



Prepared Testimony and
Statement for the Record of

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Hearing on
“Smart Health: Empowering the Future of Mobile Apps”

Before the
United States House of Representatives
Committee on Science, Space, and Technology
Subcommittee on Research and Technology

March 2, 2016

Chairwoman Comstock, Ranking Member Lipinski, and members of the subcommittee, thank you for the opportunity to testify today to discuss the role of mobile health apps in empowering physicians and patients to make value-based decisions.

My name is Jordan Epstein and I am the founder and CEO of Stroll Health, and for the past two and half years our team has worked to make healthcare easier to navigate and more affordable for the average American. We started with the belief that physicians and medical staff should make recommendations that consider the entire patient's needs, including financial responsibility--not just what is medically necessary and easily obtained by a provider. We realized that without immediate access to helpful information and software tools patients find it extremely difficult to find affordable, available, and high-quality care. Repeatedly studies have demonstrated that patients do not understand how their health insurance works or the metrics that matter in quality. While most want to know how much upcoming care might cost, only a tiny fraction are able to obtain cost information, and even fewer know how to switch to lower cost, better value care providers. And so we set out to build Stroll.

Stroll Health is a startup based in San Francisco. We make HIPAA compliant mobile and web apps used by both patients at home and by providers in a clinical setting. Our first app enables physicians and their staff to electronically order radiology procedures that are in network, affordable, and convenient for patients. To date, our clinical data demonstrate average savings of 30%, and with Stroll, physicians and their staff send patients to comparable quality, lower-than-average-cost care 86% of the time. If Stroll or a similar tool could be used in the decision-making and ordering of all non-hospital health care expenditures with similar effect, we estimate the US would save \$500-700B each year.

In my testimony today I will discuss:

- 1.) **Stroll Health:** Stroll's technology and how it empowers physicians and patients to make value-based decisions.
- 2.) **R&D Funding:** Funding sources for research and development of mobile healthcare technology, and how the federal government could play a larger role.
- 3.) **Barriers:** Technological, regulatory, social, and privacy barriers Stroll has faced, and suggestions to improve the future development of technology.
- 4.) **Health App Market Overview:** Types of health apps, their function, and my beliefs on which should be supported by the federal government and how.

1. Stroll Health

Stroll Health is embedded in the US mobile and health IT landscape. We create technology that integrates with provider workflow, optimizing clinical choice for location of care based on cost, convenience, quality and more. Stroll acts as an easy-to-use tool to discuss, find, and order best

value care for patients and their providers. In real time, we process each patient's insurance benefit, tailor a provider directory to the specific test a doctor is ordering, and personalize the results based on what is in network, nearby, and lowest out-of-pocket cost for that patient. Together with the patient, providers choose what they and their patient believe to be best value care. We electronically follow patients across the care continuum, and track that they receive the prescribed care at the arranged price, in the most efficient way possible.

To do this, we use web scraping and big data to aggregate, process, and store hundreds of thousands of records, create statistical models to regress and smooth missing data, and utilize machine learning and data science to make improvements to our algorithms. Utilizing industry best practice enterprise cloud architecture, we meet or exceed HIPAA security standards. We actively integrate with clearinghouses and insurance companies, follow standardized protocols for communication across electronic medical records and practice management software, and daily deal with the clinical frustrations of missed reports, denied care, and forgotten appointments. To date, we cover more than 300 procedures in radiology, and for those tests alone, there are more than a trillion options that a doctor faces every time she picks up our app to refer care. Stroll processes patient insurance information and doctor preferences in real time, and in a handful of seconds shows the twenty or so options that are personalized to be the best fit for the patient. The doctor is then able to choose a quality, low cost provider together with their patient.

Today, our standalone public patient web app and private provider iOS tablet mobile app are used in the San Francisco Bay Area to find and order best value radiology imaging services. In the future, Stroll's Application Program Interfaces (API) and Software Development Kits (SDK) will be embedded in third party technology used by electronic medical records (EMR), telehealth companies, clinical decision support, and other consumer facing tools and more. With the rise of high deductible and narrow network plans, many patients fear interacting with the healthcare system in any way, including long-term cost-saving preventative care. In a world empowered by price transparency and real-time patient-centered decision support at the time of care, electronic ordering, and round-trip patient monitoring and reminders, we believe we can remove the complexity, decision fatigue, and confusion facing the average patient every day in the US health system. Whether a patient or provider knowingly uses Stroll or not, we hope Stroll will become the standard of care for ordering better value, more affordable health care services across types of procedures and the nation for years to come.

