This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

RPTS MCCONNELL

DCMN ROSEN

EXAMINING FEDERAL REGULATION OF MOBILE

MEDICAL APPS AND OTHER HEALTH SOFTWARE

TUESDAY, NOVEMBER 19, 2013

House of Representatives,

Subcommittee on Health,

Committee on Energy and Commerce,

Washington, D.C.

The subcommittee met, pursuant to call, at 10:01 p.m., in Room 2322, Rayburn House Office Building, Hon. Joseph R. Pitts [chairman of the subcommittee] presiding.

Present: Representatives Pitts, Burgess, Blackburn, Gingrey, Lance, Guthrie, Griffith, Bilirakis, Ellmers, Pallone, Capps, Matheson, Green, Butterfield, Barrow, Christensen, Castor, Sarbanes, and Waxman (ex officio).

Staff Present: Clay Alspach, Counsel, Health; Sydne Harwick,

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

Legislative Clerk; Robert Horne, Professional Staff Member, Health; Carly McWilliams, Professional Staff Member, Health; Andrew Powaleny, Deputy Press Secretary; Chris Sarley, Policy Coordinator, Environment and Economy; Heidi Stirrup, Health Policy Coordinator; John Stone, Counsel, Oversight; Ziky Ablaya, Minority Staff Assistant; Eric Flamm, Minority FDA Detailee; Elizabeth Letter, Minority Assistant Press Secretary; Karen Nelson, Minority Deputy Committee Staff Director For Health; and Rachel Sher, Minority Senior Counsel.

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

Mr. Pitts. The subcommittee will come to order. The chair will recognize himself for an opening statement. In the last few years, health information technologies including mobile medical apps, or applications, electronic health records, personal health records, computerized health care provider order entry systems, and clinical decisions support have transformed the provision of health care in this country.

In September of this year, the FDA put forward a proposal in the form of final guidance indicating that software was a medical device for the purposes of regulation, except that software is not a medical device. To regulate it as such, the FDA has said it will use discretion to decide which software to regulate. Except that no matter what Dr. Shuren may tell this committee here today, there is no guarantee that its successor won't go back on this guidance tomorrow.

While guidance is a valuable tool for the FDA, there is a significant limitation, certainty. What stands today could change tomorrow. Patients and industry have told us that the FDA's involvement and guidance was a good thing. There was much, too much ambiguity around the issue and companies needed to know what the FDA intended to do. In addition, many believe the FDA acted to the best of its ability with the only tool available to them; its medical device definition. But they also are telling Congress that we need to give FDA new tools that create regulatory certainty, not just today, but

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

also tomorrow. That certainty can start with properly defining what these technologies are for the purposes of regulation.

Representative Blackburn and her colleagues on both sides of the aisle, have outlined an approach that would give the FDA a new tool, a 21st century definition to regulate a 21st century technology. The SOFTWARE Act is a starting place and an opportunity to begin a dialogue with thought leaders like the FDA. Representative Blackburn and five of her colleagues, Democrats and Republicans, have put forward one way to modernize the FDA so that it is ready to meet the challenge it has so far recognized it needs to meet.

I commend her in her thoughtful approach to this issue, and for her leadership. Dr. Shuren, I stand ready to pledge this committee's support to help you modernize the agency in a way that makes sense for patients, for industry, and for the agency. And I hope you take this offer seriously, and will agree to work with us toward a goal we all share.

And to all of the witnesses on both panels here today, I thank you for your testimony. And I yield the balance of my time to the gentleman from Illinois, Mr. Shimkus.

Mr. Shimkus. Thank you, Mr. Chairman. I applaud the calling of this hearing, and I, too, want to mention Congressman Blackburn and her bill. I am not a sponsor yet but we are looking at it seriously. It is bipartisan, and the issues we need to -- we need a new tool to

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

help us continue to modernize. Software is not a medical device, and what you call something matters, especially as we have our tech companies trying to go through a process. So I wanted to use this time to thank my colleague for her work. I look forward to you coming back, Dr. Shuren, and discussing how we can maybe give you some help and some tools so that we can label devices, devices, and label software, software. With that, Mr. Chairman, I thank you. I yield back.

Mr. Pitts. The chair thanks the gentleman. I now recognizes the ranking member of the subcommittee, Mr. Pallone, for 5-minute opening statement.

