



The regulatory outlook for telehealth advertising and promotion

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The global pandemic has increased the use of telehealth and accelerated its acceptance into mainstream healthcare. However, the regulatory landscape has yet to fully catch up with this expansion of telehealth. This article discusses some of the potential advertising and promotional regulatory implications as telehealth becomes a mainstay in the ever-evolving healthcare sector. The article explores the advertising and promotion of off-label drug prescriptions by telehealth companies, and the authors discuss how telehealth companies' categorization as a third-party platform allows for greater flexibility in the current regulatory schema.

Introduction

Scenario 1

Presentation. Kevin is a 35-year-old man living in a large city. He has no previous medical history but suffers from public speaking anxiety. On the morning of a large presentation, he found himself feeling increasingly anxious.

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His heart was racing and he was already starting to sweat as he entered the subway for his morning commute. As he took a seat and tried to calm himself down, his eyes fell upon a simple, well-designed advertisement on his social media account. The ad was for an anxiety medication that could treat the same symptoms he was experiencing. He quickly looked up the company and started scrolling through its website. Everything seemed safe, straight forward, and very simple. All he needed to do was answer some questions and exchange some messages with a doctor. The doctor would then prescribe the beta-blocker propranolol to treat his anxiety and it would be shipped to his apartment. Kevin signed up for the telehealth company.

Discussion. Telehealth has become a staple for many individuals who seek healthcare. Since March 2020, when the World Health Organization declared COVID-19 a pandemic, use of telehealth has increased by 38 times compared with before the pandemic.¹ A recent study found that 70% of in-person visits were cancelled during COVID,¹ although in-person appointments are starting to increase again. The drop-off in demand for in-person care increased the need for an alternative, and telehealth filled that need.¹ Widespread use of telehealth during COVID resulted in 76% of respondents in a survey saying they were highly or moderately likely to use telehealth in the future.¹

This rapid expansion of telehealth has created an easier way for patients to access care. However, there are potential drawbacks. For example, the regulatory industry has not yet created clear guidelines that address this new era of innovation in healthcare. This lack of guidance means that patients have trust that the telehealth companies they engage with have their best interest and safety in mind.

One aspect of the telehealth market that has been under scrutiny is the prescription and advertising of off-label medications, such as propranolol. One telehealth company in the US advertises, “prescription beta-blockers for anxiety trusted by professionals to block shaking hands, racing heart, and symptoms of nerves.” However, the US Food and Drug Administration (FDA) has not approved propranolol for the treatment of anxiety, and the company does not make it clear on its site that the therapy has not be approved for that indication. In contrast, another large US telehealth company also advertises propranolol for treating anxiety in a very similar manner, however, it makes it clear in its advertisements that the drug has not been approved by the FDA for treating anxiety. This lack of continuity in advertising across telehealth companies can largely be attributed to a lack of guidance from the FDA. These differences, though subtle, could have a significant effect on the patient.

Resolution. After signing up for the telehealth services, everything worked out well for Kevin. He was able to speak with a provider quickly and get a prescription for propranolol delivered directly to his apartment. While Kevin was not aware that propranolol is not FDA approved for anxiety, there were no

negative results. However, consider the following scenario for a different patient.

Scenario 2

Presentation. Robert, a 35-year-old man, also suffers from public speaking anxiety and saw the same advertisement for off-label propranolol that did not disclose the lack of FDA approval. He has a medical history significant for insulin-dependent diabetes. Robert exchanged a few messages with a provider and the doctor asked about his medical history and declined to write the prescription.

Discussion. Diabetes is contraindicated for the prescription of propranolol because it can alter and mask the signs and symptoms of hypoglycemia. If Robert were to have an adverse reaction to taking propranolol, could he use the lack of FDA approval to substantiate a claim and against whom would it be levelled? In Robert's exchanges with the doctor, what if the doctor had not asked detailed questions about his past medical history and Robert did not know to mention his history of diabetes? Although this new way of delivering healthcare is more convenient in many ways, Robert's case is a good example of the risks involved. Even though this novel way of delivering healthcare to patients is more convenient, patient safety should always be ensured. Regulation of the platforms from which remote healthcare is being delivered and the ways in which providers engage with patients need to be carefully balanced and is yet to be fully developed and realized.

