconsequential.

Even if these were not the case, there is no evidence that consumers are widely misinformed about any important points, except to the extent that some people (mostly those who are not vapers) believe junk science claims about the harms from e-cigarettes. There is certainly no reason to expect FDA could substantially influence the information flow on the topic. Any consumers who want detailed or technical information have ample authoritative sources for it. These are largely crowdsourced and draw upon the efforts of thousands of dedicated contributors and information from the leading experts from all of the numerous technical aspects of e-cigarette technology and science. There is simply no way that FDA has the resources to offer more than a pale shadow of this enormous body of information. In the information age, people seek advice and information about regulated pharmaceuticals from a variety of sources and do not have to rely on official FDA communications (labeling, etc.) as they once did; this will be even more true with e-cigarettes. The reality is that FDA is distrusted by networked e-cigarette consumers and this distrust will be solidified and probably made irreversible if the proposed regulation is implemented. Since smoking cessation via e-cigarette use is a social networking process, new users are rapidly introduced to this view by existing users. Thus, FDA may intend to communicate something (though, again, it is not clear what), but the consumers of e-cigarettes will not be consumers of that communication. Moreover, given the problems with FDA’s interpretation of the available science, detailed below, there is every reason to believe that FDA’s communication in this area will tend to make people less well informed rather than more.
The one area of information delivery where FDA has a comparative advantage is in mandating product warning labels. While there is much debate (and enormous amounts of dubious research) about whether such labels accomplish their goals, there is no doubt that only a regulator like FDA can cause them to appear. However, it is far from clear that labeling would lead to better information by consumers. Likely mandatory labels include statements about addictiveness, which has not actually been established for e-cigarettes (see below), as well as various labels that mislead consumers into thinking the products are as hazardous as combustible cigarettes, such as the mandate that smokeless tobacco packages say “not a safe alternative to cigarettes,” which sends the message that it is no safer. Indeed, even the mere labeling of e-cigarettes with “this is a tobacco product” with no caveats will tend to falsely imply a similarity of effects. Thus, warning labels stand a good chance of making consumers less well informed rather than more.

3.4 Nothing would be done to reduce the supposed “gateway” effect
There is no evidence that e-cigarette availability or use causes anyone who would otherwise not have smoked to start smoking. The claims that there is such evidence are transparently junk science and are easily debunked (see, e.g., http://ep-ology.com/2014/05/17/working-paper-reports-of-an-e-cigarette-gateway-to-cigarettes-by-glantz-et-al-the-study-results-provide-no-support-for-the-conclusions/). While some nonsmokers (adults and children) are naturally curious enough to try e-cigarettes, all the available empirical evidence shows that approximately 100% of regular use (among both adults and children) is among those who are using them to reduce or replace their smoking [e.g., http://www.ash.org.uk/files/documents/ASH_891.pdf]. Moreover, even if there were many de novo users, there is no basis for suggesting that those who would have otherwise eschewed smoking would then switch to smoking. There is no reason to expect e-cigarette use would alter such individuals’ preference for avoiding the health costs of smoking, and the logic of why it would happen is never explained by the gateway theory proponents. Nevertheless, trumped-up worries about such a gateway effect are common. If there were such an effect, the proposed regulations would do nothing to reduce it. E-cigarettes would still be available via the regulated market (unless the FDA has a secret plan to refuse all product applications) and the black and shadow market. Even an out-and-out possession ban on e-cigarettes would not eliminate their availability and (largely nonexistent) appeal to nonsmokers. The proposed regulation, which does not criminalize possession or use, would do approximately nothing to affect the gateway effect, if it really did exist.

3.5 Little or nothing would be done to reduce contaminants or other unwanted exposures, and the risk of those would actually increase
There simply are no provisions in the regulation or apparent plans for actually doing anything about unwanted exposures. Perhaps this is because there have been no real problems to date, and it is difficult to explain plans to solve a nonexistent problem. There are allusions to such benefits but no concrete claims. The only noted actions are hazardous and potentially hazardous chemicals (HPHC) filing requirements. These are already in place for cigarettes and smokeless
tobacco, but not only have they not contributed to any accomplishment of substance to date, but every allusion to them accomplishing something in the future consists of vague hand-waving. No one knows what to do with these lists because mapping quantities of these chemicals to health outcomes is beyond humanity’s scientific knowledge. It is assumed that lower is better for most of them, but that is just an unquantified application of general principles. This lack of usefulness of HPHC lists was made abundantly clear by the total chaos in the room and complete absence of concrete suggestions when FDA tried to get advice from TPSAC on how to handle HPHC data. These filing requirements are basically busy-work that will impose costs that raise prices for consumers and eliminate products entirely, all without providing any apparent benefit.

FDA claims, “FDA's oversight of the constituents of e-cigarettes cartridges would help to ensure quality control relative to the chemicals and their quantities being aerosolized and inhaled.” But there are no provisions in the regulations that would accomplish this. The only “oversight” consists of listing the constituents occasionally, with nothing that would contribute to ongoing quality control. Moreover, those few e-cigarette products that FDA predicts will be subject to the requirements – rather than moving into a black or shadow market – are those produced by major manufacturers who are already motivated to do testing and make changes that reduce contaminants. These are the useful actions that the proposed busy-work does not actually accomplish. Meanwhile, the majority of products will be driven to the black and shadow markets, which will tend to reduce the incentive and capability of manufacturers to address these issues. In short, there is no apparent problem, and even if there were, the proposed regulation would offer no solutions. Moreover, the regulations will create a situation that is out-and-out contra to this goal. If FDA has some notion of how these regulations will accomplish anything in this area, they are not reporting what it is.

3.6 FDA has no problem doing research in advance of regulation

FDA claims in the draft regulation, “Deeming these products would permit us to collect information about their ingredients to ensure that other potentially harmful constituents are not present. Deeming would also allow us to collect information regarding health and behavioral effects of these products.” The claim is that FDA cannot do research, or perhaps cannot learn, without regulatory authority. This is simply false. FDA is already the leading funder of non-industry research on e-cigarettes. The only change that regulation would bring is requiring manufacturers – the very few who do not move to the black and shadow market – to file HPHC statements, which as already noted provides no operationalizable information (and collecting that information on this handful of products could easily have already been done as part of the research FDA is currently funding if there was actually a belief the data was useful). Clearly FDA has demonstrated the authority and will to conduct research in advance of future rulemaking, and there is no reason to impose premature draconian restrictions on the products in order to keep doing so on the same basis. Indeed, given that there is no apparent real problem with the status quo, it seems rather more sensible to continue this research before banning 99.9%
of the products on the market rather than banning them first and then trying to figure out if that was wise.

3.7 There would be no useful information generated about e-cigarette manufacturing entities FDA states as part of the justification for the regulation, “Deeming would provide FDA with information on the location and number of regulated entities and allow the Agency to establish effective compliance programs.” While this might be true for cigar manufacturers, it is clearly not the case for e-cigarette manufacturers. Only three or four major manufacturers of e-cigarettes would even try to seek FDA approval, and CTP already knows where to find them and (with one possible exception) already regulates them. The rest of the e-cigarette market would shift into black or shadow market status, resulting in FDA having even less information about them than is now available.

3.8 There would be no use interventions regarding “adulteration and misbranding” While there is no evidence that this occurs or causes harm, if there were, this stated FDA goal would not be served for the reasons noted in the previous paragraph.

3.9 The only apparent intended effect of the regulation is having regulation The proposed regulation appears to accomplish none of its explicit or implicit objectives, and does more harm than good for most of them. Thus it appears to be a case of regulating for the sole purpose of increasing regulatory power or, perhaps, pursuit of goals that are intentionally kept hidden and that are apparently contrary to the stated goals. It is telling that the following statement is FDA’s thesis claim about the benefits of the regulation:

Deeming “tobacco products” (except accessories) to be subject to the FD&C Act would result in significant benefits for the public health. Once deemed, tobacco products become subject to the FD&C Act and its implementing regulations, affording FDA additional tools to use to reduce the number of illnesses and premature deaths associated with the use of tobacco products. For example, it would provide FDA with critical information regarding the health risks of the proposed deemed tobacco products including information derived from ingredient listing submissions and reporting of hazardous and potentially hazardous constituents required under the FD&C Act.

The basic claim translates into “if we assert jurisdiction over this, then we will be regulating it, and us regulating it is a public health benefit.” The example FDA chooses to offer as to how the regulation might actually cause some material good is that it would require HPHC filings for the dozen regulated products, which (a) are not useful and (b) are information it could easily glean without imposing the draconian regulation. In a letter to the New York Times [http://www.nytimes.com/2014/05/13/opinion/regulating-e-cigarettes-the-view-from-the-fda.html], FDA Commissioner Hamburg offered only the same example of how this regulation...
will create a benefit. If this is the only example of supposed benefits FDA can offer, there is clearly a serious problem. FDA is obliged to clearly identify what this regulation is intended to accomplish and to provide at least a *prima facie* case that it might accomplish its goals, but has failed to do either. There are simply no apparent pathways that could lead from the proposed actions to the implicit and stated goals, and FDA has effectively acknowledged as much by repeatedly failing to even try to identify any.

4. Questions posed by FDA in the draft regulations

CASAA, along with thousands of individual consumers, as well as industry, requested that FDA appropriately extend the comment period on the basis that FDA spent years preparing hundreds of pages of documents and gave only 75 days to comment. We counted 99 separate questions in the draft regulation that would be relevant for us to answer. We made clear that we could conduct research to answer many of these questions scientifically if granted the requested extension.

FDA extended the comment period only 30 days, which was grossly inadequate, as we made clear in our request. This amounts to basically one day for each question relevant to our area of interest – obviously in addition to all the other comments that need to be made about the proposed regulation – which makes systematically answering the questions impossible. We followed up with a second request for an extension [http://blog.casaa.org/2014/07/casaas-second-request-for-extension-of.html], asking to be allowed to offer an amendment to our main comment that would be limited to providing scientific information that specifically addressed the questions. Granting this would have created no delay in the process given that it would have been submitted before FDA had time to finish considering the tens of thousands of other comments filed the week of the deadline, but even this was refused.

Since it was impossible to seriously address the questions in the allotted time, we have chosen to focus on the overview points about how the proposed regulation is harmful, grossly inappropriate, arbitrary and capricious, and unsalvageable in its present form. Given these facts, answers to the specific questions are not terribly useful in any case. However, answers to many of them can be found in this document in their context.

Given the failure to grant a reasonable extension, it seems doubtful that FDA is genuinely interested in scientific answers to the questions it posed in the draft regulation, and that the questions are intended merely to create the illusion of information-seeking and an excuse for politically-motivated activists to provide off-the-cuff pseudo-scientific responses. Moreover, the phrasing of many of the questions is so loaded that they read as requests for rationalizations for restrictions that FDA is already planning to impose regardless of what the science really shows.
Finally, many of the questions imply such a lack of understanding that they would be appropriate for an ANPR, but in a draft regulation serve only to show that FDA lacks adequate knowledge to be proposing regulations.

5. The benefits of the current e-cigarette market, for public health and overall consumer welfare

FDA asserting jurisdiction over e-cigarettes in the fashion it proposes would have devastating consequences for consumers who rely on these products to reduce or replace their smoking habit. The current marketplace is far better for consumers than the marketplace that will exist in the wake of these proposed regulation. E-cigarettes are responsible for many Americans quitting smoking, almost certainly more than any tobacco control intervention for decades. The total is unknown because the U.S. government has avoided doing the research that would quantify it, but it is easily in the hundreds of thousands, with more people doing it every day. Consumers continue to use e-cigarettes after quitting smoking either because quitting e-cigarettes would cause them to return to smoking, or simply because they consider the benefits to be worth the small speculative health costs from vaping. For many vapers, e-cigarettes are second only to family and close friends in importance in their lives. In addition to providing desired nicotine, they are an avocation and a social nexus. The health benefits to consumers from smoking cessation alone are enormous, but the less talked-about consumption value is comparably large.

Taking the existing e-cigarette market from this large and growing population for no apparent benefits would be an unethical abuse of government power and a breach of public trust. Regulations of consumer goods are supposed to benefit consumers. But in this case, they would devastate the actual consumers in order to serve the goals of a tiny, but vocal, special interest group with no legitimate stake in the outcome.

E-cigarettes are generally estimated to be in the order of 99% less harmful than smoking, and there is no affirmative evidence there is any health risk except for people with specific contraindications for exposure to nicotine or other ingredients. This is based on (1) the epidemiology that shows that any risk from smoke-free nicotine in the form of snus (moist snuff) is too small to measure and thus is on this order (notably, this is the same evidence that FDA used to help conclude the nicotine products it regulates will not pose a measurable risk if used in perpetuity [http://www.fda.gov/forconsumers/consumerupdates/ucm345087.htm]), and (2) no reported chemical analysis of e-cigarettes has found any exposure that would substantially increase the risk compared to snus. This makes risk of use similar to that of countless products, including foods, OTC medicines, tools, and modes of transport, and not at all similar to that from combustible cigarettes. Appropriate regulation to make any of those minor hazards less hazardous can be justified, of course, but a near-ban of an entire product category based on such
small and speculative risks is clearly not normal or acceptable behavior in a free society. That would be the case even if it were not for the huge health benefits provided by e-cigarettes.

