Prepared statement of:

Matthew Patterson, MD

President, AirStrip

AirStrip as pioneer - the promise and challenge of mobile healthcare application innovation

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Summary

Chairman Burgess, Ranking Member Schakowsky, and members of the Subcommittee, thank you for the opportunity to share this testimony and appear before you to discuss the promise of mobile health application innovation and what challenges its realization. My goals today are threefold:

1. Share AirStrip's story as an illustration of how mobile health applications can disrupt and improve healthcare delivery,
2. Describe the trade, policy, and regulatory challenges faced by mobile health application developers, and
3. Suggest ways our government can foster an environment for mobile health application innovators to create solutions that will improve healthcare delivery and outcomes

The landscape for mobile health applications

The challenges we face to deliver high quality, affordable, and accessible healthcare are well documented so I will provide only brief context before sharing AirStrip's story. Health systems and physicians face complex reimbursement models and payments increasingly aligned to value as opposed to fee for service. After waves of traditional cost cutting to preserve financial margins, providers realize that remaining gains can only be achieved through care transformation – shifting quality care to lower cost settings using novel human and technological resources. Connected health technologies like AirStrip demonstrate that innovative solutions can reduce costs and improve care quality and engagement. Healthcare must and will look significantly different going forward.

AirStrip engages with stakeholders across medical and technology communities to improve healthcare. We participate in ACT | The App Association's Connected Health Initiative (CHI),[1] a key effort to collaborate with the connected health ecosystem to identify outdated health regulations, incentivize the use of advanced technological solutions, and ensure patients and consumers can see improvement in their health. Recently, the CHI provided comments to the Center for Medicare and Medicaid Services (CMS) to inform the implementation of the Medicare Access and CHIP Reauthorization Act of 2015 by establishing the Merit-based

[1] *See* http://connectedhi.com.

Incentive Payment System (MIPS) for MIPS-eligible clinicians or groups under the Physician Fee Schedule as well as incentives for participation in certain alternative payment models (APMs).[2]

As a physician serving in the U.S. Navy, I got my first taste of digital and mobile technology in healthcare. I served with the submarine community at Naval Submarine Base New London, the SEAL community at Naval Special Warfare Center, and the broader Navy community at Naval Medical Center San Diego. To provide consultation to remote settings we relied on digital technology ranging from simple email communication to the use of complex body sensors and scopes to transmit high-resolution diagnostic video images. We practiced what is commonly referred to as "telehealth" – a term that is often associated with real-time videoconferencing interaction between physicians and patients. In contrast, mobile health applications or "apps" are frequently discussed in the realm of mobile health or "mHealth." This term often evokes imagery of consumer oriented wearable devices or smart phone applications used to promote well-being independent of healthcare provider supervision.

For this testimony and discussion on mobile health applications, terms like "telehealth" or "mHealth" or "apps" reveal imperfections because innovation moves faster than classification can keep up. This is particularly relevant in the challenges that innovators face in the policy and regulatory landscape. The AirStrip story will illustrate this clearly, highlighting one of the most important things that mobile health applications can deliver: an optimal

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[2] *See* Comments of the Connected Health Initiative regarding CMS' Medicare Program; Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive Under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models (CMS-5517-P), filed June 27, 2016, available at https://www.regulations.gov/document?D=CMS-2016-0060-3058.

workflow for busy, information overloaded clinicians doing the best they can to care for others. Clinicians and consumers desire flexibility in how they interact with each other and with data. Sometimes it is best for real-time communication like traditional telehealth, but the preferred mode of communication is often "asynchronous" interactions through mobile applications, just like people prefer text messaging rather than phone calls in many cases.

Workflow optimization is the principal promise of mobile health applications, and it requires true interoperability and regulatory accommodation to succeed. What is workflow? It is easiest to describe as the "way" one interacts with information on a digital device to arrive at a conclusion, to make decisions, and to take action. It is the buttons pushed, the swipes of the screen, and the text entered. As consumers we take for granted the vast array of elegant, simple to use applications that allow us to shop, bank, and be entertained via intuitive workflows. In healthcare, workflows are rarely described in positive terms and are a frequent source of frustration for doctors, nurses, and patients.[3] Mobile health application innovation has the ability to address this and thereby improve healthcare delivery and outcomes, but only with improvements in the interoperability and regulatory landscape.

