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E-Cigarettes and the Multiple Responsibilities of the FDA

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ABSTRACT

This paper considers the responsibilities of the FDA with regard to disseminating information about the benefits and harms of e-cigarettes. Tobacco harm reduction advocates claim that the FDA has been overcautious and has violated ethical obligations by failing to clearly communicate to the public that e-cigarettes are far less harmful than cigarettes. We argue, by contrast, that the FDA's obligations in this arena are more complex than they may appear at first blush. Though the FDA is accountable for informing the public about the health risks and benefits of products it regulates, it also has other roles (and attendant responsibilities) that inform when and how it should disseminate information. In addition to being a knowledge purveyor, it is also a knowledge producer, an advisor to the public, and a practical agent shaping the material conditions in which people make health-related choices. In our view, those other roles call for caution in the way the FDA interprets and communicates the available evidence.



KEYWORDS

public health; regulatory issues; e-cigarettes; FDA; advice; science communication; harm reduction

Are e-cigarettes safer alternatives to combustible cigarettes? And if so, what are the U.S. Food and Drug Administration's (FDA's) responsibilities when it comes to disseminating this information? Prominent tobacco harm reduction advocates claim that (1) the evidence that e-cigarettes are safer is clear and incontrovertible (Abrams, Glasser, Villanti, et al. 2018; Abrams, Glasser, Pearson, et al. 2018; Beaglehole et al. 2019), and (2) the FDA's reluctance to actively disseminate that message is harmful for population health (Kozlowski and Sweanor 2018; Miller et al. 2017).¹ This paper interrogates the second of these claims, which has been framed as the FDA "quarantining" information the public has a right to receive (Kozlowski and Sweanor 2016). Though we generally agree with others who have asserted that the evidence is not so clear (Brandon et al. 2015), it is also important to recognize that the FDA's role is not so simple. Even if the public does have a right to be informed about the differential risks of e-cigarettes

and combustible tobacco products, it does not follow that *the FDA* is obligated to disseminate the message that e-cigarettes are safer while evidence regarding both the individual-level and population-level health effects of e-cigarette use is still rolling in. The FDA is accountable for informing the public about the health risks and benefits of products it regulates, but the agency also has other roles (and attendant responsibilities) that inform when and how it should disseminate information. In our view, those other roles call for caution in the way the FDA interprets and communicates the evidence as it becomes available.

Before discussing those various roles, we will first discuss two statistics often cited as clear evidence of the relative safety of e-cigarettes and their efficacy as tools for smoking cessation. A brief review of these statistics will provide context about the current evidentiary environment in which the FDA must make its messaging decisions:

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¹Kozlowski and Sweanor have written extensively about the FDA's failure to, in their view, "provide accurate information on major differences in risks of products[.]" (Kozlowski and Sweanor 2018). Most of their writing has focused on the reduced risks of smokeless tobacco products in comparison to cigarettes (Kozlowski and Sweanor 2016; Kozlowski and Sweanor 2017), but they have also extended the same arguments to e-cigarettes, writing that these products are "virtually certain to be significantly safer than cigarettes." (Kozlowski and Sweanor 2018). Though we reference some of their earlier papers, our argument in this article focuses solely on e-cigarettes.

STATISTIC 1: 95% LESS HARMFUL

Public Health England (PHE), in its 2015 evidence review of e-cigarettes, concluded that “best estimates show e-cigarettes are 95% less harmful to your health than normal cigarettes” (McNeill, Brose, and Calder 2015, 5). This estimate was criticized at the time for being based on nothing more than “the opinions of a small group of individuals,” some of whom had conflicts of interest (The Lancet 2015, 829). But in 2018, PHE reaffirmed its “95% less harmful” conclusion (McNeill et al. 2018, 80). It found that this estimate was broadly consistent with more recent studies comparing biomarkers of exposure in current smokers to people using only e-cigarettes. PHE noted, however, that “few specific biomarkers are included in these analyses, and it is unclear whether there are linear or threshold effects (i.e. would a 95% reduction in exposure represent a 95% reduction in harm[?])” (McNeill et al. 2018, 171). It also recognized that biomarker levels were not lowered for dual users (of both combustible tobacco and e-cigarettes), and that some of the studies were industry funded. Nonetheless, PHE concluded that the 95% number “remains a *good way to communicate* the large difference in relative risk unambiguously so that more smokers are encouraged to make the switch from smoking to vaping” (McNeill et al. 2018, 20 (our emphasis)).

