A case for tobacco content regulation by the U.S. Food and Drug Administration

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ABSTRACT

Although many people welcome the recent move by the United States to give its Food and Drug Administration (FDA) the authority to regulate the content of tobacco, some worry that such regulation constitutes unwarranted interference with the freedom of competent adult tobacco consumers. The concern for protecting the autonomy of individuals is valuable indeed, but given the highly addictive nature of tobacco products (and especially the nicotine in tobacco products), the continued use of tobacco by smokers cannot —without straining credulity—be said to be autonomous. This fact, combined with a proper construal of the FDA's role and an appreciation of the substantial morbidity and mortality associated with tobacco use, makes a strong case for content regulation.

KEY WORDS

Tobacco, nicotine, FDA, autonomy, bioethics

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Just 10 years ago, most hockey sticks were made of wood, cell phones were a novelty, Britney Spears was unblemished, and gay marriage was unheard of. The last decade has indeed ushered in many—often quite substantial—changes. Tobacco legislation has experienced something of a revolution, however. Although I can remember well a time when ashtrays were as common on restaurant tabletops as salt and pepper shakers, and when a trip to the movies guaranteed at least one good look into the "the vibrant and racy world of Peter Stuyvesant," many countries have now prohibited smoking in enclosed public places and have placed weighty restrictions on the advertising of tobacco products.

On June 22, 2009, the United States took another stride along the revolutionary road when Barack Obama signed the Family Smoking Prevention and Tobacco Control Act, giving the U.S. Food and Drug Administration (FDA) the authority to regulate, among other things, the content of tobacco products. That is to say, it will now be within the FDA's power to demand full disclosure of the constituents of tobacco products from manufacturers, and furthermore, to restrict ingredients—including nicotine—found to be harmful.

To many, this new legislation is long overdue. Given that scientific evidence linking disease and premature death to the use of tobacco products has been well established for more than half a century, it strikes them as ludicrous that (almost) no legislative attention has been directed toward content regulation. Others, however, have expressed concern that the act's proposed content regulation might well constitute an unwarranted interference with the freedom of competent adult tobacco consumers.

Is the FDA's regulation of tobacco content appropriate?

To appreciate the concerns of the critics, consider that the United States, like many other countries today, strives, albeit imperfectly, to protect the autonomy of individuals. In light of the numerous objectionable ideologies that litter human history, it is unsurprising—and indeed laudable—that so much importance is placed on respecting the capacity for self-rule. This is not to say, however, that autonomy ought to be respected at the expense of all else. Indeed, it is widely acknowledged that restrictions may legitimately be imposed when an individual's expression of choices and values negatively and unjustifiably affects the welfare of others. Such reasoning grounds the prohibition of smoking in those places in which (non-consenting) non-smokers would be exposed to harmful smoke.

Restricting the freedom of informed and competent individuals for their *own* good is, however, much more difficult to justify—if such restrictions are justifiable at all. Indeed, because having one's autonomy respected is crucial for the development of a sense of dignity (among other things), it is commonly thought that even in those instances in which self-rule leads to self-detriment, the capacity to so choose ought nonetheless to be safeguarded. Now, given the act's strong emphasis on protecting the welfare of non-smokers and minors, it will likely be

the case that only smokers *themselves* will bear any costs associated with the content of tobacco. This being the case, surely the act's additional call for regulation—and, possibly, alteration—of tobacco's content translates straightforwardly into a paternalistic restriction of freedom, a restriction which, if justifiable at all, requires justification of a strength that is unavailable to proponents of regulation?

Indeed, critics might contend that in the same way that we respect the choice of informed and competent individuals to run the risks associated with shark-diving (for example), we should respect the decision of informed and competent smokers that the pleasurable effects afforded by tobacco are worth the (serious) associated health risks. In both instances, it is argued, an informed and competent individual freely elects to prioritize some other value or values over the value of health.

That argument applies, of course, not only to the regulation of tobacco, but also to the FDA's activities more generally. However, whatever one may think about the FDA's regulation of other substances, there is good reason to think that its regulation of tobacco is justified. Indeed, what the critics of the new act have failed to appreciate is that, in the vast majority of cases, use of tobacco products by smokers does not in fact consist in their freely placing the pleasures afforded by smoking above their health. This is because of the well-established scientific fact that tobacco products—and especially the nicotine in tobacco products—are highly addictive [a].

This being the case, although smokers cannot be said to be entirely unable to resist their tobacco cravings, the nature of nicotine withdrawal is such that they can resist only through extraordinary determination. And considering that in a variety of contexts a strong likelihood of grave pain, injury, or even discomfort is routinely deemed sufficient evidence of an impaired capacity for autonomous choice, consistency requires that we view the continued use of tobacco by smokers as similarly non-autonomous [1]. Smokers—and certainly those who would prefer to quit—simply cannot be said, without straining credulity, to engage in a decision procedure in which they freely accept health risks in exchange for the pleasures of smoking. The addictive nature of (the nicotine in) tobacco greatly reduces their power to choose otherwise. And, because a significantly diminished capacity for autonomous choice uncontroversially justifies paternalistic action by the state, the FDA is justified in acting paternalistically toward smokers. Indeed, it seems clear that if the motivation is to protect and promote the autonomy of individuals, then society ought, at least in the case of the addicted, to be in favour of tobacco content regulation.