Mr. Pallone. Thank you, Mr. Chairman. The possibilities for mobile health technologies are promising and exciting and there is so many functions that mobile health applications can be designed for, from diet logs and medication reminders, to medical textbooks reference tools to ECG monitors, and they play an increasingly important role in getting health information into the hands of consumers and helping patients take control of their health. They may also help doctors improve and facilitate patient care by, for example, providing instant mobile access to standards of care, or helping to streamline their business processes.

I think it is fair to say that we all want to encourage continued innovation, but it is also important that we shepherd these emerging technologies and make sure that they are safe and effective for

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

patients. As with traditional medical devices, some mobile apps that operate in the health sphere could pose a risk to patient safety if they don't work as they are supposed to, and we want to make sure consumers can have confidence in the products they use. When we last had a hearing 6 months ago on health information technologies, we heard from stakeholders a desire for clarity on FDA's regulatory approach to mobile health applications and support for risk-based strategy that protects patients, ensures product quality, and at the same time, fosters innovation. The FDA has since finalized its guidance and laid out examples of the type of mobile applications where to close mobile medical applications that the agency will apply its regulatory authority to.

To me, and from what I have heard from industry, FDA's guidance is very measured and risk-based. We had heard concerns before the final guidance was out, that FDA was going to regulate smartphones and tablets as medical devices and stifle innovations through regulation. In fact, as we see now, FDA's guidance clearly states that it would not regulate the sale or general use of smartphones or tablets and will not consider the manufactures of these products to be medical device manufacturers. Rather, the agency directs its oversight to those apps that are medical devices, as defined in existing statutes, and that could pose a risk to patient safety.

For certain mobile apps such as those that purport to diagnose

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

cancer or that recommend a dosage plan for radiation therapy, there should be a role for FDA to play to ensure they are safe and effective. And these are the kinds of apps FDA has said it will direct its oversight to. I appreciate that we have the opportunity today to discuss the SOFTWARE Act, a bill introduced by my colleagues on our committee, Ms. Blackburn, Mr. Green, Ms. DeGette, Mr. Butterfield, and Mr. Gingrey. However, I have several concerns about this bill starting with the timing. FDA's guidance was released barely 2 months ago, and we have not had the opportunity to see how it works in practice, or to hear from industry whether it poses any barriers to innovation.

In addition, a small but important provision was passed as part of the user fee law last summer which required FDA, along with other Federal agencies, to recommend an appropriate regulatory framework that ensures patient safety, but also promotes innovation. These recommendations are not due until January of 2014. And I think it would be prudent for this committee to analyze and examine that report before moving any legislation.

And that leads to my second concern which is whether legislation is even necessary and whether it is the right approach to take. As we all know, the legislative process is slow, and in an environment where technologies are changing so rapidly, I question whether it makes sense to enshrine in statute something that may not work for an ever-evolving industry. Regarding the content of the bill itself, I

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

also have concerns about what it seeks to achieve, whether it meets those goals as written, and what the consequences down the road would be if we were to permanently carve out certain types of mobile health apps from FDA's oversight.

So in closing, I look forward to learning more today about FDA's regulatory approach to mobile health apps and the potential impact of the SOFTWARE Act. And again, thank you, and of course, I thank Dr. Shuren for being here.

Mr. Green, I will yield the remainder of the time to my colleague from Texas.

Mr. Green. Thank you, Ranking Member Pallone, for yielding time and I appreciate the majority holding the hearing on the SOFTWARE Act which I cosponsored. I understand that there are concerns, but this proposal is a work in progress. It is important that we take time to get this right. A few weeks ago the FDA issued guidance on mobile medical apps and other software and I commend them for their thoughtfulness and leadership. Medical software and other health-related software is a quickly growing sector with unbelievable potential. The FDA has done all it can through enforcement discretion to implement commonsense steps to foster innovation and protect patient safety. Enforcement discretion is not the right tool, but it is all they have. It is Congress' obligation to give the FDA the tools necessary to properly protect patient safety, and also to encourage

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

innovation and create regulatory certainty. That is why the SOFTWARE Act is important, and it is a work in progress.

And I guess, this is the first time the Senate passed our compounding bill, and we learned with our effort on compounding that the FDA didn't have the authority or didn't think they had the authority, so we needed to deal with that. And I would hope we could get in front of the curve on software instead of behind the curve like we were on compounding. And I yield back my time.