2. R&D Funding

Stroll is in the process of expanding from our clinical pilots in the Bay Area to integrating with some of the largest health systems in metropolitan areas across the country, including Washington D.C. We are also raising our first institutional capital from healthcare and technology venture capitalists across the country. Stroll has been supported to date through private grants and in-kind services from Robert Wood Johnson Foundation, Blue Cross Blue

Shield, Google, Microsoft, Wilson Sonsini Goodrich and Rosati, in addition to private angel investors. In addition, Stroll has participated in programs with some of the top research universities in the world, including the University of California at Berkeley (UCB), Cornell, Stanford, and the University of California at San Francisco (UCSF). Stroll applied for, and did not receive, federal funding via the NSF (National Science Foundation) Small Business Innovation Research (SBIR) program. Stroll never received any information regarding why our application was rejected.

More federal research dollars should be made available to app developers, particularly those outlined in Section 4 below. At the time we applied for an SBIR grant, we did not fit neatly into any NSF or National Institutes of Health (NIH) topic area. In the few years since, NSF has created a “Smart Health and Biomedical Technologies” topic, which should simplify and facilitate mobile health app developers looking for government support. Still, there is a disturbing trend in how dollars are allocated, particularly when you look at distribution of age and education across grantees. The average age of a mobile developer is 33¹ and 71% have college degrees, which are both significantly lower than the typical SBIR grantee, particularly related to health technology (the average age of an NIH SBIR grantee is 53). It is important for grant evaluators to recognize that the majority of successful innovators creating the sharing/app economy are young and early in their careers, and that awards should weigh the significance of the change more than the length of credentials. More development of clinically viable apps that improve quality of care, reduce the cost of care, and improve the patient experience is exactly what this country needs. Gifted app developers with experience in other fields should be supported in the endeavor, regardless of age or education.

Private funding alone is not enough. Even socially conscious investors expect a return, and when Stroll started, we did not know how we would make money. My cofounder and I simply believed that this was a problem worth solving, and if we solved it, we would find a way to make a business. Private investors, especially typical app investors, look for two key metrics when determining whether to invest--growth in active users, and revenue per active user. However, apps in the health care market like Stroll’s need to be clinically tested, tuned, and studied to confirm efficacy, all of which take time that traditional investors tend to avoid in search of quicker returns. The federal government needs to fill the gap to take best practices and core technology from one field to another, especially in mobile healthcare applications, before they are ready to be commercialized.

In addition, the Centers for Medicare and Medicaid Services (CMS), the Department of Veteran Affairs (VA), and Congress have allocated millions of dollars to innovation and improvements to quality of care, yet very few app developers have received their support or funds to create new apps, nor have existing and independently developed apps received funding to be piloted to later commercial success. Many health systems now have both venture arms to financially back,

¹ <http://www.onlinedegrees.com/degree360/hot-job-report/december-2013-app-developer.html>

and innovation arms to clinically implement and test new technologies. As the nation's largest payer², the government would be the largest beneficiary of spearheading this effort.

3. Barriers

While many of the barriers Stroll Health faces are specific to its deep data and provider integrations, none are unique. In no particular order, the following are some of the issues we face, along with recommendations on how the federal government can help mitigate them.

Technological Barriers

Standardization for Machine Readable Plan Benefits and Provider Networks

Congress should mandate standardization for communicating in-and-out of network provider designations and plan benefit specifications that are updated on at least a weekly basis. Few payers, if any, provide such information in a machine readable format, and many payers provide plan benefit information in ways that have non-standard, second-order definitions, leaving benefit experts, patients, and even their own call center staff confused about which benefits apply when, and for whom (examples include designations such as "choice" and "outpatient free standing"). Even for CMS, with some of the most standardized network and plans in the country, it is near impossible to determine which providers are participating, non-participating, balance bill or are privy to the Outpatient Prospective Payment System (OPPS)--all of which, and more, are "in-network" Medicare providers.

Standardization and Electronic Protocols for Utilization Management

Utilization Management (UM), the umbrella term used when a provider has to go through a third party to ask a payer for permission to perform medically necessary services, is an incredibly complex and time consuming aspect of our health system. Many studies suggest that no savings are actually created, and instead simply shift the cost burden from payers to providers. In addition, sometimes necessary care can be delayed by weeks or more, resulting in detrimental outcomes for patients. While I do not disagree that some level of population health management needs to be exerted on providers, the existing method of requiring providers to use separate portals or fax machines for each payer, and make sometimes three or more phone calls as a review escalates from agent to nurse to peer-to-peer is entirely outdated, dangerous, and wasteful. Instead, Congress should mandate electronic UM standards and require payers to adopt them, including Medicaid (and Medicare when it adopts UM standards in 2019).

