Before the
Federal Trade Commission
Washington, DC

In re Consumer Generated and Controlled Health Data	Project No. P145401

COMMENTS OF
COMPUTER & COMMUNICATIONS INDUSTRY ASSOCIATION

In response to the Federal Trade Commission's ("FTC" or "the Commission") call for comments[1] requesting further input on the May 7, 2014 workshop on health data, the Computer & Communications Industry Association ("CCIA") submits the following comments.

CCIA is an international nonprofit association representing a broad cross section of computer, communications, and Internet industry firms. CCIA remains dedicated, as it has for over 40 years, to promoting innovation and preserving full, fair, and open competition throughout our industry. Our members employ more than 600,000 workers and generate annual revenues in excess of $465 billion.[2]

I. The Commission must do a cost-benefit analysis when considering health data.

Before regulating in any nascent industry, it is essential that the Commission conduct an evidence-based review of the costs and benefits of the use of consumer generated data in the healthcare ecosystem. It is necessary to weigh the life-saving benefits of health data against harms that are concrete and cognizable, rather than purely speculative. Collecting data is not a harm in and of itself; harms arise when bad things are done with data.

Given its history of competition advocacy in the healthcare space, the Commission has a clear track record of aggressively promoting competition in these markets. Mobile applications and the more robust use of consumer generated health data promise to assist the FTC's mission to accelerate competition and innovation in these critical markets, such as by facilitating healthcare competition by enabling consumers to easily take their health information with them

[1] *See* http://www.ftc.gov/news-events/events-calendar/2014/05/spring-privacy-series-consumer-generated-controlled-health-data.

[2] A list of CCIA's members is available online at http://www.ccianet.org/members.

or by allowing remote healthcare services to be provided to underserved areas. It is important for the Commission to recognize and control for the "innovation asymmetry"[3] problem when framing a response to new technology and nascent markets. Overemphasizing the potential negatives of a new technology can lead to suboptimal public policy outcomes as the benefits foregone surpass the harms prevented.

Innovation in healthcare applications has transformed the healthcare market by providing users access to their data, enabling them to monitor their own health. This leads to a shift from a costly, reactive approach to healthcare to a preventative approach.[4] Using consumer generated health data, apps can increase efficiency and accuracy in healthcare, resulting in fewer easily avoidable deaths. One panelist explained at the workshop the immense amount of lives that could be saved:

> There are somewhere between 100,000 to 400,000 deaths due to medical errors every year. There are at least 700,000 adverse drug events that result in injury or death.[5]

The use, development, and investment in new healthcare innovations should not be deterred by overreaching privacy regulations, that may not even be possible to fulfill. As stated in a 2010 White House report on health information technology, "[i]t is important that criteria for electronic security measures not be overspecified to the point of impossibility."[6]

II. Innovations based on health data benefit consumers in many ways.

In 1970, the United States spent approximately 7 percent of its GDP on healthcare.[7] By 2011, that percentage had climbed to 17.2 percent,[8] which was more than 4 percent more than

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[3] Michael Carrier, *Copyright's Blind Spot: The Innovation Asymmetry*, DISRUPTIVE COMPETITION PROJECT, Dec. 18, 2013, *at* http://www.project-disco.org/intellectual-property/121813-copyrights-blind-spot-the-innovation-asymmetry.

[4] *See* Molly Wood, *Samsung Stakes Claim on Wearable Tech that Monitors Health*, N.Y. TIMES, May 29, 2014, *available at* http://bits.blogs.nytimes.com/2014/05/29/samsung-stakes-claim-on-wearable-tech-that-monitors-health.

[5] Transcript of FTC, *Spring Privacy Series: Consumer Generated and Controlled Health Data* (2014), *available at* http://www.ftc.gov/system/files/documents/public_events/195411/ftc_spring_privacy_series_-_consumer_generated_and_controlled_health_data_-_transcript.pdf (hereinafter "2014 Workshop Transcript"), at 35.

[6] Executive Office of the President, President's Council of Advisors on Science and Technology, *Realizing the Full Potential of Health Information Technology to Improve Healthcare for Americans: The Path Forward*, (2010) (hereinafter "PCAST Health IT Report"), *available at* http://www.whitehouse.gov/sites/default/files/microsites/ostp/pcast-health-it-report.pdf, at 48.

[7] Clayton Christensen et al., *The Innovator's Prescription: A Disruptive Solution for Health Care* (McGraw-Hill 2009), at xv.

the next highest spending advanced economy in the world. Furthermore, since healthcare costs are growing at a rate significantly higher than inflation, and have been for nearly a half-century, healthcare is becoming increasingly unaffordable for the average American and threatens to bankrupt the country if costs are not brought under control. If ever a sector of the economy needed to embrace the disruptive potential of both big data and mobile applications, healthcare is it.

