Expanded FDA Regulation of Health and Wellness Apps

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ABSTRACT: This paper argues that the Food and Drug Administration’s (FDA) policy for health and wellness apps is ethically problematic. Currently, the FDA does not regulate health and wellness apps that are not intended for medical use. As a result of this hands-off policy, preventing harm to consumers is left primarily to developers and app marketplaces. We argue that the FDA’s duties to prevent harm and maintain accountability to the American public require that they play a much stronger role. We also discuss concerns about efficiency and fostering innovation, and argue that while they should help shape FDA regulation of health and wellness apps, they do not justify complete absence of FDA involvement.

Introduction

The Food and Drug Administration (FDA) does not currently regulate health and wellness apps that are not intended for medical use. FDA oversight largely focuses on apps intended for medical use that pose significant risk to patients. For example, the standard functions on FitBit’s Ionic smart watch are not regulated by the FDA but FitBit’s proprietary software for diagnosing heart arrhythmia is. Even if FitBit’s standard functions provide sufficient data for users to self-diagnose heart problems, the FDA does not regulate those functions because they are designed to improve general wellness, not provide medical diagnoses.

As a result of the FDA’s hands-off policy, there is very little oversight of mobile health apps not intended for medical use. Evaluating an app’s safety and risk to users is largely left to developers and app marketplaces (like Google Play and the App Store). Individuals harmed by these apps can sue their developers, and the Federal Trade Commission (FTC) can penalize companies for engaging in deceptive practices, but only companies that sell medical apps currently try to prevent harm from occurring. The policies of companies like Apple and Google provide the main protection for most individual consumers of mobile medical apps.
Some think that the tendency toward private regulation of this sort is a good thing. Many helpful apps that pose little to no risk would never exist if the developers had to undergo the lengthy and resource-intensive FDA approval process. The FDA also has many other oversight responsibilities that arguably should take priority. In fact, former FDA Commissioner Scott Gottlieb has suggested that the FDA should leave more mobile health regulation to private industry.

This paper argues for more extensive FDA regulation of health and wellness apps that are not intended for medical use. The FDA’s duties to prevent harm and maintain accountability to the American public require that they play a much stronger role. The current regulatory gap allows potentially harmful apps onto the market. There are significant obstacles in regulating the hundreds, if not thousands, of health-related apps on the market, but we argue that the FDA is properly situated to take on this task. We also consider the goals of regulatory efficiency and fostering innovation, which are often cited in favor of weaker FDA regulation. These considerations should help shape FDA regulation, we argue, but do not justify the FDA’s current hands-off policy.

The Current Regulatory Status of Health Apps

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FDA Oversight

The FDA, as part of the Department of Health and Human Services, is the primary agency responsible for regulating mobile medical devices. The 21st Century Cures Act, which came into effect in December 2016, excludes from the definition of regulated devices any software that is used “for maintaining or encouraging a healthy lifestyle and is unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition.” This places many mobile medical apps outside of the scope of FDA regulation.

For apps that may meet this definition but still place minimal risk on users, the FDA has decided to “exercise enforcement discretion.” This means that they will not enforce violations of FDA policies that typically apply to regulated medical devices. It also means that developers and manufacturers do not have to apply for premarket review or register their apps with the FDA.

Apps that fall under this unregulated category include those that help users self-manage a disease without providing specific treatment suggestions, tools to organize and track health information, and databases that contain information about health conditions, among others. Below we will

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discuss under this category apps like Fitbit, which collect and track heart rate data, as well as certain apps that help people cope with psychiatric conditions. Because these apps are not intended for medical use, the FDA does not evaluate them, even if people frequently use them to make inferences about their personal health.

