Mr. Donald S. Clark
Federal Trade Commission
Office of the Secretary
Room H-113 (Annex J)
600 Pennsylvania Avenue, NW
Washington, DC 20580

Re: Spring Privacy Series: Consumer Generated and Controlled Health Data, Project No. P145401

Dear Mr. Clark,

On behalf of the Center for Data Innovation (www.datainnovation.org), I am pleased to submit these comments in response to the Federal Trade Commission's (FTC) request for public comment on consumer generated and controlled health data (also referred to as patient-generated health data).[1]

The Center for Data Innovation is a non-profit, non-partisan, Washington, D.C.-based think tank focusing on the impact of the increased use of information on the economy and society. In addition, the Center formulates and promotes pragmatic public policies designed to enable data-driven innovation in the public and private sectors, create new economic opportunities, and improve quality of life. The Center is affiliated with the Information Technology and Innovation Foundation (ITIF).

As a result of the continued development of technologies such as online personal health services, mobile devices, and low-cost sensors, patients now directly produce and control a significant amount of data directly or indirectly related to their health including physiological data, such as heart rate and blood glucose level; behavioral data, such as physical activity or medication adherence; and unstructured textual information, such as written accounts on health websites, online review portals, and web queries. This is a major departure from the old model of patient health data collection and storage, in which clinicians were the primary sources and holders of this data and patients could only get access to their health information through their physician.

Patient-generated health data is an enormously valuable resource. Patients can use mobile health technologies to collect health data more frequently, conveniently, and at a lower cost than could be done in a clinical setting. Not only does this give patients and their caregivers the ability to track health indicators in real time, it also creates a rich dataset for potential analysis. An emerging group

[1] "Consumer Generated and Controlled Health Data," Federal Trade Commission, May 7, 2014, http://www.ftc.gov/news-events/events-calendar/2014/05/spring-privacy-series-consumer-generated-controlled-health-data.

of users, including patients, health care providers, medical researchers, government organizations, and commercial entities, have begun to experiment with how to use patient-generated health data, but many are still in the early stages of development. Unfortunately, some advocacy groups have overstated the risk of potential consumer harms and have called on government regulators, including the FTC, to limit the use of patient-generated health data, which we believe will discourage innovation. Yet as we describe in this filing, many of the purported risks about how patient-generated health data may be misused are already addressed by existing laws. Furthermore, many of these advocacy groups assert, incorrectly, that health data cannot be de-identified, a view which ITIF rebuts in a forthcoming report.[2]

While the benefits from patient-generated health data are tangible and concrete, the harms cited by detractors are mostly hypothetical and speculative. Given the wealth of opportunities that may be possible from patient-generated health data, policymakers should be cautious about imposing unnecessary regulations on this data. Instead, policymakers should identify opportunities to promote data sharing and encourage the nascent industry around patient-generated health data to grow.

PATIENT-GENERATED HEALTH DATA HAS MANY BENEFICIAL USES

Patient-generated health data lends itself to a broad range of potential beneficial uses. Accordingly, users fall into five general categories: patients, health care providers, medical researchers, government entities, and the private sector.

Patient-generated health data allows individuals to stay up-to-date on their own health, learn how different treatments and behaviors affect their health, and find patients with similar characteristics who can share information about their experiences. Patients can use their health data to monitor their own health or allow others to do so on their behalf. One way patients can use health data is by getting alerts when something goes wrong. For example, the Owlet Baby Monitor is a sensor-equipped garment parents can use to monitor various aspects of their baby's health through readouts and alerts on an accompanying smartphone app.[3] Parents concerned with sudden infant death syndrome and other preventable conditions can use the app to receive an instant alert if any aberrant data comes in. Another way individuals can use their own data is by observing trends in key health indicators and changing their treatment or behavior accordingly. For example, SCiO, a handheld molecular sensor slated for shipment in December 2014, can scan organic substances to determine caloric content and other nutritional facts, allowing users to track changes in their diet

[2] Ann Cavoukian and Daniel Castro, "Setting the Record Straight: De-Identification Does Work," *Forthcoming June 2014*.
[3] "FAQ," Owlet Baby Monitors, accessed June 6.2014, http://www.owletcare.com.

