NY Attorney General Sanctions Highlight Need for Higher Standards for mHealth Research and Development

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NY Attorney General Sanctions Highlight Need for Higher Standards for mHealth Research and Development

April 5, 2017 - Jennifer S. Geetter Chelsea M. Rutherford

Summary

On March 23, 2017, the New York Attorney General's office announced that it has settled with the developers of three mobile health (mHealth) applications (apps) for, among other things, alleged misleading commercial claims. This settlement highlights for mHealth app developers the importance of systematically gathering sufficient evidence to support their commercial claims.

In Depth

On March 23, 2017, the New York Attorney General's office announced that it has settled with the developers of three mobile health (mHealth) applications (apps) for, among other things, alleged misleading commercial claims. As part of the settlement, each developer must revise its advertising, consumer warnings and privacy practices, and must pay a monetary penalty to the Office of Attorney General. This settlement underscores for all mHealth developers the importance of having sufficient scientific evidence to support their commercial claims.

According to Attorney General Eric Schneiderman, two of the apps claimed to accurately measure heart rate after vigorous exercise, using only a smartphone camera and sensors. The third app claimed that it could cause a smartphone to function as a fetal heart monitor

and be used to play an unborn baby's heart rate, even though the app was not approved by the Food and Drug Administration (FDA) as a fetal heart monitor.

This settlement highlights for mHealth app developers the importance of systematically gathering sufficient evidence to support their commercial claims. When mHealth apps are subject to the jurisdiction of the FDA, the FDA approval process ensures that any labeling claims are appropriately supported by clinical evidence. Many mHealth apps, however, are *not* medical devices (meaning such mobile apps do not meet the definition of a device under the US Federal Food, Drug, and Cosmetic Act), and the FDA does not regulate them. Where FDA rules do not apply, determining whether research and development efforts are adequate for health care-related applications may be a different calculation than what might be appropriate or typical in the standard minimum viable product (MVP) calculus. As the health care industry as a whole is accustomed to products, services and claims that are backed by strong scientific evidence, hospitals, health plans, patients, consumers and other health care stakeholders have an expectation that mHealth apps will meet those traditional evidentiary standards. Understanding —and meeting—the expectations of regulators as well as consumers and their health care providers by conducting sufficient research to support commercial claims will be critical to gain acceptance, approval and commercial success.

mHealth app developers also need to be aware that the law governing human subjects research often extends to individuals whose data is used even when there is no human interaction with the researchers. Though many developers may think of their research activities from a traditional software development perspective, when developing

products to be used with patients or by consumers for health and wellness applications, development activities may unexpectedly constitute research involving human subjects when the development process uses consumer or patient data. For example, research and development efforts that mine patient medical records, deploy surveys that collect personally identifiable information or aggregate and analyze data collected from wearable technology could all constitute research with human subjects. This additional, and perhaps unanticipated, legal consideration could open the door to significant additional regulatory requirements. As such, developers should familiarize themselves with human subjects research requirements and their potential application when consumer data is used in the development process and structure their research accordingly. When identified at the outset, research regulations should not pose a barrier to the design and implementation of studies.

As evidenced by this settlement, state enforcement actors can impose penalties if the regulator or law enforcement agency believes that an app is not properly developed, supported and/or marketed. Given that mHealth solutions are deployed on a national scale, the enforcement efforts of just a few attorneys general are relevant to mHealth developers everywhere. mHealth developers can take immediate and concrete steps to align their research and development and marketing efforts with the expectations of health consumers and the broader health care community by focusing on clinically valid evidence in developing and marketing their apps.