Testimony of Jim Bialick
Co-Founder and Executive Director, Newborn Coalition

To the Energy and Commerce Committee
Subcommittee on Health

Examining Federal Regulation of Mobile Medical Apps and Other Health Software

November 19, 2013

Chairman Pitts, Ranking Member Pallone, and Members of the Subcommittee,

Thank you for the opportunity to testify today on the very important issue of regulation of mobile medical apps and other health software. 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 works domestically and internationally to promote the development and use of safe and effective technologies for newborns.

Current Landscape

This hearing is very timely and this issue directly impacts healthy babies and those with special needs. There have been a number of events over the last few months, with others forthcoming that will help determine how health technologies are regulated:

- In early September, the Food and Drug Administration Safety and Innovation Act (FDASIA) Working Group released its final recommendations to the Office of the National Coordinator for Health Information Technology's (ONC) Policy committee on the strengths and weaknesses of the current regulatory process for health technologies. The Workgroup indicated there are issues "broken in law" that only Congress can fix;

- In late September, the Food and Drug Administration (FDA) finalized its Guidance of Industry and Agency Staff outlining how it will use its enforcement discretion in the regulation of Mobile Medical Applications (MMA);

- In October, six members of this Committee: Vice Chairman Blackburn alongside Representatives Green, Gingrey, DeGette, Walden, and Butterfield introduced H.R. 3303 – the Sensible Oversight for Technology which Advances Regulatory Efficiency (SOFTWARE) Act of 2013, a bipartisan bill addressing the changing nature of medical technology and how it should be regulated; and,

- By January 2014, the HHS must release a report containing a strategy and recommendations on a risk-based regulatory framework pertaining to health IT, including mobile applications, which promotes innovation, protects patient safety, and avoids regulatory duplication.

These actions represent efforts by both Congress and the Administration to address how the changing health technology market should be regulated. With so much activity on this issue, it is fitting and appropriate for Congress to take a deeper look into the many complexities of our regulatory system, solicit stakeholder input, identify the limits of what can be changed administratively, and determine where legislation is necessary.

Impact on Newborns

Newborns are an inherently high-risk population. They are difficult to diagnose and to treat, their bodies are very sensitive, and it is often difficult to quantitate how much a baby has developed at the time of birth.

For these reasons medical devices with indications for newborn populations are appropriately subject to more regulatory scrutiny and post-market evaluation, which has led to a relatively small market for newborn-specific devices.

In addition, the high costs associated with pre-market regulation of newborn-specific products has caused a number of medical device manufacturers to shy away from designing products specifically for newborns and to instead bring similar products to market with adult indications. Newborns are not little adults, but, facing limited treatment options, doctors often use the smallest available version of an adult device on babies. In this sense, newborns are underserved by our healthcare system. While we argue that more should be done to incentivize the development of newborn-specific devices, we also believe that we should promote the innovative analysis and use of all device data to make it more relevant to newborns.

Our ultimate goal is to improve health outcomes and lower costs for newborns and their families and we fundamentally believe the expanded availability and use of medical device data is central to this pursuit. Mobile apps and the smartphones and tablets are easily accessible, intuitive, and commonly used by parents. These technologies will continue to play a central role in healthcare but their impact will be stunted unless there is a concerted effort to allow these technologies a way to access and creatively use clinical data to better inform the decision making by both providers and parents in the ongoing care of a newborn.

Congress should clarify existing statute to distinguish information systems from traditional medical devices so that more can be done with data from existing products. We believe that newborn-specific medical devices should continue to be regulated by the FDA and be subject to significant pre and post-market evaluation. We do, however, support an alternative certification process for companion information systems that are designed to interact with regulated medical devices or networks of devices in novel ways.

We believe there are three major areas of work that must be undertaken to foster the transparency and efficiency needed to align the statutory mission of regulators with the needs of the market:

1. Update the definition of a Medical Device to reflect the evolving nature of medical technologies by differentiating between those that manage health information and those used to diagnose and treat patients.

2. Create an alternative certification pathway to market for health information software, which may interact with a device or network of devices, to ensure they reliably function as designed.