Interoperability

Every electronic medical record (EMR), picture archiving and communication system (PACS), practice management system (PMS), and radiology information system (RIS) should have standardized APIs for accessing patient information and sharing with other providers as

² http://www.americanhealthpolicy.org/Content/documents/resources/Government_as_Payer_12012015.pdf

appropriate. Alternatively, such systems could integrate with a health information exchange (HIE) or single, standardized data aggregator, which would then allow easy, standardized integrations. Congress should direct industry to set these standards, and set a timeline for adoption, with penalties for non-compliance. Without such policy, apps like Stroll literally have to integrate with more than 1,000 other software systems in complex, expensive, unique point to point integrations, which will likely never happen and thereby limits the scope and benefit of such apps.

Data Barriers

Electronic Eligibility Data

While most payers have some sort of mechanism for communicating electronically with clearinghouses and providers, many do not, especially safety net, county, Medicaid payers, and many state and federally funded plans like Children's Health Insurance Program (CHIP) and Civilian Health and Medical Program of the Department of Veterans Affairs (CHAMPVA). Apps such as Stroll and others cannot interface with these payers without this data, which prevents their enrollees from receiving any of the benefits of these apps.

CMS Claims Data

While in recent years CMS has done an admirable job of releasing data sets, it still preferentially shares only some of its data, often with researchers and non-profits, and sometimes to private for-profit businesses as well. If de-identified data is safe to be shared with one company, it should be safe to share with all. Today server and sharing costs are so low, there is no justification why smaller companies and app developers have continued to be locked out of this data.

Quality data

While Medicare has made strides in advancing quality metrics and outcomes measurement, there is still little useful data for entire segments of patient care, including radiology. The continued use of outdated and obsolete equipment, or providers without the correct subspecialty, can directly cause inferior patient outcomes. CMS should create more and more relevant quality metrics, and make those easily available to app developers via an API format.

Regulatory Barriers

Health Insurance Portability & Accountability Act (HIPAA)

HIPAA is not designed for today's health IT market where a non-clearinghouse, highly technical organization that sees no patients and has no physical servers goes to market using modular service integrations. The technical standards are relatively easy to understand and implement given today's enterprise security and privacy architecture, but the law needs to be simplified. In particular, with today's complex "app-in-app" and data sharing infrastructure, it is not always clear who should be signing a Business Associate Agreement (BAA) with whom. This can lead to an arduous process of, for example, integrating with an EMR, only to have to obtain

authorizations from each individual provider on a case-by-case basis, even when the total solution is already authorized by the provider with a BAA in place. This problem does not affect just small app providers, but also some of the largest, most innovative, publicly traded healthcare IT companies. While I applaud the Department of Health and Human Services (HHS) Office for Civil Rights (OCR) recent guidance on when HIPAA might apply to apps³, it needs to make clearer when patient permission is needed, when a BAA applies and to whom, and what sort of communication is permissible to patients without explicit consent.

Gag Clauses, Most-Favored Nation Clauses, and Usual, Customary, and Reasonable (UCR) Rate Clauses

Healthcare providers and payers should be able to share fee schedule, claims, and other data freely with app and other technology providers without fear of legal recourse. However, most contracts that describe fee schedules expressly prohibit sharing data (Gag Clauses). Even without those clauses, many providers still won't share their pricing data because they are afraid that one payer might see lower rates and decide they should also be entitled to them, regardless of their negotiated contractual obligation (Most-Favored Nation Clauses). Finally, some contracts with payers note that if a provider offers lower rates on an UCR basis, that that rate somehow will become the providers new contracted negotiated rate. This inhibits providers from wanting to offer discounts based on availability and more. In order to make healthcare a free market and drive competition, these types of price control provisions should be prohibited at a federal level.

Stark Law, Federal Anti-kickback Statute (Federal AKS), False Claims Act

In every other industry (and indeed for selling healthcare insurance plans), it is entirely legal and indeed beneficial for society for a company to receive remuneration for connecting a buyer and seller (i.e. Expedia), such that efficient markets can be made and competition can determine consumer costs. The Stark Law, AKS, and False Claims Act together do the exact opposite, and are written so broadly as to make illegal to even "offer" to be paid, much less actually be paid, for such market-making activity. In total, these laws create a fear of felony conviction and high fines, and larger companies have added entire legal strategy teams whose responsibility is to validate the appropriateness of their payment schemes within the confines of AKS. In addition, there are 36 separate state-level AKSs that interact with the Federal AKS. Such laws directly inhibit innovation in the field, especially by small mobile health app developers, and such laws should be changed.

