
**Testimony of Jim Bialick**
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**To the Energy and Commerce Committee**
**Subcommittee on Health**
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Chairman Pitts and Raking Member Pallone, Members of the Subcommittee, thank you for the opportunity to testify on this very important issue. My name is Jim Bialick and I am the Executive Director and co-founder of the Newborn Coalition. The Newborn Coalition is an all-volunteer organization that came together to promote the development and use of technology in newborn and infant health.

**Why We Started**

The catalyst for our beginning was the birth of a baby named Eve in Minnesota who, at 40 hours old, was diagnosed with a critical congenital heart defect. Congenital heart defects are the most common birth defect in the U.S., affecting nearly 1 in 100 births. While a simple screening tool, pulse oximetry, exists to identify these conditions, there still is no national requirement for routine screening.

Had it not been for an attentive nurse that went the extra mile, Eve would have been sent home missing part of her heart. After Eve's recovery from two open-heart surgeries, her mother – our co-founder– started a crusade to prod law makers, regulators and health plans to adopt technology to advance newborn screening for heart defects. We want to make sure that babies like Eve are never sent home without first being screened.

**Screening Newborns for Heart Defects**

Our ongoing work includes the nationwide implementation of heart disease screening through the pursuit of state legislation. To date, we have aided in the drafting of legislation in 23 states and the enactment of 9 laws. The first was in New Jersey where a baby with a hypoplastic left heart syndrome was identified before discharge *on the very first day screening was required by law.* The most recent law was enacted in California last year, the state where my wife and I grew up and where our parents want us to return and have newborns of our own.

We estimate that since our efforts began, the number of babies screened for heart defects in the U.S. has increased nearly 4,500%. We are very proud of these numbers because we can be confident that more little Americans will go on to live happy and healthy lives. It also gives us hope that healthy babies remain a bipartisan issue.

**Technology Helps Babies, Parents, Health Care**

As our efforts progress nationwide, we have learned that screening babies for heart defects is not where our jobs end, but rather where they begin. It is not enough just to screen, but we also have a responsibility to accommodate the short term and long-term follow-up needs of those diagnosed by the screening.

There are often very different clinical paths families of a baby diagnosed with a heart defect may take: sometimes this includes at-home monitoring, follow-up imaging to diagnose the defect, or maybe it means emergency surgery to correct an imperfect heart that is trying to sustain an otherwise healthy little baby.

It is important to remember that of the more than 4 million babies born in the US every year, not all of them are born in advanced cardiac surgery centers. They may have been to several hospitals, been seen by more that a few doctors, and been given a number of medications, which in today's less-than-interoperable healthcare system, means mom and dad will likely be responsible for managing and reconciling most of this information on what is likely the best and worst day of their lives.

So what do parent's do? They rely on what they know and use every day: the same smartphone or tablet that they use to manage all of their other important information. And why not? There are more than 97,000 medical applications available in the iOS app store alone.

Because the clinical journey will be different for every baby, we often hear from our network of parent advocates that they are using one or more mobile apps to stay on top of their baby's health information in order to keep their baby's health at the center of his or her ongoing care.

There are apps available that allow parents to access online services such as personal health records to document procedures their baby has undergone and drugs that their baby has been given. In other cases, newborns will be released from the hospital and monitored using a pulse oximeter from home. These babies are special because they have heart defects but they are still, just babies and their parents, are still exhausted. Many families have come to rely on mobile applications that allow them to capture readings from home monitoring devices so they may easily share them with a provider. This means less time having to focus on being a nurse and more time available to be a parent.

**Technology Is Transforming Care and Culture**

Be it patients, families, or providers, broad-based demand for information technology in healthcare has fostered a creative and innovative market that is has evolved to address the many needs of a diverse consumer population. With this evolution in engineering has come an equal progression in our culture. We are not only demanding more from our applications and devices, but also that the information we manage be platform agnostic and work on our phones, tablets, and PCs identically.