The primary role of e-cigarettes is tobacco harm reduction (THR), to replace smoking with a low-risk alternative. To date, this consists almost entirely of smokers switching to e-cigarettes. As time progresses, it will include many would-be smokers who take up the low risk habit instead, as has occurred with snus in Sweden. E-cigarettes are probably the most effective existing smoking cessation and prevention aid, with the exception of snus among populations where it is socially accepted, far surpassing the effectiveness of FDA-approved pharmaceutical products.

Many smokers who quit smoking using e-cigarettes were actively pursuing quitting. Many of them have tried and failed to quit, numerous times, using some or all of the officially recommended (but nearly-useless) “approved” aids that exist. Smokers who are willing and able to quit unaided just do so, and the availability of e-cigarettes does nothing to interfere with this option. But many need help, and e-cigarettes are purpose-built to provide that help, and are very effective at it. Indeed, many smokers who try an e-cigarette without the intention of switching find that vaping is sufficiently attractive that they become “accidental quitters.” Moreover, for those whose goal is total abstinence but cannot bring themselves to quit unaided, e-cigarettes are a useful bridge. Vapers who had an irresistible urge to smoke before they switched generally report that quitting e-cigarettes is or would be relatively easy (though they do not necessarily choose to do so because the benefits from vaping for them exceed its modest costs).

Consumers are best served by diversity in the marketplace. Having a wide range of products – a variety of ever-improving devices, and liquid with varying nicotine strengths and flavors – allows consumers to customize the experience to find a combination that works best for them. Trying to forbid the variety that consumers prefer is always bad for consumer welfare, as with restrictions on consumer product variety under a centrally planned economy. But in this case it is also bad for public health.

Diversity in devices is critical to the success of e-cigarettes as THR. The cigalike products made by the largest producers (the traditional tobacco companies and perhaps one large independent e-cigarette manufacturer) that might seek FDA approval under the regulation play an important role in piquing the interest of smokers. They are widely available in convenience stores and most places where combustible cigarettes are sold, do not require a large up-front investment, have a familiar shape and feel, and attempt to mimic the taste of smoking (though few do this well). However, most experienced vapers prefer more advanced systems with larger batteries, refillable tanks (and thus the choice of a wide variety of liquids), and other features. The benefits of these improvements are not just that consumers prefer using them – though this is a huge benefit in itself – but that it is only these more advanced systems that allow many smokers to quit.
There are no population-level statistics about this from the USA (due to funded research on e-cigarettes being directed toward far less useful pursuits), but systematic surveys from elsewhere, convenience surveys, and testimonial evidence from thousands of Americans\(^1\) show that many smokers who eventually quit by using e-cigarettes find the cigalikes to be unsatisfying. For example, a recent convenience sample survey [http://vaping.com/data/vaping-survey-2014-initial-findings] found that half of the respondents who use disposable e-cigarettes still smoked, compared to less than 10% of those using high-end systems. Undoubtedly many smokers have quit via the use of cigalikes, but many find that while using those products their urge to smoke remains, or they continue to smoke some of the time although they would prefer to switch entirely. The reasons for this are obvious. The batteries in cigalikes are too small to provide satisfying aerosol delivery (or enough nicotine unless the concentration in the liquid is quite high), and the flavors are a poor imitation of the taste of cigarette smoke. This means that they serve as an inferior imitation of a combustible cigarette and never let the user forget how smoking is more satisfying in just about every way. The health benefits might be enough to cause someone to switch completely in spite of this, of course, but the patent inferiority of the experience ensures the consumer will not forget the advantages of smoking.

This experience changes radically when those consumers try a more advanced device, those products made by various small- and medium-sized companies and sold in specialty e-cigarettes stores and via the internet. The inferiority of the delivery is solved via larger batteries and other components that cannot be included in mass-produced, disposable, cigarette-sized devices, and the batteries last longer. Because the devices are rechargeable and refillable, they are far cheaper than disposables in the long-run (and far more eco-friendly). Refillable and rechargeable systems are also cheaper than smoking, given the high taxes on cigarettes, while disposable cigalikes are generally more expensive than smoking, further lowering their comparative appeal. Perhaps most important, the access to attractive flavors creates a true advantage of the experience over that of smoking. Vaping ceases to be wholly a poor substitute for smoking, done solely because of the health benefits, and acquires active advantages. Users of imitation-tobacco-flavored e-cigarettes find it quite easy to pick up a cigarette instead, while vapers who use more naturally appealing flavors frequently report that after only a few weeks they tried a puff on a combustible cigarette and found it terribly unappealing.

Put simply, the advanced devices that would be eliminated from the above-board market by this regulation are the ones that work best for complete smoking cessation. Cigalikes are better suited as a starter product and for partial substitution (typically referred to with the politically motivated

\(^1\) CASAA is collecting consumer testimonials and has more than 3,000, many of which can be viewed at: http://mediad1ff.onlineview.it/FullScreenSlideShow.aspx?gallery=4442381&mt=Photo
term, “dual use”). This is not to denigrate the role of cigalikes as starter products or as partial substitutes – both of these are beneficial for consumers’ health and welfare. But a world with only cigalikes would be a world with far more smoking than the status quo, including many more dual users as well as those who gave up on their e-cigarette experiment and returned to just smoking. Moreover, advanced devices address the trumped-up concern that vaping renormalizes smoking. (Though this is absurd on its face: how can someone ostentatiously demonstrating that he has chosen to not smoke encourage smoking?) Unlike cigalikes, the advanced devices do not resemble combustible products, and so help make clear the contrast between vaping and smoking.

Much is made by members of the tobacco control community (whose goals are flatly contrary to those of consumers) about how non-tobacco and non-menthol flavors are designed to attract children and therefore should be eliminated. This, of course, ignores the fact that adults enjoy flavors, too. But beyond the enjoyment factor (which is significant and valid in and of itself), flavors benefit public health. Simply stated, the variety of flavors are not only enjoyable for adults, they also help a significant number of adults distance themselves from their former smoking habit. The aforementioned survey found that only a small minority of vapers chose tobacco flavor when given a choice or used the same flavor all the time, and that two-thirds of respondents reported that flavors were important in helping them quit. There is no evidence that suggests that the availability of attractive flavors is leading to more underage e-cigarette use than would otherwise occur, and there is no evidence that any available flavor is more attractive to children than adults. The e-cigarette flavors cited by FDA in the proposed regulation as being particularly attractive to children are mint mocha and spiced apple cider; anyone who has ever visited a Starbucks or attended a church social will know that these flavors are highly popular with adults.

It is certainly possible to imagine an e-cigarette marketplace that is even better than the current one for consumers, and there are regulations (see below) that could lead to improvements that the free market is unlikely to provide. But the current marketplace is actually amazingly good for consumers. In just a few years, e-cigarettes have gone from expensive, unreliable devices that leaked liquid and barely delivered nicotine to efficient and effective high-tech wonders that people love more than their iPhones. Despite rhetoric about the marketplace being “like the Wild West” (which, incidentally, is also an inaccurate characterization of the historical western USA [http://antithrilies.com/2014/05/13/clueless-prohibitionists-the-west-was-not-wild-but-is-now-due-to-prohibitions/]), there have been very few problems. There have been no reports of serious contamination problems despite many millions of units being sold. No death has ever been credibly attributed to e-cigarette use, in contrast with Chantix, an FDA-approved drug that is an alternative method for smoking cessation, which is still on the market despite being responsible for hundreds of deaths.
There have been a few minor fires caused by mishandling of e-cigarette batteries (far fewer than the fires caused by combustible cigarettes), a few cases of accidental poisoning (far fewer than from pharmaceuticals – including NRT – or other household products, and none of them serious), ongoing complaints that cheaper products often fail prematurely and need to be replaced, and more specific problems about functionality. But the de facto regulations that are in place, namely brand equity, potential civil liability, and word-of-mouth – which the proposed regulation will dramatically diminish, as detailed below – are quite effective at evolving the market and behavior away from these problems. There is nothing in the proposed regulation that would solve any of the existing problems. Indeed, addressing many of these problems requires market innovation, not regulation (imagine trying to create a regulation to eliminate crash bugs in software). Most consumers are not particularly worried about the absence of regulations any more than they are worried about the lack of regulation to force improvements in software and computers, because the existing innovative and competitive market is addressing almost every issue better than any conceivable regulation.

5.1 Regulations that would benefit consumers
There are regulations for e-cigarettes that would benefit consumers rather than harming them. Mandatory child-resistant packaging and mandatory disclosure of ingredients are simple requirements that would benefit consumers. Standards for manufacturing facilities and practices and required batch-testing for e-cigarette liquid would be valuable, though not so simple, and perhaps better handled by industry certification rather than government regulation. Other more involved regulations could be implemented once it was understood what constitutes a genuine improvement of the products for the consumers. (In addition, a national ban on sales to minors can also be easily justified, though it does nothing to benefit the adult consumers who benefit from e-cigarettes. However, it is of little consequence since, as previously noted, it is redundant with state laws; a majority already ban sales to minors and most of the rest would have followed but for their anticipation of a federal law.)

While it is true that FDA could not implement any of these without asserting jurisdiction, and thus having jurisdiction – without all the TCA baggage – could be genuinely beneficial, there is nothing in the proposed regulation that accomplishes any such beneficial regulation and no indication it is planned. Indeed, because it will drive most manufactures into shadow and black markets that FDA cannot regulate, the currently proposed regulation effectively prevents beneficial regulation.
6. Expected results of the currently proposed regulation

6.1 *De facto* ban of the vast majority of available products, including all those preferred by experienced consumers

In its economic impact statement, which predicts how many e-cigarette products will be submitted for approval, FDA concedes that the proposed regulation would preclude approval for more than 99.9% of the products currently available. This is certainly a reasonable prediction, since the cost of filing the application for approval precludes applications for all but standardized mass-production products with millions of dollars in annual sales for the particular SKU. This is legitimately described as a *de facto* ban, and thus it is improper that FDA has disguised it as anything else. As we commented previously [http://www.regulations.gov/#!documentDetail;D=FDA-2014-N-0189-42893] this approach in itself constitutes an abuse of the regulatory process, using the paperwork filing burden as a barrier to commerce in the absence of any substantive restrictions on the products in question.

The attempted ban will fail. As detailed in the next section, a realistic appraisal of the actual results of this includes continuing availability – sometimes illegal, but often legal or borderline-legal – of most of the product types that are now available. However, the FDA tries to imply a future scenario under the regulation where the market consists of the products, and only those products, for which approval is sought. That even these products would receive FDA approval is not a foregone conclusion. CTP has taken great pains to never explain what would be sufficient, or even necessary, for a new tobacco product to gain approval. The closest to concrete statements that have been made refer to a net positive effect on public health (though what this means and how it would be shown remain mysteries). It would seem this requires that the applicant show that the product replaces smoking, which primarily means that it aids in smoking cessation. But FDA has also said that e-cigarette manufacturers cannot claim that their products are useful for smoking cessation, which presents a potentially fatal dilemma.

Assume for the moment that the implied FDA scenario came true. In that world, the only e-cigarette products that exist are mass-produced disposables and perhaps a few rechargeable cartridge-based cigalikes, available in a small number of imitation-cigarette flavors (the latter would probably be mostly or entirely true even if other flavors were not prohibited, and obviously true if they were). These are unsatisfying for many smokers who would consider switching to e-cigarettes or who have already switched, resulting in less smoking cessation and increased smoking resumption.

However, these are exactly the products that are most convenient for nonsmokers to experiment with, and will be conveniently available from the many non-specialty stores where combustible cigarettes are sold. Smokers are highly invested in their habit and, in many cases, in their desire to quit, and thus actively pursue inconvenient or expensive options. But few nonsmokers would
visit a specialty store, physical or online, and buy a more complicated and expensive e-cigarette system on a whim. Yet it is these products and stores that would be eliminated under the FDA’s scenario. Though nonsmoking minors have showed very little interest in becoming e-cigarette users, much of the rhetoric surrounding the regulation touts some magical ability of the regulation to prevent this supposed (though actually barely existent) phenomenon. Yet the products that will remain are far better suited to supply this supposed demand than are the ones that would be eliminated.

Similarly, there is much rhetoric about the regulation discouraging “dual use” of e-cigarettes and cigarettes. It is difficult to see why this is a goal, given that someone replacing some of his smoking with a low-risk alternative is better than replacing no smoking. (Additionally, the NRT products that are embraced by FDA are equally well suited for dual use, but no such concern is voiced about them, making clear that those stating such concern are not actually serious about it.) But setting aside the fundamental error and disingenuity of this stated goal and simply taking it as a goal, once again, the regulations are counterproductive. Under the FDA scenario, the e-cigarette products that are optimal for dual use – sold alongside combustible cigarettes in the same stores, require no big investment, and fit in a cigarette pack – would exist, while the products that are more likely to encourage someone to complete her transition to nonsmoker would be eliminated.