Mr. Pitts. The chair thanks the gentleman. I now recognize the gentlelady from Tennessee, Ms. Blackburn 5 minutes for an opening statement.

Mrs. Blackburn. Thank you, Mr. Chairman. I think it goes without saying that I am very pleased that we are holding the hearing today. Tennessee is home to hundreds of health IT innovators and they are grateful that we are turning our attention to this issue. They feel like it is needed and so, Dr. Shuren, I thank you for being with us. To the other witnesses that we have today, we welcome you. We look forward to hearing from you, and I do want to thank my colleagues here on the committee, Dr. Gingrey, Mr. Green, Mr. Butterfield, of course, Ms. DeGette, who have worked on the legislation. We appreciate the efforts that they have put into this.

The health informatics industry is innovating at a pace that I think is startling to everyone who is watching. I am constantly amazed

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

as I visit with these innovators and hear of their plans, and look at their research, and view the platforms that they are working with. Every day the use of technology becomes more engrained in how health care is delivered in the U.S. As such, Congress has a very important role to play to ensure that our agencies tasked with ensuring the safety and efficacy of these technologies has the proper tools necessary to do the job to understand their mission, and not to overstep.

Unfortunately, the FDA is stuck trying to use a 1970s definition of a medical device to regulate mobile medical apps and other health care-related software. We can all agree that there is certainly a role for the FDA to play as we go about determining the regulatory playing field for this growing sector and trying to funnel these products into existing outdated definitions is just not going to make any sense and it will not work.

The SOFTWARE Act would give the agency a needed tool for emerging technologies where necessary, while allowing moderate to low risk technology developers the certainty necessary to proceed with development, knowing full well what the regulatory playing field is going to be.

It would provide certainty for our innovators who are constantly working to deliver health care in a more efficient manner. With their decisions and the September 2013 mobile apps guidance to use, enforcement discretion to regulate only a subset of mobile medical

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

apps, the FDA took an important step to acknowledge where their focus should be. Congress has the opportunity to go a bit further and codify this intent to ensure that our innovators have the clarity and certainty they need to continue to invest in this area, and develop tools that will help make us healthier.

At this time, I yield the balance of my time to Dr. Burgess, vice chair of the subcommittee.

Dr. Burgess. I thank the vice chair for yielding, and Dr. Shuren thank you for being here. It is always good to see you in our subcommittee. Don't make yourself so scarce now that you know where we are.

I do want to emphasize the point that providing that certainty for software developers, providing clarity for industry is one of the things that we seek to accomplish today. We want predictability for our providers. There are areas of, emerging area of clinical decision support has the ability to transform practice of medicine in the realm of continuing medical education, always a challenge for clinicians to meet the requirements that are imposed, generally at a State level, but now you also have the new Sunshine Laws that perhaps may make it harder to keep up with these programs that otherwise we would have the ability to support our doctors.

The issue is that the lack of careful regulation could end many of these programs before they even begin, and it is a bright future

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

ahead of us, and we want to be certain we do everything to provide that predictability and clarity for our providers and for industry alike. And I yield back the balance of my time.

Mr. Pitts. The chair thanks the gentleman. And now recognize the ranking member of the full committee, Mr. Waxman, for 5 minutes for an opening statement.

Mr. Waxman. Thank you very much, Mr. Chairman. Mobile medical applications hold incredible promise for patients and health care provider, potentially reducing cost, improving health care delivery, and saving lives. We should all want to see this exciting innovation continue. At the same time, we must be cognizant of the need to protect patient safety, so just as we do when it comes to all types of medical devices, we logically look to the FDA to oversee the safety of these cutting-edge technologies. FDA has been regulating software under its medical device regulatory scheme for decades. At the end of September FDA issued final guidance regarding mobile medical applications, and I think it struck the right balance. It ensures that patients are not placed in harm's way by these medical apps, and they do not apply undue regulatory restraints in the way of innovation.

As the FDA says in its guidance something like a dietary tracking app which reminds you of a medical appointment, or some dietary information, help you follow a diet. That kind of app purports to -- that kind of app is certainly one that we don't want FDA to

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

regulate. But an app that tells you whether you have cancer or not, well, that deserves a lot of scrutiny.

Because let me give you an example. A group of dermatologists recently published a study of four apps that claim to be able to diagnose melanomas. That is a very serious skin cancer. The dermatologists found that three of the four apps incorrectly classified 30 percent or more of melanomas as benign when they were actually malignant. Well, that is a kind of device where you want FDA to take a look at. We don't want you to just say you don't have to be involved, FDA, we are going to let people get access to it. We can't tell the American people buyer beware when potentially life and death care decisions are at stake.