[3] Recent research has explored why certain technologies or systems, such as electronic health record products and services, intended to make providing healthcare easier instead make patient encounters more cumbersome and inefficient. See, *e.g.*, Holman *et al*, *The myth of standardized workflow in primary care*, Journal of the American Medical Informatics Association, DOI: http://dx.doi.org/10.1093/jamia/ocv107 (published Sept 2, 2015).

The AirStrip story – disrupting and improving healthcare delivery

AirStrip, which started more than 10 years ago with a chance meeting between a software engineer and an obstetrician in a church parking lot in San Antonio, TX, is today a recognized leader in mobile healthcare innovation. AirStrip software is deployed at hundreds of U.S. hospitals and used by thousands of clinicians for millions of patient encounters annually. The company was the first to create mobile health application software cleared by the FDA as a Class II medical device. AirStrip also pioneered advanced security in mobile health such as multi-factor authentication, at one point even achieving Department of Defense Information Assurance Certification Accreditation Process (DIACAP) certification - the highest level of certification for mobile medical device solutions we could identify at the time.

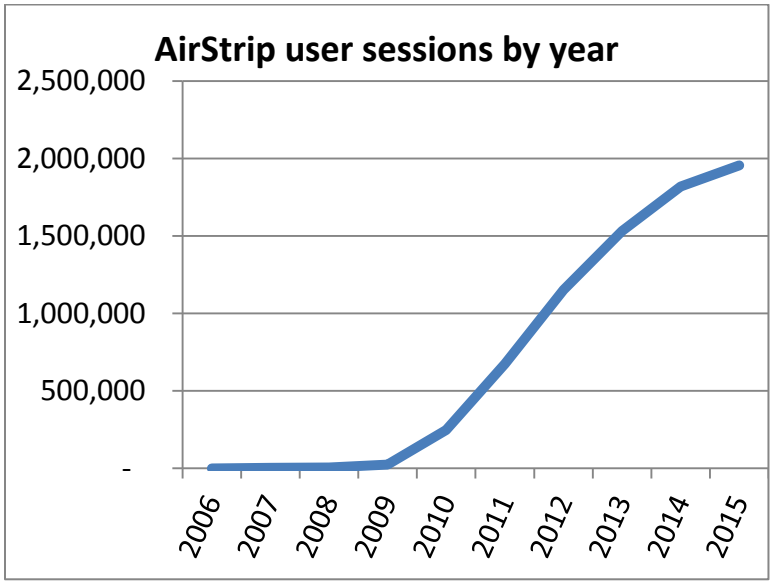

Figure 1 – AirStrip utilization

From the beginning, the core innovation and disruption that AirStrip brought to the market was to be agnostic when connecting to clinical data sources and when displaying information on disparate devices. In other words, AirStrip provided a way that a clinician could use any smart device they wanted to connect to any vendor system anytime, anywhere. While today the concepts of mobility and interoperability are touted by health IT solutions, this was highly disruptive at the time and essentially created mobile application care delivery models.

AirStrip began with solutions for obstetric care. Even before smartphones, AirStrip allowed doctors who were away from the hospital to view waveforms of fetal heart rate and maternal contractions on their portable devices. Prior to AirStrip, nurses had to describe over the phone highly visual and nuanced waveform data that evolved over long periods of time. With AirStrip, it was as if physicians and nurses were standing side by side at the bedside, no matter where the physician was. In Figure 2, you see an example of a mobile application providing both near real time as well as asynchronous capabilities that defies traditional classification of telehealth or remote monitoring. In a practical sense, it allowed physicians to expedite decisions and attend to life-threatening events during labor in ways that were previously impossible. It was recognized as clearly benefiting patient outcomes for mothers and newborns, safety, and clinician efficiency. This obvious use case of technology is essentially becoming the standard of care in obstetrics. AirStrip software is used on over 20% of annual births in the United States and has been used during over 4 million births to date.