I propose the following amendment:

Currently, monetary or other in-kind incentives to providers are illegal. In-kind incentives should be re-defined to make clear that "controlled, two-way" communication devices for the purpose of communicating between providers and payers, so that being paid for new innovation in electronically passing ePHI and improving workflow efficiency in clinics and medical settings are expressly allowed. In addition, businesses and apps should be allowed to be paid for directing

³ <http://hipaaqportal.hhs.gov/community-library/accounts/92/925889/OCR-health-app-developer-scenarios-2-2016.pdf>

patients to lower cost, better value care. Indeed this is the whole concept of the modern risk-sharing and accountable care organization (ACO) arrangements. As long as there is no financial influence on the provider for a specific choice, it should be made clear that this is allowed, just as numerous private companies already do this at the employee level. Stroll Health, in conjunction with Cornell University and Robert Wood Johnson Foundation, are currently conducting research on this topic, and funding further studies are recommended on both the potential financial impact from this policy and on clinical pilots of this technology. If effective, I believe that making clear that market making tools are allowed and beneficial will dramatically reduce the cost of American healthcare.

Reimbursement Barriers

As CMS goes, so too does the rest of the commercial healthcare market, and establishing a unified policy on telehealth visits, reimbursement and codes for mobile health apps and devices needs to happen.

Operational Barriers

Small Business Health Benefits

Providing health care benefits is essential to attracting highly skilled software talent in extremely high demand. However, procuring healthcare for a small company is expensive, time consuming and financially inefficient. If a company provides healthcare to its employees it is entitled to a tax deduction for the expense and the employee does not pay income tax on the benefit. But small company employees would enjoy more choice and better value if they could secure their healthcare independently via a private or public exchange. Allowing the company to reimburse the employee or providing a voucher (without such payment to the employee being taxable) would greatly simplify healthcare procurement for small businesses, lower costs and improve portability and coverage for employees.

The current system creates a series of inefficient and negative financial and social consequences, which I outline below:

Negative financial impact from directly providing employee health insurance

1. Businesses pay an additional 3-7% indirectly in premiums to cover the cost of brokers
2. Businesses have to define their own healthcare package and customize benefits for their employees, which complicates the system unnecessarily and adds costs to pay the middle man, human resources staff, and for providers, payers, patients, and administrators downstream
3. Businesses and their employees are divided into smaller risk pools, thereby increasing the insurance risk and cost of insurance
4. Business pay for higher actuarial value insurance than their employees ideally would like (and in most cases, they would prefer to have the marginal healthcare dollar to spend as they choose)

Negative social impact from directly providing employee health insurance

5. Businesses tie their employees' benefits to employment at their company. If the employee leaves, they lose their insurance, thereby reducing liquidity and efficiency in the labor market.
6. Businesses limit the opportunity of plans and payers to only those that the broker or HR department decide to customize in the "best interest" of their employees

I believe that clarifying the Internal Revenue Service (IRS) tax ruling and allowing small businesses to provide employees with a Health Savings Account (HSA) compatible voucher with the same tax treatment as directly providing insurance would help mitigate these issues.

4. Healthcare App Market Overview

The mobile health technology field is incredibly diverse, consisting of the following segments:

- Consumer wearables, fitness, wellness and other bio-monitoring trackers and accompanying apps
- Consumer search, information, and ordering tools
- Telehealth/Digital therapeutics
- Medical-grade diagnostics, remote patient monitoring
- Care coordination, patient communication and payment, and patient medical record apps
- Provider workflow and communication tools
- Clinical decision support

I will discuss each category below:

Consumer wearables, fitness, wellness, and other bio-monitoring trackers with accompanying apps

(i.e. Fitbit, iHealth, myFitnessPal, MapMyRun, Pacer)

These are apps and gadgets used for a variety of cosmetic, fitness, and leisure purposes. These applications provide users with continuous access to health information and quick, easy-to-understand health metrics. However, these products typically lack clinical viability, and physicians often distrust these apps and devices due to lack of accuracy and emphasis on self-reporting. From both a regulatory and consumer threat perspective, I believe that the FDA's approach to enforcement discretion is adequate, and that consumers are fairly warned about privacy and efficacy in terms of use. It is unfortunate that without the clinical evidence of effectiveness, some employers have tied usage of such devices with incentives for healthcare

insurance rebates. My belief is that the marginal healthcare dollar can be spent in a more efficient manner.

