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Commentary

The Conundrum of Online Prescription Drug Promotion

Comment on "Trouble Spots in Online Direct-to-Consumer Prescription Drug Promotion: A Content Analysis of FDA Warning Letters"

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Abstract
This commentary discusses pertinent issues from Hyosun Kim's paper on online prescription drug promotion. The study is well-designed and the findings highlight some of the consequences of the Food and Drug Administration's (FDA's) decision to deregulate online advertising of prescription drugs. While Kim's findings confirm some of the early concerns, they also provide a perspective of implementation challenges in the ever-changing technological environment.
Keywords: Prescription Drug, Online Promotion, Food and Drug Administration (FDA)

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The main purpose of the study is to understand the Food and Drug Administration's (FDA's) concerns regarding online promotion of prescription drugs advertised directly to consumers. Hyosun Kim's paper, "*Trouble spots in online direct-to-consumer prescription drug promotion: a content analysis of FDA warning letters*,"[1] analyzes warning letters to pharmaceutical firms over a 10-year period. The study finds six categories of violations: risk information, efficacy information, indication information, product labeling, material information issues, and approval issues. The study concludes with the difficulties of presenting drug information in mass media in a fair and balanced way. The study is well-designed and the paper clearly written. While the findings are not new, the study sheds new light on the increasingly complex issues surrounding direct-to-consumer advertising (DTCA). Looking back to when the FDA loosened the restrictions more than 15 years ago, Kim's findings offer an important contribution on the long term consequences of the decision and whether potential benefits outweigh the risks. In addition, the findings highlight the broader challenges of regulating the ever-changing industry.[2] The prevailing state of the regulation is far from what was initially conceived and is fraught with unintended consequences.

The findings raise important issues regarding the state of the regulation. According to the findings, 95% of alleged allegations were found in branded drug websites, online paid ads and online videos. This raises the question of whether the FDA is focusing specifically on these platforms and how it is aligning its enforcement strategies with the rapid transformation of social media.[3]

There are a number of implications from the findings: insufficient risk information, limited advertising space to provide necessary information and little consumer protection from misleading information. While the study is aimed at diagnosing issues that pharmaceutical marketers should avoid in their online promotional material,[1] these implications should be of concern to other stakeholders.

Following the FDA's decision in 1997, pharmaceutical companies were allowed to advertise prescription drugs over mass media. Studies, including the federal government's own Government Accountability Office,[4] have found inadequate review of pharmaceutical advertisements by the FDA and poor enforcement or remedial actions.[5,6] On the other hand, some studies have argued that direct-to-consumer (DTC) is more honest and forthcoming than most other consumer advertising and has potential life-saving benefits if deployed appropriately.[7]

Evidently, since the FDA let the genie out of the bottle, the prescription promotional industry has grown exponentially to a multibillion industry and will continue to thrive in the foreseeable future.[2] Ultimately, Kim recommends industry guidance in addressing visibility and accessibility of information in the web environment to help pharmaceutical marketers meet the requirements for DTC promotion and to protect consumers from misleading drug information. The viability of these recommendations needs to be understood by looking at some of the following assumptions.

The study and its conclusions appear to make some implicit assumptions. The first assumption is that pharmaceutical firms have a selfless motive and their interests are aligned with those of consumers and the FDA. While some interests are aligned, there is a world of conflict and motivation to act in ways that are at odds with each other. In addition, warning letters imply serious violations, and there is no way of knowing whether these were deliberate or honest mistakes. Kim's study found that major violations were based on the lack of risk information and/or misrepresentation of efficacy information. The fact that some pharmaceutical firms did not include these essential attributes in a drug points to an underlying problem of self-interest-seeking behavior

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and possibly deceptive marketing.[8] Kim's findings appear to highlight the conundrum of marketing efforts that are focused on increasing sales. Deception, whether calculated or unintended, that continues to prevail.

The second implicit assumption is that the FDA has sufficient knowledge to identify potential violations. Due to asymmetric information, the FDA may not be in a position to know all the happenings in the industry and must rely, in part, on self-disclosure by the pharmaceutical firms. Kim's article alludes to the emergent nature of online advertising platforms and efforts by regulators to catch up. There is a bigger problem of information impactedness. The pharmaceutical firms have deeper knowledge on their prescription drugs than the FDA; in addition, the FDA lacks the necessary capacity and resources to fully process this information and have to rely on the pharmaceutical firms. In an ideal world, promotional packages would have to be pre-approved by the FDA in order to ensure full compliance with the rules.

Consumers are also assumed to be "enlightened enough" to decipher information that is made available to them. The other issue raised by Kim regarding character space limitations is relevant here.[1] Vulnerable consumers, including patients with chronic illnesses and despair due to illness, may minimize side effects and contraindications of drug options availed to them.[9]

The findings shed light to institutional challenges surrounding violations that involve warning letters. Do letters of violation incentivize marketers to comply with the FDA's regulations? While the specific nature of violations has not been documented, it would be assumed that these violations fall on a spectrum of gross to not-so-serious in terms of deleterious impact on patients. The question is whether the FDA has sufficient will to institute proportionate actions and remedial actions for affected consumers.

Over the decades the FDA has continued to provide a leadership role in regulating the pharmaceutical industry around the world. Since most pharmaceutical firms are global, there is increased pressure on other regulatory agencies to liberalize the online advertising space in Europe and beyond. This is against the backdrop of controversy regarding deregulation by FDA. Kim's findings highlight the complexity of implementing such regulations without the necessary tools to do so.[10]

The proliferation of and new prescription drug promotion online and specifically over social media will continue to exacerbate the hazards and unforeseen consequences in the foreseeable future. The competitive environment in the pharmaceutical industry has also gone through significant transformation and is increasingly competitive. More significant, in the absence of data-driven risks and benefits, regulatory actions will continue to be determined in the context of incomplete information, lobbying and politics. Kim's findings begin to put some of the issues into perspective.

Ethical issues

Not applicable.

Competing interests

Author declares that he has no competing interests.

Author's contribution

IW is the single author of the paper.

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