Opening Remarks for House Energy and Commerce Subcommittee Hearing
on Health Care Apps

Nicolas P. Terry
Hall Render Professor of Law
& Executive Director, Hall Center for Law and Health
Indiana University Robert H. McKinney School of Law

July 13, 2016

Chairman Burgess, Vice Chairman Lance, Ranking Member Schakowsky and members of the Committee, it is a privilege to share my thoughts on some of the legal and regulatory issues involving health care apps. I congratulate the Committee on its “Disrupter Series” and its engagement on these forward-looking and exciting issues.

Some of my work has examined the question why health information technologies (HIT) have failed to transform or disrupt healthcare. I concluded that there were several overlapping explanations. These included typical healthcare market failure problems, overarching structural issues, the illiquidity of healthcare data, and underperforming technologies. As a result, federal and state policymakers have turned towards subsidy and command-control models in an attempt to promote HIT adoption.

Mobile health and health care apps potentially avoid these problems. They posit inexpensive care pulled by patients only when needed and delivered away from inconvenient, centralized locations. Obviously, many mobile health apps will be developed with regard to existing health care relationships, offering improved condition management particularly for chronic diseases. Many of those apps will be subject to existing regulatory models. However, the most disruptive mobile health apps are those that are patient-facing. Those create a direct app-patient “relationship” that lacks professional intermediation and, as a result, traditional regulation of safety, quality, and confidentiality.

The regulatory framework for most of these apps is complicated and in some cases troubling. Here, the oversimplified binary of regulation versus innovation is a poor frame. Rather, we have a current technological space that is subject to both over-regulation and under-regulation.

For present purposes I restrict my comments to three issues, safety, effectiveness, and data protection. First, the Food & Drug Administration has used a sub-regulatory guidance to signal a light touch regarding most categories of apps. However, patient diagnosis and treatment recommending apps that arguably could be useful and stimulate innovation typically remain subject to traditional device regulation. Arguably this approach frightens off responsible innovators while the FDA lacks the bandwidth to deal with the many industry minnows selling apps that cross the regulatory line. Such a state suggests that additional regulatory clarity is required together with some innovative regulatory model that is more attuned to the rapid iteration of the mobile industry.

Second, there is the question of app efficacy or effectiveness. Even if they are safe, many health apps are simply ineffective. The structure of the app market and the absence of effective infomediaries creates immense problems for consumers looking for quality apps, creating doubts as to whether the market will function effectively. This is a classic consumer protection problem and, in my opinion, the Federal Trade Commission has taken the correct approach in

demanding competent and reliable scientific evidence in app cases involving, for example, claims of melanoma detection and vision improvement. Sufficient regulatory resources must be deployed in this endeavor lest innovative apps are drowned out by mobile health "snake oil."

Third, data protection. This is an area of acute under-regulation. Most patient-facing apps exist in a "HIPAA-free" zone, subject to a small number of state laws and, in the most egregious cases, by the FTC's "unfairness" jurisdiction. Here, our flawed sectoral, downstream approaches to data protection are on full display.

This country has enjoyed a deep-rooted cultural expectation of and professional commitment to health privacy, no doubt in part because healthcare data seems particularly susceptible to discriminatory and other harmful uses. Every day doctors rightfully reassure their patients as to the legally-enforced confidentiality of the information they share while their offices distribute required privacy notices. However, the same or similar data collected on mobile devices lack these protections. Most mobile health apps (particularly the more disruptive, patient-facing examples) are not subject to the HIPAA privacy and security rules leaving patient wellness and health data woefully unprotected. In my opinion federal data protection law that obviates the gaps between our commercial sectors and protects health information wherever it happens to reside is overdue and a necessary precondition for the full embrace of disruptive health apps by both medical professionals and consumers.

Again, I express my thanks to the Committee for permitting me to raise these issues.

References

- Nicolas Terry, Information Technology's Failure to Disrupt Healthcare 13 Nev. L.J. 722 (2013), http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2118653
- Nicolas Terry, Mobile Health: Assessing the Barriers, Chest. 2015;147(5):1429-1434
- Will the Internet of Things Disrupt Healthcare? xx Vand. J. Ent. & Tech. L. xx (forthcoming 2016), http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2760447
- Nicolas Terry & Lindsay F. Wiley, Liability for Mobile Health and Wearable Technologies, Annals of Health Law (forthcoming 2016), http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2725450
- Nicolas Terry, Regulatory Disruption and Arbitrage in Healthcare Data Protection, 17 Yale J. Health Pol'y L. & Ethics xx (forthcoming 2017), http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2774471
- Nicolas Terry, Hearing Aids And The Sound Of Mobile Health Disruption, Health Affairs Blog, June 17, 2016, http://healthaffairs.org/blog/2016/06/17/hearing-aids-and-the-sound-of-mobile-health-disruption/