What makes this trend even more troubling is that much of the money spent on healthcare is spent in vain. As one expert has noted, "as much as a third of healthcare spending in the United States maybe wasted on inappropriate, useless, or even harmful care."[9] Lowering costs through more accurate diagnoses and better-targeted treatments are areas that big data and analytics is well suited for. In fact in its recent report on big data, the White House articulated the transformative effect that consumer generated personal information and big data analytics could have on improving both the quality and cost-effectiveness of healthcare delivery:

> Big data can identify diet, exercise, preventive care, and other lifestyle factors that help keep people from having to seek care from a doctor. Big data analytics can also help identify clinical treatments, prescriptions drugs, and public health interventions that may not appear to be effective in smaller samples, across broad populations, or using traditional medical research methods. From a payment perspective, big data can be used to ensure professionals who treat patients have strong performance records and are reimbursed on the quality of patient outcomes rather than the quantity of care delivered.
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> The emerging practice of predictive medicine is the ultimate application of big data in health. This powerful technology peers deeply into a person's health status and genetic information, allowing doctors to better predict whether individuals will develop a disease and how they might respond to specific therapies.[10]

While there are myriad ways that big data, mobile health and high-end analytics are transforming (or have the potential to transform) healthcare delivery, we wanted to highlight both high level estimates and discrete healthcare solutions as examples of the rapid innovation in this space and its nearly boundless potential. According to the McKinsey Global Institute, over 200 businesses formed between 2010-2012 to develop innovative tools to make better use of

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[8] Bloomberg Visual Data, *Most Efficient Health Care: Countries*, BLOOMBERG, Aug. 19, 2013, *available at* http://www.bloomberg.com/visual-data/best-and-worst/most-efficient-health-care-countries.

[9] Frank Pasquale, *Grand Bargains for Big Data: the Emerging Law of Health Information*, 72 MD. L. REV. 682, 689 (2013).

[10] Executive Office of the President, *Big Data: Seizing Opportunities, Preserving Values* (2014), *available at* http://www.whitehouse.gov/sites/default/files/docs/big_data_privacy_report_may_1_2014.pdf, at 23.

existing healthcare data. This is just the tip of the iceberg, as the supply of healthcare information is growing exponentially:

> Fortunately, we now have a better supply of information to satisfy the increased demand. In the clinical sphere, the amount of patient data has grown exponentially because new computer-based information systems. In 2005, only about 30 percent of office-based physicians and hospitals used even basic electronic medical records (EMRs). By the end of 2011, this figure rose to more than 50 percent for physicians and 75 percent for hospitals.[11]

Clearly, with the growing number of innovators in this space and a growing amount of raw material at their disposal, we are on the cusp of a major – and much needed – healthcare revolution. McKinsey estimates that fully utilizing big data to create "new value pathways" has the potential to reduce the annual U.S. healthcare spend by $300 - $450 billion, or roughly 12 to 17 percent of the $2.6 trillion baseline U.S. healthcare costs.[12]

Even relatively simple healthcare applications show huge amounts of promise. In a 2008 study, Bob Litan estimated that the widespread adoption of remote monitoring technologies can save $197 billion (in constant 2008 dollars) over a 25 year period.[13] Since that time, there has been a surge in innovation to capitalize on the potential of remote monitoring. The workshop cited recent inventions such as Mimo, an infant onesie that is equipped with an attached monitoring device that measures the heartbeat, respiration rates and other vital signs of an infant, relaying the information back to the application a parent's mobile device.[14] It not only allows to parents to monitor sleep patterns, but also equips them to detect sign of potential fatal conditions, such as Sudden Infant Death Syndrome.[15] AgaMatrix has developed iBGStar, also a blood glucose monitor, which attaches to the iPhone and transfers the data to the application, permitting the user to monitor levels over time.[16] Health and fitness apps "measure all types of physical performance from sleep quality to exercise effectiveness," allowing users to monitor

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[11] McKinsey & Co., *The 'big data' revolution in healthcare: Accelerating value and innovation* (2013), *available at* http://www.mckinsey.com/~/media/mckinsey/dotcom/client_service/healthcare systems and services/pdfs/the_big_data_revolution_in_healthcare.ashx, at 3.

[12] *Id.* at 8.

[13] Better Health Together, *Vital Signs Via Broadband: Remote Health Monitoring Transmits Savings* (2008), *available at* http://www.corp.att.com/healthcare/docs/litan.pdf, at 2.

[14] 2014 Workshop Transcript at 2.