and even scan their own body to reveal chemical changes over time.[4] A user trying to keep to a particular diet might want to track a week's caloric intake and cut down if it is too high. Finally, all of this data allows individuals to discover others who share similar medical profiles and trade advice and discussions. The social network PatientsLikeMe integrates patient-reported information on symptoms, care strategies, and other health factors to connect similar patients anonymously.[5] The company has reported that its users are more comfortable discussing some types of information in this way than through paper forms and questionnaires.[6]

Health care providers can use patient-generated health data to make better care decisions and thereby improve the quality and cost of health care. For example, doctors can use patient-generated health data to detect and diagnose conditions. The Parkinson's Voice Initiative, a research project to detect Parkinson's disease, does this by analyzing telltale sounds in digital audio recordings of patients speaking.[7] Although systems inspired by the initiative have not yet been deployed clinically, future doctors could use audio recordings to diagnose patients who lack access to transportation or establish quantitatively that a patient's condition is getting worse. Health care providers can also use patient-generated health data to improve the quality of care they provide. For example, some providers have begun using data generated from diabetic patients' continuous glucose monitoring systems to observe how blood glucose levels change both over time and at different times of the day.[8] Doctors can view this data at regular check-ups and make changes to patients' care management plans accordingly. Researchers at the Massachusetts General Hospital Diabetes Center in Boston found that the devices have significantly improved in accuracy since 2008 and that glucose monitoring can improve glucose control when used in conjunction with intermittent self-monitoring.[9] Finally, health care providers can use mobile data collection devices to treat patients' chronic conditions more cost-effectively than with frequent in-person visits.[10] A 2008 study of the

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[4] Consumer Physics, Inc, "SCiO: Your Sixth Sense. A Pocket Molecular Sensor For All!" Kickstarter, April 30, 2014, https://www.kickstarter.com/projects/903107259/scio-your-sixth-sense-a-pocket-molecular-sensor-fo.
[5] "PatientsLikeMe Help Center," PatientsLikeMe, accessed June 6, 2014 https://support.patientslikeme.com/hc/en-us.
[6] "Share and Compare: Be a PRO! Understand Your Experiences in Context," PatientsLikeMe blog, December 6, 2010, http://blog.patientslikeme.com/2010/12/06/share-and-compare-be-a-pro-understand-your-experiences-in-context/.
[7] "Science," Parkinson's Voice Initiative, accessed June 6, 2014, http://www.parkinsonsvoice.org/science.php.
[8] "Diabetes and Continuous Glucose Monitoring," WebMD, http://www.webmd.com/diabetes/continuous-glucose-monitoring.
[9] Doug Brunk, "Three continuous glucose monitoring devices highly reliable," Family Practice News, June 24, 2013, http://www.familypracticenews.com/single-article/three-continuous-glucose-monitoring-devices-highly-reliable/0ca5a61057b56974cd468c8e6d1a1a0f.html.
[10] Joseph Conn, "Staying connected: Providers and patients increasingly relying on home-based monitoring," Modern Healthcare, January 18, 2014, http://www.modernhealthcare.com/article/20140118/MAGAZINE/301189929#.

Department of Veterans' Affairs home-monitoring program, which uses a combination of wireless Internet-connected devices such as a scale, pulse oximeter, breath flow monitor, and blood pressure cuff, showed a 25 percent reduction in hospital bed days and a 19 percent reduction in admissions, and allowed care coordinators to oversee a much greater volume of patients.[11]

Medical researchers can use patient-generated health data to study a variety of health-related topics and develop new methods for physicians to care for patients. Research based on patient-generated health data is still in its infancy, but a number of studies have already been published examining the data's potential for future clinical use.[12] For example, a 2013 study from the Mayo Clinic showed that patient data collected with Fitbit, a wearable activity tracker, can be used to predict recovery time from heart surgery.[13] The study's authors found that monitoring surgery patients with mobile devices is a promising avenue for further investigation, since these devices offer much more continuous and consistent data than traditional data sources, such as nursing notes. Another study from the University of California, San Francisco and the University of California, Berkeley used Bluetooth blood pressure monitors to measure indicators of heart health.[14] Traditional methods of measuring these indicators in a lab require considerable skill and training, but the consumer device was able to capture high-quality measurements from patients with no special technical skills. Another team of scientists from the University of California, Irvine School of Medicine demonstrated that smartphones outfitted with accessory lenses could be used for remote medical screening of tiny bacterial infections, successfully diagnosing a patient's infection without using a traditional laboratory microscope.[15] Finally, a team of researchers at the University of Manchester in the UK have developed a carpet that can detect when someone has fallen on it, which could be installed in elderly people's homes to alert family members or emergency response teams.[16]