To the extent that any products were approved by the FDA, they would then be subject to the Substantial Equivalence (SE) process – or perhaps even the prohibitively onerous modified risk tobacco product (MRTP) process or a new PMTA – before any improvements could be made. Important improvements in e-cigarette technology appear every month, in contrast with the simple and largely static combustible cigarettes that FDA has experience regulating. The improvements are beneficial for consumers in many ways, including reducing unwanted chemical exposures and reducing the comparative advantages of smoking. Given that the SE process is already in disarray, with a multi-year backlog for simple changes to simple products, this would effectively freeze technological improvements for the products that FDA regulates. This would be yet another negative public health impact of the proposed regulations.

In theory, a product could be improved, or introduced, using the MRTP process, on the basis of it being lower risk than alternatives. However, that process is really the illusion of an option, not a real option. MRTP is so opaque and expensive that there has never been an attempt to use it to secure approval for a product. The only MRTP application to date has been about changing the claims that can be made for an existing product, one that already has a major presence in the market and thus could justify the millions of dollars that went into producing the application.
6.2 The real result of the attempted *de facto* ban: Emergence of parallel markets

Contrary to the fiction implicit in the proposed regulations that e-cigarette products currently not approved by FDA will simply cease to exist, it is obvious to any honest and informed observer that this will not be the case. Instead, there will be a vibrant black and shadow market. FDA states, that “greater regulatory certainty created by premarket authorizations should help companies to invest in creating novel products, with greater confidence that improved product will enter the market without having to compete against equally novel, but more dangerous products.” Setting aside the disturbingly Orwellian nature of that statement (“because we might refuse to let your product on the market, or might take two years to allow you to implement an improvement, you have more incentive to innovate”), it is simply not true at two levels. The products will still have to compete with those in parallel markets, and the parallel markets are likely to be far more innovative because they are not subject to CTP’s glacially slow approval process.

Many of the myths surrounding tobacco product consumption are predicated on the fiction that supply creates demand rather than the other way around. Once it is recognized that there is demand for e-cigarette products (as there is for tobacco products in general), it becomes clear that this demand will not magically disappear when FDA asserts jurisdiction over the supply. The reality is that the products that exist now will continue to exist, and will result in a market that is far less regulated and safe than the current situation. E-cigarette products, in the variety and quality that currently exist, provide enormous improvements in consumer welfare (including the health benefits of providing an attractive alternative to smoking), and this creates demand that will not be eliminated by regulation.

6.2.1 The nature of the continuing market.

It is not difficult to predict the response to the proposed *de facto* ban by manufacturers and consumers. There are many smokers who will be denied the opportunity to quit due to the restriction in the open and legal market for higher-quality e-cigarettes. But there are hundreds of thousands of vapers already using refillable component systems in the USA, and there will be many more before the *de facto* ban takes effect after more than two years. Some will switch to the handful of cigalike products that can pass the paperwork burdens to get FDA approval (assuming FDA grants any approvals), but many of these consumers – probably most – will not be interested in this lower-quality and more expensive option. They will have no difficulty in continuing to do what they do now, because this huge demand will continue to attract supply.

The continuing market for e-cigarettes in the USA, under the proposed regulations, will contrast with the minimal markets for banned or almost-banned low-risk tobacco products, such as snus in the European Union (EU). In the case of snus in the EU, the product is available to consumers who seek it, but obtaining it is not convenient and the ban appears to have reduced awareness about the advantages of snus and so has kept this low-risk alternative from becoming a popular
alternative for smokers in subpopulations who did not use it traditionally. By contrast, e-cigarettes are already very popular as a smoking cessation method and alternative in the USA, there is an established strong social network associated with them, and there is near universal awareness of them. Moreover, the proposed regulation is a backdoor ban that only regulates sales, and not a full-on ban that criminalizes acquisition, usage, or manufacture (absent sales). Thus there will be very little legal exposure in continuing to use the products openly, and social networking around them will not be hindered. These factors also mean that the regulation will create very little, if any, social stigma; in some cases, making something illegal causes people to think of it as immoral, but there is little chance of that occurring here.

It is generally agreed that FDA has no authority to regulate, under the TCA, e-cigarette liquids that do not contain nicotine (or other chemicals derived from tobacco plants). Thus, current manufacturers of the liquid will be able to continue to make and market zero-nicotine versions of their current products. Unless additional legislation is passed to enable FDA to regulate these products, perhaps as foods, FDA appears to have no authority to limit the variety of available flavors (which is good for the consumer), nor to regulate what ingredients can be used (which is potentially bad for the consumer if it is ever discovered that particular ingredients create a nontrivial health risk). Given that many manufacturers have acquired industry-specific skills and infrastructure and have developed brand equity in the sector, it is inevitable that many will stay in the market on this basis, though most will be forced to dramatically downsize because they can no longer openly sell nicotine-containing liquid, the majority of their business.

CTP has been rather more ambiguous about whether they will attempt to assert authority over e-cigarette hardware that is sold independently of the liquid. But it is clear that hardware manufacturers will have an easy option given that zero-nicotine liquid will continue to be legally sold: They can continue to market their products, duly labeling them as “not for use with nicotine-containing liquids.” It seems unlikely that, should CTP attempt to exert jurisdiction over such products when they do not have authority over nicotine-free liquid, the courts will uphold it. It seems unlikely that such sales could be prevented on the basis that some of the hardware is being diverted to use with nicotine-containing liquid (compare: the inability to ban products that were clearly designed to smoke cannabis because they were sold under the transparent fiction of being tobacco-smoking devices). Moreover, ironically, since most e-cigarette hardware components can be used for vaping increasingly-legal cannabis, the legal cannabis market will create an additional safe-haven for hardware sales, and also ensure that the powerful cannabis lobby will join vapers in opposing new laws that restrict hardware sales.

Thus, the components of open-system e-cigarettes will continue to be legally sold outside the jurisdiction of FDA. It is difficult to imagine that consumers will be criminalized for repurposing the hardware for the legal act of vaping nicotine, and such a law would be unenforceable in any case, for obvious reasons.
That leaves only the nicotine-containing liquid, which can easily be supplied in any of several ways.

The first option is a black market for the same e-cigarette liquid varieties that are available now, which is inevitable given the large number of tiny domestic manufacturers that exist and have local distribution networks, and the social networking surrounding vaping. It would be easy for such small manufacturers to stockpile years' worth of nicotine, and probably not much harder to continue to untraceably acquire it. Foreign manufacturers – existing or new – who are not seeking FDA approvals and are in jurisdictions where the U.S. FDA has little influence would have no incentive to not ship to U.S. consumers. The products are sufficiently inexpensive that the risk of customs seizure would be tolerable. The supply chain for black-market e-cigarette liquid would be easier to operate than that for popular banned drugs, products which are easily available to consumers who seek them, and distribution would be similar. The risks involved would be less than for suppliers of those other products, given that possession would be legal and it is unlikely that draconian anti-drug punishments would be replicated for selling e-cigarette liquid. However, there would still be some risk, and thus prices would rise to provide a risk premium for suppliers.

The second possibility involves legal sales of an approved liquid. It is possible that FDA would never approve any refillable e-cigarette. If such approval were granted, however, the approved liquid would be available for repurposing. It would almost certainly be offered in an unflavored variety and this would create a secondary market in flavored (zero-nicotine) liquids that were designed to be mixed with it to achieve the desired flavor level in the mixture. For those who did not want to dilute the nicotine concentration of the approved product, concentrated flavor drops or do-it-yourself flavor mixing would be options.

A hybrid version of these two market possibilities is a black market in unflavored nicotine solution, with nicotine concentrations that are optimized for easy mixing with legal zero-nicotine liquids. The equivalent products are already sold for do-it-yourself mixing.

The third method, which would also be impossible to stop, is do-it-yourself nicotinization of the liquid or full-on do-it-yourself manufacture. A year’s supply of nicotine for a typical vapor is in the order of 10 g., about two teaspoons. This would be trivial to distribute and stockpile, or smuggle if necessary. Smuggling might not be necessary, given that nicotine is not a controlled substance and it is not clear whether it would be covered under the deeming, given that pure nicotine is a manufacturing input for e-cigarettes but is not a consumer good in that form. While major nicotine manufacturers are unlikely to enter this business, it would not be difficult for some of their corporate customers to stock up and divert the nicotine to the consumer market. If nicotine remains legal, the logistics are simpler, but a ban would be a fairly minor obstacle.
While the process for mixing the highest-quality (and safest) e-cigarette liquid requires artistry and engineering skill, mixing e-cigarette liquid can be done at home by most anyone with easily available ingredients. It already occurs to a sufficient extent to provide proof-of-concept.

6.2.2 Consequences of the new market for e-cigarette products

The result of the de facto ban of the legal e-cigarette market will be less regulation and greater risk than currently exists, and it would also prevent many of the benefits that might come from good and proper regulation. While FDA ostensibly seeks to improve safety for consumers, forcing consumers to obtain their preferred product from black, shadow, and do-it-yourself manufacturing will increase risk, as detailed below. Nevertheless, even with the increased risk, the alternative markets will serve consumers better than a total lack of e-cigarettes or the rump market that exists under the FDA’s fictional scenario of only a few approved products existing. But the alternative markets created by the regulation will result in substantial negative consequences for consumers compared to the status quo.

First, to take the most obvious concern, the do-it-yourself manufacture or mixing will create more health risks. Thousands of vapers possessing and handling pure nicotine would dramatically increase the accidental poisoning hazard posed by e-cigarettes. Despite the engineered hype about poisonings that exists now, the current risk is very close to zero due to the low toxicity of e-cigarette liquid. That would not be the case for pure nicotine. There is even interest in do-it-yourself extraction of nicotine from tobacco leaf. Although most consumers who are toying with this idea will abandon it when they discover how difficult it is and how easy it is to access the black market, any attempts will further increase the health risks caused by the regulation.

As is typical for prohibitions of drugs that people choose to use, the do-it-yourself market presents far greater risks of accidental overdose than a legal market would. There is no formal quality control and the risk of badly erring in proportions is much greater due to the smaller quantities and lack of experience. Once again, one of the frequently hyped engineered concerns about e-cigarettes – that nicotine concentrations sometimes vary somewhat from what the consumer intends to use – would be dramatically exacerbated by the supposed solution. FDA claims “users who expect consistency in these products may instead be subject to significant variability in nicotine content among products” though the reality is that there is no serious problem and the evolving branded marketplace (and marketplace of information) is effectively correcting such problems to the extent they exist. Do-it-yourself (and to a lesser extent, the black market) would create the problem that FDA claims to be solving. Moreover, with so many people mixing their own liquids, it is inevitable that some will try adding ingredients that no reputable manufacturer would use, and that would increase health risks.
Second, the existing *de facto* regulatory system, which has proven quite effective so far, would be hugely eroded. The current rhetoric about “there is no regulation” or that the e-cigarette market is “the Wild West” ignores not only the many command-and-control regulations that already do apply to these products, but also the fact that regulation of consumer goods comes substantially from brand equity and, in the USA, from the civil liability system. The benefits of these regulations would be dramatically reduced in the world that would be created by the proposed regulations.

For obvious reasons, full-on black marketeers gain limited benefit from building brand equity. They have incentives to not use consistent branding, and the value of their reputation is capped by their need to stay small enough to escape serious scrutiny. They are generally impossible to sue should something go wrong. To a lesser extent, the same factors will reduce the brand equity incentives for manufacturers of hardware or liquid products for the legal shadow market.

Even as the FDA approval process favors only the largest companies, the evolving black and shadow markets will almost certainly favor very small domestic producers over the existing medium-sized domestic manufacturers that tend to have better quality control. Existing medium-sized e-cigarette liquid companies who stay in operation will lose the large part of their business that is nicotine-containing liquids, which will force downsizing and cost-cutting. The regulations will create a climate of risk for manufacturers – obviously for the black marketeers, but also for the shadow markets where there will be constant fear of new regulation or government enforcement actions, which are still financially devastating even when they are unlawful (as evidenced by the financial devastation inflicted by FDA unlawfully directing customs to seize e-cigarette products in 2009). This will discourage investment in the physical facilities and brand equity that lead to higher-quality and safer products. There will also be a reasonable fear that greater size will attract more scrutiny.

These disincentives for investment and growth – making investment risky, favoring tiny producers over larger ones, and destroying brand equity – will also slow the remarkable month-to-month quality improvements in the technology. While black- and shadow-market producers will inevitably continue to innovate far more than the FDA-regulated sector, and will take advantage of innovations from elsewhere in the world, improvements in safety and quality control will no longer be as well rewarded. The rewards for innovation will probably shift away from such qualities and toward “gadget factor” and similar whimsical innovations. There are, of course, rewards for the latter type of innovation now – and those who express concerns about e-cigarettes seem to find this to be bad – but they will become relatively stronger. Driving most of the market into a borderline-legal status will turn what is a rapidly maturing industry into permanent adolescence.
In short, most of the *de facto* regulatory protection and continuous quality improvement that is now in place will be lost, with no apparent offsetting benefit. Manufacturers that are currently motivated and able to produce higher-quality products will be disadvantaged compared to fly-by-night producers who can simply disappear if something goes wrong. The market for manufacture and distribution will favor those with high risk-tolerance and willingness to walk away, as with the illicit drug market, rather than those who are committed to long-term improvements in the quality (including safety) of the products, and possess more desirable skills and traits.