Figure 2 - Screenshot of AirStrip obstetrics functionality

Success in obstetrics led AirStrip to develop cardiovascular solutions to display static and dynamic electrocardiogram (EKG) and other monitoring waveforms. This allowed AirStrip to address prevalent and costly conditions such as myocardial infarction (heart attack), congestive heart failure (CHF), and dysrhythmias. For example, AirStrip pioneered the ability to send a digital EKG directly from an ambulance to a cardiologist's smart device before the patient even arrived to the hospital. This allowed for the activation of the cath lab and an expedited "door to balloon time" – the critical metric of how quickly hospitals get a heart attack patient from arrival to the deployment of an angioplasty balloon in their obstructed artery. Though national benchmarks of 90 minutes or less are standard of care, public accounts of the use of AirStrip reported times as low as 18 minutes. There is overwhelming evidence that shorter times lead to less cardiac damage, greater survival, and lower costs.

Figure 3 - Screenshot of AirStrip patient monitoring functionality

Given the success of waveform related solutions and feedback from clients, in 2014 AirStrip released AirStrip ONE. AirStrip ONE is a mobile interoperability software platform that enables care coordination and serves as a catalyst for health system innovation. Plainly, AirStrip ONE allows a clinician to log in to one application and view relevant information on their patient from essentially any clinical data source anytime, anywhere – no matter where they are and no matter where their patient is. Though seemingly an obvious solution for healthcare, it is difficult to explain the massive disruption this solution represented when introduced. Instead of creating a mobile app exclusively linked to a specific branded data source like a monitor or an electronic medical record, AirStrip ONE represented the first solution to focus exclusively on creating the optimal workflow for clinicians. No matter what systems were capturing data on patients (FDA regulated or not), and no matter what device a clinician wanted to use, we would bring everything to their fingertips in one place in near real time.

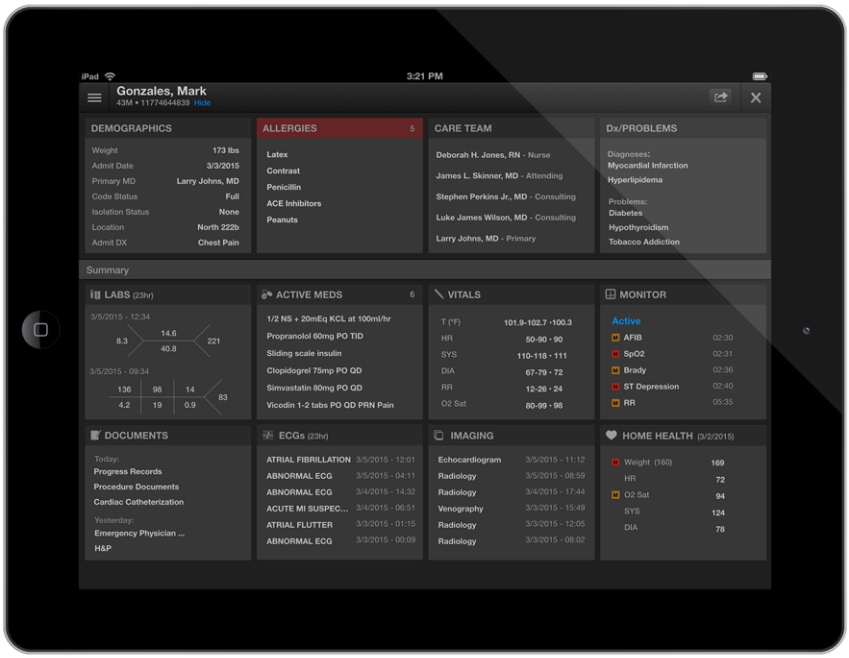

Figure 4 - Screenshot of AirStrip ONE

While the potential uses of AirStrip now span all clinical domains, what is most exciting is how our software can enable the necessary shift of healthcare delivery to lower acuity and increasingly out of hospital settings. Doctors are managing large populations of individuals with significant chronic disease burdens. They are being tasked with producing better outcomes at lower costs and this is only possible with the appropriate tools.