What is more, if we consider that tobacco manufacturers have long been aware of the highly addictive nature of nicotine, that they have conducted research to establish the minimum dosage of nicotine required for the inducement of addiction, and that they design their products to deliver addictive dosages, nicotine certainly seems to constitute an item (other than food) that is "intended to affect the structure or any function" of a human or non–human animal's body [2]. This is the federal definition of a drug, as stated in the Federal Food, Drug and Cosmetic Act [b]. Thus, the way seems paved for the FDA's regulation of tobacco content.

However, some might object, saying that because nicotine has no (clearly established) therapeutic benefits, it is unlike other drugs regulated by the FDA and thus should not fall within the FDA's jurisdiction. There are two problems with this objection, however. The first is that it is an objection against tobacco content regulation *by the FDA*. This argument is much weaker than the one that critics initially hoped to make: that tobacco content regulation is inappropriate *simpliciter*. Secondly, although it is true that nicotine is unlike other drugs regulated by the FDA, to think that this dissimilarity speaks strongly against the FDA's regulation of tobacco's content is to construe the role of the FDA too narrowly. The FDA's concerns are not limited to the regulation of foods and of (particular) drugs. Indeed, in view of the fact that the FDA also regulates cosmetics and radiation-emitting substances (for example), the agency is best understood as being dedicated to protecting the health of Americans. And given that tobacco use is associated with substantial morbidity and results in about 430,000 deaths every year [3], the regulation of tobacco is certainly a matter of public health.

This last point goes some way toward responding to the concern that regulation by the FDA is not thought appropriate for all addictive substances—such as those containing caffeine, for instance. If, as I have argued, the FDA is appropriately justified in regulating the content of tobacco by virtue of tobacco's addictiveness, then can society face the task of stipulating a regulatory threshold? That is, is it possible to specify just how addictive (and harmful) a substance must be before its regulation is apposite?

Although the stipulation of such a threshold is beyond the scope of this paper, it seems quite clear that, given the severe and well-known risks of tobacco use and the fact that the vast majority of smokers desire to quit [c], FDA regulation is apposite, if not required, in this case.

[a] Interestingly, according to the National Institute of Drug Abuse, new research is suggesting that, although nicotine is the primary culprit in tobacco addiction, it may not be the only one.

[b] This definition is problematic, but not in a way that undermines the case for FDA regulation of tobacco. The problem is that "drug" ought not to be defined in terms of whether the relevant substance is *intended* to affect the structure or any function of a human or non–human animal's body. It is not the intended effects, but rather the *actual* effects, of a substance's chemical nature that are relevant.

[c] According to Fiore, Bailey, Cohen *et al.* [3], more than 70% of all Americans addicted to tobacco products in 2000 expressed a desire to stop smoking.

Still, if tobacco is so highly addictive, it might well be wondered whether a consideration of this fact, contrary to what I have claimed, ultimately serves to undermine the case for regulation by the FDA. Surely those already addicted to tobacco products will just seek out alternative means of satisfying their cravings. Given that other drugs continue to be used despite their illegality, there is no reason to suppose that the criminalization of illegal tobacco consumption will prevent its use. What, then, is the point of regulation?

This worry is indeed a serious one. However, regulation is not the same as prohibition. Moreover, even if the assumption is made that regulation will, as a matter of fact, result in the generation of a black market, it would be a mistake to think that nothing can be gained from regulation. Indeed, although regulated tobacco products will fail to satisfy those already addicted, these products will ensure that no additional individuals become addicted. Given that benefit, regulation is certainly worth trying. And if it turns out that the consequences of tobacco content regulation are, on balance, unacceptable, the legislation can simply be revised or rescinded.

Thus, although the concern for respecting and protecting the autonomy of individuals is a valuable one indeed, as I hope to have shown, it fails to undermine the appropriateness of the FDA's regulation of tobacco's content. Rather, it provides strong grounds for such regulation. The case for regulation is strengthened by adopting a broad construal of the FDA's role—a construal which, given the types of regulation in which the FDA is involved, is surely the correct one. Moreover, neither the issue of a regulatory threshold nor that of the generation of a black market suffices to undercut that case. Doubtless, the very good reasons for regulation will nevertheless be clouded by the tendency to give convention far more moral weight than it deserves. Indeed, simply because tobacco use has long been both prevalent and accepted, many people will be hesitant, if not unwilling, to support content regulation. Convention ought not to hold this kind of sway—especially in cases such as this one, in which the costs of non-regulation are so very high.

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