3. Create a collaborative mechanism for robust post-market surveillance that incentivizes safety and addresses adverse events quickly with a mix of punitive and non-punitive enforcement options.

Congress alone has the power to set many of these changes in motion but we believe that it will be through an iterative and deliberate process defined by collaboration between Congress,

regulators, and other relevant stakeholders that will bring about a scalable, transparent, and competitive health system for new technologies where safety is paramount.

Aligning the Statutory Roles of Regulators

The road to market for industry is crowded with regulators and the potential for duplication, which is costly and time consuming. While the volume of emerging technologies has strained the current regulatory process, it remains functional because the majority of medical technologies coming to market are discreet and fit reasonably into regulatory silos. The convergence of technologies and multi-function devices is challenging the current regulatory paradigm because many products combine functionality that has historically been evaluated by more than one regulator. The FDASIA Work Group highlighted an example of where regulation is very clearly duplicative in its recommendations to the ONC Policy Committee:

> FCC and FDA do not coordinate their review processes on converged medical devices that are brought independently before both agencies (FCC's equipment authorization program and FDA's premarket review). Coordination between agencies should be transparent and help ensure consistency thereby eliminating duplicative, time consuming, and costly hurdles. – *FDASIA Work Group Presentation to the Policy Committee September 2013*

This duplication will be most commonly seen in enforcing FDA's final guidance on the regulation of Mobile Medical Applications (MMA). The available computing power and portability of smartphones and tablets has made them a popular platform for patients and providers alike. Applications may leverage the cellular connection on a smartphone or tablet to access wireless spectrum, something currently regulated by FCC.

The MMA guidance is very clear that the onus of passing through the 510k or PMA process falls on the MMA developer, not the smartphone manufacturer. This means that a smartphone manufacturer will continue in the FCC Equipment Authorization (EA) program and not be drawn into the FDA process for merely providing a platform for a MMA to function.

This does not mean the FDA will *not* evaluate the smartphone at all. If a MMA is designed to leverage a smartphone's cellular connection then the FDA will evaluate that functionality in its pre-market review in the context of ensuring the MMA can function as designed. FCC, however, has already certified the smartphone's ability to access wireless spectrum through the EA program making FDA's evaluation of the exact same capabilities in its pre-market review process duplicative.

Despite the fact that the MMA guidance was released weeks after the FDASIA Work Group made its final recommendations, it does not seek to clarify how FCC EA certification will be used or regarded in the FDA process. And it remains unclear, outside of the non-binding HHS report due out at the end of the year, what specific options are available for improving interagency collaboration. It may be the case that options for fundamental changes to coordination across regulators are limited or non-existent. In its recommendations, the FDASIA Work Group identified a number of issues across FDA, FCC, and ONC that are "broken at the

written law level," or that cannot be remedied without a legislative change. Statutory limitations and the costly nature of regulatory duplication raises two complementary issues that may require legislative clarification:

1. **There is no transparent mechanism for regulatory reciprocity across agencies.**

   It is unclear how; if at all possible, increased interagency coordination could allow regulators like FCC and FDA to use the certification or evaluation completed by another agency in the fulfillment of their own statutory duties. This change may not be administratively possible within the confines of existing statute and should be clarified legislatively.

2. **No single entity has a complete view of all health technology regulation.**

   FDA may regulate a single device that accesses wireless spectrum (FCC EA program); that makes marketing claims about its intended use, user, or functionality (FTC Health Claims guidelines); and that curates information to coordinate care in hospitals (ONC-ACB). In the absence of a single entity with a longitudinal view of the regulation of health technologies, this duplication will only worsen as technologies become more convergent.

   FDA has been a leader in mitigating *intra-agency* duplication through the Office of Combination Products[i], which governs drugs with a technology component such as a pill with an ingestible RFID chip. FDA created the Office as a gatekeeper to mediate intra-agency jurisdictional disputes. Allowing an entity within HHS to act as a gatekeeper that would nationally coordinate *interagency* regulatory efforts, would infuse efficiency into the process, allow all regulators to better target their limited resources on effectively fulfilling their statutory duties, and allow the regulatory process to remain transparent and nimble as technologies evolve. Implementing such an approach, however, could not be achieved through administrative changes and would require Congressional intervention.