For example, consider a doctor called after hours about a Medicare patient who was recently discharged from a hospital after a CHF exacerbation, is feeling short of breath, and is wondering what to do. Whether in an accountable care organization (ACO) or another “at-risk” financial model or not, an avoidable readmission for this patient would be both medically and financially unacceptable in today’s climate. If this doctor is being asked to do whatever they can

to prevent an avoidable readmission, then this doctor deserves to have any data point they need at their fingertips instantaneously. He or she should be able to see medical record data from disparate sources (e.g. different systems deployed for hospitals vs. office) or remote monitoring data from body sensors deployed in the patient's home – all displayed in a simple, intuitive workflow that would lead to the best decision possible. Not only does the doctor deserve this kind of access, but the patient, in other words all of us, expects his or her doctor to have immediate access to all of our relevant medical information to make the most informed decision possible. As obvious and necessary as a solution like this may sound given the economic realities of healthcare in the United States, this simply did not exist in the world we released AirStrip ONE to. The challenges we encountered revealed many of the reasons why.

Challenges to healthcare mobile application innovation and deployment

Though the previous section was focused specifically on AirStrip's story, the challenges presented here are intentionally not unique to AirStrip and resonate among fellow innovators in mobile health application development. While certainly not exhaustive, the focus here is on two themes highly relevant to this subcommittee. The first involves the intersection of health information technology (HIT) policy and trade practice realities. The second relates to the intersection of Food and Drug Administration (FDA) regulation and technology innovation.

Initially, I'd like to note that a consistently growing body of evidence demonstrates that the wide array of connected health technologies available today – whether called "telehealth,"

"mHealth," "store and forward," "remote patient monitoring," or other similar terms – improves patient care, reduces hospitalizations, helps avoid complications, and improves patient engagement, particularly for the chronically ill.[4] Importantly, a literature review from the Department of Health and Human Services' Agency for Health Research Quality recently validated this.[5] These tools, ranging from wireless health products, mobile medical device data systems, telehealth screening and preventive services, converged medical devices, and cloud-based patient portals (to name a few) are revolutionizing the medical care industry by allowing the incorporation of patient-generated health data (PGHD) into the continuum of care. To illustrate the effectiveness of these diverse solutions, we have appended to this comment a non-exclusive list of studies we strongly urge CMS to review.

Interoperability is frequently mentioned, poorly defined, poorly understood, and yet remains a principal obstacle to mobile health application development. What is needed most is an open landscape for systems to talk to each other in a manner that gives clinicians and consumers the information they need in near real time so they can make the right decisions. In technical terms, what are needed are open, bidirectional, complete, and affordable application programming interfaces (APIs). Though these solutions are available today and tremendous efforts have been taken to bring about adoption of standards that address the interoperability

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[4] See Hindricks, et al., The Lancet, Volume 384, Issue 9943, Pages 583 - 590, 16 August 2014 doi:10.1016/S0140-6736(14)61176-4. See also U.S. Agency for Healthcare Research and Quality (AHRQ) Service Delivery Innovation Profile, Care Coordinators Remotely Monitor Chronically Ill Veterans via Messaging Device, Leading to Lower Inpatient Utilization and Costs (last updated Feb. 6, 2013), available at http://www.innovations.ahrq.gov/content.aspx?id=3006.

[5] Agency for Healthcare Research and Quality, *Technical Brief Number 26, Telehealth: Mapping the Evidence for Patient Outcomes From Systematic Reviews*, AHRQ Publication No. 16-EHC034-EF (June 2016.

challenge, serious issues remain. The sad truth is that the technology already exists to address this challenge. Unfortunately, financial distortions were introduced by otherwise well-intentioned policies that created disincentives for HIT firms to allow for the free sharing of data.