This demand is coming from patients and families as well as providers. A full 62 percent of providers have begun using tablets to deliver care; that number is up 27 percent from only a year ago. Families are using these tools, why shouldn't providers use the of mHealth apps designed specifically for them? The families that we work with want their devices to connect directly to what their doctor is using so that they can know the instant something changes with their baby's health.

As mobile technologies advance, clinicians and entrepreneurs have developed applications to address increasingly complex healthcare and data management issues. While the availability of these technologies has created a revolution in how we interact with our data and engage in our health, it has also created legitimate safety concerns that must be addressed.

**Mobile Apps Are Not Medical Devices**

Most medical apps are not medical devices as most understand that term and regulating mobile apps as such does not make sense. Mobile apps are developed and sold in a dynamic marketplace: estimates indicate that the number of smartphone consumers using medical apps will grow to 500 million by 2015.

That's why we were so surprised when the FDA issued a draft guidance to regulate mHealth apps as medical devices in 2011. Even then it seemed like the definition the FDA was using for a "mobile medical app" was outdated. Cloud computing has enabled us to access incredibly innovative and powerful software with the click of a mouse or the tap of a touchscreen. Mobile apps can no longer be considered discreet pieces of software that reside on a specific device; the cloud has allowed us to access a myriad of programs through a single app: our Internet browser.

The traditional process for approving and regulating health technologies is not nimble enough to appropriately scale or keep pace with its unprecedented expansion. While the Food and Drug Administration (FDA) has a legitimate role to play in maintaining patient safety for the highest risk products, it is readily apparent that Congress can and should adopt a more flexible model for products that simply manage information. In addition, sequestration is a political reality that has certainly impacted FDA's in-house expertise available to manage a broad range of products. A concern shared by many is whether FDA possesses the manpower and expertise, as well as whether the regulatory science has been fully developed to take on regulation of the mobile medical app market. Many shared these concerns even before sequestration took effect.

Furthermore, the existing FDA structure for regulating medical devices was conceived in an era where personal computing was in its infancy and adoption of consumer technologies in healthcare was nearly non-existent. The device approval process (510(k)) was implemented when our ability to share data was limited to what we could fit on a 5 ¼ inch floppy disk. Why then, do we believe that the approval process will be flexible enough to accommodate the future of multi-function technology and a software market that we literally cannot imagine? The Institute of Medicine put it best in its 2012 report, Health IT and Patient Safety: Building Safer Systems for Better Care: "The current FDA framework is oriented toward conventional, out-of-the-box, turnkey devices."

Applications, and the platforms that support them, have the ability to integrate and interoperate with any device that will allow it. At a point we must assume that increased connectivity between networks will make mobile device data —and what we consider as more traditional data—indistinguishable. Consumer demand for integrated technology solutions will drive the market to a wholly interoperable system that can be accessed at any time, anywhere, and by any device. We are fooling ourselves if we think this revolution will not include health information.

App developers are concerned—and absent change, should continue to be concerned—that their products will be subject to new or additional regulation by a system designed for products that are not information or health management systems. Congress should be concerned that the creativity and innovation that is helping patients and parents may evaporate under well-intentioned, but ill-conceived regulations.

**Towards a New Framework: Patient Safety and Innovation**

As a result, we need to be thinking about regulating technology differently. What we need is a new framework for evaluating health technologies that can scale to effectively regulate what we are using today, and anticipate technologies yet to be conceived.

A new framework that accounts for data sharing, innovation and patient safety is important to help ensure patients have access to safe and helpful technologies. Patient safety and innovation are not mutually exclusive; they are complementary concepts in a system that clearly lays out the rules of the road. Congress should reevaluate the current process, including FDA's draft guidance on mobile applications, and pass legislation to promote safety and advance innovation.

The Newborn Coalition believes such a system should include the following principles:

1. *Regulations should evaluate technologies and their functionality as designed.* To promote competition and job creation, manufacturers and end-users (consumers and healthcare providers) need clarity about the rules and requirements of the regulatory process. Regulators and end users need guarantees that a product will function as designed. We believe the approach to regulating health information systems must be scientific and based on testable consensus-based standards.

