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Moral Wrongs, Epistemic Wrongs, and the FDA: A Commentary on Svirsky, Howard, and Berman's "E-Cigarettes and the Multiple Responsibilities of the FDA"

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Svirsky, Howard, and Berman argue that the Food and Drug Administration (FDA) inhabits two types of roles which must be balanced: those of bringing about beneficial material change and those of creating and transmitting knowledge. Two categories of reasons are involved in these roles: moral reasons and epistemic reasons. These reasons may justify the FDA's hesitation to endorse "a course of action in its guidance," namely in not "asserting that e-cigarettes should be considered as a more effective tool for smoking cessation" than nicotine replacement therapy (Svirsky, Howard, and Berman 2022, 13). Reasons against this advisement include the avoidance of moral wrongs and epistemic wrongs.

The authors target a bundle of views: that the FDA must "tell the truth" regarding e-cigarettes, that the FDA gathering more information before taking regulatory action is unjustified, and that the FDA is wrongful in not issuing the above advisement (15). Underlying these views is the belief that the FDA is epistemically wronging the populous. Another view holds that the FDA is morally wronging the populous by stifling harm-reduction opportunities. We will now consider the FDA's capacity to commit epistemic and moral wrongs in these contexts.

Moral wrongs are familiar and are typically evidenced by "normative footprints" (Hieronymi 2022). Normative footprints may result from the FDA's utilization of regulatory power, including unrealized benefits, unpromoted interests, or outright harms. The FDA is uniquely placed to risk moral wrongs as it is an "institution purportedly responsible for helping to keep [individuals] safe and otherwise to promote public health" (13). It has the breadth to affect massive material change and has the explicit charge and public funding to do so. Epistemic wrongs include suppressing evidence, conceptual impoverishment, improperly modifying credences, and more broadly "unfair treatment that relates to issues of knowledge, understanding, and participation in communicative practices" (Kidd, Medina, and Polhaus 2019, 1). Svirsky, Howard, and Berman show that the FDA uniquely risks epistemic wrongs as it is a uniquely legitimated purveyor and producer of knowledge.

Normative footprints constitute evidence of wrongs. For instance, in response to the FDA endorsing 'healthier' filtered cigarettes in the 1960s, we may cite a normative footprint (such as increased adenocarcinoma risk or specific cases of adenocarcinoma) in blaming and making restitution claims. Studies suggests that one in every five drugs approved by the FDA ends up causing harm, and that prescription drugs are the fourth leading cause of death in the United States (Leight, Lexchin, and Darrow 2013). So, for the FDA, avoiding moral wrongs and subsequent normative footprints is as vital as it is difficult.

Svirsky, Howard, and Berman rightly suggest that moral and epistemic "considerations inevitably inform each other" (Svirsky, Howard, and Berman 2022, 11). This is reflected in the rich "pragmatic encroachment" literature in epistemology, which states that pragmatic reasons impinge on epistemic reasons. Pragmatic reasons include moral reasons (such concerns over harms, benefits, and wellbeing) and non-moral (or prudential) reasons. Consider a putative epistemic wrong, such as sacrificing accuracy for speed. Svirsky, Howard, and Berman propose that "the FDA … should guard against [a] research program driven primarily by whether it can get answers quicky" (10). Examples may include artificially lowering an evidential threshold or engaging in a research project due to projected expediency. However, since moral reasons affect epistemic reasons, the epistemic wrong of getting answers quickly *could* be overridden by a more

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powerful moral reason such as promoting wellbeing, safety, or public health.

One means of accounting for the alleged epistemic wrongs of the FDA is by showing that the FDA's epistemic role is asymmetrical to the epistemic role of ordinary individuals. The authors show the FDA must utilize higher-order evidence, including historical precedent, evidence regarding funding sources, and time management constraints when determining what policy should be formed. This seems right, however, historical precedent and time management are also utilized by individuals in generating and purveying knowledge, and therefore may not fully account for the FDA's unique role. One may respond that knowledge generated by individuals is not taken to be the same epistemic touchstone as institutionally purveyed knowledge. However, the unique linkage between FDA-perpetuated epistemic wrongs and FDA-perpetuated moral wrongs may bear greater explanatory power.

The FDA's advising capacity implies that epistemic wrongs are tied to moral wrongs. For advisors, the former magnifies the possibility of the latter. Advisement does not entail being an open codex of all the relevant facts and probabilities, or a being "neutral observer providing information" (15). If it did, the FDA's primary role would be to present all facts relevant to a healthcare intervention with as much immediacy and clarity as possible.[1] This view would rule out the FDA's regulatory approval process for prescription drugs as unjustified, along with other actions beyond the provision of information. Such views mischaracterize the FDA as an informant, rather than as an advisor engaged in "citizen protection" (14).

