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Consumer Health Information Update from Both Sides of the Atlantic

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The ***Federal Trade Commission (FTC)*** convened stakeholders to explore whether health-related information collected from and about consumers — known as ***consumer-generated health information (CHI)*** — through use of the internet and increasingly-popular lifestyle and fitness mobile apps is more sensitive and in need of more privacy-sensitive treatment than other consumer-generated data.

One of the key questions raised during the FTC's CHI seminar is: "what is consumer *health* information"? Information gathered during traditional medical encounters is clearly health-related. Information gathered from mobile apps designed as sophisticated diagnostic tools also is clearly health-related — and may even be "Protected Health Information," as defined and regulated by Health Information Portability and Accountability Act (HIPAA), depending on the interplay of the app and the health care provider or payor community. But, other information, such as diet and exercise, may be viewed by some as wellness or consumer preference data (for example, the types of foods purchased). Other information (*e.g.*, shopping habits) may not look like health information but, when aggregated with other information generated by and collected from consumers, may become health-related information. Information, therefore, may be "health information," and may be more sensitive as such, depending on (i) the individual from whom it is collected, (ii) the context in which it is initially collected; (iii) the other information which it is combined; (iv) the purpose for which the information was initially collected; and (v) the downstream uses of the information.

Notably, the FTC is not the only regulatory body struggling with how to define CHI. On February 5, 2015, the European Union's Article 29 Working Party (an EU representative body tasked with advising EU Member States on data protection) published a letter in response to a request from the European Commission to clarify the definitional scope of "data concerning health in relation to lifestyle and wellbeing apps."

The EU's efforts to define CHI underscore the importance of understanding CHI. The EU and the U.S. data privacy and security regimes differ fundamentally in that the EU regime broadly protects personally identifiable information. The US does not currently provide universal protections for personally identifiable information. The U.S. approach varies by jurisdiction and type of information

and does not uniformly regulate the mobile app industry or the CHI captured by such apps. These different regulatory regimes make the EU's struggle to define the precise scope and definition of "lifestyle and wellbeing" data (CHI) and develop best practices going forward all the more striking because, even absent such a definition, the EU privacy regime would offer protections.

The Article 29 Working Party letter acknowledges the European Commission's work to date, including the European Commission's "Green Paper on Mobile Health," which emphasized the need for strong privacy and security protections, transparency – particularly with respect to how CHI interoperates with big data – and the need for specific legislation on CHI-related apps or regulatory guidance that will promote "the safety and performance of lifestyle and wellbeing apps." But, in its annex to the Article 29 Working Party letter, the Working Party notes: "due to the wide range of personal data that may fall into the category of health data, this category represents one of the most complex areas of sensitive data and …display[s] a great deal of diversity and legal uncertainty." Thus, even within the more protective EU data privacy regime, regulators acknowledge the likely need for specific privacy and security protections in light of the consumer-driven nature of CHI, the myriad mechanisms in which such data is collected and aggregated in the digital landscape, and the difficulty in tracing, tracking and predicting how such data will be aggregated, disaggregated and otherwise used.

As a starting point, the annex to the Article 29 Working Party letter presents a framework for determining when personal data are health data, which is:

1. "The data are inherently/clearly medical data.

2. The data are raw sensor data that can be used in itself or in combination with other data to draw a conclusion about the actual health status or health risk of a person.

3. Conclusions are drawn about a person's health status or health risk (irrespective of whether these conclusions are accurate or inaccurate, legitimate or illegitimate, or otherwise adequate or inadequate)."

The Annex also notes the importance of obtaining "the unambiguous consent of the data subject," given that many CHI-related mobile apps collect and process location data and data collected through sensors, which, when combined with other data, could identify a person's health status.

Back in the United States, the FTC continues to signal its interest in mobile applications that collect and analyze CHI. On February 23, 2015, the FTC released a pair of consent orders about two different mobile applications, alleging that the apps did not perform as advertised. Although these consent orders do not expressly address the data privacy implications of the apps, they signal that the FTC is monitoring the representations that apps collecting and using CHI are making to consumers.

As mobile apps become more sophisticated and assist patients and providers with the active detection and management of health conditions, we expect that the need for clarity and consensus about reasonable data privacy and protection practices with respect to CHI will intensify because this need for clarity and consensus is something about which both U.S. and EU regulators can agree.

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