In January 2019, the FDA launched a precertification program to help address the regulatory challenges posed by novel medical software (Apple and Fitbit being two of the nine companies selected for the initial pilot). The program allows the FDA to review broad components of a company, like its organizational culture and commitment to quality and safety, instead of reviewing individual pieces of software. Companies that have been precertified are allowed to bring medical apps to market without further review. However, health and wellness apps not intended for medical use are not specifically addressed in the precertification review. Because the FDA does not regulate those apps, even companies that are not precertified would still be able to bring the apps to market without review.

The FDA also recently proposed a regulatory framework for artificial intelligence (AI) in mobile medical apps. Regulating AI in mobile medical apps is particularly challenging because the software’s function can change over time as the AI learns. For example, AI chatbots can adapt to

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the particular health needs and communication styles of users. This means the software submitted to the FDA for review could be very different from the software eventually experienced by users. Though not an official guidance document, the FDA’s proposed framework excludes health and wellness apps not intended for medical use, which suggests that AI in such apps will also go unregulated.

**FTC Oversight**

The FTC has oversight of medical apps after they have been released through its authority to regulate “unfair or deceptive acts or practices.” While the FDA has the power to declare a device unsafe or medically unsound, the FTC’s consumer protection powers typically focus on false or misleading claims about what a device can do.

The FTC has thus far taken on more of the regulatory role that one might expect the FDA would play. For example, a number of app developers have agreed to pay settlements to the FTC for making false claims about their app’s ability to improve vision, cognitive performance, and accurately measure blood pressure. In all these cases, the FTC reviewed relevant research on the

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2. 15 U.S. Code § 45
effects of the app and compared the results to claims made by the developers. The developers were found in violation of FTC regulations not because their apps posed risks to consumers, but because they made deceptive claims about health benefits without scientific evidence to support those claims.

Because the FTC only provides post-market evaluation, these apps had already been downloaded and used by consumers before being revised or removed from the market. Presumably they would not have passed review if they had undergone the typical FDA approval processes, which would have investigated the empirical basis for the promised health benefits and assessed the risk of harm. As a result of these cases, and the FDA’s lack of regulation, other private entities have expanded their own attempts at preventing harm to users.

Industry Oversight

There are many places to purchase or download health and wellness apps, but the most prominent are Google Play and the App Store. Both have policies aimed at reducing the risk of harmful apps. Their language mirrors that of the FDA and FTC, but they also take the stronger step of evaluating whether an app causes harm to users.

For example, Apple states that apps that risk physical harm will be rejected, and that greater scrutiny will be applied to “apps that could provide inaccurate data or information, or that could be used for diagnosing or treating patients.” In June 2018 Apple expanded this policy to explicitly require that apps include data to support any health claims. In response to some of the

FTC cases mentioned above, Apple now also forbids any apps that “claim to take x-rays, measure blood pressure, body temperature, blood glucose levels, or blood oxygen levels using only the sensors on the device.” Similarly, Google Play says that it does not allow apps that “feature medical or health-related functionalities that are misleading or potentially harmful.”

Neither Apple nor Google release statistics on how many health apps they have rejected due to their policies, but they clearly are exerting much more enforcement power than the FDA and FTC. Though still limited mostly to post-market evaluation, both companies have directly aimed to protect harm to consumers, and Apple has specifically required supporting data for any health app on the market. These actions fill the void left by the FDA’s decision not to regulate health apps unintended for medical use.

The FDA is currently developing a Digital Health Center of Excellence, which will combine expertise from government and industry, to address the regulatory challenges posed by mobile medical apps and other new technologies. However, there are few details available about what will fall under this Center’s purview and how government and industry might share responsibilities.

Should the FDA Regulate Health and Wellness Apps?

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"FDA (2018, February 13). Statement from FDA Commissioner Scott Gottlieb, M.D., on Administration’s request for new FDA funding to promote innovation and broaden patient access through competition. Retrieved from https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm596554.htm"
The FDA’s mission is to protect public health, which includes ensuring the safety of medical devices. On the face of it, it seems irresponsible to scale back regulations just because something has been declared as “unintended for medical use” (a point seemingly recognized by Google and Apple). The public relies on the FDA to protect them from health risks, regardless of the intentions behind those risks. Let’s evaluate the arguments for thinking that the FDA should enact more stringent regulations on mobile health and wellness apps.