[15] *Id.*

[16] Peter Wayner, *Monitoring Your Health with Mobile Devices,* N.Y. TIMES, Feb. 22, 2012, *available at* http://www.nytimes.com/2012/02/23/technology/personaltech/monitoring-your-health-with-mobile-devices.html.

habits and patterns that are conducive to a healthy lifestyle.[17] Even insurance companies, such as Aetna, which was mentioned at the panel, have taken advantage of monitoring to set up apps similar to the design of health and fitness apps, allowing beneficiaries to "track progress on all sorts of health indicators."[18]

There is also substantial benefit from the instant access of health information through mobile apps. There was much discussion at the workshop about the BlueButton app, which is allowing over 37 million Medicare subscribers to consolidate family health records, and receive "critical information about their medications."[19] A panelist observed the advantage of simply having access to synthesized records, noting that "just having your mom's medication record available to you . . . can go a long way to preventing adverse drug reactions."[20] Other innovations include iTriage, which allows the user to input symptoms which the app then processes to refer you to a local provider, efficiently directing the user to the appropriate care.[21]

This data can be analyzed to "improve personalization of care, as genetic profiles and health histories can be mined to predict which treatment programs would be most effective."[22] The consumer, therefore, is not only receiving immediate benefits, but with proper use of health data, will assist in radically changing the industry for themselves and future generations. Stringent regulation of data exchange can discourage advancement in the research field and improvement of healthcare systems, which, undeterred, could lead to a "fully interoperable, less costly, more effective national health IT ecosystem."[23] Innovations built on consumer health data will significantly reduce healthcare costs and place the patient in a more powerful position to negotiate care.

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[17] Accenture, *Racing Toward a Complete Digital Lifestyle: Digital Consumers Crave More* (2014), *available at* http://www.accenture.com/SiteCollectionDocuments/PDF/Accenture-Digital-Consumer-Tech-Survey-2014.pdf, at 7.

[18] 2014 Workshop Transcript at 4-5.

[19] Id. at 32.

[20] Id.

[21] Eric Braverman & Michael Chui, *Unleashing Government's Innovation Mojo: Interview with US Chief Technology Officer*, Jun. 2012, MCKINSEY & CO., *available at* http://www.mckinsey.com/insights/public_sector/unleashing_governments_innovation_mojo_an_interview_with_the_us_chief_technology_officer.

[22] Dominic Barton, *Sectors Where Big Data Could Make an Impact*, WALL ST. J., Mar. 28, 2014, *available at* http://blogs.wsj.com/experts/2014/03/28/sectors-where-big-data-could-make-an-impact/.

[23] Executive Office of the President, President's Council of Advisors on Science and Technology, *Realizing the Full Potential of Health Information Technology to Improve Healthcare for Americans: The Path Forward*, (2010) (hereinafter "PCAST Health IT Report"), *available at* http://www.whitehouse.gov/sites/default/files/microsites/ostp/pcast-health-it-report.pdf, at 43.

III. The online healthcare ecosystem already has many privacy checks.

While the Commission understandably wants to act in this space to protect consumers, there is already significant self-regulation in the market. Many mobile apps already have built-in privacy checks to address identified harms. For example, a panelist at the workshop explained that many apps give consumers control of their privacy, and can dictate what records, "item by item," they want to release.[24] Additionally, data can be stored locally on a device, rather than on the cloud,[25] giving consumers more options for controlling their data.[26]

The mobile app industry has guidelines their applications must follow when dealing with sensitive health information, as stated at the workshop.[27] The Department of Commerce's NTIA Mobile APP Transparency Code of Conduct requires disclosure before sharing biometric data.[28] The Digital Advertising Alliance and the Network Advertising Initiative have mobile behavioral advertising guidelines that cover health data, requiring explicit consent before they can use the information.

It is also important to keep in mind that online records are also often more secure than paper records, due to increased opportunities for protecting privacy and security, as the White House made clear in the PCAST Health IT report.[29] In particular, paper records lack intrinsic security that is provided by even "the most elementary electronic security protections."[30] As alluded to previously, many of these privacy checks are at the hands of the user and, consequently, education is essential to ensure the user is well-informed to take advantage of them to secure their data. The Commission needs to move concurrently towards a solution where mobile app companies "move forward with the benefits while addressing the risks."[31]

IV. User education is essential for the digital healthcare ecosystem to flourish.

The Commission should encourage an atmosphere that supports user understanding about the use of their data. In its recommendations, the McKinsey Global Institute makes the point that

[24] 2014 Workshop Transcript at 37.
[25] *Id.* at 33.
[26] *Id.* at 37.
[27] *Id*. at 43.
[28] *Id.* at 43.
[29] PCAST Health IT Report at 48-49.
[30] *Id.*
[31] 2014 Workshop Transcript at 14.

it is important to "[s]hift the collective mind-set about patient data to 'share, with protection,' rather than 'protect.'"[32] Without widespread sharing of consumer generated health data, consumers will not realize the potential benefits of these new technologies and tools and the marketplace itself will stagnate.