The Health Information Technology for Economic and Clinical Health (HITECH) Act enacted in 2009 created significant incentives for the rapid deployment and "meaningful use" of electronic health record (EHR) solutions. The initial goals of meaningful use were well intentioned (Stage 1 – data aggregation & data access; Stage 2 – healthcare information exchange and care coordination; and Stage 3 – outcomes improvement). While Stage 3 introduced measures for incorporating patient-generated health data into the EHR system, the interoperability aspects of the first stage were not enforced as much as needed to achieve later outcomes improvement. Instead, the effort was directed to the implementation of EHRs for data entry, which created silos around few vendors who subsequently protected their market position. Then, the consolidation and collaboration of healthcare providers that resulted from the Affordable Care Act (ACA) exposed even further the necessity and lack of interoperability. Health systems were faced with government and commercial reimbursement models that demanded interoperability but had no choice to proceed down a roll out of data system silos and vendors reluctant to make data sharing easy.

Data blocking is real. It can take political, financial, and technical forms. Politically, it happens when large HIT firms put pressure on health system clients to shun innovative firms or else risk the deployment timeline of critical systems such as HITECH Act meaningful use

incentivized functionality. Financially it occurs when HIT firms demand exorbitant fees to allow data to be shared with third party workflow solutions. Technically it occurs when HIT firms deliberately turn off functionality that would allow bidirectional sharing of data because it threatens their underlying business model. I understand that this Committee has been looking into this issue, but I would re-iterate that time is of the essence. Enabling true interoperability represents the single most important thing that can be addressed to unleash the power of innovation for mobile health applications.

As we move from the "essential" to the merely urgent, we see physicians and hospital systems confronting uncertainty on other fronts as well. For example, the Health Insurance Portability and Accountability Act (HIPAA) privacy and security rules provide a set of minimum standards for protecting electronic protected health information that a covered entity and business associate create, receive, maintain, or transmit.[6] The concerns addressed by these laws are taken seriously by AirStrip, and we implemented processes and measures to ensure we meet the letter and spirit of the law through such means as strong encryption. However, some of the relevant HIPAA guidance applicable to mobile apps has not been updated since before the introduction of the iPhone. This persistent lack of clarity around HIPAA applicability in a mobile environment (for example, the use of texting or storing data in the cloud) prevents many patients from benefiting from these services. As a result, clear guidance does not exist to explain how physicians and patients can text or email each other appropriately. Similar to

[6] 45 CFR Part 160; 45 CFR Part 164 Subparts A and C.

interoperability, this is a problem more with policy than technology – if hospitals aren't sure what the rules are, they will not use technology no matter how well it works.

There is some hope on HIPAA: through efforts such as ACT | The App Association's Connected Health Initiative, we have worked with Congress to attain a direct public commitment from Department of Health and Human Services (HHS) Secretary Burwell to provide much-needed clarity.[7] But progress has been slow, and even positive efforts are stymied by an HHS website that is very difficult to navigate.

AirStrip has and always will be a strong proponent of thoughtful FDA regulation on mobile healthcare applications and appreciates ongoing dialogue on how best to evolve the regulatory landscape to support innovation. We maintain that all mobile software applications displaying near real time medical device and body sensor data and waveforms need careful oversight – even for software only solutions. Though our path to FDA clearance was long it resulted in a better and more differentiated solution for the market. In addition, any solution that aggregates data or analytics powered insights that directly guide a decision-making clinician such as a physician to come to a conclusion on what is best for a patient (i.e. clinical decision support) requires FDA oversight. The FDA's current risk-based framework, as outlined in the September 2013 guidance, appears to be a functionally sound approach, though there are continuing challenges with an FDA trying to modernize its approach.

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[7] Letter from ACT | The App Association, et al., to Reps. Tom Marino and Peter DeFazio, U.S. House of Representatives (September 15, 2014).

The challenges on the FDA regulatory front emerge from the predictable predicament of innovation outpacing regulation. Specifically, there is a risk that innovative solutions not fitting an existing FDA classification or not matching the functionality of the predicate device(s) that must be identified when submitting for clearance, get pushed by the FDA toward a pre-existing best-fit classification. This can result in the FDA indirectly determining a technology firm's development roadmap instead of what should be the opposite. For example, consider a situation where a firm develops the ability to detect important changes in a patient's condition being monitored at home through a body sensor. If the FDA can only best classify this as an alarm solution, it may apply requirements that are only relevant for hospital situations because that is the closest best-fit classification it has to consider the new solution. As a result, the firm applying for clearance may be faced with a hopeless path of engineering "hospital-like" features to its solution even though everything in the world of healthcare is pushing that firm to create something that can solve problems outside of the hospital.