Updating the Definition of a Medical Device

FDA currently regulates medical devices as well as companion technologies that in some way use or interpret a device's actions or the data they create; this includes implantable devices, diagnostic tools and laboratory tests, among others. Over time, FDA has expanded its working definition of a medical device beyond its original statutory definition into other health-related technologies through sub-regulatory guidance and enforcement discretion.

As the computing power consumer devices have evolved, technologies such as smartphones are able do things previously thought to be impossible. The usefulness of these mobile devices has blossomed in recent years is due to their ability to act as a platform for a myriad of applications that extend their functionality far beyond the ability to make and receive calls. Mobile apps have transformed our cellular telephones into our cameras, our maps, and in some cases our doctors. What were originally multiple different technologies have all converged onto a single, very powerful platform.

The convergent nature of the technology market is making it increasingly difficult to put new products into traditional regulatory boxes and in the not so distant future it will become impossible. This is particularly important now that the MMA final guidance is effectuated. Many in industry were pleased with the final product because they think it brings certainty in how existing products will be regulated.

The Newborn Coalition's mission is to promote the development and use of safe and effective technologies in the newborn period while leveraging that technology to create better health outcomes throughout that child's life. Considering the pace of the marketplace and the needs of newborns, we would be profoundly disappointed if the technologies of today remotely resemble the technologies available to our core constituency by the time they have children of their own. Our disagreement with those who believe that the final MMA guidance creates certainty, is that we believe the certainty will evaporate as technologies evolve..

Enforcement discretion by definition is discretionary and will need to be constantly updated to address emerging technologies. We question the ability of the current regulatory system, with its limited resources and staff expertise, to address these new demands. We believe there is still an opportunity to put policies in place that will allow the flexibility that accommodates a changing marketplace before the needs of the market dwarf the capabilities of regulators and our current system.

Creating a New Definition of Technologies

We believe this process begins with updating the definition of a medical device to mean only those technologies that pose the highest risk to patients. Congress should work with FDA to focus agency resources on technologies that pose the highest risk by creating a bright line between medical devices and health information software that may interact with a medical device.

We offer the following definition as a guideline in clarifying when a technology is medical in nature and therefore poses a higher risk to patient safety:

> *A technology becomes medical in nature when it is designed or marketed to change or evaluate the end user's current state physiology without informed context or with limited or no time for informed human intervention.*

The unique nature of human physiology is a significant variable that may make a device function out of its expected range and harm the end user. This specific concept is what makes these technologies medical devices and why they require strict oversight and pre-market evaluation: they are engineered around an unknown, which is the end user's physical individuality.

We believe Congress should create a bright line between technologies that function as high risk medical devices and that should be regulated by the FDA, and those that are lower risk that should fall outside the FDA process.

This Committee has already begun to address the need for a distinction by introducing the SOFTWARE Act of 2013. As mentioned previously, the concern from the patient community with the current process is that it only addresses technologies that exist today and does not give sufficient clarity as to what will be regulated as a medical device in the future. The approach taken in the SOFTWARE Act differs from the guidance-led process used by the FDA because it very clearly distinguishes between what the FDA will regulate and what is outside of their jurisdiction.

Establishing this line means Congress should also address how non-medical devices that fall outside the FDA process should be determined safe and effective. We believe this requires an alternative certification pathway.

Alternative Certification Pathway for Health Data Systems

When the function of a technology is not dependent on analyzing or changing the user's current state physiology it is inherently lower risk because it is more predictable. These technologies can be certified in lieu of the FDA approval process because premarket evaluation of the product will be an exercise in engineering, not biological science. A certification process will ensure the safety of health information software by ensuring it adheres to known standards for information exchange with one or more regulated medical technologies without changing or adversely affecting the original functionality or usability of the devices that are cleared by the FDA.

To be successful, a certification-based regulatory pathway must require that products adhere to consensus based technical standards to execute their core functionalities. Further, developers must be transparent in the technical standards used in the design of a product and provide guarantees that their product does not engage in restrictive business practices that may limit a technology's ability to interoperate with a secondary system or adversely impact the integrity data during an exchange.