Consumers are eager to take advantage of the new mobile health technology available through their mobile apps. A recent Accenture report of digital tech consumers showed that 54 percent of respondents were interested in buying a health monitor as an application and 52 percent were interested in buying a fitness monitoring device.[33] Furthermore a panelist at the workshop stated that "[w]e know that nearly 75 [percent] of adults in the United States are already online looking for information and many of those, about 60 [percent] of those are actually looking for health information."[34] With over 100,000 apps available in the mHealth market, there are multiple opportunities to acquiesce this demand.[35]

There is also a willingness among users to share the data procured from mobile apps. Users recognize the benefit of sharing their experiences through mobile platforms that operate as social networking sites. PatientsLikeMe is an organization that enables patients with a chronic illness to track their health and share their experiences and data with other users with the same illness.[36] They conducted a study that surveyed users' responses to the service who suffered from epilepsy, and the effects it had on their health.[37] According to PatientsLikeMe, 55 percent reported that it helped educated them more about seizures, 27 percent agreed it help them be more adherent to their medication, and 18 percent suggested they needed fewer visits to the emergency room.[38]

To effectively capitalize on this demand and willingness, users should be educated so as to be adequately versed in how their data is used, thereby establishing trust. As stated in the

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[32] McKinsey & Co., *supra* note 11, at 13.

[33] Accenture, *Racing Toward a Complete Digital Lifestyle: Digital Consumers Crave More* (2014), *available at* http://www.accenture.com/SiteCollectionDocuments/PDF/Accenture-Digital-Consumer-Tech-Survey-2014.pdf, at 6.

[34] 2014 Workshop Transcript at 28.

[35] research2guidance, *mHealth App Developer Economics 2014: The State of the Art of mHealth Publishing* (2014), *available at* http://research2guidance.com/r2g/mHealth-App-Developer-Economics-2014.pdf, at 6.

[36] PATIENTSLIKEME, *available at* http://www.patientslikeme.com.

[37] *Survey Reveals PatientsLikeMe® Helps People with Epilepsy* (2011), *available at* http://news.patientslikeme.com/press-release/survey-reveals-patientslikeme-helps-people-epilepsy-improve-seizure-understanding-and-.

[38] *Id.*

PCAST Health IT report, "[a] patient cannot make meaningful privacy choices unless he or she understands the flows and uses of information and can therefore make informed choices."[39] Many applications have privacy policies that are readily available to the user. For example, the BlueButton app has a privacy policy within the app and a FAQ statement that explains how to use the app, and what the app does with the data. More importantly, statements such as these tell the user when their data is not being shared at all.

Even when the data is shared, users are often willing to use the app if there is adequate disclosure over where the data is going. PatientsLikeMe first notifies the user that the site is conducting a survey using their data, discloses all the partners of the project, and then sends the findings of the survey back to the user.[40] In contrast, others still seem reluctant when asked the same information by insurers who might use that same information to increase their deductibles.[41]

The advent of these mobile apps has empowered consumers to a degree not seen previously. As one panelist noted, as consumers we are going to need to expand our awareness and understanding of what we can do personally with our medical information, which we have previously not had as much access to.[42] The mobile health revolution has enabled users to have instant access to data and empowered them to take a more proactive stance in their healthcare. They are "going to be expected to have a lot more ownership of their health and their health care,"[43] and, consequently, will have a greater role in the security of that data. The FTC should be proactive about educating the public on how to use this largely beneficial technology while ensuring privacy.

V. The Commission must not stifle disruptive innovation and competition in the healthcare market.

Given the Commission's multi-faceted role as both a consumer watchdog and a promoter of competition, the agency is well positioned to weigh the costs and benefits of prescriptive regulation in this space. Although the potential consumer harms of improperly used or

[39] PCAST Health IT Report at 46.

[40] *Id.* at 61.

[41] Craig Mundie, *Privacy Pragmatism: Focus on Data Use, Not Data Collection*, FOREIGN AFFAIRS (2014), *available at* http://www.foreignaffairs.com/articles/140741/craig-mundie/privacy-pragmatism.

[42] 2014 Workshop Transcript at 54.

[43] *Id.* at 65.

inadvertently shared personal health information are considerable, so too are the foregone benefits when outdated or poorly targeted regulations prevent the beneficial exchange and analysis of potentially live-saving, or cost-reducing, information. The healthcare marketplace desperately needs a competitive shakeup, and disruptive innovation through the use of consumer generated health data, mobile health applications, and big data analytics is an essential pathway for providing that competition and innovation.

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