*Health and wellness apps cause harm*

Preventing harm is one of the most widely accepted justifications for government intervention in private affairs. Objections to government interventions for public health usually arise when individual autonomy is affected—for example, when New York City proposed to limit the sale of large-sized soda. It is widely accepted, however, that the government is justified in intervening when the risks of harm are significant, affect the public as a whole, and are outside of the control of individuals. The FDA regulates pharmaceuticals, for instance, because people otherwise have no way of knowing whether medicine is safe and effective, and if they make a bad decision the consequences can be deadly.

The FDA regulates health and wellness apps for the same reasons. Individual users of mobile medical apps lack the ability to know whether the apps are safe and to take steps on their own to reduce any risk. If health and wellness apps do in fact cause significant harm to users, the FDA must take stronger steps to make sure they do not cause harm before entering the market. The

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current system where the FTC conducts post-market evaluation, and corporations determine the potential for harm, is ethically problematic, for the reasons given below.

Health and wellness apps do not *generally* cause harm. But there have clearly been enough documented risks to users to argue that stronger pre-market evaluation is needed. Let’s consider, for example, the blood pressure app mentioned previously that was found to be inaccurate. One study of the app found that more than 78% of people who actually had hypertensive blood pressure levels, indicating a potential health risk, were told that their numbers were in the normal range.² During the year and a half the app was on the market it was downloaded hundreds of thousands of times. Anyone with hypertension who used the app during that time could very well have been in danger but received false reassurances from the app that they were perfectly healthy.

Fortunately, in this case, the FTC responded to evidence of inaccuracy. But without greater FDA oversight it is difficult to prevent people from receiving this sort of risky information through health apps. It is notable that the developers even cited FDA policy to defend their blood pressure app. They were aware of potential inaccuracies but did not think it was problematic because, after all, they had not intended for the app to be used as a medical device.² The FDA’s policy allows developers to use this excuse any time their apps put people at risk. The FTC can

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still step in if in fact developers are making misleading claims. However, this only comes after clear documentation of inaccuracy is available, which is too late to prevent harm.

Let’s look at another type of app with the potential to cause harm: mobile mental health apps. As with any other health app not intended for medical use, mental health apps are not supposed to provide diagnoses. Most provide encouragement and tips to deal with common conditions, like anxiety and depression. However, surveys of mental health apps have found that they still make recommendations that put people at risk. They tend not to follow established guidelines and best practices recommended by psychiatrists. They also tend to characterize conditions like anxiety as an abnormal response to mild triggers, putting most of the blame on the individual experiencing mental health issues. As with the blood pressure app mentioned above, there are also many apps that people use to self-diagnose their mental health problems, which leads to harmful misinformation. For example, a review of 35 apps used to screen for bipolar disorder found that the majority failed to take into account basic diagnostic information used by health professionals (e.g., medication and amount of sleep). These apps seem to pose enough risk to be worth regulating by the FDA.

Mobile apps that use AI may be particularly susceptible to slipping into the domain of medical treatments and diagnoses. For example, health chatbots like Woebot, GYANT, and others provide feedback that seem very much like treatments and diagnoses despite stating up front that they are not intended for such uses. We messaged a health chatbot about lower back pain one of

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us was experiencing, and after a few minutes it concluded that the underlying cause of the pain was likely “cord compression,” and recommended that we see a doctor. This may not be bad medical advice, but other chatbots could be much less reliable, especially if they incorporate AI that adapts to feedback over time. Regulating AI is challenging, but excluding health and wellness apps outright from FDA review makes it even more difficult for consumers to know which apps can be trusted.