FDA's final guidance should put to rest any concerns that this agency is interested in a regulatory overreach now or in the future. FDA, very reasonably and clearly, sets forth the types of mobile medical applications that the agency intends to oversee, as well as those it does not. For instance, FDA's guidance says that it intends to look at only those apps that could impact patients' safety. At the same time, the guidance specifically states that the agency does not intend to regulate distributors of mobile medical apps like iTunes store or the makers of smartphones or tablets like Apple.

Today we have before us a bill. It is called the SOFTWARE Act and it attempts to codify, put in law some of what FDA has set forth

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

in this guidance. And I appreciate the offer of the sponsors of this bill to work on that legislation, and talk more about it. But I am skeptical of the need for legislation in this area at this point in time for a number of reasons.

First of all, FDA's guidance was just issued at the end of September. We barely had an opportunity to see how it is working out, whether there are instances of burdensome requirements stifling innovation in this area. It is not appropriate to legislate based on unfounded fears of what might happen in the future.

Second, by almost all of the accounts I have heard, the guidance has been favorably received by most of the industry. It is written in a clear and concise manner, including a litany of specific examples that provide the regulatory certainty so many in the industry were seeking.

And third, as I mentioned, FDA's guidance strikes the right balance between protecting patient safety on the one hand, and promoting innovation on the other. As I think we will hear today, the current draft of the SOFTWARE Act does not strike that balance. This bill upsets that balance. I think there are several examples of mobile medical apps that I think we all would agree should not be permanently removed from FDA's oversight, but that is exactly what the current draft does.

I am not suggesting this was the intent of the sponsors, but it

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

does illustrate a major concern I have whether the blunt instrument of legislation is the appropriate tool for regulation of mobile medical apps given the rapidly changing nature of technology in this area. As we all know, once the law is in place, it is very difficult to change it, and it is exceedingly difficult to craft the perfect legislative language that would preserve FDA's ability to oversee appropriate subsets of these changing technologies now and in the years in the future. Thank you, Mr. Chairman.

Mr. Pitts. The chair thanks the gentleman. That concludes the opening statements of the members. We have two panels today. On our first panel we have Dr. Jeffrey Shuren, director of the Center for Devices and Radiological Health at the U.S. Food and Drug Administration. Thank you for coming today, Dr. Shuren. You written testimony will be entered into the record. You will have 5 minutes to summarize your testimony. And at this time, you are recognized for 5 minutes.

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

STATEMENT OF JEFFREY E. SHUREN, M.D., J.D., DIRECTOR, CENTER FOR DEVICES AND RADIOLOGICAL HEALTH, UNITED STATES FOOD AND DRUG ADMINISTRATION

Dr. Shuren. Thank you, Mr. Chairman, and members of the subcommittee for the opportunity to testify today. The use of mobile apps is revolutionizing health care delivery and has the potential for transform health care by allowing doctors to diagnose patients outside of traditional health care settings, and help consumers manage their own health and wellness. We are excited about these technologies, and have been taking steps to facilitate their development and safe use. Developers of mobile apps have been asking for guidance about which mobile apps are subject to FDA oversight and not. Such clarity is critical for tracking investment in accelerating innovation.

Recently we provided that clarity by issuing final guidance. The gist of that guidance is the following: Although many mobile apps pertain to health, of which many may be medical devices we are only overseeing a very small subset of those mobile apps that are medical devices. We have called that subset mobile medical apps. We believe this pragmatic, narrowly-tailored approach will promote innovation while protecting patient safety by focusing on those mobile apps that pose greater risks to patients. Our regulation of software as a

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

medical device, and a mobile app is software, is based on risk and function, their intended use. A foundational principle is that we treat devices that perform the same function for a patient the same regardless of the platform on which it is used.

For example, an electrocardiography device, an ECG machine that measures heart rhythms to help doctors diagnose patients, is still an ECG machine regardless of whether it is the size of a bread box or the size of a smartphone. The risk it poses to patients and the importance of assuring for practitioners and patients that it is safe and effective is essentially the same. That is what our guidance does. It makes clear that if a mobile app is a medical device, specifically, it transforms a mobile platform into a medical device, like an ECG machine, and we have cleared apps for that, or it is an accessory to a medical device, such as an app that acts as a remote control for a CAT scanner and is the kind of function we already regulate so we have approved it, cleared it, or classified such a device, we would continue to regulate that kind of technology if it is on a mobile platform rather than on a non-mobile platform. A mobile medical app is simply a mobile app that is a medical device and a kind of device we have approved cleared or classified.