STATISTIC 2: NEARLY TWICE AS EFFECTIVE AS NRT

A recent randomized controlled trial (RCT) in England found that among current smokers seeking support to quit, 18% of those randomized to receive e-cigarettes were abstinent from combustible tobacco products at 1 year, compared with 9.9% in the group given nicotine replacement therapy (NRT) (Hajek et al. 2019). This study has been taken as strong evidence that e-cigarettes have an important role to play in supporting smoking cessation. But while encouraging, there are major limitations to this study’s predictive power in real-world settings. Most notably, the study provided behavioral support to participants in both arms, which, although best practice, is not used by the majority of people trying to quit smoking (Shiffman et al. 2008). The results of this study conflict with earlier findings (Kalkhoran and Glantz 2016), and two more recent U.S. studies using longitudinal survey data from the Population Assessment of Tobacco and Health (PATH) concluded that in real-world settings, those using e-cigarettes to assist in smoking cessation were no more likely to succeed

than those using NRT (Chen et al. 2020; Pierce et al. 2020).

A quick look at these two examples shows that even the most prominent claims in support of e-cigarettes can be called into question. Our point is not to contest these specific claims in depth; e-cigarettes *may*, in the end, turn out to be much less harmful than cigarettes and *may* prove to assist in smoking cessation. But at this point the evidence is limited, contested, and often uncontextualized. Even as more research is called for, regulatory bodies like the FDA still must make difficult decisions about how to communicate to the public at present. Thus, we seek to raise broader questions about the FDA’s communicative responsibilities in light of current uncertainties and the continuing emergence of new evidence.

Given the level of uncertainty with respect to the risks associated with e-cigarette use as well as their efficacy in smoking cessation, regulatory bodies like the FDA must account for a number of evidential, evaluative, ethical, and pragmatic concerns in determining how to communicate to the public about e-cigarettes. To date, most discussions have focused exclusively on the FDA’s role as a knowledge purveyor. But the FDA plays other important roles as well: it is involved in knowledge production, in advising the public, and in shaping the market conditions in which people make health-related choices. As the PHE example attests, government bodies are already taking pragmatic considerations into account when strategizing about communication. Recall that PHE chose the “95% safer” claim because it determined it was a “good way to communicate the large difference in relative risk” between e-cigarettes and combustible tobacco products (McNeill et al. 2018, 20). We do not consider these sorts of considerations to be out of place. Rather, we argue that determining the optimal communication strategy requires attending to all of the roles that the FDA occupies. This paper will enumerate the variety of roles of the FDA in order to argue that although the public may possess a “right to information” regarding health risks, the FDA should be hesitant about endorsing e-cigarette use in the current context of scientific uncertainty.

ROLE 1: FDA AS KNOWLEDGE PURVEYOR

Those who argue that e-cigarettes are effective tools for harm reduction are concerned about the public being unaware or misinformed of the differential health risks of e-cigarettes and combustible tobacco products. They argue that the FDA is withholding this

knowledge from the public, and that its regulations (based on the 2009 Tobacco Control Act) make it impossible for e-cigarette manufacturers and retailers to effectively communicate this information. Kozlowski and Sweanor, for example, write:

FDA, despite its mandate to engage in public education, has to date transferred the responsibility for providing accurate life-critical consumer product information to the commercial marketing of tobacco companies. But such a high regulatory standard [for health-related claims by e-cigarette companies] ... contributes to smokers being ill-informed about product risks (Kozlowski and Sweanor 2016, 19).²

In this discussion, they are highlighting one important role the FDA plays in relation to public health: the FDA serves as a knowledge purveyor. The FDA is responsible, among other things, for assessing scientific research and then distilling and sharing that knowledge so that the public has adequate information to make informed health-related choices.