Finally, the establishment of a thriving black and shadow market will likely make future regulation more difficult and less effective. A time may come when a beneficial regulatory regime – one that is designed to genuinely benefit consumers by improving quality rather than hurt them by removing options, as the present proposal does – is enabled and enacted. But by then, regulated legal manufacturers will have to compete against an established black and shadow market which consumers have become accustomed to using, and which will probably be able to maintain lower prices by avoiding taxes and regulatory paperwork.

For example, if it is ever discovered that particular flavoring ingredients cause needless substantial health risk, a sensible regulatory system could forbid those ingredients in all e-cigarette liquid (with or without nicotine). But if such regulation is attempted after the currently proposed regulation creates a black and shadow market, it is likely that many manufacturers would ignore it. If such a discovery were made today, the suppliers who represent the vast majority of sales volume would voluntarily stop using the ingredient because they are respectable companies who care about their customers and their reputations. This effective self- and community-regulation would be severely weakened by the proposed regulations, which would largely replace the reputable companies with a black and shadow market.

To summarize, in just a few years, the market has evolved away from the "Wild West" characterization that represents much of the motivation for the proposed regulation, and it continues to evolve in a direction that is good for consumers and public health. Ironically, the only apparent way to stop such evolution, and thus to bring about the out-of-control market that exists in the politicized mythology, is to impose a regulation like the current proposal.

7. The regulation has no apparent potential to provide any health benefits

As detailed above, the proposed regulation does little or nothing to address *any* of the goals that FDA has vaguely outlined in the regulatory documents and elsewhere. Indeed it will be detrimental for achieving the most important goals that good regulation could serve. It is worth addressing the specific failure to provide any health benefits in more detail. The proposed regulation is an attempted *de facto* ban of most products on the market (albeit one that will prove
largely unsuccessful due to the workarounds and black market described above), with enormous harm inflicted on consumer welfare and health. This could possibly be justified if e-cigarettes were causing substantial harm or if there was legitimate concern that some unobserved harm were lurking. However, neither of these is the case.

If e-cigarettes were not in use or barely in use and FDA tried to keep them from existing (as the agency successfully did for variations on the product over the past several decades) on the basis of their unknown impact, there might be a leg to stand on. Though any claims about negative impact would have been tenuous speculation, they would not have been disproved by experience. When CDER attempted to ban e-cigarettes in 2009, claims of risk had arguably already been disproved by experience, and the benefits were fairly well established. E-cigarettes had been studied and used enough by then that if there were reasons to believe there were serious risks, they would have been noted. Five years later, it is clearly the case that e-cigarettes do not cause any substantial negative acute effects and do not create exposures that cause serious concern about substantial long-term effects. It is equally clear that they provide huge net benefits.

The extensive epidemiologic evidence from smokeless tobacco, along with supporting evidence from other small-scale research, shows that any health risk from nicotine in a smoke-free form is too low to detect. While this does not ensure that e-cigarettes or any other smoke-free product is quite as low risk as smokeless tobacco, there is every reason to conclude it is quite similar. This is how real regulatory science works: It is never possible to study exactly the worldly phenomenon of interest, so extrapolation based on scientific reasoning always occurs. In this case the evidence from which to extrapolate is obvious. Indeed, this extrapolation has been accepted by FDA’s CDER as sufficient to allow long-term use of other smoke-free nicotine products.

With smoke-free nicotine shown to be low risk, the only worry about e-cigarettes are potential hazards from the inactive ingredients. Following years of use by millions of people, we have sufficient evidence to rule out all but utterly trivial risks of important acute effects. The review of available chemistry studies by Burstyn [http://www.biomedcentral.com/1471-2458/14/18/] (which is inexplicably not among the 194 references in the proposed regulation even though it is the single most important piece of research on e-cigarettes to date) shows that none of the measured ingredients or contaminants come close to a level of exposure for vapers that would prompt concern even for an involuntary exposure.

Any environmental risk from e-cigarettes (that which is sometimes referred to with the intentionally inflammatory “second-hand vapor”) is utterly trivial compared to the user’s own exposure. That, however, is moot for purposes of the proposed regulation, which is not a usage ban and thus does not affect such exposures.
Thus, so long as the products are manufactured to the present standards, there is little health concern to offset the enormous health benefits of providing an appealing alternative to smoking. Despite hundreds of thousands of batches of e-cigarette liquid being manufactured and sold, there is no evidence of any serious contamination. The single example of contamination that is repeated ad nauseam is FDA’s finding a single case of diethylene glycol contamination in 2009. Despite being at a level well below what would pose a health threat (see Burstyn), this example has, to our knowledge, never been replicated and is the only concrete example cited when claims of contamination are made, including in the proposed regulations. This desperate grasping at straws when trying to present an alarmist note about contamination is, in itself, overwhelming evidence that there has never been a problem.

If there were a dangerous contamination of a batch of e-cigarette liquid, the proposed regulation would not solve the problem. The regulations include no quality-control measures, let alone testing. FDA implies they might impose such regulations in the future, but a vague plan to impose substantive regulations in the future, to solve a problem that has never actually occurred, is clearly not sufficient justification for a de facto ban. Moreover, FDA seems to have no notion of what such regulations might look like. The only intervention that FDA suggests might occur is inspection after the fact, and then only in the unlikely event that the problem occurred at one of the few FDA-regulated manufacturers and not in the black and shadow market that the regulations will create. There is no proposed mechanism for stopping hypothetical contamination problems before they happen. Yet the current checks against a serious contamination problem – those de facto existing regulations described above and the effective networking of e-cigarette users – would be diminished by the proposed regulation, increasing the chance of a serious problem.

Should it be discovered that a particular ingredient, process, manufacturer, or other factor is causing some e-cigarettes to be substantially more risky than necessary, it would be eliminated or altered under the status quo much more rapidly than it would under FDA regulation. The networking of informed consumers and responsible vendors would ensure this, whereas a regulatory response would probably be comparatively plodding. However, the black and shadow market that the regulation would create would reduce the penetration of such corrections. The most likely sources of any serious error or bad process are the manufacturers that FDA would not have effective control over. FDA might believe that its research efforts could uncover bad ingredients or processes and thus propose improvements; we strongly encourage the pursuit of such research. But such research is just as possible under the status quo as it would be with the proposed regulation, and any useful actions recommended by the results would be more likely to occur under the status quo.

We understand that the FDA corporate culture is such that there is great frustration about not being able to inspect facilities and not being able to intervene in the case of some kind of
“outbreak” situation, and that this represents much of the motivation for imposing regulation. These are understandable desires in a context where they could be done effectively. But the proposed regulations will provide only the illusion of serving those goals. FDA will gain those powers only over three or four manufacturers and a few dozen products – notably those that are already least likely to create any problem – while diminishing its potential to influence or later effectively regulate the rest of the market.

The other major motivation for the precipitous rush to create bad regulation appears to be pressure from a handful of ill-informed elected officials. This has resulted in a classic case of blind assertion of government power without an understanding of the situation, and thus no notion of how the world could be improved (or would be harmed) by the assertion of power. As the joke goes, “Something must be done! This is something. Therefore, this must be done.” That may sound glib, but in fact it seems to be a legitimate assessment of the current proposal and the motives behind it. All of the hand-waving references to the benefits of the regulation mention goals and then describe how FDA will have more power. In no FDA document or statement we are aware of is there any presentation of how that power would translate into actions designed to bring about those goals, let alone of an analysis of how likely that is to work out as planned. (As we have noted here at length, such analysis shows that it will not.) Thus it appears that FDA shares our view that this new power does not seem to translate into any beneficial worldly changes for public health.

8. Consumers are inappropriately excluded from consideration or participation in this regulatory process

The exclusion of consumers from the regulatory process, as well as ignoring their interests in the analyses thereof, is unethical, arbitrary, and capricious. It has resulted in both unnecessary ignorance on the part of FDA and out-and-out falsehoods in its statements.

Consumers are the primary, and by far most important, stakeholder in the CTP regulatory process. The secondary stakeholder, industry, while well-represented in the process for traditional tobacco products, is also poorly represented in the case of e-cigarettes. Far better represented are those who are not stakeholders at all, particularly those who morally oppose use of all tobacco products (who misleadingly self-style as “public health” advocates, though they are actually motivated by specific ideology and not by genuinely improving health).

“Stakeholder” is often abused as if it meant “anyone with an opinion on the matter,” but it actually means “anyone who has a material stake in the matter,” which does not include those who are merely opinionated about it.
For decades, it has been considered an ethical and political mandate for stakeholders to have a seat at the table in FDA rulemaking. Yet consumers have been excluded from such a seat in the CTP process. The slot on the TPSAC committee that is supposedly reserved for a consumer representative has been occupied by advocates who are not only not consumers of the products or representatives thereof, but whose political goals include eliminating consumption of the products, the diametric opposite of representing consumer interests.

Part of the explanation for FDA’s apparent lack of understanding about the role e-cigarettes and other tobacco products play in consumers’ lives, as well as what will actually happen if these regulations are implemented, is the lack of consumer involvement. There are many people who could have explained these matters to the CTP, but they were intentionally excluded from the process.

FDA’s economic impact statement excludes what is, by far, the greatest economic impact of the proposed regulation, the loss of consumer surplus. Under the FDA’s implicit scenario about what will occur under regulations, consumers will lose access to thousands of beneficial products. Consumers derive an enormous benefit from e-cigarettes. A large part of this is the health benefits of using such products rather than smoking. But a great deal of it is consumer surplus generated by the benefits of using the products rather than being abstinent. This is a very large number, as is obvious from the fact that the same consumers were recently choosing to smoke, with all of its costs, rather than be abstinent, and they retain roughly the same gross benefits by continuing to use e-cigarettes. While FDA may believe its mandate is to maximize longevity even at the expense of the overall welfare of American consumers (even though this is an ethically indefensible position), this does not excuse pretending that there is no such expense. By excluding consumer interests from the assessments of the impacts of the regulation, FDA has based this regulation on patently false claims. Moreover, it has demonstrated blatant disregard and contempt for the consumers it claims to be benefitting.

A further observation makes clear that this exclusion of consumer interests represents class-based discrimination. The majority of consumers of tobacco products – whose socio-economic status is lower than the American average – are ignored in the process, but wealthy consumers’ interests are considered, as evidenced by the proposed carve-out for premium cigars.

9. **Most every justification for the premium-cigar carve-out applies to e-cigarette products**

The possible carve-out for premium cigars in the proposed regulation, without a similar consideration for e-cigarettes, is arbitrary and capricious favoritism for a group of products that are favored by wealthy and politically-connected consumers. We take no position on the carve-out or how combustible products should be regulated. Instead we note that the justifications for
the proposed carve-out (which were put on record by FDA, and thus represent a recognition on its part that they are legitimate considerations, regardless of the final decision about the carve-out) apply equally or more so to some or all e-cigarette products.

Part of FDA’s justification for a possible carve-out hinges on price. For example, “It has been suggested that adolescents are not attracted to large and premium cigars, because they are offered for sale at a much higher cost relative to other types of tobacco products and are more difficult to access (e.g., large and premium cigars are typically sold at tobacconists' shops versus convenience stores).” This same observation clearly applies to the majority (as measured by SKU count) of e-cigarette products. Many e-cigarettes and e-cigarette components have purchase prices far above the premium-cigar price threshold. They are available only from specialty shops, not convenience stores. Moreover, many such products require an investment in technical knowledge by the consumer that further discourages random youthful experimentation. These are the products that have no chance of becoming approved under the proposed regulation, and thus will be eliminated or relegated to black and shadow markets, whereas the inexpensive, simple products that are available in convenience stores are the only e-cigarettes that could become FDA approved.

The other major justification for the proposed carve-out is that premium cigars may pose lower public health risk than other combusted tobacco products, and lead to less tobacco use initiation. But there is overwhelming evidence that e-cigarettes – even if used far more frequently – pose far lower health risk than combustible products. There is a good case to be made that using e-cigarettes regularly poses less risk than smoking a few cigars a year [see: http://www.harmreductionjournal.com/content/6/1/29], let alone the more frequent consumption that is represented by most of the premium cigars sold. Initiation of tobacco product use with e-cigarettes appears to be far less frequent than the use of premium cigars among people who are otherwise nonsmokers, and there is no evidence that anyone has become a smoker as a result of using e-cigarettes.

To reiterate, these observations are not to suggest a position one way or another about the cigar carve-out. Rather, they point out that given that such a carve-out was proposed, the lack of a similar proposed e-cigarette carve-out – for “premium” e-cigarette products – is arbitrary and capricious, and seems to reflect preferential treatment for a socially privileged class of consumers. There has been a flood of concern expressed by those in the wealthy or political class about how premium cigar makers could not possibly adhere to SE requirements and would be put out of business, in contrast with the relative silence and lack of remorse that the same applies to premium e-cigarette makers. The proposed regulation imposes unequal protection for a class of Americans based on their lack of wealth and political influence.
Earlier this year, the FDA was widely chastised for proposing and then backing off on a ban of wood-plank aging of artisanal cheeses. The backing off was widely attributed to the fact that consumers of those products were wealthy and well connected, whereas most consumers who have been hurt by similar prohibitions of non-luxury foods could not get them reversed. The present proposed regulation appears to be another case of burdening consumers with restrictive regulations only when those consumers do not have any political clout. If e-cigarette consumers were given the voice they deserve as stakeholders, this would not have occurred.