Again, it is not about the platform. It is about the function. An ECG is an ECG. And regulating mobile apps is nothing new for us. In the past 15 years, we have cleared over 75 mobile apps, roughly 20

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

in the past year. For all other types of mobile apps that meet the regulatory definition of medical device, we will exercise a policy known as enforcement discretion. This means we do not intend to enforce requirements under the law. In addition, we will exercise enforcement discretion for some functions we have been actively regulating; for example, medication reminders, and drug-drug interactions.

Taken together, we have focused our priorities and taken a big deregulatory action, the biggest we have taken in over a decade. We received about 130 comments in a draft guidance, which were generally supportive of the approach we propose, but wanted even more clarity; therefore, the final guidance keeps the same core policy, but provides clearer explanations and more examples. Also, we clarify that at the request of some of our stakeholders, this guidance does not apply to what has been called clinical decision support software; software to aid a practitioner or patient in making a decision.

Instead, we have been asked to and will address clinical decision support software as part of the ongoing effort we have with the Office of the National Coordinator of Health Information Technology, and the FCC, to post a proposed strategy and recommendations on a risk-based regulatory framework pertaining to health IT as required by FDASIA. As part of this effort, we established a multi-stakeholder working group to provide us some recommendations on what to consider when

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

proposing a framework. The working group gave their final recommendations in September. They recommended the FDA explain which forms of clinical decision support software it regulates. They also highlighted the importance of treating function the same across platforms, what we are doing, and recommended that we expedite our guidance on mobile medical apps because of its critical importance in providing clarity.

We will provide ongoing clarity to mobile app providers through a new Web site to which we will continually pose new examples of apps that we are not actively regulating. App developers who have questions can contact us through several means, including a new email address. Queries will be handled by a special team under the guidance of CDRH senior managers. Smart regulation by FDA can help promote innovation in mobile apps, and protect patient safety.

Mr. Chairman, I thank the subcommittee for its efforts. I am pleased to answer any questions you may have.

[The prepared statement of Dr. Shuren follows:]

******** INSERT 1-1 ********

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

Mr. Pitts. The chair thanks the gentleman, and we will now begin questioning. I will recognize myself 5 minutes for that purpose.

Dr. Shuren, the FDASIA working group produced a report on the issue of regulation of mobile medical apps and other software. Included in the FDASIA report are problems associated with the challenges faced by FDA related to wellness and disease, accessory issues, post-market requirements for networks, enforcement, interoperability of medical devices, regulatory jurisdiction on converged medical devices, and resource constraints among other issues. Is that correct?

Dr. Shuren. Yes, they did make recommendations pertaining to all of those.

Mr. Pitts. And isn't it true that the FDASIA working group stated there are issues in each area that I just mentioned that are "broken at the written law level."

Dr. Shuren. They did say that. In reality from our perspective many of the things we need to do are about providing clarity in those areas which is something we intend to do.

Mr. Pitts. Now, Dr. Shuren, as the opening statements here today suggest, and in light of reports like the FDASIA working group report, there is a strong role for Congress to modernize the FDA to regulate software and other forms of health information technology because the written law is antiquated and did not take into account such

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

technologies when it was written 30 years ago. Understanding this, did your office reach out to my office or other offices of Members on the health subcommittee with an offer to work together on this issue before you released the proposed or final guidance?

Dr. Shuren. Not to my understanding, but we have certainly gotten lots of input from the stakeholder committee. It is something we have been working on for roughly 2 years.

Mr. Pitts. Can you tell me why your office did not reach out to offer collaboration on this issue when you knew the important role Congress needs to play in this space?

Dr. Shuren. I think in this space, we were trying to provide clarity regarding our current authorities which is what we did. I will tell you that if we certainly felt that at the time there was a need for legislation, we would absolutely have reached out to you, and you have handled -- had hearings on this matter before, and we have stated the same previously. But we certainly welcome opportunities to work with you, and I will say it is Congress' prerogative to pass legislation. That is certainly your choice to make. We would hope, though, that we have an opportunity to engage and certainly point out implications of any legislative path that may be under consideration.