Within that role, the FDA must of course set priorities. It cannot provide in-depth health education on all topics, and it must prioritize where its public health communications can make the greatest impact. So the argument that the FDA, as a knowledge purveyor, must correct the public's misimpressions requires predicate assumptions that (a) the public is misinformed, and (b) FDA's efforts to correct that misinformation would provide meaningful benefits to public health. We are skeptical that the public is, in fact, misinformed. Though many people rate e-cigarettes as "as harmful" as cigarettes (Churchill et al. 2020), this may be a heuristic for indicating that both product categories are addictive and toxic (which is accurate). When asked to rate products head-to-head, strong majorities, particularly of youth, indicate that e-cigarettes are less harmful than cigarettes. (Strong et al. 2019; Wackowski et al. 2016).

In its role as a knowledge purveyor, if it was evident that these predicate assumptions were met, then it would be irresponsible for the FDA to outsource its responsibility to inform the public to e-cigarette and tobacco companies—who, as well as being untrusted sources, do indeed face high regulatory barriers to making health-related claims. But, in addition to the evidence being less clear than Kozlowski and Sweanor suggest, informing the public is only one among many roles that the FDA plays. In order to

understand how the FDA should communicate the scientific evidence as it becomes available to the public, we must analyze the multiple responsibilities placed on the FDA for it to fully realize its public health mission.

ROLE 2: FDA AS KNOWLEDGE PRODUCER

It is vital to remember that the FDA is not merely a knowledge purveyor. It also plays an active role in knowledge production. As both a regulator and a source of research funding, it shapes the agenda for scientific research on nicotine and tobacco products. For example, in outlining the evidence that must be submitted in the premarket review process (and in insisting the companies go through the proper regulatory authorization processes before selling new products or making health claims), the FDA determines the research questions that must be investigated by e-cigarette companies and thus what evidence will (and will not) be gathered. If the FDA, in its regulatory efforts, focused its attention solely on the comparative harm that different products pose to current smokers, there would be significantly less incentive for tobacco companies to conduct research related to important and currently unanswered questions related to the long-term public health effects of putting new products on the market.

Moreover, the FDA does not only set the research agenda through regulation. Through the Tobacco Centers of Regulatory Science program and other research grants, it spends close to \$200 million a year funding research to inform its regulatory efforts (US Department of Health and Human Services 2020). In this capacity, the FDA has finite resources to devote to researching new products and interventions. There is always more one *could* know about new products, but the FDA has to prioritize some concerns over others.

Because the FDA has a role to play in setting the agenda for scientific research as well as communicating the data that results from the research, the agency should be sensitive to myriad evidential sources—not merely the outcome of studies conducted in clinical and laboratory settings. Some of the evidence that should be taken into account is what philosophers have called "higher-order evidence"—that is, evidence about how good our evidence is, and what it supports (Christensen 2010). Here are at least three categories of higher-order evidence that the FDA should take into account in order to determine the quality of its current evidence, what new evidence should be

²As noted above, Kozlowski and Sweanor primarily discuss smokeless cigarettes, but they extend their argument to e-cigarettes as well. Though there is evidence demonstrating that the public is misinformed about the risks of smokeless tobacco, that is far less clear for e-cigarettes (Czoli et al. 2016).

gathered, and consequently what should be communicated to the public:

1. Historical precedent as evidence
2. Funding sources for research
3. Time required for certain types of evidence to be established

Historical Precedent as Evidence

The FDA's actions should not be taken in a historical or social vacuum. The FDA sets its research agenda against the historical background of the "light" and "low tar" debacle which undoubtedly (and, in our view, appropriately) shaped the Tobacco Control Act's cautionary approach to health-related claims.