The American National Standards Institute (ANSI) accredited standards development organizations (SDOs) and the International Organization for Standardization (ISO) go through in-depth processes to convene multi-stakeholder working groups to drive consensus on standards that meet a particular need in the market, implement them throughout industry, and subsequently audit programs to ensure they have been properly implemented. Standardization strengthens the integrity of data used across multiple technologies, creates clarity for developers that aid in design and operation, and incentivizes industry to collaborate on the development of new standards thereby creating a holistically more interoperable marketplace.

There are several models already used in federal programs that could be a basis for certification of health information software. Most notably are the ONC-ACBs used in the Meaningful Use program that certify electronic health records or EHR modules and accommodate the large number of vendors participating in the program. These are private sector technology and standards experts contracted with the ONC to ensure technologies operate according to program standards. Since the beginning of the Meaningful Use certification process in 2010, nearly 5,000 products have been certified for use in the program[ii]; many of which are being used in Medicaid

hospitals and are greatly improving care coordination and the portability of health data for newborns.

ONC was able to ramp up its certification process quickly because it used a decentralized model, identifying certifiers and test beds that had the regulatory expertise to effectively test that EHRs and EHR modules could comply with previously identified certification criteria. It is important to clarify that requiring adherence to known standards is very different than mandating how those standards must be used. The FDASIA working group, in its final report, noted that EHR products brought to market after the beginning of the Meaningful Use Program were being built to meet the quality measures laid out in the program and not necessarily the diverse needs of providers and their patient populations. This so-called "compliance innovation" dilutes the effectiveness of the free market and should be avoided whenever possible.

The challenge in implementing a certification program to address a diversity of technologies with applications in healthcare is that there will be significant variation in functionality, product engineering, and the ability for systems to interoperate. The goal of basing a new regulatory model around adherence to standards is to ensure that a product will function as designed when connected or networked with other technologies. Public-private certification relationships can address this concern.

Currently FDA deals head on with the issue of design and technical standards between products, having to develop unique test beds for new products as they move through the 510k or PMA process. Allowing independent, contracted software experts to certify these technologies will greatly expand the speed and venues available to developers to bring technologies to market. It would also address the diversity of expertise required in regulating a diverse marketplace.

While the certification program will require strict governmental oversight, the certifiers should be encouraged to compete on quality and attract customers (vendors) by establishing a race to the top for patient safety endorsements that are sought after by patients and providers alike.

Costs are a significant barrier for many moving through the FDA process. A public-private certification program can lower these costs by supplanting annually set user fees with certifiers competing against one another on price. We see this in the ONC certification market today. Private certification entities may also have more capacity in certifying certain technologies, and therefore may be able to offer evaluation of a product more expeditiously, an attractive quality for developers seeking to speed products to market.

Competition over cost and quality, paired with strict governmental oversight, will create a virtuous cycle of efficiency gains and quality improvement that will address many of the issues FDA is facing due to limited resources and regulatory expertise. A public-private certification process is an appropriate means of fostering this competition and, when paired with the certainty of updated regulatory definitions and robust post market surveillance, the system as a whole will continue to improve over time.

Post Market Surveillance

There are many health technologies that have the potential to pose significant risk to patients that are not currently regulated by the FDA. Electronic Health Records (EHRs) have evolved well beyond simple file storage and have become increasingly integrated into the delivery of clinical care. In the next stages of Meaningful Use, providers will be required to attest to having implemented a minimum of five Clinical Decision Support (CDS) interventions tied to quality measures and the delivery of care. This requirement fundamentally transforms an EHR, which was previously an administrative tool, into a clinical tool.

As noted, EHRs are not regulated by the FDA but are certified by the Office of the National Coordinator for Health IT (ONC). ONC has the power to enforce agreements with Accredited Certification Bodies (ACBs) and their Test Labs but it does not have the statutory authority to audit functionality to intervene when required functionality of a certified EHR, such as information exchange, is prevented due to restrictive contracts or business practices.