Mr. Pitts. Now, Dr. Shuren, you have publicly intimated in the past that the FDA could regulate electronic health records as medical devices. Can the FDA regulate electronic health records as medical

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

devices?

Dr. Shuren. Arguably, yes, but we have stated on the record and we have put into formal policy that that is not what we are doing. And that is now official policy of the agency.

Mr. Pitts. Now, in her testimony on behalf of the FDA to this committee on March 21st, 2013. Christy Foreman said, that the FDA could change its mind tomorrow and regulate items and products not described in its final guidance, products like electronic health records, or clinical decision support programs.

Dr. Shuren, do you agree with Christy Foreman that the FDA could change its mind and regulate beyond the FDA guidance it published in September 2013?

Dr. Shuren. So I don't know what Christy actually said, but we have now put in place a final policy. I can't change that overnight. There is statutory requirements that we have to comply with to change any such policy which requires extensive public input on proposal, and there is congressional oversight. Changing policies like that, if there is disagreement within the community is exceptionally difficult to do.

The value, though, of such policies and guidance, and I will tell you that we have had extensive conversations during FDASIA about the invaluable nature of guidances to provide both predictability, and flexibility, both are critical to industry, particularly an industry

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

like health care IT that is rapidly innovating. So our guidance, we spent 2 years with extensive input with a public meeting, a proposal, public comment, then final guidance, and that is about 40 pages long with extensive explanations and examples, and answering questions. And it gives us the ability that if the health care IT community -- and it gives them the flexibility that if they, over time, as their technologies evolve, they feel, you know what FDA, we want you to make certain changes, we have the ability to do that. The challenge with statute, and it is your call whether or not to do that, is to take what is a 40-page document, and hone it down into a few sentences of statute, is not only very challenging, it becomes difficult to make changes to because statute is so much inflexible compared to --

Mr. Pitts. My time is expired. I just want to clarify your answer. Can FDA change it, a guidance at any time -- its guidance at any time?

Dr. Shuren. Not overnight. Not overnight. We have to go through a long process.

Mr. Pitts. All right, the chair recognizes the ranking member, Mr. Pallone, 5 minutes for questions.

Mr. Pallone. I wanted to thank Dr. Shuren for being here again. As you know Representative Blackburn has introduced a bill, H.R. 3303, that would create an entirely new regulatory framework for medical software. It creates three new categories, medical software, clinical

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

software, and health software, the effect of the bill is to remove entirely from FDA's jurisdiction clinical and health software, and if I read the bill correctly, FDA could still regulate so-called medical software, but the bill says the medical software would no longer be considered a medical device even though FDA could continue to use all of its device authorities to regulate it.

Now, supporters of this bill assert that it is essentially an effort to codify FDA's mobile medical apps guidance. So I wanted to ask you briefly, is that what this bill does and do the two cover the same policies? Quickly, though, because I got a lot of questions for you.

Dr. Shuren. No, this doesn't codify our policy. It takes out from our authority the ability to assure the safety and effectiveness of devices that we currently regulate, including some high-risk devices.

Mr. Pallone. All right. Now focusing on the medical software, it appears this category is intended to describe software that is marketed directly to consumers and would make clinical recommendations that could result in the consumer taking some health action in response to that recommendation, but without actually seeing a doctor. And that certainly is a type of software I would want FDA to look at too, but I am concerned about the way it is drafted and what the actual effect would be. So the question is, are there examples of software FDA

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

currently regulates, or would be interested in overseeing that would be excluded by this definition?

Dr. Shuren. Yes. And our read of it, this is not just limited to software for consumers. So our read is we would no longer be able to assure safety and effectiveness of blood glucose meters, which measures sugar in the blood and used by diabetic patients and doctors to determine if they need insulin and how much insulin. We have cleared an app for it. We wouldn't be able to assure the safety and effectiveness of software is used to analyze the Pap smear slides, and highlight the fields that the health care provider should look at to then screen for cervical cancer. And if we can't assure it is accurate, then those providers may be missing cervical cancer.

Mr. Pallone. All right, let me move on. I am also concerned about what the impact would be of giving this broad set of software a new definition and excluding it from the device definition. Is there any question, is there any precedent for that kind of legislation, and what would the effect be to saying something is not a device but authorizing FDA to use all of its device regulatory authorities?