When cigarette sales dropped in the early 1950s and 1960s owing to health concerns, the industry introduced ostensibly "safer" cigarettes that gave health-conscious smokers an alternative to quitting (Cummings, Brown, and Douglas 2006). Filtered cigarettes, which implicitly (and, in some cases, explicitly) conveyed the message that filters removed dangerous substances while preserving flavor, were marketed aggressively and came to dominate the market (Fairchild and Colgrove 2004). Public health entities and authorities, including the Surgeon General, encouraged smokers who were unable to quit to switch to lower-tar cigarettes (Fairchild and Colgrove 2004). Dozens of epidemiological studies, including by highly respected academic researchers, appeared to confirm that people smoking "light" cigarettes were effectively reducing their risk of lung cancer—only in retrospect do the methodological flaws of these studies appear obvious (Thun and Burns 2001). The tobacco industry, however, knew (based on extensive internal company research) that these products would not in fact reduce tobacco-related harms (US Department of Health and Human Services 2014; *US v. Philip Morris USA*) because users "compensated by smoking more intensely," (Centers for Disease Control and Prevention, Office of Smoking and Health 1999) and the tar yields were more toxic (Johnson et al. 2009). Yet the industry hid this information, and it took decades for these effects to be detected by independent researchers (National Cancer Institute 2001). More recent research has revealed that lower tar cigarettes likely *increase* lung adenocarcinoma risk (Song et al. 2017).

The point here is not to paint the e-cigarette industry as similarly vicious or manipulative. Rather, historical evidence should be considered so the FDA can

assign the appropriate weight to the evidence that has been collected so far about e-cigarettes and can incentivize a diverse array of research questions to be funded over the long term. Although there are plausible reasons to believe that e-cigarettes are far less harmful than cigarettes, the same was true of "light" cigarettes. And although some e-cigarette companies played no role in the tobacco industry's past misconduct, there is increasing overlap between e-cigarette and tobacco companies (Tobacco Tactics 2020). Moreover, all e-cigarette companies have the same incentive to minimize risks so they can sell more of an addictive product. Insofar as the FDA has the power to encourage research that will serve as a counterweight to some of these known historical forces, it is responsible for doing so.

Funding Sources for Research

Recent studies have found that industry-related conflicts of interest were strongly associated with research concluding that there are no harms associated with e-cigarettes (Martinez, Fu, and Galán 2018; Pisinger, Godtfredsen, and Bender 2019). These findings build on an extensive, broader body of research suggesting that industry-backed studies are more likely to find favorable outcomes for the sponsor's products (Lundh et al. 2017). These "funding effects" do not depend on wrongdoing by individual researchers or flaws in the research design of particular studies; rather it appears to be the result of how market forces and the subtle power of personal relationships bias research on a broader scale. For example, industries may disproportionately fund a subset of researchers whose ongoing research programs are generally more amenable to their interests (Bauld 2018). And, building upon findings from political science, economics, and the cognitive sciences, a growing body of literature in bioethics has highlighted the centrality of motivated bias as the key to understanding conflicts of interests (Goldberg 2019). Such motivated bias cannot be known to influence the results of any particular study, but there is strong evidence that industry funding will "tend to give rise to favorable states of mind that in turn *tend* to give rise to behavior of partiality over the long run of cases" (Goldberg 2019). The FDA thus has a duty to both mitigate the biasing effects of usual market forces that drive research and to interpret industry-funded research with caution.

Time Required for Evidence-Gathering

Finally, the body of research as it exists today is the combined product of what research questions have been prioritized and when answers to these questions become available. The FDA, in its key role in knowledge production, should guard against research programs driven primarily by whether it can get answers quickly. It would be irresponsible to focus primarily on the short-term and individual-health impacts of e-cigarette use rather than on the harder-to-determine long-term effects on the population as a whole (Bauld 2018).

Harm reduction advocates are keen to point out evidence suggesting that the constituents of e-cigarette aerosols are significantly less toxic than those in cigarette smoke (indeed, this is what the “95% less harmful” number was originally based on) (McNeill and Hajek 2015). But a harm reduction strategy is only a health-promoting one if harm is actually reduced—that is, if the availability of e-cigarettes actually decreases smoking-related illness at the population level. This in turn depends, among many other things, on the likelihood that current smokers would, in the absence of e-cigarettes, stop using nicotine products altogether. Emerging evidence suggests that in countries around the world (or at least in high-income countries), it is becoming easier for the remaining smokers to quit as the proportion of smokers in the population declines (Feliu et al. 2019; Hughes 2020). This undermines the “hardening hypothesis” that was a central *raison d’être* for the promotion of e-cigarettes—the idea that as smoking rates declined, only a “hard core” of smokers who were unable to quit would remain.