One final concern relates to privacy issues with mobile health apps. There have been many documented data sharing problems, even by health apps that have been evaluated and approved by third party accreditation organizations. A recent study found that 19 popular mobile health apps shared data with third parties like Amazon, Facebook, Google, and even the Department of Health and Human Services. Mobile apps for mental health are particularly concerning. A review of 116 apps for treating depression concluded that only five adequately described their privacy protections (e.g., provided an explicit description of their treatment of identifiable information) and found that most had no privacy policy at all. Some mental health chatbots, including those incorporated into Facebook Messenger, have privacy policies that appear to give permission to share users’ identifiable information broadly with third parties.

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When health apps are not regulated, there is no real oversight of their privacy policies, and very little control over how they use the data they collect. Currently, American courts do not consider most privacy violations as causing harm. For example, increasing the risk of financial injury or increased anxiety from the release of personal information is not sufficient to count as harm. This provides yet another reason for more extensive FDA control over health and wellness apps. The Health Insurance Portability and Accountability Act (HIPAA) does not cover privacy violations from mobile medical apps when they occur outside of a healthcare context. Regulating privacy violations is difficult, but at the very least FDA oversight could require apps to have a clearly stated data protection policy.

Protection against health risks requires public accountability

Even if the public should be protected against harm, it could be argued that the FDA isn’t necessarily properly situated to provide that protection. Google and Apple might be better. Why is it wrong for the FDA to offload their public protection duties onto corporations?

Perhaps the most important reason it is ethically problematic is public accountability. The FDA is a publicly funded federal agency, subject to Congressional oversight, and its commissioner is appointed by the President. Ultimately its actions are accountable to the American public.

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Private companies and corporations like Apple and Google are not ultimately responsible for public health. They lack the permanence of the federal government, do not employ any elected officials, and while they might be effective at protecting against health risks, that is not their guiding purpose. They also lack most of the enforcement powers of the FDA. Apple’s guidelines, for example, only threaten rejection of an app from the App Store. That doesn’t remove the app from the market. Apple is also not required to remove apps that cause harm. If an app is especially lucrative, perhaps they would be willing to overlook significant risk to users. Corporate policies without the backing of federal regulation often lack real teeth.

For comparison, imagine if FEMA and the EPA decided to leave “low risk” natural disaster recovery and pollution prevention to corporations. Walmart, for example, has a strong interest in developing their own disaster recovery system, maybe even one that would be far better than the government’s. But it would not be wise to leave disaster recovery just to them. They also have other instrumentally rational but publicly problematic incentives in creating such a system: insurance to minimize revenue losses without investing too much in public protection, a recovery plan that enhances their public image, and so on. In short, we would not be able to count on Walmart to prioritize public well-being in the way we would FEMA.

Similarly, Google and Apple have reputational and other self-interested reasons to monitor the apps they sell. If forced to make tradeoffs between revenue and protecting the public, their incentives lean toward protecting revenue. The FDA, by contrast, has a duty to prioritize public health and can also be held directly accountable if they fail to do so. Even if corporations share
duties with federal agencies, ultimately the responsibility to protect the public from harm resides with those governmental entities.

**Why the Government Should Not Regulate Health and Wellness Apps**

Recent statements from the FDA indicate that their approach is meant to foster innovation and “efficient regulation.” By sharing regulatory duties with companies like Apple and Google, the FDA is making it easier for developers to bring products to the market, as well as efficiently using the FDA’s limited resources only on devices that pose the greatest risk to the public. Even if the arguments above were persuasive, one might object that there remain good reasons for the FDA to maintain its hands-off policy. Let’s try to flesh out what that objection might look like.

*Sharing regulatory duties with corporations and private companies improves efficiency*

Threats to public health are hard to anticipate, and the FDA does not have the resources to investigate every possible health risk. This is one reason why Congress does not specify in detail how the FDA must spend their budget. Threats are constantly changing. Instead the FDA is given discretion on where to spend their resources, so long as they adhere to relevant laws and guidance documents. There’s no expectation, however, that every rule and regulation will be fully enforced (as with any other federal agency).