Government agencies can use patient-generated health data to stay better informed about disease outbreaks, determine whether a drug might need to be recalled, and improve public health. New York City's Health Department, for example, is piloting a project using Yelp review data to track

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[11] Ibid.
[12] "Publications & talks," PatientsLikeMe, accessed June 6, 2014, http://www.patientslikeme.com/research/publications.
[13] Larry Husten, "Fitbit Could Help Monitor Progress After Heart Surgery," Forbes, August 29, 2013, http://www.forbes.com/sites/larryhusten/2013/08/29/fitbit-could-help-monitor-progress-after-heart-surgery/.
[14] Jonah Comstock, "iHealth's role in Health eHeart study revealed," MobiHealthNews, December 18, 2013, http://mobihealthnews.com/28248/ihealths-role-in-health-eheart-study-revealed/.
[15] Gannno Burgett, "Scientists are Using the Nokia Lumia 1020 to Get a Better Look at Diseased Tissue," PetaPixel, June 3, 2014, http://petapixel.com/2014/06/03/a-look-at-how-the-nokia-lumia-1020s-camera-is-helping-scientists-in-the-lab.
[16] Douglas Heaven, "Smart carpet detects falls and strange footsteps," New Scientist, September 4, 2012, http://www.newscientist.com/blogs/onepercent/2012/09/smart-carpet-detects-falls---a.html?DCMP=OTC-rss&nsref=online-news.

health code violations in the city.[17] Looking for reviews mentioning diarrhea or vomiting after a meal, the city investigated three restaurants as part of the pilot program and found that all three had serious health code violations. In another case, a team of researchers from around the country found that Internet search data could be used to detect adverse drug reactions with an accuracy comparable to the Food and Drug Administration's (FDA) adverse event reporting system.[18] The FDA could use this data as an inexpensive complement to its current system or to gather additional evidence for a drug recall. Government agencies can also leverage patient-generated health data to improve public health. To help address the problem of an aging population that often lives alone, the city of Bristol, UK, is partnering with universities and the private sector to develop a home sensor system that can monitor the health of individuals in their home.[19] For example, the system could be used to detect an overnight stroke and send that information to a local emergency room or remind individuals with memory-affecting conditions to take their medication.

Commercial entities can use patient-generated health data for drug development, human resources planning, and athlete analytics, among many other applications. For example, pharmaceutical companies can use symptoms reported by patients in online forums and other patient-generated sources to aid in drug development.[20] The FDA has acknowledged these data sources' utility and has issued guidelines for pharmaceutical companies using patient-reported outcomes to justify claims made on medicine labels. Using patient-generated health data, employers may also be able to predict when employees will get sick and plan to provide support staff during periods of increased illness. Researchers at Lancaster University in the UK have developed models to make such predictions based on factors such as bad weather and large sporting events; although their research did not focus on patient-generated health data, it is easy to see how such data might improve such models even further.[21] Finally, data from wearable technology is making professional sports safer for athletes. Australian wearable manufacturer Catapult helps teams tailor fitness regimens and better prevent athlete injury based on highly granular stress and movement readings from wearable

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[17] Chris Gayomali, "New York City is Using Your Yelp Reviews to Find Health Code Violations," Fast Company, May 23, 2014, http://www.fastcompany.com/3031043/fast-feed/new-york-city-is-using-your-yelp-reviews-to-find-health-code-violations.
[18] R.W. White, et al. "Toward Enhanced Pharmacovigilance Using Patient-Generated Data on the Internet," *Clinical Pharmacology & Therapeutics*, advance online publication, May 7, 2014, http://www.nature.com/clpt/journal/vaop/ncurrent/full/clpt201477a.html.
[19] Jesse Berst, "British city promotes high-tech healthcare as a smart city service," Smart Cities Council, May 28, 2013, http://smartcitiescouncil.com/article/british-city-promotes-high-tech-healthcare-smart-city-service.
[20] Ethan Basch, "Toward Patient-Centered Drug Development in Oncology," *New England Journal of Medicine*, August 1, 2013, http://www.nejm.org/doi/full/10.1056/NEJMp1114649.
[21] Neil Shotton, "Lancaster University experts hope to predict sickness in the workplace," Lancaster Guardian, October 10, 2013, http://www.lancasterguardian.co.uk/news/business/lancaster-university-experts-hope-to-predict-sickness-in-the-workplace-1-6135412.

sensors.[22] It is likely that, as their costs come down over time, some of these devices will become available to amateur athletes as well.