Though this evidence is not conclusive, it highlights that a comprehensive assessment of population-level trends requires substantially more time than short-term biomarker studies or RCTs. For example, the most recent study refuting the “hardening hypothesis” in Australia (where the sale of e-cigarettes containing nicotine is prohibited) looked at data collected over 16 years (Brennan et al. 2020). Population level considerations—including concern that e-cigarettes may be a “gateway” to smoking for youth, another issue that requires an extended time frame to study—further justifies the FDA incentivizing the gathering of more information before authorizing new products or health claims.

Proponents of e-cigarettes as harm reduction suggest that such a cautionary approach is based solely on conflicting values; in their view, the evidence that e-cigarettes (as well as smokeless tobacco products)

are safer than combustible cigarettes is clear (Kozlowski 2017). They argue that the FDA should value the life-saving benefits of e-cigarettes to current smokers over any increase in youth nicotine addiction. But in this context, values and evidence are not neatly separable. The evidential considerations elaborated in this section—such as historical precedent, funding sources, and time requirements—cannot be reduced to a disagreement about values. As the emerging population level evidence undermining the hardening hypothesis can attest, the debate does not depend solely on an ethical conflict concerning whether to prioritize current and future smokers over never smokers when it comes to tobacco policy. It also depends on the still open question about the sorts of public health interventions and policies that are most effective in reducing harm to current smokers.

In this section, we have delineated some concerns that place responsibilities on agencies such as the FDA to ensure that the research community at large is producing the types of evidence needed to inform policies that best promote public health. As Helen Longino has argued, objectivity in science is a property of the epistemic practices found in the scientific community at large, rather than a feature found in individual scientists (Longino 1990). As a knowledge producer, the FDA has the power and responsibility to mitigate against biases that we can expect to arise in the way that research about e-cigarettes gets funded and conducted. It does this in part by setting the standard for what counts as sufficient evidence, knowing that there could always be complicating or contradictory evidence on the horizon. This standard is surely shaped by the current status of the evidence, as well as the FDA’s evaluative priorities and pragmatic concerns about how to use its limited resources. All of these considerations inevitably inform each other.

ROLE 3: FDA AS ADVISOR

The way the FDA relates to evidence is not merely mediated by the complex set of responsibilities it has as a knowledge purveyor and a knowledge producer. The FDA, along with other health agencies, also has a mandate to offer practical guidance on the basis of the evidence as it becomes available. One may think that in its role as advisor, the FDA should principally be guided by the same norms as those pertaining to knowledge purveyance. That is, in offering guidance, the FDA should stick to distilling the available and sometimes contradictory scientific evidence, making it

legible to members of the general public so they can, in turn, make their own well-informed decisions.

Criticism of the FDA's caution about e-cigarettes is often framed as matter of the agency's failure to respect individuals' right to information (Fairchild, Bayer, and Lee 2019; Kozlowski and Sweanor 2016). For instance, Kozlowski and Sweanor call the FDA's refusal to publicly acknowledge that e-cigarettes are safer than combustible alternatives an ethically dubious "information quarantine" (Kozlowski and Sweanor 2016). Similarly, Fairchild, Bayer, and Lee believe that adolescents have "a right to know" about differences in product risks, "even if that information results in an increase in e-cigarette experimentation and use" (Fairchild, Bayer, and Lee 2019, 1005). On this view, the right to information should be respected even if such transparency may lead to imprudent decisions for specific individuals.

In such a framework, the function of the guidance offered by the FDA is to improve consumers' epistemic position, so they can make the most informed decision regarding their health. Advice is meant to merely offer people information; it should not aspire to push them to act one way or another. This framing fits well with a common view of advice in the philosophical literature. Moral philosophers often distinguish advising from more directive speech acts such as commands or requests. For example, Stephen Darwall claims it is indicative of advice that we can say, "I'm not telling (demanding, requesting, etc.) you to do anything. I'm just giving you advice" (Darwall 2006, 257). When we command others, we try to get others to act on the basis of our interactions with them. They should do as we say because we told them to do it. By contrast, when we advise others, we try to get them to *recognize* the reasons that were there all along, independent of our interactions with them. From this perspective, one could argue that the FDA should not be understood as telling people to do anything, but rather as merely giving them advice.