10. The FDA impact assessment is inaccurate, arbitrary, and capricious

FDA was obligated to assess the impacts of the proposed regulation, and produced a supposed assessment (http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/UCM394933.pdf). However, the contents of the document grossly underestimate the true impacts of the proposed regulations of e-cigarettes. In particular, the reported costs are limited to the costs of paperwork compliance for the very few manufacturers and the very few products that would survive the de facto ban imposed on most of the market. The much greater costs to consumers are ignored.

10.1 The real costs to industry

As we noted in our previous comment [http://www.regulations.gov/#!documentDetail;D=FDA-2014-N-0189-42893], this is a gross perversion of the Paperwork Reduction Act (PRA), whose requirements the cited document explicitly claims to respond to. The paperwork burden alone – without any substantive restrictions – would effectively ban most of the products on the market.

The spirit of the PRA and OIRA review of regulations include an attempt to ensure that the mere paperwork burden – as opposed to beneficial substantive requirements – is not unduly burdensome. The FDA is flouting the spirit of the PRA and OIRA review in their proposed regulation documentation. In particular, FDA ignores the greatest cost to industry created by the paperwork burden: Most manufacturers will find the paperwork burden to be so great that they will abandon products or, for the vast majority, their entire (above-board) businesses without even attempting to deal with the paperwork. This lowers the naively measured burden of paperwork as reported by FDA – limited to the paperwork costs for products that are not driven from the market – by ignoring its greatest costs, the elimination of the products and the resulting loss of consumer surplus (as discussed in more detail below). This is blatantly contrary to the goals of the PRA.

FDA predicts that there will be no applications for e-cigarettes based on a product being substantially equivalent to products on the market in February 2007. This is consistent with the
fact that either no such products existed in the U.S. market at that time or that the very few available products were extremely primitive, bearing little similarity to today’s products. (There is some disagreement about which of these is the case, but no doubt that one or the other is.) FDA predicts that there will be only 25 PMTAs for e-cigarette products. This is a tiny fraction of what we estimate are in the order of 100,000 e-cigarette products currently in the U.S. market, with new products being developed every day.

Clearly FDA has not underestimated the number of products on the market by three or four orders of magnitude. Rather, they are admitting that the vast majority of manufacturers cannot even attempt to comply with the enormous paperwork requirements they are imposing (and, indeed, FDA has basically stated as much). Thus, the estimated costs of paperwork compliance for those 25 products grossly underestimates the true effect of the paperwork burden in a manner that perverts the intent of the PRA. This burden is still substantial for the remaining 25 products; FDA predicts it would require over 5000 hours of work per product to just comply with the applications requirements. But the burden imposed upon the other thousands of products is even greater: It is effectively infinite.

It is important to note that the compliance requirements in question consist entirely of paperwork. FDA is predicting that in the order of 99.9% or 99.99% of the e-cigarette products in the market will disappear without even an attempt to comply with the filing requirements that could let them stay on the market. If the paperwork application burden were, say, 1 hour per SKU, we would predict that there would be tens of thousands of applications. This means that most of the products on the market are being eliminated (or forced into black or shadow markets) because of the paperwork burden per se.

That estimate of 25 applications is approximately the number of e-cigarette products currently sold by the major traditional tobacco companies. Since these are the only companies that have the resources to comply with the paperwork burdens, this equivalence is clearly more than coincidence. While it certainly would be better for consumers and public health if these few e-cigarette products survived the paperwork burden rather than none at all, these products would be the cigalike products that are a dispreferred option for a large portion of those ex-smokers who quit smoking using e-cigarettes, as detailed above. This represents a huge public health cost and loss of consumer surplus, in addition to the costs to industry.

It could be argued that many e-cigarette manufacturers might believe that their products could never be approved under the premarket application process. However, there are fundamental ambiguities about this approval process, and there are no clear reasons for many manufacturers to assume their products would not qualify for premarket approval. FDA has not made clear what data and facts would be sufficient for such approval. There is certainly no doubt that use of all e-cigarette products (with the possible exception of a few highly flawed products which are
sufficiently rare that we are unaware of them) pose lower risk than the cigarettes that FDA regulates without banning. Assuming the approval process is not just a façade and there is a genuine possibility of approval, this means that many products would have been allowed onto the market were there not a paperwork burden that prevents their manufacturers from even attempting to apply.

To put this in concrete terms, consider a scenario where a mere 1% of current e-cigarette products would meet the approval requirements. This is in the order of 1000 potential approvals. But the paperwork burden would preclude applications for all but 25 of them. So even under this pessimistic scenario about approvals, there would still be about 1000 products that could be approved but will instead exit the above-board market because of the paperwork burden. Since these products have been proven by real-world experience to pose no measurable hazard and are used as a substitute for a very hazardous behavior, it seems that far more than 1% should qualify, raising this number. (If not even 1% of such products could qualify if their manufacturers could afford to apply, then the approval process should be acknowledged to be a method of prohibition and should be presented and evaluated as such.)

It is important to emphasize that no products could be driven from the market due to any substantive requirements of the proposed regulation; it is entirely due to the paperwork and the approval process. There are no substantive requirements – such as manufacturing standards or ingredient bans – in the current proposed regulation. All of the proposed regulations consist entirely of filings and approvals.

It is worth reiterating that nowhere in the proposed regulations, nor in any other FDA publications to our knowledge, are there statements about how these filings and approvals (or disapprovals) would provide any benefits.

In sum, the FDA is openly predicting that the paperwork burden alone will destroy almost all of the e-cigarette products on the market, and is making no concrete claim about how the required paperwork or any other requirement they are imposing will lead to beneficial regulation. Even if we allow for the possibility that 99% of existing products would be banned on substantive grounds, the vast majority of the potentially approved products would still be eliminated due to the paperwork burden.

Imposing paperwork costs that are so great that they cannot possibly be complied with does not create zero paperwork cost. And yet this is exactly what FDA is claiming. The reported cost estimates assign no cost where there would not even be an attempt to comply. This is inappropriate at two levels: First, it is basically creating a hidden ban, using the paperwork burden to impose it. This clearly violates the fundamental goals of the PRA. Second, it is underestimating the true costs because no attempt is made to estimate the social costs of the
paperwork requirements eliminating companies and products from the above-board market. FDA is aware that such costs exist (from FDA’s regulatory impact analysis: “We acknowledge that product exit reduces product variety and the range of choices available to consumers, but we do not estimate the value of this loss of consumer choice.”), but improperly ignores them in the quantification. By this logic, had FDA made the paperwork burden even more onerous, such that no one would try to meet it, they would have claimed that the paperwork costs were zero.

The elimination of products due to paperwork burdens creates all the obvious costs for commerce, including loss of employment, reduction of consumer spending in an already depressed economy, and a loss of business profits. But much more important in this case is the enormous loss inflicted on consumers.

10.2 Loss of consumer surplus is ignored
The greatest net cost of eliminating products from the market falls not on producers but on consumers. The benefits of the higher-quality products that would be eliminated (if we assume FDA’s scenario of only regulated products existing) come overwhelmingly from the consumer surplus they create. A former smoker who switched to e-cigarette products and has found these to be an appealing substitute (or a current smoker who will do so in the future) gains consumer surplus roughly equivalent to the health costs of smoking. Under the FDA scenario, current consumers who find cigalikes unacceptable, and thus either return to smoking or become abstinent, will lose the consumer surplus gain that came from switching from smoking to vaping. (Some commentators might consider the switch to abstinence to be a win, but it still constitutes a loss of consumer welfare, and a legitimate economic impact analysis must acknowledge this even if such loss of that welfare is actually preferred by FDA.)

This impact is not difficult to roughly quantify: If we assume that, for the average switcher, high-quality e-cigarettes produce roughly the same benefits as smoking, exclusive of the health impact, which appears to be approximately accurate, then the health benefits are increased net consumer surplus. These can be quantified in terms of years of potential life lost or other standard measures used in regulatory cost-effectiveness analysis. This is a huge number, well into the six-figure range (using dollars as the numeraire and typical rates of conversion for life years save) per consumer. This rough estimate could be refined with further research into product preferences, accounting for the differences in costs compared to combustible cigarettes, accounting for other lifestyle costs and benefits, etc. But the order of magnitude is unlikely to change. Yet, the FDA impact analysis basically assumes it is zero.

This simple and cold analysis – though appropriate for an economic impact statement – actually grossly understates the burden. To many consumers, e-cigarettes are an enormously important part of their lives, something that FDA would understand if they allowed consumer representation in the regulatory process. People’s relationship with them is not like the casual
preference for wood-aged cheese or even the hobby of occasional premium-cigar use. It is this that FDA is proposing to casually take away from society.

It should be noted that the common refusal to acknowledge that there are net benefits from tobacco product use does not change this analysis. That refusal generally takes the form of some hand-waving invocation of the concept of addiction. But even setting aside the empirical tenuousness of those claims and the lack of any viable definition for “addiction,” this does not matter. Tobacco consumers have a particular preference, whether or not a derogatory label is attached to it, as evidenced by their behavior. The science of welfare economics recognizes that preferences derive from many different hereditary and environmental factors, and that the benefits and costs of an action are not affected by the sources of the preferences. Ad hoc decisions to not count certain costs and benefits from immoral activity is sometimes acceptable, such as refusing to count losses to criminals as a cost of law enforcement, but dismissing a cost or benefit because of how preferences came into being is never defensible. If a product is considered “addictive,” it can be argued that initiating use creates a cost, but once the addiction is extant, it is simply part of someone’s preferences, no different from anything else in the complex set of factors that yields preferences. It contributes to the welfare gains and losses from actions. If someone is choosing to smoke rather than be abstinent despite the health costs, then the gross benefits must exceed the health cost, whether or not some of the benefits of continued use derive from a condition labeled “addiction.”

Moreover, even if FDA wants to pretend that there is no consumer surplus from tobacco product use, there is no observer on any side of this issue who would deny that the health costs from smoking are real and quantifiable. Thus eliminating them must be seen as a gain in consumer surplus compared to smoking. Even the most extremist anti-tobacco activist would not deny that causing smoking among people who would not otherwise continued to smoke creates a real cost.

A current or would-be consumer of higher-quality e-cigarette products who willingly switches to the approved cigalikes will suffer some lesser reduction in welfare from being forced to use a dispreferred product. Such consumers, along with consumers who prefer cigalikes, will be further burdened by the oligopoly pricing of the major tobacco companies whose products are approved by FDA for above-board sales. Basically, the regulation would turn a vibrant and highly competitive market where producers compete on quality and price into a static market where competition mainly takes the form of brand advertising and purchasing of premium shelf-space in retail outlets. (The similarities to the current market for combustible cigarettes are not coincidental.)

The analysis of consumer (and producer) impacts becomes far more complicated once the inevitable shift into black and shadow markets is incorporated into it. A proper economic
analysis would attempt to predict the nature of this market and its impact on consumer and producer surpluses. Indeed, FDA could choose to seek some refuge in this (as noted, the negative impacts on consumers will be substantially mitigated by the alternative markets), though this would require acknowledging the inevitable failures of the regulation.

10.3 Remediing the arbitrary and capricious economic impact analysis

The only apparent remedy for FDA providing blatantly false information in its impact analysis is to create an accurate analysis, publish it, and reopen the proposed regulation for comments. As it stands, those commenting on the proposed regulation, as well as OIRA, interested lawmakers, and every other interested observer, are doing so on the basis of false claims that ignore billions of dollars worth of costs.

The new impact analysis must provide some estimate of the loss to consumers. As noted above, this is actually quite easy to approximate. It should also quantify the impact on producers who would not even try to comply with the paperwork burdens. As part of that, FDA needs to explicitly report its estimates of which or how many products would not get approval on the merits if they did apply, and how many are simply prevented from applying.

It is important to reiterate that this is not a dispute about the details of calculations and estimates, where one reasonable analyst could defend what was done, even as another argued it was wrong. This is about complete omission of almost all of the economic impacts in what is supposedly an economic impact analysis.

11. The FDA scientific analysis in the draft regulations is biased, naive, inaccurate, arbitrary, and capricious

Arguably the most glaring evidence that FDA is not fulfilling or even pursuing its obligations to the public is the presentation of the scientific evidence about e-cigarettes in the proposed regulation and related documents and statements. It is FDA’s job to evaluate the research in an unbiased manner. But in its presentation of the scientific information, FDA has not adopted the role of judge, but has inappropriately assumed the role of prosecutor. Evidence is cherry picked from areas full of legitimate controversy in order to imply greater support for particular conclusions than an honest review would. Indeed, FDA has even violated the ethical obligations of a prosecutor, not just emphasizing what it thinks might justify the proposed regulations and downplaying exculpatory evidence, but actually fabricating claims that tend to support the rules and hiding evidence that does not.