Some adverse events related to technology are not an issue of design or standards: some technology vendors—as well as some providers—pursue business practices to create what are called "walled gardens," strategies that block information sharing between different systems in order to capture market share. It is important that we identify and quickly remedy this problem as it occurs as the practice fundamentally diminishes the value of health IT, forces taxpayers to subsidized suboptimal business practices that consolidate markets and lead to price and cost increases, , and directly threatens patient safety.

Creating an office within HHS or expanding ONC's authority to audit or intervene in cases of adverse events related to health information technology, including information blocking, would improve the overall safety of our health system and greatly inform the certification or regulatory processes across all Agencies.

Similar to the gatekeeper described previously with a view across all regulators, a comparable entity is needed to facilitate post market surveillance. Models for such a body exist: FAA coordinates the Aviation Safety Information Analysis and Sharing (ASIAS) System, which is a collaborative effort between Airlines and government to openly exchange safety information in order to continuously improve aviation safety. ASIAS has the ability to access public and private aviation data, air traffic control reports, weather, and maintenance reports. The body allows the FAA and NTSB to quickly identify and remedy accidents and near missies so that they do not happen again.

Imagine such an entity for health information technology: an open collaboration between regulators, industry, patient safety organizations, ACBs, providers, and the patient community with access to timely data reported across agencies for the purposes of continuous quality and safety process improvement. This would have a significant and immediate impact on health technologies particularly as they converge with consumer products and become more integrated into our daily lives. Creating a mechanism for these entities to openly collaborate in a protected way would allow regulators engaged in post-market review to identify problems and develop solutions before an adverse event or near miss harms another patient.

Suggestions

Updating the existing regulatory process to safely bring products to market at the speed of innovation will require some statutory changes only possible through legislative action. Congress has the opportunity to take immediate steps to remedy the most pressing obstacles to effective regulation and to lay a foundation for a systemic reform in the near term. The Newborn Coalition, in collaboration with providers, industry, and patient advocates, has compiled seven specific ways Congress can act immediately to improve patient safety:

1. Focus FDA's resources on medical technologies that change or evaluate the end user's current state physiology without informed context or with limited or no time for informed human intervention. Congress should create a bright line that defines FDA's authority over high risk medical devices. Other technologies should fall outside of FDA's purview.

2. Require HHS to contract with independent, private certification bodies that would certify non-FDA technologies as safe and effective.

3. Require HHS to establish an office that acts as a gatekeeper to nationally coordinate interagency regulatory efforts. This gatekeeper would direct products to FDA or private certifiers as appropriate.

4. Refine the law where necessary to allow regulatory reciprocity across FDA, FCC, and ONC to eliminate costly duplication.

5. Direct FDA, FCC, FTC, and ONC to complete a collaborative report on statutory changes needed to implement a public-private certification program for health information software designed to interact with cleared medical technologies, and complete it in advance of the next Medical Device User Fee and Modernization Act.

6. Expand ONC's regulatory authority to include post-market surveillance authority, usability audits of certified and implemented technologies, and the enforcement authority to disqualify vendors or providers that engage in information blocking from federally funded programs.

7. Create a collaborative environment for adverse event reporting by expanding PSO legal safe harbors to include vendors of regulated health technologies to incentivize transparency in adverse event reporting and require all health IT products in federally funded programs have a relationship with a PSO.

Conclusion

In providing this testimony, laying out the bottlenecks and barriers we see in the current process, and in suggesting options for moving the system forward, I feel it critical to note that there is no magic bullet that will transform the system we have today into what we will need in the future.

We believe that collaboration between Congress and Regulators will be critical in identifying where the law must be updated to reflect the changing marketplace.

With the level of interest from government, industry, providers, and the patient community it would be a shame to miss the opportunity to reform the system in a way that will foster innovation and improve patient safety.

Thank you again for the opportunity to testify today. I stand ready to help the Committee in any way possible and am happy to answer any questions you may have.

---

[i] Combination products are defined in 21 CFR 3.2(e)

[ii] 3,629 for Ambulatory care & 1,231 for Inpatient Care. CHPL accessed 9/12/13.