While compelling in theory, this distinction between advising and more directive speech acts does not map neatly onto actual speech situations. Following J.L. Austin, we want to challenge the notion that advising is best understood as a merely an informative act. Rather, we view advice as a kind of endorsement of certain courses of action over others. When the FDA advises the general public about e-cigarettes, it is expressing "a decision that something is to be so, as distinct from a judgment that it is so." (Austin 1975, 155). The FDA is—as is appropriate for a "public health agency" (Hamburg and Sharfstein

2009)—using its communication to direct behavior through lending its institutional authority to certain courses of action. Thus, it is important to examine not only the content of advice, but also the context in which it is communicated, by whom, and to whom (Byron and Howard 2017). Advice doled out by private companies has a different salience to their recipients than advice doled out by public regulatory bodies like the FDA. When an agency with institutional power like the FDA endorses certain courses of action, the very fact that it has chosen to advise lends legitimacy to certain choices, delegitimizes alternatives, and hence influences the social norms and collective responses to the smoking health crisis (Byron and Howard 2017).

Once the FDA endorses a course of action in its guidance (e.g. e-cigarettes should be considered as a more effective tool for smoking cessation than NRTs), its audience has not merely gained new information. The practical predicament of individual consumers has been changed as well, at least to some extent: they now must consider not only whether to use e-cigarettes in their attempt to quit smoking, but also whether to act according to what has been advised by the FDA. If someone then rejects that choice, he or she may be liable to certain kinds of blame from physicians, employers, and others for disregarding the FDA's advice. For example, a U.K. report found that "nearly all clinicians" said they would be more likely to recommend e-cigarettes to their patients for smoking cessation if advised to do by the government (Ferrety et al. 2019, 6). Such physician recommendations exert real pressure on patients, as the "the very nature of [a doctor's] relationship with patients is asymmetrical" as a result of "physicians possessing legitimized, referent, and expert power and patients being reliant on physicians to provide the care and services they need" (Nimmon and Stenfors-Hayes 2016, 2). That patients feel pressured to follow their doctors' recommendations is often taken to be a positive thing for health (though fear of such conversations may lead some current smokers to avoid physician visits entirely (Taber, Leyva, and Persoskie 2015)), but it results in a communication that is categorically different from merely providing "information" that informs autonomous decision-making. Similarly, lawmakers take advice from the FDA seriously and use it to make determinations about public policy, with wide-ranging consequences. By contrast, e-cigarette companies, academics, non-profit organizations, and others do not have the same

authority to legitimize and delegitimize certain courses of action with their public endorsements.

People, upon hearing guidance from the FDA, are not mere recipients of information from any source whatsoever. They are agents being advised by a federal institution purportedly responsible for helping to keep them safe and otherwise promote public health. This role the FDA plays as an advisor again weighs in favor of a cautious approach. When a government agency issues advice and then later reverses its position—even if those changes are justified by new scientific discoveries—it can undermine public trust over time.³ That is why the Office of the Surgeon General, starting with its first report on smoking and health in 1964, has been consistently conservative in its conclusions, sometimes to the frustration of public health advocates (U.S. Department of Health and Human Services 2014). The Surgeon General's Reports are consequently seen as a trusted source, while, in contrast, the public has arguably “lost faith” in the federal government's dietary guidelines, which have changed repeatedly over time in response to both evolving science and industry influence (National Academies of Sciences, Engineering, and Medicine 2017). The FDA is more highly trusted than other government agencies and public institutes in part because of its reputation (developed mainly outside of the tobacco regulatory context) for “citizen protection,” “vigilance against risks,” and “commitment to scientific principles of assessment.”⁴ (Carpenter 2010) A growing body of research establishes that such “organizational trust” is, in turn, “a key determinant of how well risk communications are processed and received by the public.”⁵ (Osman et al. 2018)

³As a recent example, “after months of recommending that healthy individuals not wear face masks, the U.S. Centers for Disease Control and Prevention (CDC) changed its guidance in early April 2020 in response to mounting evidence of asymptomatic transmission [of the COVID-19 virus].” Though justified by the science, this reversal “open[ed] the door for politicization by critics of science-based policies” (Kreps and Kriner 2020).