It is not just the overt bias that is troubling. Evaluation and analysis of the science is required. FDA is asserting that it has sufficient expertise to regulate businesses and millions of consumers
in this sector. Yet it presents scientific evidence in the naive manner of a child writing his first research paper, treating any assertion that is written down as if it must be correct. CDER would not regulate based on such naivety, and it is similarly inappropriate for CTP to do so. The scientific analysis by FDA in and surrounding the proposed regulation falls far short of what is required for good public policy and what is demanded by White House and OMB directives. It falls even further short of the standards of evidence demanded by FDA itself of manufacturers of tobacco products and other goods it regulates.

11.1 Clear bias in the treatment of information
FDA’s blatant bias in interpreting scientific information is exemplified by the following statement, which appears several times in the proposed regulation:

“some researchers have stated that substituting e-cigarettes for tobacco cigarettes ‘may substantially reduce exposure to tobacco-specific toxicants’.”

This statement takes a fact that is beyond dispute and presents it as if it were the speculation of only a few researchers. A single source is quoted, as if this claim were rare, and moreover the chosen quotation includes an absurd caveat (“may”). Notice that the statement is merely that there is reduced exposure to toxicants, with no claims about effects or even quantities. There is simply no doubt that substituting e-cigarettes for combustible cigarettes dramatically reduces the exposure to almost all the toxicants from smoke to approximately zero. This could be derived from a basic understanding of chemistry and of e-cigarettes, and is also supported by every empirical study of the exposure from e-cigarettes. Notably, the Burstyn review of the available empirical chemistry about e-cigarettes is not even referenced in the document.

A similar gross understatement in the regulation is:

“Some have advanced views that certain new tobacco products that are noncombustible (such as e-cigarettes) may be less hazardous than combustible products....”

along with the similar subsequent statement:

“Some have advanced views that certain new non-combustible tobacco products (such as e-cigarettes) may be less hazardous, at least in certain respects, than combustible products given the carcinogens in smoke and the dangers of secondhand smoke.”

This is a stronger claim than the one about exposure since it refers to effects and not just chemistry, but it is also beyond any serious doubt. Even so, it is also phrased in terms that imply this is a relatively rare belief (“Some have advanced views...”). This is in spite of the phrasing of the claim already being extremely weak (“may be,” “at least in certain respects”). The accurate
statement would be “almost every expert addressing the issue agrees that e-cigarettes are far less hazardous.” Stating it as a simple fact would also be appropriate, given the lack of credible doubt.

This following statement is a bit more defensible still, but only if interpreted with a tortured literality:

“The scientific evidence remains as yet unclear what the public health impact will be from products such as e-cigarettes.”

It is, of course, true that we cannot precisely predict the magnitude of future impact (of anything). But this “we just don’t know” phrasing is typically used as an excuse for denying what evidence does exist in debates about e-cigarettes. The natural interpretation, rather than the vacuous extreme interpretation, is “we cannot predict whether e-cigarettes will be solidly positive, solidly negative, or somewhere in between.” Given that millions of people worldwide (and probably soon a million Americans) have quit smoking thanks to e-cigarettes, and that e-cigarettes are clearly very low risk in themselves, the direction of the impact is obvious.

Consider analogous statements from another much-discussed area of practical science that is also fraught with political controversy. If someone wrote “some have advanced the view that human activity may be causing global warming” this would be immediately recognized as an attempt to mislead the reader, given that many experts have declared this is definitely true. Of course, someone would be free to make a science-based argument that it is not true, but to imply that the contrary position was merely speculation of a few commentators would clearly be misleading. (Notably, scientific arguments that the majority view is wrong have been made in the case of global warming, but we are aware of no case where anyone has made a scientific argument that would call into doubt the claim that e-cigarettes are far less hazardous than combustible cigarettes.) The analogy to the first-quoted statement would be the claim that “some researchers have stated that humans may be producing a lot of atmospheric carbon dioxide,” which would clearly be absurd phrasing, since the statement is indisputable.

A more detailed tortured understatement is:

“Emerging technologies such as the e-cigarette may have the potential to reduce the death and disease toll from overall tobacco product use depending on who uses the products and how they are used. If such products result in minimal initiation by children and adolescents while significant numbers of smokers quit, then there is a potential for the net impact at the population level to be positive. If, on the other hand, there is significant initiation by young people, minimal quitting, or significant dual use of combustible and non-combustible products, then the public health impact could be negative.”
E-cigarettes obviously do (not “may”) have that potential, and indeed there is ample evidence they have delivered on it. The first scenario presented – seemingly an accurate description of reality, though presented as a hypothetical – is far stronger a condition than is needed for e-cigarettes to reduce the health impacts of tobacco use. If a significant number of smokers quit due to e-cigarettes (indeed, probably no more than already have), none of the other conditions are needed. Yet it is still phrased in terms of “there is a potential.” The second scenario (notably phrased without “potential”) is actually not sufficient for the net impact to be negative.

Of course, it is possible for authors to choose to be so epistemically modest in their claims that they couch every scientific claim, no matter how solid, in such caveats. It would be rather odd for regulators to do this since it borders on the intellectual nihilism that leads to the conclusion that we can never know anything about what worldly actions are better. But this is very much not what FDA has done. Instead, while they include denialist caveats for positive statements about e-cigarettes, they present numerous negative statements about e-cigarettes and other products – including statements that are mere speculation or even clearly false – as if they were established fact.

For example:

“Because of their addictiveness and the marketing and sale of these products and their subsequent use by youths, some non-cigarette tobacco products can introduce youth into a lifetime of addicted tobacco product use and related harms, including premature death (Refs. 13, 14, 15, and 16).

“Further, many of the products proposed to be covered by this rule are offered in fruit and candy flavors, such as chocolate and grape flavors, making them especially attractive to children and young adults. For example, from 2010 to 2012, one cigar company introduced grape, white grape, and blueberry flavors to its line of little cigars and cigarillos (Ref. 17). In 2012, a manufacturer of nicotine solutions for e-cigarettes introduced Mint Mocha and Spiced Apple Cider flavors for their e-cigarette solutions (id.).”

Claims about “addictiveness,” the effects of marketing, and the effects of flavors are stated as fact, even though there is far more legitimate dispute about these claims than there is about the above-quoted claims about e-cigarette exposures and effects.

The concept of addiction is invoked numerous times in the document. FDA leans heavily on the concept of addiction, but never offers any explanation for what they mean, which is not a trivial problem in itself since there is no standard or widely accepted scientific or medical definition of
the term. (Indeed, there is a good argument to be made that there is no candidate scientific definition that matches the casual use of the word, though that can be ignored for present purposes.) All of the claims cited about addiction refer to the properties of cigarette (or cigarette-like little cigar) smoking. If we take “addiction” to roughly mean “the captivation which is experienced by habitual cigarette smokers,” then there is serious doubt about whether e-cigarettes have that property. FDA accepts the claims that the pharmaceutical nicotine products it regulates (NRTs) are not addictive, and e-cigarettes are much more similar to some of those than they are to combustible cigarettes. E-cigarette users often report that while they felt like they could not quit smoking no matter what they did, after using e-cigarettes for a while instead, they could largely take it or leave it. Most switchers reduce their total nicotine intake quite dramatically. There is no evidence of any nonsmoker ever becoming addicted to tobacco products as a result of e-cigarette use. Thus the assertion that e-cigarettes are addictive (the phrasing in the regulation has FDA asserting this about all the products in the proposed regulation) is declaring something that is far from established.

(Note that one implication of the above observation is that it would be inappropriate to impose labeling on e-cigarette products warning about addiction until and unless there was some evidence that these products actually are addictive.)

Similarly, the claim that certain flavors are “especially” attractive to children is far from established in the case of e-cigarettes. Indeed, there is no empirical evidence about e-cigarettes to support the claim that the flavors are attractive rather than repulsive to children. Of course, we know that people of all ages like attractive flavors, but the claim is phrased as implying they appeal to children more than the target adult consumer, which is doubtful. As noted above, experienced adult e-cigarette users have strong preferences for flavors other than imitation tobacco smoke. There is no evidence to suggest the existence of attractive flavors causes more nonsmoking children to try them than otherwise would. It is a valid testable hypothesis, but nothing more than that, and yet FDA asserts it as fact.

The statement about marketing implies that marketing is causing children to use tobacco products. Again this is a plausible hypothesis, though it hardly is self-evident (consider: more children are regular users of cannabis than cigarettes, but there is no marketing for cannabis; children used tobacco historically, long before there was marketing). Nonetheless, it is stated as

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2 Note that the use of the word “flavor” here, which follows FDA’s use of the term, is actually a misnomer. Everything has flavor. What FDA is referring to is presumably (they never actually define it) what are technically called “characterizing flavors” and refers to added flavors that evoke a particular defined taste association that is not the natural taste of the product in question. This creates a confusion in the case of e-cigarettes, which FDA gives no indication of understanding: Every flavor in e-cigarettes is an added characterizing flavor, including flavors that try to imitate cigarette smoke.
fact. The cited references do almost nothing to support the claim. Reference 13 reports some information about what a few people in industry may have once hoped to achieve from marketing efforts, but no actual information about what occurred. Reference 14 reports that smokeless tobacco was advertised in magazines, some of the readers of which were under age 18. The fact that some children merely saw ads for tobacco products (other than those under discussion in the proposed regulation) is a far cry from supporting the stated claim. The authors of reference 15 observe that a tiny increase in use of smokeless tobacco (among both adults and children) corresponded temporarily to an increase in the number of available sub-brands, and assert with no further analysis that this was causal, ignoring the many other possible explanations for the increase. But even if the authors’ evidence actually supported their conclusion, their conclusion does little to support FDA’s assertion. Reference 16 merely showed that many young people who use smokeless tobacco are more likely to smoke, which does not support any of FDA’s claims in the sentence. In sum, the cited sources report information that is only tangentially related to the aggressive claims that FDA is asserting they support.

The passages quoted above reflect a consistent pattern of FDA claiming the obvious established benefits of e-cigarettes are speculative while baldly asserting alarmist negative claims about e-cigarettes that are, to put it most charitably, debatable. The source citations demonstrate FDA’s cherry-picking approach to the science. In addition, the implication that the references 13-16 support the claim to which they are attached shows a fundamental lack of understanding about scientific reasoning that suggests that CTP lacks the scientific expertise to regulate e-cigarettes effectively.

11.2 Naive understanding of how to seek and analyze scientific information
Even where FDA is not obviously attempting to spin the available information in a particular direction, they show a very naive understanding of the nature of scientific information. This is a serious failure in any context, and is particularly glaring for an agency whose job it is to vet scientific claims.

Shortly before publishing the proposed regulation, CTP personnel authored a supplement issue of Tobacco Control [http://tobaccocontrol.bmj.com/content/23/suppl_2.toc] that purported to summarize the available scientific knowledge about e-cigarettes. Any expert reader of this collection is struck by an apparent Dunning-Kruger phenomenon: These authors seem to know so little that they do not even understand how far from being expert that they really are.

This publication was clearly intended to presage and provide the FDA’s views on the topic, and thus should be considered part of the accompanying documentation for the regulation. The articles were, to put it mildly, far short of what should be expected from expert regulators. They reveal far more about the (lack of) expertise of the authors and their institution – on the topic of e-cigarettes and about how to do scientific research in a complex area – than they do about e-
cigarettes. The project appears to be less an attempt to provide the world with useful reviews than a desperate attempt to gain a basic (clearly inadequate) understanding of the topic before aggressively intervening. It is also notable that there is basically no reference to consumers in the discussions of why e-cigarettes matter.

Very little of the world’s knowledge about e-cigarettes appears in ivory-tower journals, something that is obviously true of any emerging technology or social phenomenon. Yet the authors naively act as if this were the case and restrict their supposed review of knowledge to whatever happens to have been published in journals and patent applications. At the same time, they demonstrate an even more naive faith that anything someone happened to write in a journal (be it a research result or just an offhand claim in the introduction or conclusion sections) is true. No exception seems to be made for claims that other authors have pointed out are wrong, nor even statements that can be shown to be wrong by simply reading the paper in which they appear.

Relying only on journals for information and blindly trusting their content would be a poor strategy in any field, but is especially true in tobacco research, where most of the journals that publish on the topic have a strong political bias. In publishing about tobacco, peer review – not a promise of accuracy in any area, and far worse than average in public health in general – largely consists of a political litmus test about the conclusions. Publishing anything in public health journals about tobacco that is not wholly critical of tobacco is extremely difficult, and few of those generating the bulk of the knowledge about e-cigarettes even bother to try. Funding for research on tobacco is available almost exclusively from anti-tobacco institutions (who typically impose a political litmus test) and industry, and many journals refuse to publish anything funded by industry. FDA is undoubtedly aware of all this.

Even the paper in the collection about product design characteristics – something that changes rapidly, making any journal article out of date before it is published, but that is extensively documented in other forums – relies entirely on the information contained in 14 journal articles and 16 patent filings. The paper about nicotine failed to show the authors were aware that e-cigarette consumers’ actual experience with nicotine is widely documented, but not in journals. In fairness, another paper in the series did acknowledge there is a human factor; however, since the authors also restricted themselves to journal publications, the paper offered no learning on the topic. (Note that further details about the flaws in this collection of papers can be found here, http://antithrlies.com/2014/04/15/fda-reveals-its-views-on-ecigs-in-new-publication/, which incidentally is one of the many sources of published expert knowledge about e-cigarettes that exist outside of journals.)