Suggestions for fostering an environment for mobile health application innovation

Given the pervasive nature of mobile technology broadly, hopefully similar approaches will flourish in healthcare. I humbly offer suggestions to foster this path.

1. **Enforce interoperability** – HHS and more specifically the Office of the National Coordinator (ONC) for Health Information Technology have an opportunity to focus on

and enforce meaningful interoperability as opposed to pushing a future standards-based agenda that will not meet the needs of the market today. Specifically, there is messaging that the third stage of meaningful use (requiring portability of data to consumer facing applications) will address interoperability challenges but this is not completely thought through. Creating consumer-facing applications that allow patients to assimilate all of their healthcare data will not be enough to solve the workflow challenges of those who care for them. When a patient shows up to an emergency department as part of an ACO and all incentives are aligned on preventing an avoidable admission of that patient to the hospital, the emergency room doctor needs a solution that works for them. Consumer facing applications will absolutely fall flat in this setting. As a minimal initial step, HHS should promote true interoperability via open, affordable, complete, bidirectional application programming interfaces by withholding incentives and innovation grant funding for any applicants who are not using vendors that comply.

2. **Create a "hot-line" between innovators, health systems, and the FDA** – The greatest benefit of having a long history of clearance with the FDA when it comes to mobile health applications is the opportunity for dialogue. Innovation will always outpace classification and regulation. Therefore, real-time dialogue is essential to expedite classification and clearance. As stated previously, careful regulation is essential for mobile health applications that are in the realm of near real time monitoring and clinical decision support. That said, innovation by definition will blur all lines and therefore expanded resources are needed at the FDA for thoughtful dialogue, problem solving,

and co-navigation to clearance. The FDA should be viewed as an innovation and safety partner and not an obstacle.

3. **Help clarify the markets of "consumer driven" and "health system driven" mobile health applications** – There is great confusion about what mobile health means. To some, it involves consumer oriented body sensors and applications focused on fitness and wellness in the absence of clinician supervision. To others, it involves FDA regulated body sensors and applications involved in the remote delivery of healthcare. The former market is important and will be consumer directed and paid for. This forms the leaves of the health care delivery tree. The latter market is equally important and will be directed and paid for by providers, payers, and joint collaboration risk-bearing entities like ACOs. This is the trunk of the tree. Different policy and regulatory standards are likely appropriate and should be clarified broadly for those innovating in the marketplace. As a threshold issue for subsidized medicine, CMS cannot continue to rely on Medicare's over 15-year-old definitional restraints on "telehealth" in 42 CFR 410.78 to serve as a definition of telehealth. To shift to a value-driven approach, the Medicare system must leverage the wide array of advanced connected health technology solutions available today, as well as future innovations we cannot predict, by evolving its telehealth definition to one that takes a technologically-neutral approach to the use of connected health and provides the flexibility for eligible practitioners to appropriately utilize the range of these solutions, lowering costs to Medicare while vastly improving patient care.

4. **Incentivize and fund efforts to prove value** – The traditional method of randomized controlled clinical trials, or the FDA investigational device process, to prove efficacy are extremely difficult to apply to the fast paced world of mobile health application innovation. Innovators would benefit from dialogue with government and health system partners on how best to demonstrate value so that appropriate, fast paced initiatives can be funded and publicized for others to learn about clinical and operational benefits of mobile health application technology.

5. **Feed the pipeline of software developers** – Any efforts to promote the interest and education of future software developers in the realm of healthcare technology would be widely welcome.

In conclusion, mobile health technologies like those that Airstrip create incredible benefits to the American healthcare system, but their full potential can not be met without a careful and coordinated effort between Congress, federal agencies, and the industry as a whole. Without meaningful action to address important issues like interoperability, market clarity, agency efficiency, and the talent gap, we risk the quality of care physicians can provide patients. I thank you again for the opportunity to present testimony about Airstrip and our role in the mobile health ecosystem. I look forward to answering your questions, as well as continuing this important dialogue and offer my support to help advance measures that empower mobile health.