⁴The FDA's overall reputation for scientific integrity may have been tarnished by the response to the COVID-19 pandemic, during which the FDA was subjected to unprecedented and relentless political pressure from the Trump White House. The FDA sometimes succumbed to this pressure by, for example, “making dubious public statements that drastically misrepresented scientific data or by issuing [emergency use authorizations] for products shortly after public statements from the White House urged the FDA to do so” (Parasidis et al., *forthcoming*).

⁵An agency's reputation for quality and reliability has important practical consequences. As former Federal Trade Commission Chairman William Kovacic writes, “A good reputation can help the agency recruit skilled personnel, gain deference from courts, build credibility with business managers, and build popular support that can yield larger budgets and enhancements to its powers.” (Kovacic 2015) All of these outcomes enhance an agency's ability to fulfill its mission.

Understanding the public's right to be appropriately advised by the FDA is thus different from the public's right to information. While it is the duty of the FDA to not deceive the public or misrepresent the evidence, the guidance that the agency chooses to endorse on the basis of the evidence should be evaluated on both epistemic and ethical grounds.

ROLE 4: FDA AS MARKET AGENT

Finally, apart from its role in providing information or advice, the FDA can itself, by exercising its regulatory authority, change the options available to the public and to corporations. Thus, in contrast to PHE, the FDA is not a neutral observer providing information and advice; rather, it is a powerful actor that shapes the tobacco/nicotine marketplace.

Whether e-cigarettes are a net benefit or detriment inherently depends upon the regulatory scheme in which these products are marketed and promoted. This regulatory framework is, in turn, overseen by the FDA. To date, e-cigarettes have been largely unregulated, due to the FDA's delay in promulgating and then enforcing the Deeming Rule (Berman 2019). This resulted in a free-for-all that led to dangerously low-quality products, unverified health claims, and marketing and flavors that appealed to children. By regulating the terms of their manufacture, marketing, and sale, the FDA has the direct authority to create the conditions in which e-cigarettes are most likely to improve public health. Critically, however, it also can act to make cigarettes and other combustible tobacco products less addictive and less attractive. E-cigarettes are far more likely to be beneficial to public health overall when the FDA is acting aggressively to reduce combustible tobacco use (Berman 2019).

Thus, calling on the FDA to “tell the truth” (Sullum 2015) about e-cigarettes misses the key point that the FDA has the ability to shape what the truth can turn out to be. As already mentioned, it is because of successful past regulatory efforts and their transformative effects on the market that new evidence is now coming to light prompting us to question the validity of the hardening hypothesis. Harm reduction advocates and skeptics should be able to agree that the FDA can make its most important contribution to public health not by acting as an information provider, producer, or advisor, but by using the extensive power granted to it by Congress to reduce combustible tobacco use, making combustible products less appealing while simultaneously making e-cigarette products safer.

CONCLUSION

We have outlined four different roles that the FDA plays that inform whether and how it should communicate evidence about e-cigarette risks and benefits to the public. The first two roles relate to the FDA's responsibilities with respect to knowledge transmission and knowledge creation. The final two roles relate to the FDA's ethical responsibilities related to its distinctive practical authority; the FDA acts as an advisor with significant practical implications for those whom it advises (and others), and it also possesses regulatory power through which it can directly change the material conditions of current smokers and nonsmokers. In seeking to balance these four roles, the FDA must also remain cognizant that—as outlined at the outset of this paper—the evidence presented to establish the benefits of e-cigarettes for public health still comes with significant caveats and is far from definitive. As such, while the FDA should ensure that everything it says accurately reflects the best available science, it does not violate any right to information by remaining hesitant to endorse conclusive claims about the safety and efficacy of e-cigarettes while it continues to gather evidence bearing on those concerns.

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