The paper about e-cigarette chemistry could have been fairly complete based on only journal articles had it considered the Burstyn article (which reviewed all publicly available chemistry
studies, whether in journals or not), but it mysteriously ignored the existence of that article. The authors also seemed to not even understand the differences between solid particles (where certain particle sizes can create inhalation hazards) and liquid droplets (where such concerns do not apply), going into a discussion of droplets from e-cigarette aerosol as if they were particles. They also failed to understand that the toxicity of metal atoms depends entirely on what parent molecule they are part of. (The authors would have learned about both of these had they even read Burstyn, which had been available for most of a year before FDA’s publication. It is worth noting that Burstyn is cited in one of the other papers in the collection, so FDA cannot be unaware of it, though they pretend they are in the regulation document.)

The articles also contain extensive anti-e-cigarette innuendo and alarmist claims. For example, the article on product design (the one that relied on 30 random bits of out-of-date information) declares “e-cigarette aerosols may include harmful and potentially harmful constituents. Battery explosions and the risks of exposure to the e-liquid (especially for children) are also concerns.” However, the substance of the analysis did not support such conclusions. The authors of the paper about human health report no serious short-term problems but – ignoring the experience of millions of person-years of e-cigarette use – claim that we really do not know anything. The discussion of nicotine safety emphasizes one individual who committed suicide by intentionally injecting a fatal dose, hardly relevant to the safety of e-cigarettes. The ultimate, obviously false, claim in that paper is that we do not know that smoking is any worse for one’s health than vaping.

Perhaps what is most notable in this collection is CTP’s palpable sense of frustration about how complicated the available information about e-cigarettes is. Several authors practically concede that they wish more of the information was spoon-fed to them, and that they are unable to deal with a world in which all knowledge is not collected into a small number of indexed papers (i.e., the real world of e-cigarette science). FDA’s tobacco regulators, and those in CDER from which many CTP personnel come, are simply not used to dealing with complicated bodies of knowledge as many regulators in other arenas are. Instead, their practice is to control the generation of knowledge by setting rules about what research is required and how it must be reported. This is not a viable option in the case of e-cigarettes.

The authors of these papers seemed unaware (or they pretended to be unaware) that reading journal articles is only a small first step in acquiring an understanding of this topic, let alone expertise. Their response to this in the papers was to simply ignore the bulk of the world’s knowledge on the topic and imply that it did not exist. The proposed regulation responds to this challenge by suggesting that manufacturer filings will organize all the needed knowledge (which they clearly will not) and by trying to change the world (via banning most products) such that it is less complicated. But this will not succeed in making the world’s knowledge about e-cigarettes
simple enough for CTP to keep up with it given their limited resources and limited current understanding.

This pattern is further illustrated by the example in the next section.

11.3 Biased and inaccurate scientific analysis on the topics of flavors and use by minors
FDA makes clear that they are looking for an excuse to ban flavors in e-cigarettes. They ask several loaded questions in the proposed regulation, including:

“Given this initial data regarding the increased prevalence of flavored tobacco products following the 2009 flavored cigarette ban, FDA seeks comments, data, and research regarding the following:

• Aside from this proposed rule, what additional actions, if any, should FDA take to address the sale of candy and/or fruit-flavored tobacco products to children and young adults? For example, what data should FDA request manufacturers submit in new tobacco product applications to establish that flavorants either do not raise different questions of public health, in the case of SE reports, or are appropriate for the protection of public health in the case of premarket tobacco product applications?

• What is the likelihood that individuals who engage in flavored tobacco product use will initiate cigarette use and/or become dual users with cigarettes?

• The prohibition against characterizing flavors established in the Tobacco Control Act applies to cigarettes only. Consequently, when this regulation is finalized and other tobacco products are deemed subject to FDA’s tobacco product authority, the statutory prohibition against characterizing flavors will not apply automatically to those products. However, once they are deemed, FDA may establish a product standard prohibiting flavors in those products. FDA requests information and data that would support establishing such a standard.”

The prosecutorial approach to science of FDA here is clear. They seek information (presumably scientific) that would support banning flavors. They ask merely about the likelihood of users initiating cigarettes, suggesting they will misinterpret this as answering the decision-relevant question, whether flavored products cause smoking (they could have asked for genuine evidence that flavored products cause people who would not have otherwise smoked to do so, but did not). It is also disturbing that young adults are grouped in with children, implying a failure to understand that there are fundamental worldly and ethical differences between the two populations.
These questions do not specifically mention e-cigarettes, but the phrasing refers to all the product categories covered by the proposed regulation that have characterizing flavors (both little cigars and e-cigarettes, along with shisha, a comparatively minor issue). If FDA were really just focused on closing the little cigar flavor “loophole” (products that are little different from combustible cigarettes, but currently avoid the ban on characterizing flavors in cigarettes), they could have just referred to little cigars. Thus, the intent appears to be to seek excuses for banning flavorings in e-cigarettes (presumably other than fake tobacco-smoke flavor). The reference to dual use with cigarettes strongly implies this is not about little cigars, given that they are effectively the same as combustible cigarettes. Moreover, given that so much of the political rhetoric that seems to be motivating FDA about e-cigarettes focuses on the (false) assertion that flavors are designed to attract children, there is little doubt that readers will interpret this as being as much about e-cigarettes as little cigars.

FDA’s continuing scientific discussions of flavors, following the above quoted paragraph containing reference 17, is a clear indictment of FDA’s understanding of science:

“The first nationally representative study (derived from more than 4,000 young adults aged 18 to 34) to examine the prevalence of the use of flavored tobacco products following the 2009 FDA flavor ban in cigarettes found that 20 percent of tobacco users in the study currently use a flavored tobacco product (Ref.17). The most common flavored products include flavored pipe tobacco, little cigars, and hookah tobacco (id.). Research has shown that flavored product use is higher among 18-to-24-year-olds than 25-to-34-year-olds, and that sugar preference is strongest among youth and young adults and declines with age (id.).

“Such findings indicate that flavored product use may influence tobacco-use patterns in young adulthood, a critical period when lifelong patterns of tobacco use are often established (Ref. 17 citing Ref. 18).”

The entire discussion of the role of flavors references only a single paper, which relies on a black-box statistical model from a single non-public survey. The paper is written as an advocacy broadside, with long discourses into political opinion and staged photographs of tobacco products alongside packaged confectionaries, which make for excellent propaganda posters but are decidedly unscientific. As noted in these paragraphs, the survey was limited to adults, though FDA’s statement quoted in the previous section asserts that it is informative about children. The actual study results merely show a very modest higher rate of trying flavored products among the younger half of these adults compared to the older. There is no basis in the study for the assertion about preferences. Various factors other than preferences could explain the (slightly) higher rate of trying. To name just two obvious ones, having less established product preferences and having a broader social life both increase the chances of trying something new.
The reference to “sugar preference” is even more of an absurd stretch. It is a background observation by the author of the paper, not something supported by the paper itself. The cited paper cites three references which the FDA could have used as the basis for the claim but did not. Those papers are about younger people being more likely to prefer sweeter sucrose solutions (i.e., soda), which has little apparent relevance to the subtle differences in sugariness among tobacco products, which are obviously very different from soda. Moreover, there is no analysis at all in the paper about sweetness (characterizing flavors may or may not be more sweet than “unflavored” products).

The cite-through to reference 18 is an even more glaring example of over-interpreting one author’s interpretations of the implications of other material. Reference 18 is a 1981 Philip Morris USA internal paper that, based on the date alone, obviously has very little relevance to today’s world of radically different products and usage patterns. Unsurprisingly, the only product mentioned is combustible cigarettes and the only flavor mentioned in it is menthol, making it irrelevant to the claims at hand. The author FDA cites apparently used the 1981 paper to support an assertion about lifelong usage patterns. Obviously, tobacco use behavior has changed radically since 1981 (e.g., regular consumption now more often begins in adulthood rather than childhood), and products that are very unlike combustible cigarettes change this pattern further. What is worse is that studying lifecycle patterns is not the substantive content of the 1981 paper, and it appears that the author FDA cites was basing the claim entirely in a few throwaway background observations from the introduction, and even these are far more equivocal than the attributed assertion. In sum, FDA took an aside assertion by an author whose study was on a different topic, which itself was an exaggerated version of a background assertion by some authors writing more than a generation ago about entirely different products, and stated it as established fact. This occurred in the same document where FDA suggested there was doubt about whether e-cigarettes cause lower exposure to toxicants compared to combustible cigarettes.

Later FDA asserts:

“More youth who report they would never have used a tobacco product are experimenting with e-cigarettes (Ref. 4, 18)”

This is presented as if it were a useful scientific claim, but it is either hopelessly sloppy or intentionally inflammatory, either of which is inappropriate in the present context. The reader should ask, “more than what?” Presumably the intended claim is “more than sometime in the past.” But it is obviously true that “more X are experimenting with e-cigarettes than a few years ago” for any population X in which anyone has tried e-cigarettes, since e-cigarettes only became popular in the last few years and were not even available until fairly recently. But the statement clearly implies that the magnitude is great, which appears to not be the case. In context (the
previous sentence is about the public health impacts of e-cigarettes), the innuendo is that this implies a negative public health impact, though it is far from clear that even if every single child were forced to try an e-cigarette that there would be a nontrivial negative public health impact.

Moreover, the cited CDC statistics (reference 4) do not include data that could be effectively used to assess whether an individual would have ever used tobacco, so the actual claim made is not at all supported by the reference. The results of this survey of tobacco use by minors have been widely abused by ideologically motivated anti-e-cigarette activists. The survey primarily shows an increase over time in the number who have tried e-cigarettes, an inevitable result of newness that should surprise no one. But the absolute numbers are not as large as generally implied, and there is no information on real usage rather than mere trialing (the survey only asked about having tried one puff), motives, effects of flavors, or effects of marketing. And yet naive and/or dishonest commentators have aggressively cited the study as supporting all of these conjectures, and FDA is among them. One bit of information that is available from the survey, though not reported by those seeking to abuse the results, is that trying of e-cigarettes was concentrated among those minors who already smoked, rather than those who would have never used a tobacco product. Indeed, the use of e-cigarettes in the underage population may be primarily for THR.

Reference 18, the aforementioned 1981 paper, has even less information about experimenting with e-cigarettes. Its inclusion here is obviously an error, which suggests a different sort of question about the validity of FDA’s document.

The limited level of effort and skill devoted to the analyses on which the proposed regulation was based is grossly inadequate considering the implications of the regulation. Even apart from the bias, the quality of the scientific analysis – the inaccuracy of many statements, the incomplete research, and the misattribution to sources – is inadequate for a master’s-level term paper, let alone for the purpose to which it is applied. FDA spent years writing this proposed regulation, but apparently did not even download original source material. Moreover, the document reads like the assertions were written based on preconceived conclusions pushed by the small but vocal anti-e-cigarette faction, and then sources were sought and cited that vaguely related to (but in most cases did not actually support) the claims. This is not an acceptable way to make regulation, especially regulation that has enormous implications for people’s health and welfare.

11.4 Scientific claims as blatant innuendo

Some example of FDA’s phrasing of scientific (or pseudo-scientific) statements as innuendo have already been cited. The following are a few more examples from the regulation document. This tendency suggests that FDA is not behaving as a proper regulator, but as propagandist. The
Phrasing of technically true scientific statements in ways that tend to imply something false is a common tactic of anti-tobacco activists, not of science-based regulators.

“the number of cigarette smokers who actually quit tobacco product use with e-cigarettes is low (Ref. 19);”

This statement is literally true, given that e-cigarettes are defined as a tobacco product and most people use them as a substitute for smoking, not a method of becoming abstinent. However, the phrasing will cause most readers to interpret it as few people have quit smoking with e-cigarettes. In either case, however, the use of the vague word “low,” without any explanation for what it means, is inappropriate. This statement also illustrates a tendency of FDA to confuse legal definitions with scientific information. In a conceivable alternative history, e-cigarettes would be legally defined as medicines. In that case, this sentence would be false, though the physical reality would be unchanged. Similarly, FDA makes numerous scientific assertions that say, in effect, “e-cigarettes are tobacco products, and therefore their effects must be like those of other tobacco products.” But if the TCA were written differently, FDA would not be able to say this, which means their reasoning is fallacious. Obviously no scientific knowledge can be gained from where lawmakers and regulators have drawn arbitrary lines, and yet FDA is relying heavily on exactly that.

Further on the point of references that do not support the claim to which they are attached, reference 19 is about a randomized trial of e-cigarettes in a cessation clinic setting, which can offer no information about the number of smokers who have actually quit.

The sentence continues:

“current cigarette users experimenting with e-cigarettes have become dual users (id.)—with unknown health impacts.”

The first part of this is obviously true, and indeed understated. Few switchers never touch a combustible cigarette again after trying their first e-cigarette, and thus become “dual users” for some period. Gradual transition is the norm and is in no way disturbing. But the innuendo is that there is something harmful about the dual use as compared to just smoking. The opposite is almost certainly true. This is a critical point, since FDA seem to be trying to present something that is beneficial (partial substitution of a low-risk product for would-be smoking) as if it were harmful. There is nothing in e-cigarettes that could conceivably create negative synergistic health effects when combined with smoking, but smoking less – by replacing some would-be smoking with vaping – is healthier.
The reference is again to the clinical cessation experiment which tells us nothing about what is happening in the world, and thus provides no support for the claim.