Given the nature of public health risks, it frequently will make sense for the FDA to share duties with non-governmental entities, including companies like Apple and Google. On their decision

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to ease regulation of mobile health apps, the FDA stated, “These policies were designed to allow lower risk beneficial technologies to be readily available to Americans while assuring connected products continue to be high-quality, safe and effective.”

Sure, the FDA could restrict health and wellness apps, but it would be resource intensive and would prevent helpful products from entering the market when they are needed most. Some harm would be prevented, but a lot of benefit would be lost as well. By outsourcing its regulatory duties, the FDA is able to invest its resources into preventing harm from the riskiest devices while allowing beneficial apps on the market. Corporations and other third parties are perfectly capable of preventing harm from low-risk devices, and are subject to lawsuits if they fail, so it is prudent to ask them to share the regulatory burden.

To the point made in the previous section about public accountability, it could be argued that the FDA is in fact adhering to their duties to the public by sharing some of their responsibilities with corporations. Health is a public good, and worth government protection, but resources are limited. The FDA is required to analyze the costs and benefits of their regulatory options. If public health is best protected by outsourcing some of the government’s traditional duties, then outsourcing oversight would seem to be permissible.

While we find much of this argument convincing, it only takes us so far. Efficiency arguments can be used to justify any proposal for deregulation. In the case of pharmaceuticals, for example, many agree that the FDA evaluation process is overly burdensome, and prevents beneficial

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treatments from entering the market in a timely fashion. However, it is much more contentious to claim that Bayer or other pharmaceutical companies should therefore take over evaluation of entire classes of drugs. Even if they are “low risk,” the potential for harm and need for public accountability, as already discussed, are too great for the FDA to absolve itself of oversight duties. Concerns for efficiency should influence the types of policies the FDA adopts, but they cannot justify complete absence of FDA regulation for health and wellness apps.

**FDA regulation stifles innovation**

In commenting on the FDA’s shift to lighter regulation of mobile health apps, then Commissioner Scott Gottlieb said that the FDA should “help reduce the development costs for these innovations by making sure that our own policies and tools are modern and efficient, giving entrepreneurs more opportunities to develop products that can benefit people’s lives.”

This statement suggests that achieving regulatory efficiency, as just discussed, will also help foster innovation. By avoiding over-regulation of mobile health, the FDA will make it easier for developers to bring beneficial new products to the market.

It can be difficult to specify how exactly the FDA’s approach might foster innovation. One possibility, as suggested above, is by lowering the cost of bringing an app to market. Developers of otherwise beneficial apps would not be able to afford the cost of the typical FDA evaluation

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The FDA fosters innovation by allowing developers to focus only on their product, not bureaucracy.

However, this is unconvincing. Innovation comes in degrees. It is certainly possible to create a review process that preserves innovation without maximizing for innovation. This of course involves numerous difficult questions—how much innovation is enough, and at what cost—but the general point is that it is possible. There are other ways to reduce the costs of development and incentivize innovation than avoiding regulation entirely.

Imposing minimal pre-market review, for example, does not thereby eliminate all innovation. The FDA could employ a tiered review program to ensure that truly low risk apps remain easy to develop. Similar to an IRB, the FDA could review basic information about an app to decide whether it is exempt from further review. It could focus more on safety of the app rather than efficacy, because efficacy can be a difficult standard to meet for particularly novel software. The FDA could also require a short deadline (e.g., 30 days) to deliver a decision. This would provide a minimum, low-resource standard that provides better protection for public health than the current policy.

The main point here is that an argument based on innovation needs to be more nuanced. Deregulation does not equal innovation. One way we might make it more nuanced is to focus on the uncertain uses of health apps and their developmental potential. It is not always clear whether a new app will be revolutionary, nor how consumers will use the app. Regulatory requirements pigeonhole developers in ways that prevent other novel uses that might develop in the future.
For example, the blood pressure app discussed already was based on an innovative use of fingerprint sensors embedded in most smart phones. Fingerprint sensors turned out to be a poor method for measuring blood pressure, but it would have been astonishing if it had turned out otherwise. We do not want to completely exclude the possibility of fortuitous discovery.