Many Laws Already Protect Patient-Generated Health Data from Harmful Uses

Existing laws and self-regulatory guidelines already offer significant protections for how patient-generated health data can be used. In particular, many laws, including the Americans with Disabilities Act (ADA), Genetic Information Nondiscrimination Act (GINA), the Fair Credit Reporting Act (FCRA), and the Employee Retirement Income Security Act (ERISA), protect consumers from employers, creditors, landlords, and others who may take adverse actions against them based on health information. These protections are generally extended regardless of whether or not the data is collected in a clinical setting by a health care provider. For example, FCRA limits how employers can use information in background reports, including information about medical conditions, for employment decisions. The act defines medical information in broad terms as "information or data, whether oral or recorded, in any form or medium, created by or derived from a health care provider or the consumer, that relates to (A) the past, present, or future physical, mental, or behavioral health or condition of an individual; (B) the provision of health care to an individual; or (C) the payment for the provision of health care to an individual."[23] This definition would seemingly include most patient-generated health data. In addition, ERISA protects employees from being fired, suspended, or otherwise discriminated against if the purpose of the action is to prevent the employee from obtaining some protected benefit, such as access to retirement or health benefits. Since the protection in this case is based on how the data is used, not where it comes from, patient-generated health data would need no additional protection.

If the FTC identifies gaps in laws wherein specific uses of consumer health information have been restricted in the past but those restrictions can be circumvented using new types of patient-generated health data, it should narrowly seek to curb those uses. Otherwise, it should allow, and even encourage, data sharing. For example, GINA prohibits health insurers and employers from using genetic information for insuring and hiring decisions.[24] Individuals and organizations can still use and share genetic information for beneficial purposes, such as contributing to the Personal Genome Project, a volunteer-driven effort to create an open genomic database for longitudinal medical

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[22] Travis Korte, "5 Q's for Applied Sports Scientist Gary McCoy," The Center for Data Innovation, May 22, 2014, http://www.datainnovation.org/2014/05/5-qs-for-applied-sports-scientist-gary-mccoy/.
[23] Fair Credit Reporting Act, http://www.consumer.ftc.gov/sites/default/files/articles/pdf/pdf-0111-fair-credit-reporting-act.pdf.
[24] "Background Information for EEOC Final Rule on Title II of the Genetic Information Nondiscrimination Act of 2008," U.S. Equal Employment Opportunity Commission, http://www.eeoc.gov/laws/regulations/gina-background.cfm.

research.[25] Similarly, the ADA prohibits discrimination based on disabilities and medical conditions in a variety of contexts. For example, employers cannot make hiring and firing decisions about employees based on medical information unrelated to the essential functions of the employee's job, regardless of the source of the information.[26] Laws like GINA and the ADA seem to strike the right balance between providing consumers assurances that their data will not be used to harm them while protecting data-driven innovation. Policymakers who are concerned about patient-generated health data being used for harmful purposes should demonstrate detrimental uses that cannot be prevented through this sort of framework before calling for new rules that restrict collecting or sharing of data.

In addition, policymakers should encourage the private sector to develop voluntary self-regulatory guidelines to address how it uses health data.[27] Self-regulation is generally more responsive to technological innovation than government regulation, thereby better serving rapidly evolving industries. In addition, it can often produce and update codes of conduct faster than government, thereby protecting consumers sooner. For example, the Network Advertising Initiative's code of conduct states that online advertising companies should disclose their data collection, purchase, and use practices in an understandable and prominent manner. The code also details several limitations on the use of health data, such as requiring opt-in consent before showing ads for culturally sensitive health conditions such as sexually transmitted diseases and mental health issues.[28] In cases where self-regulatory guidelines govern data usage, it is critical to hold companies accountable when they violate their commitments or deceive consumers. Government oversight and enforcement by agencies such as the FTC supplement these efforts to ensure their effectiveness and accountability.