Practice of medicine

The FDA does not have the authority to regulate the practice of medicine. That authority belongs to the states and state medical boards.² Prescribers possess prescriptive authority to prescribe off-label use(s) for medications with no FDA interference.² However, the agency regulates all aspects of prescription drug advertising and promotion.³

As technology advances, telehealth companies are charting new waters within a new sector of the healthcare industry. A telehealth company is an electronic platform that provides patients access to health care practitioners via telecommunication. These companies use various social media platforms to provide consumers with solutions to their medical conditions by promoting the drugs prescribed via the services offered their website. The relationship between states' regulation of medicine and the FDA's regulation of advertising and promotion and the associated legal issues fall into a regulatory gray area when telehealth companies advertise or promote prescription drugs. The advertisements and promotions in question focus on:

- The benefits of prescription drugs but with safety information not as conspicuously displayed as seen in manufacturer advertising and promotional pieces, and

- Prescriptions for indications that have not been approved by the FDA. It should be noted that, according to FDA regulations, only manufacturers and distributors are prohibited from promoting off-label use of prescription medications.³

Telehealth companies hire prescribers, such as physicians, nurse practitioners, and physicians' assistants, to conduct medically appropriate screenings of patients to ensure patients are properly diagnosed and suited for the medications prescribed to them. However, some may promote medications by emphasizing their benefits while downplaying their side effects. This advertising practice may violate the American Medical Association (AMA) Code of Ethics if telehealth is considered to be a prescriber and would violate the Federal Food, Drug, and Cosmetic Act if it were considered to be a distributor of prescription medications.^{3,4} According to the AMA's Code of Medical Ethics Opinion 9.6.1, physicians should not provide any messages containing false or misleading statements, and any information that is unjustified or deceptive regarding medical expectations should be avoided.⁴ However, telehealth companies operate outside of any hard-coded regulation because they are in that regulatory grey space that is neither a prescriber nor distributor.⁵

FDA regulation

Currently, telehealth companies are not required to comply with federal drug marketing rules.⁶ Under federal law, drug marketing rules apply to drug manufacturers, drug distributors, packers, and their representatives.⁷ However, it remains unsettled whether telehealth companies fall within that definition. A "manufacturer" is anyone who is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of a prescription drug.⁸ "Wholesale distributor" refers to anyone engaged in wholesale distribution of prescription drugs.⁸ In contrast, telehealth companies make certain products and services available to individuals through third-party medical providers, pharmacies, or other vendors.⁹ They also provide another channel of access to medical groups that provide healthcare and mental health services.⁹

Telehealth companies can avoid complying with FDA regulation by claiming they are a third-party, unaffiliated with the drug manufacturer and merely a platform connecting doctors and patients.⁵ There is no FDA guidance for that approach, and no federal or state agencies oversee telehealth companies. The regulatory environment for telehealth has allowed companies to thrive by allowing flexibility in their advertising and promotion.¹⁰ Specifically, telehealth companies are unrestricted compared with drug manufacturers in regard to promoting off-label uses of drug products that have not been approved by the FDA. However, this lack of regulation will likely be short-lived. Telehealth companies anticipate that they may be subject to direct and indirect adoption, expansion, or reinterpretation of various laws and regulations.¹¹ Thus, if regulated, the FDA would be able to request telehealth companies modify product promotion and subject themselves to regulatory and legal enforcement

actions, including issuing warning letters, injunctions, seizures, civil fines, and criminal penalties.¹¹ Overall, telehealth companies can circumvent existing regulatory standards by asserting they facilitate interactions between patients and physicians.

Implications of telehealth for regulatory professionals

Telehealth creates a new and exciting space for regulatory professionals. Questions remain around when the FDA will implement regulations and if it does, what that will entail. In the meantime, telehealth companies continue to advertise and promote off-label use(s) of prescription drugs that continue to be disseminated into the public domain. The agency's response to digital therapeutics continues to mature as more of those technologies are developed. It will soon have to dedicate effort to drafting guidance specifically on the advertising and promotion on new technologies such as telehealth. The future of telehealth advertising and promotion is undetermined, but it is reasonable to expect some form of guidance from the FDA soon. That uncertainty may keep telehealth companies and their regulatory advertising and promotion teams vigilant.

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