Consumer search, information, and ordering tools
(i.e. “Uber” for healthcare apps, ZocDoc, iTriage)

These apps attempt to provide quick how-to’s, explanations and diagrams, and bookings for healthcare services, and there are two levels in this segment. The first is the general repackaging of material already found online into a user-friendly, easy-to-understand format, requires neither regulation nor federal funding. The second is a much more specific type of application that use big data, machine learning, data science, and statistical modeling to create new insight and value. Because this second segment typically has long development cycles and unpredictable returns, especially in the short term, some allocation of government funding to this category is in the nation’s best interest, as it will enable the technology to demonstrate effectiveness and subsequently become commercially viable.

Telehealth/Digital therapeutics
(i.e. Teladoc, Omada, DoctorOnDemand, HealthTap, Pingmd)

Telehealth and digital therapeutics attempt to replace a doctor or provider visit and provide guidance for follow-up steps to maintain weight and stay healthy. Overall, large self-insured employers have been especially enthusiastic about paying for this technology, which has made private funding of such technology in the capital and venture markets relatively easy and frequent. These apps appear to be reaching a maturation of the technology and product features, and there are large numbers of them. I anticipate a market consolidation, largely to the benefit of the average American consumer. Regardless, while reimbursement changes are needed and should be led by CMS, no further government funding is needed for this type of apps.

Medical diagnostics, remote patient monitoring
(i.e. Proteus Digital Health, Eko Devices, iRhythm, Vital Connect)

Monitoring and diagnostic apps and their accompanying hardware improvements propose a net benefit by improving access to care, enhancing the patient experience, and reducing the cost of care. Examples are monitoring programs that can track data such as patient heart rate, vital signs, and blood sugar levels and transmit this information securely to health professionals. Another example is technology empowered stethoscopes that can use big data and machine learning to find trends where a simple scope cannot. It is in the nation’s best interest to support such apps with federal research dollars, and more of these diagnostic tools could rapidly come to fruition with a relatively small investment.

Care coordination, patient communication, and patient medical record apps
(i.e. MyChart, The Patient Portal, eClinicalWorks Patient Portal, CareMessage, CareNotify)

An incredibly important part of the healthcare app ecosystem, these applications prevent unnecessary doctor visits and duplicate tests, and strengthen patient compliance to physician recommendations and medications. Technologically, they are not particularly complex, but provider-specific barriers and the diversity of the health IT landscape hinder wider adoption of such applications. A number of the proposed policy changes presented earlier in my testimony might help to remove many of these technological barriers. Due to its low risk and complexity I do not believe additional federal funding is necessary to speed adoption or development of this technology.

Provider workflow and communication tools

(i.e. TigerText, Doximity, Stroll Health, DrChrono, DocBookMD)

This is an incredibly broad category, including EMRs, peer-to-peer texting apps, and more. These applications allow for quick communication between healthcare team members, improving clinic efficiency and flow. In general, I believe sufficient federal funds have been spent on EMRs through the Health Information Technology for Economic and Clinical Health (HITECH) Act. However, while that act has substantially accelerated adoption of such technology, the lack of adequate standardization has interfered with interoperability. Many states have taken it on themselves to create their own HIEs, and it is important that such HIEs should be funded and administered at the federal level, or new regulation and policy should be created to mandate adoption of interoperable standards.

Clinical decision support

(i.e. UpToDate, Medscape, Medcalc, Epocrates, Skyscape)

Clinical decision support apps help physicians make proper diagnosis, perform appropriate tests, and prevent errors. While there are many clinical apps for specific specialties and drugs, almost all focus on medical outcomes but fail to engage patients, improve their experience, or reduce the cost of their care. More apps should focus on value and the total cost of care, and because such projects typically require long development times and clinical trials, government support and funding should be available to speed commercial release and to improve outcomes.

Conclusion

Medical mobile apps like Stroll have the promise to reduce the cost of care, improve outcomes, and enhance the patient experience. While many barriers to adoption and commercial success exist, Congress can adopt legislation that will improve access to data, reduce burdensome regulation, and provide funding to accelerate development and adoption of these beneficial new technologies. Thank you for the opportunity to testify, and I look forward to your questions.

Witness Biography

Jordan Epstein

Jordan Epstein is the founder and CEO of Stroll Health, which makes software applications that help doctors and their patients find and follow through with lower cost, best value health care. Prior to Stroll, he worked on the client services team of Merced Systems, a business intelligence startup. After their acquisition by NICE Systems (NASDAQ: NICE), he led development of the small and medium-sized business (SMB) performance management product line, which today is used by hundreds of thousands of people on five continents. His clients have included such Fortune 500 companies as United Healthcare, Kaiser, Delta Airlines, and Chase. He holds a B.A. from Carleton College.