Finally, it should be noted that the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule prohibits covered entities, including health plans and health care providers, from sharing personally identifiable health information with other entities without patient consent. HIPAA also prevents researchers from sharing personally identifiable health information without individual

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[25] Travis Korte, "5 Q's for Personal Genome Project Director George Church," The Center for Data Innovation, May 30, 2014, http://www.datainnovation.org/2014/05/5-qs-for-personal-genome-project-director-george-church/.
[26] Questions and Answers: Enforcement Guidance on Disability-Related Inquiries and Medical Examinations of Employees Under the Americans With Disabilities Act, U.S. Equal Employment Opportunity Commission, http://www.eeoc.gov/policy/docs/qanda-inquiries.html.
[27] Daniel Castro, "Benefits and Limitations of Industry Self-Regulation for Online Behavioral Advertising," (Information Technology and Innovation Foundation, December 2011), http://www.itif.org/files/2011-self-regulation-online-behavioral-advertising.pdf.
[28] "2013 NAI Code of Conduct," Network Advertising Initiative, accessed June 6, 2014, http://www.networkadvertising.org/2013_Principles.pdf.

authorization, unless the researcher obtains approval from a special privacy board or claims other special circumstances.[29] Although it does not always apply to patient-generated health data, particularly when the data is not held by a physician or other provider, HIPAA has had the unintended effect of discouraging legitimate data sharing in the health care sector since organizations do not want to run afoul of the complex HIPAA rules. For example, the developers of New York University's Databrary, an open data library for behavioral scientists, noted the irony that parents of disabled children are often the most eager to see researchers share and use data to pursue better treatments, but because their children are among HIPAA's protected populations, it is difficult to do so.[30] Or as one cancer researcher at the University of California Berkeley noted recently, "Patient privacy is important but so is making progress on cancer."[31] Ultimately laws and regulations should not create such a high-risk environment that beneficial uses of data are discouraged. While health data is indeed more sensitive than some other types of data, arguably health innovation is also more important than other types of innovation.

Policymakers should also recognize that there will be some "dual use" data which may be used to infer information about an individual's health status but has other principal uses as well (e.g. online purchases or geolocation data). Policymakers should avoid "regulation creep", i.e. extending existing regulations, such as HIPAA, to entities it was never designed to apply to.

Conclusion

Patient-generated health data offers myriad potential benefits to consumers, clinicians, researchers, government agencies, and commercial entities. In order to realize these benefits, data users of all kinds acting in good faith must be able to share and reuse data with ease. Rather than limit data sharing, efforts to protect consumer privacy should be targeted toward preventing harmful uses. Many existing laws already accomplish this goal, such as preventing discrimination based on genetic or other health information, and any gaps in these laws should be filled with limited reforms that specifically address the gap. In addition, policymakers should support the development of robust de-identification techniques and model data sharing agreements. As long as health data cannot be shared seamlessly, either because the data is not digital, not interoperable, or not permitted to be shared by law, patients cannot receive the best possible care, doctors cannot make decisions based

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[29] "Health Information Privacy: Research," U.S. Department of Health & Human Services, June 5, 2013, http://www.hhs.gov/ocr/privacy/hipaa/understanding/special/research/.
[30] Taylor Beck, "NYU Builds Data-Sharing Network For Scientists--But Is It Legal?" Fast Company, July 23, 2013, http://www.fastcolabs.com/3014757/nyu-builds-data-sharing-network-for-scientists-but-is-it-legal.
[31] See quote from David Patterson in James Temple, "Medicine's Big Problem with Big Data: Information Hoarding," Recode.net, June 7, 2014, http://recode.net/2014/06/07/medicines-big-problem-with-big-data-information-hoarding/.

on the most complete information, and medical researchers cannot pursue scientific inquiry into the most pressing health challenges of our time.[32]

One of the major health policy challenges in the coming years will be to ensure that opportunities to use this data to improve the welfare of individuals and society are neither overlooked nor limited. It is imperative that policymakers not only avoid erecting new barriers, but also work diligently to promote more widespread data sharing in health care. To do this, policymakers should strive to be a voice of reason, counteract alarmist rhetoric around health data, and champion efforts to build the technical and legal foundations for health data sharing platforms that will serve all individuals.

Sincerely,

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[32] Amalia R. Miller and Catherine Tucker, "Can Healthcare IT Save Babies?" April 14, 2011, http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1080262.