Similarly, many mental health apps innovate by tapping into everyday behaviors unlike what mental health professionals could ever provide. For instance, there is evidence that the conversational elements of the chatbot Woebot help reduce symptoms of depression. To get the timing and content right, developers need to experiment with real users. However, they may not be able to say beforehand precisely how someone experiencing mental health issues will use their app (especially if incorporating AI). And if the app is unlikely to generate revenue, many will refuse to invest the resources to test it in a clinical trial. FDA regulation would prevent too many of these kinds of novel, highly beneficial, and likely low risk apps from entering the market just because we cannot be entirely certain that they are low risk. That would seem to stifle innovation in an objectionable way.

There are a couple problems with this innovation argument. First, we know that some of these apps do in fact cause more than minimal harm. Grounding regulation in the mere potential for harm or uncertain uses of an app would be an unreasonable application of the precautionary

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But that’s not the case here. The FTC’s actions have documented the existence of harm (even if that’s not what they were acting against).

Second, as with the efficiency argument, innovation can be used to justify any sort of deregulation. Developers will always have an incentive to claim that the FDA’s policies are overly burdensome. Indeed, with respect to mobile mental health, some have concluded that the FDA has been too eager to satisfy tech companies’ incessant complaints about loss of innovation.\textsuperscript{34} There is no straightforward answer to the question of how much innovation we need in mobile health, but the answer should not be “as much as Google and Apple will allow.” While the considerations mentioned above are important, the FDA has a duty to protect public health. Again, the need for innovation should influence the shape of FDA policy, but it does not justify complete lack of regulation. As others have argued, stronger oversight from the FDA may in fact be crucial for the long-term innovation potential of mobile medical apps.\textsuperscript{35} This is in part because the presence of strategic regulation boosts consumer confidence above what would be the case in an unregulated market, which in turn boosts consumption and market competition for that increased consumption.\textsuperscript{36}

\textbf{Conclusion}

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The current regulatory approach that focuses on post-market evaluation of health apps is ethically problematic. Some apps pose more than minimal risk to users, and only Google and Apple have done anything to protect users from harm. While outsourcing might save FDA resources, protecting public health requires stronger public accountability that only the federal government can provide. Concerns about efficiency and fostering innovation should shape FDA regulation of health apps, but they should not be used to justify complete absence of FDA involvement.

The FDA’s new Digital Health Center of Excellence has the potential to expand their regulation of health apps without sacrificing regulatory efficiency or innovation. As it has been described, the Center will consist of experts from both the FDA and private industry. The Center should ensure that accountability remains with the FDA while also utilizing the skills and natural gatekeeping role that companies like Apple and Google play in society.

The FDA’s new precertification program could also be adapted to incorporate reviews of health and wellness apps not intended for medical use. The “Excellence Appraisals” for precertification already include a selective review of internal company policies and product claims. This would seem an opportune time to evaluate policies and products that apply to both medical and non-medical apps (e.g., privacy policies).

Finally, there remains an open question of how the FDA should choose which apps require review. We have argued for expanding review beyond just apps explicitly intended for medical use, but admit that it is difficult to state with any confidence where exactly the expansion should
end. Yet, from the fact that it is difficult to say just where the expansion should end, it does not follow that there is no reasonable limit to the expansion. In cases like the above-mentioned blood pressure app, the potential for harmful health outcomes was predictable enough. One option for establishing an appropriate class of apps for review is for the FDA to require developers to submit an application if they expect consumers will use their device for medical purposes (even if that is not the intended usage). The FDA could also request feedback from app marketplaces on harmful apps they have identified to help inform the development of review criteria. Further clarification on this issue of scope will be particularly important in implementing an expanded review policy.