NY AG Enters Mobile Health App Enforcement Arena with Settlements Targeting Health Claims and Privacy Practices

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New York Attorney General Eric Schneiderman recently announced settlements with three mobile health app developers resolving allegations that they made deceptive advertisements and had irresponsible privacy practices. The Attorney General alleged that the developers sold and advertised mobile apps that purported to measure vital signs or other indicators of health using just a smartphone. The apps had over a million downloads, giving these concerns considerable consumer reach. The Attorney General's office reportedly became aware of the apps through consumer complaints and reports to the Health Care Bureau.

Failure to Properly Substantiate Health Benefit Claims

The NY AG's core concerns regarding the advertising claims were as follows:

- Runtastic created "Heart Rate Monitor, Heartbeat & Pulse Tracker". The NY AG alleged that Runtastic promoted its app as a product that purports to measure heart rate and cardiovascular performance under stress but had not tested the app with users engaged in vigorous exercise.
- Cardiio created and sold the "Cardiio Heart Rate Monitor". Cardiio allegedly also marketed its app as a means of monitoring heart rate following vigorous movement but had not tested the app under those conditions. In addition, the NY AG alleged that Cardiio's representations that its product was endorsed by MIT were deceptive.

Representations Consistent with a Regulated Medical Device

- Matis's "My Baby's Beat-Baby Heart Monitor App" raised slightly different concerns. Matis allegedly promoted the app with statements such as "Turn your smartphone into a fetal monitor with My Baby's Beat app" and language that encouraged consumers to use the app as an alternative to more conventional fetal heart monitoring tools. The app allegedly had not undergone proper review by the FDA to be marketed as such, however.

As readers of this blog and our sister blog, Food and Drug Law Access, know, the FDA has authority to regulate medical devices and has taken a risk-based approach to consumer-directed mobile health products. The FTC has been even more active than the FDA in bringing health-related enforcement actions, as we have written about here, here, and here. As these federal agencies transition into a new administration, the NY AG is making clear with these settlements that regulators are still watching for potentially misleading health claims.

The NY AG also alleged several problematic privacy practices, including the following:

- Failing to disclose the risk that third parties could re-identify de-identified user information,
- Issuing conflicting statements on data sharing under the Privacy Policy and under the Privacy Settings,
- Failing to disclose that the company collected and provided to third parties consumer's unique device identifiers,
- Employing a practice of consent by default, where a consumer is deemed to have consented to a privacy policy just by using the website, and
- Failing to disclose that protected health information collected, stored, and shared by the company may not be protected under the Health Insurance Portability and Accountability Act.

As we noted in a previous post on privacy and data security in mobile health apps, legal compliance is all too often an afterthought when it comes to app development. These allegations underscore the importance of understanding and reconciling data collection and use practices with the statements companies make to consumers.