2. *Regulatory structures should evaluate technology based on risk and according to standards.* Products and their level of regulation should be categorized by risk. Risk is determined by the potential for variability in the health information system's operation or a system's ability to function *ad infinitum*: meaning that it is able to generate a response within an expected range regardless of input. FDA should evaluate the highest risk products. Private certifiers with expertise in software design and testing and contracted to the federal government, should evaluate lower risk products.

3. *Standards should incentivize safer products through market signals.* Software and devices developed in accordance with consensus-based standards are more predictable and therefore safer. We suggest creating a process to standardize the assessment of risk and create incentives for developers to create products that conform to standards.

4. *Products should be evaluated by those with the best expertise and experience.* Regulatory bottlenecks can be addressed by implementing a process similar to the Office of the National Coordinator's (ONC) approach in certifying Electronic Health Record (EHR) systems and EHR modules for use in the Meaningful Use Program through accredited industry certifiers. Congress might authorize private certifiers to affirm mobile apps do what they say they can do. In light of the significant regulatory science demands entailed in certifying an array of technologies, ONC, in its Permanent Certification Program, created a process for Standards Development Organizations (SDOs) and private industry, to accredit certifiers for the program. Such an accreditation process will help ensure credible, unbiased certifiers for mobile apps.

It is important to note, the FDA has an important role to play in this regulatory framework, but

that role should be reevaluated based on what is best for patients, parents, and providers. We must be thinking about how this consolidated information network will interact with medical devices that are currently FDA regulated. If consumer technologies are all sharing data across a common network, including with medical devices, then do all technologies on the network become accessories to those regulated medical devices? Will they need to be regulated themselves?

The old adage rings true: you are only as strong as your weakest link. In the era of connected health, the biggest danger to patient safety is being unable to determine where the weak link is. To combat this threat, we must change our thinking from categorically regulating technologies that *may* be used in health care, to evaluating them based on the risk they have of not functioning as designed.

To move away from regulation by categorization we must focus on how these applications have been engineered. Do they comply with a known standard for a given functionality? Is there a way to test that a technology will function as designed? If the answer to these questions is yes, than the software or device is more predictable and therefore poses lower-risk to the end-user.

I know that the concept of a new regulatory framework designed to encourage innovation in the marketplace is daunting to some, but another question we must ask ourselves is: will using a process that was conceived in a different era that is already overburdened by backlog going to create more certainty or will it raise more questions?

**Regulatory Policy Has a Real Impact on Patients**

I cringe when I hear from patient organizations that are dedicating a significant amount of their budget to developing a mobile medical app for their community because I know that there is a potential that their product is going to have to go through a process that is going to cost them a great deal of money that they don't have, rendering their initial investment worthless.

I worry when I hear from Medicaid providers that are telling their patients to engage in their health through free apps. If apps are medical devices, are they then subject to the 2.3 percent medical device tax? If so, will those apps continue to be free?

And I was disheartened when my wife, who is now four months pregnant, asked me which mobile medical app she should use to track her pregnancy. My gut reaction was to say: the one with the fewest, least-complex features, because I wanted to make sure that she didn't lose all of the data that she would enter throughout the pregnancy in the event that the app was pulled off of the market if FDA advanced their final regulation. I was also concerned the manufacturer might depreciate certain functionalities related to the app to avoid potential regulation.

This feels like the opposite of certainty to me. It is definitely not pro-patient.

This Committee has had the foresight to hold this hearing because collectively you recognize that mobile apps have the capacity to transform how patients, families, and providers engage in the delivery of health care. Congress has a tremendous opportunity to intervene, here and now

before this vibrant and robust market is thrust into an ill equipped regulatory process. Reform of this magnitude will not be without some controversy and growing pains, but it is far better to address this issue now then to wait for traditional approaches to fail. Inaction is something we simply cannot afford.

Thank you again for this opportunity to testify. I look forward to working with you on this important issue and I am happy to answer any questions.