“Although the health consequences of e-cigarettes are not well understood because of their relatively new entrance into the market, the health concerns and addictive properties of other tobacco products have been widely recognized in Surgeon General Reports and scientific literature.”

This is an example of the above-noted use of legal definitions as if they provide scientific information. The innuendo is that because some tobacco products (combustibles) are highly hazardous, anything defined as a tobacco product must be, which is obviously fallacious. Moreover, we know far more about e-cigarettes than simply that they are tobacco products, rendering that categorization uninformative. The statement is also another example of conflating lack of exact knowledge with lack of sufficient knowledge at the relevant level. The reality is that we have sufficient evidence to conclude that the risk is probably in the range of 99% less hazardous than smoking. It is also worth noting that this passage, which explicitly invokes scientific claims made by others as authority, includes no citations.

Another example:

“Additionally, young adults often mistakenly think non-cigarette tobacco products are safe alternatives to cigarettes (Ref. 8).”

The reference is to a paper from 2006, which used data from 2002. At best, this could be used to make a statement about perceptions from more than a decade ago, not the present tense assertion in the text. Knowledge, behavior, and products have all changed radically since then. The source paper itself is based only on two focus groups and is so badly written that it is difficult to be sure what the authors actually found. But basically the participants were forced to guess about which other tobacco products were more or less hazardous compared to regular cigarettes, and guessed that they were more hazardous about as often as less. There was no apparent quantification, so even those who said another product was less risky might have been guessing it was only 1% less risky. The main results actually showed that the participants were overly pessimistic about alternative products. Most, but far from all, rated smokeless as lower risk than smoking (which is clearly true, and this was known in 2002), as well as hookah smoking (true based on everything we know, though the epidemiology is weak). They mostly rated small cigars and other cigarette variants as higher risk (which might or might not be true, but the magnitude of the difference is relatively small, so it is a guess either way). The results of the paper generally contradicted rather than supported what FDA claimed.
Similarly:

“Research has shown that youth are also particularly vulnerable to the appeal of novel tobacco products (Refs. 9, 10, 11, and 12).”

References 9, 10, and 11 are all about hookah smoking, which is rather odd to refer to as “novel” given that it is a 400-year-old practice. That hookahs are used more among younger people in Western countries is unsurprising (though the word “vulnerable” is inappropriately inflammatory) given that hookah smoking is more about drawn-out social outings than a product use per se, and so is unlikely to appeal to older people with families and regular working hours (unless, of course, they are culturally part of the centuries-old tradition). However, this really tells us nothing about tobacco products themselves. Perhaps such observations could justify regulating shisha, but they tell us nothing about the impact of novel tobacco products. Reference 12 is about R.J. Reynolds’s dissolvable smokeless tobacco products, and its primary finding is that there was a fair bit of awareness, but very little interest in using them. Only 4% in the younger group had even tried them. The “youth” in this case were the age category 18-39, which while perhaps a tempting definition for a middle-aged author, is obviously a misleading use of the term.

11.5 Miscellaneous misleading statements

“Electronic cigarettes (or e-cigarettes), for example, are widely available in retail outlets such as kiosks in shopping malls and on the Internet and their online popularity has surpassed that of snus and nicotine replacement therapies which have been on the market far longer than e-cigarettes (Refs. 6 and 7).”

It takes a few readings of this to realize this is probably technically true but misleading. Snus (moist oral snuff) is used by far more Americans than e-cigarettes. But its online sales are a much smaller portion of the total, and that is what this actually says. It is not clear why this particular comparison would matter, and it only serves to confuse the reader. Additionally, reference 7 is about product popularity, but reference 6 is a study of nicotine concentrations which is uninformative on the point.

Though we take no position on the regulation of combustibles and did not analyze the scientific claims about them in detail, it is worth noting one glaring example of FDA’s failed scientific reasoning from that context:

“When similar products are taxed or regulated differently, substitutions across products occur. For example, industry documents indicate that tobacco firms have been aware of disparities in the legal treatment of cigarettes and cigars and have made efforts to develop
small cigars that cigarette smokers would smoke (Refs. 20 and 21). Sales of small cigars quadrupled in the early 1970s, when cigars were taxed at a much lower rate than cigarettes and cigarette (but not small cigar) advertisements were banned from television and radio (Ref. 21). While researchers posited that this change in prevalence rates is likely due to the lower taxes (and ultimately lower cost to the consumer) ([Ref 22] at 566), the lack of regulation over certain tobacco products may be a contributing factor. Without a common regulatory framework, tobacco firms can exploit differences in regulatory requirements to drive consumers to different product markets.’’

Even as FDA explicitly notes that the substitution of products is driven primarily by different tax rates (which FDA cannot control), they convolute the scientific statement to suggest that the mere act of FDA regulation would magically change the situation.

11.6 Remedying the FDA’s gross failures to properly interpret and present the science
The only conceivable remedy for FDA’s failure to understand the science and act as judge rather than prosecutor is for it to retreat on regulating until such a time that it is capable of making informed science-based regulation. After it acquires the requisite expertise, FDA needs to present an accurate and unbiased scientific analysis of e-cigarettes based on it. If the situation were such that the mere act of deeming did not trigger irreversible and extremely harmful events, or if the proposed regulation were just an ANPR as it should have been, the lack of understanding would not be so problematic (though the aggressive bias would still be grossly unacceptable). FDA could get up to speed on the topic before imposing substantive rules. However, that is not the case, and FDA is planning to create large and irreversible harm without apparently understanding the most basic science about the topic.

12. Changing the grandfather date for Substantial Equivalence is not a good alternative
An alternative to the proposed regulation has been floated in which e-cigarette products on the market as of the day the regulation is announced, rather than 2007, will be grandfathered in and serve as the predicate products for SE applications. FDA may be contemplating this as a “compromise” position (though it is not clear that it is a legal option). This would reduce some of the negative impacts noted above. But it would do nothing to address the lack of any apparent benefits, and the regulation would still be arbitrary and capricious, and have net negative impact. Moreover, it would create additional responsibilities for CTP that it would be unable to fulfill.

With a later grandfather date, many manufacturers would be able to register their products, a non-prohibitive paperwork burden for medium-sized and many small producers. This would keep a variety of high-quality products on the regulated market. However, the problems would begin immediately.
FDA states that the regulations “would allow FDA to monitor product development and changes and to prevent more harmful or addictive products from reaching the market. The proposed provisions would also provide a mechanism through which those products that are less harmful or addictive could enter the market.” This claim is simply wrong (with regard to e-cigarettes) for the regulations as written, since product development and changes would occur almost exclusively in the shadow market. It becomes plausible under the later grandfather date, but the reality would be that the assessment would still be wrong.

Since there is continuous quality improvement in the e-cigarette hardware market, and the liquid manufacturers act basically like chefs, manufacturers who wanted to remain compliant would immediately start filing numerous SE applications. CTP would be even more overwhelmed than it already is with SE applications, probably by several multiples, and many of these would be far less polished than those from the major tobacco companies that CTP currently deals with, making them harder to process. To put it bluntly, the only way that FDA can regulate e-cigarettes under the current TCA regime is to do what it is proposing to do, basically ban them. This speaks to our original point that FDA should ask Congress to give it new enabling legislation that would allow for rational regulation of e-cigarettes.

Because of the dysfunction of the SE process, the later grandfather date would effectively freeze the technology in the regulated market, resulting in not just lower quality products for consumers, but a lack of the current innovations that allow the products to become safer over time. However, it is likely that many manufacturers would not even attempt to stay compliant. The rules are fuzzy and the dynamic industry is more like Silicon Valley than the staid pharmaceutical and fast-moving consumer goods companies and relatively unchanging food products that FDA knows how to work with. Manufacturers are unlikely to be willing to wait the equivalent of several generations of new technology for an approval (or disapproval). Some will just start making changes without approval, counting on the limited enforcement mechanisms available. Thus they would have the incentive to transition into the same black or shadow market status, much as they would if there were no grandfathered predicates.

Indeed, many manufacturers will anticipate that this will happen, and will simply not register in the first place. Others will recognize that regulatory uncertainty makes registration ill-advised: A liquid manufacturer who anticipates that a ban on flavors is soon forthcoming might rationally choose to move immediately into the black market rather than call FDA’s attention to itself and then try to move into the black market after the ban. The result will be a marketplace that is ostensibly regulated more than under the proposed regulation, but that is still incompletely covered and will become more so long before any substantive or genuinely useful regulation could be imposed.
This same assessment would apply to any other minor changes in the regulation which would still freeze product development via the SE process. The majority of producers and most all innovation would shift into black and shadow markets as soon as the restrictions became binding.

13. Summary of the effects of the proposed regulation

*Consumer welfare* will be dramatically diminished. Consumers will lose easy access to the variety of products that provide them with huge benefits. Prices will increase and quality will decrease. On the other side of the ledger is basically nothing: the proposed regulation creates no apparent benefits for consumers.

*Consumer health and safety (public health)* impacts will be severely negative. The barriers to easy access to high-quality e-cigarettes that are created will cause some vapers to resume smoking and many smokers who would have quit by switching to e-cigarettes to never do so. Consumers of e-cigarettes will be forced to buy products from the black and shadow markets, or manufacture for themselves, resulting in less safety than the current market provides. Diminished incentives and ability to innovate will further lower the quality over time compared to the *status quo* trend.

*Risk of contamination, use of ill-advised ingredients, and related manufacturing issues* will be made worse. FDA will have control only over the largest manufacturers for whom this was never a serious problem. Smaller manufacturers will be driven underground, which will both increase the risk of problems and diminish the incentives to avoid them. Consumers will engage in more do-it-yourself, which will also dramatically increase risks.

*A “Wild West” marketplace* will be created. The current evolution is toward a more mature and disciplined marketplace, with huge improvements on a year-to-year basis. The proposed regulation will reverse this trend, forcing most manufacturers to become more “wild” and putting them permanently out of the reach of potentially beneficial regulation.

*Consumer knowledge and information* will be largely unaffected or somewhat diminished. FDA does not have the capacity to communicate effectively about this topic. Moreover, given FDA’s apparent poor grasp of the relevant science, it is likely that to the extent they are heard, it will reduce rather than increase knowledge. The only substantive information-generating provision of the regulation, HPHC filings, does not contribute to useful knowledge.
Access by and appeal to children will be unchanged. The products that are most easily accessible will remain on the market and in convenient retail locations. All other products that are currently available will remain widely available via black and shadow markets, who have relatively little incentive to obey existing standards and existing and new laws prohibiting sales to minors.

Are there any benefits for anyone? The only apparent benefits of this regulation accrue to:

- manufacturers of combustible cigarettes, whose competition will be diminished,
- manufacturers of the few e-cigarette products that could clear the paperwork hurdle to become FDA approved, who will have an oligopoly for above-board sales (these are basically the same companies as in the previous bullet point),
- politicians (both elected and appointed) who can claim to a naive public that “something” is being done,
- anti-tobacco extremists (those who oppose all tobacco use, regardless of its costs and benefits) who secretly prefer that people smoke rather than use a low-risk alternative because smokers have good reason to quit, while low-risk product users have little incentive to quit using low-risk products,
- those who make a living in the anti-tobacco industry, since their funding and support is eroded by low-risk alternatives to smoking.

It is worth noting that FDA and CTP, as institutions, are not on that list. It is safe to predict that imposing this regulation would not work out well for them.

14. Conclusions

In summary, if FDA really wants to do what is best for the primary stakeholders or wants to fulfill its own stated goals, it needs to remove e-cigarettes from the proposed deeming. The deeming of e-cigarettes and resulting application of TCA provisions does far more harm than good in terms of welfare, health, and fulfilling FDA’s stated goals. Worse yet, most of the harm would be irreversible. No conceivable minor change in the regulation would alter this. Instead, FDA should ask Congress to provide enabling legislation for beneficial regulation of e-cigarettes.

If however, for some reason, FDA wishes to go forward with a harmful regulation like the one proposed, it is morally and legally obligated to: (1) revise its scientific analysis so that it is complete, accurate, and unbiased; (2) revise its impact analysis so that it actually assesses all the impacts; (3) assess and report the predictable real effects of the regulation (e.g., black markets) rather than the present implicit fantasy about what will happen; (4) complete and report an analysis of the full public health effects of the regulation, in keeping with its own stated goals and standards it insists upon for any change in the tobacco market, including at least a prima
facie explanation for how the regulation would translate into actions that fulfilled public health goals; (5) include consumer representatives in the rulemaking process; and (6) eliminate the unequal treatment of different social classes by giving “premium e-cigarettes” the same consideration granted to premium cigars. Without these changes, FDA’s documentation and processes are not a legitimate basis for rulemaking. FDA should also explain its motivation for wanting to move forward with harmful regulation. Only after doing these can FDA legitimately issue a new proposed draft regulation, which should have a comment period that is long enough to respond to the volume of the content, particularly explicit or implicit questions.

Notes: Some of the content of this document is adapted from posts that appeared at CASAA blogs. Direct quotations where no source is cited are from the proposed regulation document.