Advising requires paternalism, of which there are two general types. Soft paternalism involves redirecting an agent's means such that they more efficaciously achieve their own ends, whereas hard paternalism involves redirecting an agent's ends. Svirsky, Howard, and Berman recognize that FDA advisements entail a statement "that something is to be so" (12). This necessarily renders advisements as forms of soft or hard paternalism in relation to their audience; they either issue hypothetical or categorical claims. Advisements (such as 'e-cigarettes are a smoking cessation tool') are hypothetical, and mandates (such as mandatory recalls or prescription restrictions) are categorical in structure.[2] As institutional bodies shift their advisements and mandates, their perceived legitimacy decreases. This provides yet another reason in favor of FDA messaging hesitancy, lest the FDA's advising capacity deteriorate such that their hypothetical and categorical advisements lose force.

While the FDA can paternalistically express "that something is to be so", the authors contend that the FDA has "the ability to shape what the 'truth' can turn out to be," which may be overstated (15). The FDA issues ought-claims and is-claims relative to antecedent desires regarding health outcomes in the population. Though the FDA issues these claims, the administration falls short of shaping what the truth can be, since objectivity in science is a property of the global scientific community at large (10). Also, the FDA's ability to shape the truth turns on its status as an advisor and its relationship with its advisees. In the absence of a recognized paternalistic warrant, the administration's is-claims and ought-claims would cease to function.[3]

The FDA's ability to function turns not only on the content of its advisements but also on the "context of what is communicated, by whom, and to whom" (12). Critical to this context is the FDA's status as advisor, which can be undermined by prescribing harmful advisements, by failing to prescribe helpful ones, and by generating blameworthy normative footprints. Moral wrongs, rather than epistemic wrongs, particularly threaten the FDA because the "size and shape of the footprint" of FDA-perpetuated moral wrongs is clear and measurable in terms of health outcomes (Hieronymi 2022, 10). The grievousness of these footprints can be judged against the FDA's explicit warrant to protect public health. In contrast, normative footprints resulting from epistemic wrongs are unclear as "the right to be appropriately advised is .... different from the public's right to information," though

[1]Advocates of such a system have called this a "fee-for-service" view of healthcare, in which doctors and pharmacists are procurers, rather than advisors. Under this view, prescription requirements should not exist. Under these views, which the authors are right to oppose, the FDA's primary duty is in "merely providing "information" to inform autonomous decision-making" (13).

[2]Soft paternalism fits this format in that (if you want X you should Y) indicates that something "is to be so" given antecedent conditions (wanting X, i.e., wanting to quit smoking). Hard paternalism fits this format in that redirection of ends entails an explicit statement that "something ought to be so." The authors rightly note that advice we might expect from strangers, or from self-interested agents such as private companies and carries with it less "salience" and "legitimacy" such that these "to be so" relations fail to obtain.

[3]When issued, soft paternalistic "to be so" advisements are legitimated by helping the agents under advisement achieve their own ends. So, advising that e-cigarettes should be considered as a more effective tool for smoking cessation would only be justified if it showed that the end would be better achieved had the communication been issued. However, counterexamples to the "hardening hypothesis" have shown that e-cigarette proliferation may hamper population-level smoking cessation. Therefore, this communicative action would likely be hurtful both to the populous (by contributing to the proliferation of smoking) and to the FDA (by weakening its paternalistic warrant).

this does not imply that epistemic wrongs ought to be dismissed (14). However, for the FDA, avoiding moral wrongs likely takes lexical priority over avoiding epistemic wrongs.

Epistemic wrongs are vague for knowledge creating institutions. Consider that, since "population level trends require substantially more time than short-term biomarker studies or RCT's," one may allege epistemic injustice in the absence of unpublished RCT data as the FDA waits for population level trend studies (9). When collecting any data set, one may make an analogous complaint if a datum is not shared until the set is compiled. If the FDA was withholding mere information, it may be permissible for it to do so for epistemic reasons (in the name of awaiting better evidence or the formation of reliable trends) or moral reasons (such as promoting wellbeing or avoiding harms). However, the FDA is not withholding mere information. Rather, it is refraining from advising that something hypothetically or categorically ought to be so. This outstrips sharing a datum and ought to meet a higher level of stringency prior to being issued. Numerous justifications of the permissibility of withholding propositional expression exist for cases of sharing typical information (DePaul 2004). Given the contents of FDA communications (which are is-claims and ought-claims, rather than mere information) we need not suspect that the FDA's hesitancy is epistemically wrongful in the first place.

The alleged epistemic wrongs of FDA messaging hesitancy would not leave any clear normative footprint, in contrast with moral wrongs of blameworthy advisement which leave a clear and citable normative footprint. Additionally, the FDA's status as an advisor influences its capacity to instantiate moral or epistemic goods and issuing ill-founded or harmful advisements diminishes this status. Svirsky, Howard, and Berman's call for caution in FDA advisements about the safety and efficacy of e-cigarettes is well justified.

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