Dr. Shuren. I am not aware, and I have asked my agency. We are not aware of any similar case. And it is very confusing to us what this actually accomplishes.

Mr. Pallone. Yeah, I would agree with that. Lastly, I am not going to have enough time to explore the other two categories in the

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

bill with you, but hopefully somebody else will. But let me ask you a more general question. The reason we are even talking about legislation today on the heels of the release of FDA's guidance is that some are apparently concerned that the guidance leaves too much room for chance and it is unpredictable. But in the face of what I know is a rapidly changing marketplace, I am concerned about using legislation as a tool here at all.

So do you think it is appropriate to be looking at legislation at this point, and you can -- can you say anything to alleviate fears that FDA is going to stray far from this final guidance in the future and begin regulating every mobile app on the market? I think that is the concern.

Dr. Shuren. Right. Like I said for legislation, it is your prerogative. We want to make sure you understand from our perspective the implications, at least for the bill as currently drafted. We think at the present time, it may be premature for legislation. If we are going to talk about things that suddenly are not regulated and go into a new framework, what is that framework? What is being put in place? And once you draw lines, and it is chiseled in stone, we are sort of locked in for a long period of time. Are those the lines then on which you develop a framework around? Now, we are not saying there isn't going to be a need for legislation at some point. There may well be. But we think at the present time, this is just simply premature.

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

Mr. Pallone. What about my last thing, Dr. Shuren, the fear that FDA is going to stray from its final guidance and regulate every mobile app?

Dr. Shuren. Yes. No, we are not going to do that. There are a lot of hoops and hurdles for us if we ever go there, and quite frankly, let me put a sensitive topic on the table, laboratory developed tests, I think people know we have been trying to change an enforcement policy. While I have been at the agency we have been trying to change that policy for 15 years.

Mr. Pallone. All right. I don't know if you answered my last question, but I guess that is the best I am going to get, right?

Dr. Shuren. The answer is no, we are not going to be going after a whole bunch of other mobile apps.

Mr. Pallone. All right, thank you Mr. Chairman.

Mr. Pitts. The chair thanks the gentleman and now recognizes the gentlelady from Tennessee, Ms. Blackburn, 5 minutes for questions.

Mrs. Blackburn. Thank you, Dr. Shuren, and we do appreciate that you are here, and look forward to working with you as we continue to go through this process. Let me stay with the framework, and of course, FDASIA requires your working group deliver a framework, regulatory framework, what it would look like, the various agencies, where the responsibility would lie, and when do you expect that we are going to be able to see that?

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

Dr. Shuren. So I am expecting that it won't be our call to make because it will go through administration review. I think it is more reasonable to expect that more in the February time frame. But again, I can't make -- I am not the one to make that decision.

Mrs. Blackburn. Do you think we are safe saying first quarter next year?

Dr. Shuren. Yes, I think that is realistic.

Mrs. Blackburn. Okay, that is great. And then do you know what the report is expected to say about strengths and weaknesses of the FDA regulating in this space?

Dr. Shuren. Excuse me, the report --

Mrs. Blackburn. You are excused.

Dr. Shuren. Thank you. I had a teenage moment right there. The report isn't done so it is hard to comment on what is in there, but you can anticipate what we are focusing more on are the things where FDA isn't dealing with technologies than what is the framework that should be in place? And where are the areas where there are additional clarity between what the different agencies do? That is, and that should be in place. And I will tell you, the report will give thinking. It will give proposals. We will be seeking public comment on that before proceeding to even do anything on the framework. So that framework isn't going to say here is the proposed policy, give us comment, and we move to final. It is a step before even getting to

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

trying to put formal proposals in place for a framework. So there are lots of opportunity for input. In fact, we believe it is essential that we are working closely and collaboratively with the stakeholder community in trying to put in place what best meets the needs of the entire stakeholder community, the innovators, and patients, and practitioners.

Mrs. Blackburn. Okay, do you think that your framework would require the FDA to modify its approach if it identifies FDA's -- some regulatory weaknesses, we will say it like that, and then would you expect those changes to be big or small?

Dr. Shuren. So right now there is nothing written in stone. What we will do is we will put out ideas. We will get feedback on that. Things may change based upon what we hear back from stakeholders as we move forward. And there are particular areas where there is still need for greater clarity that we are going to take the time and attention to work with stakeholders on what final policy should look like. We are not rushing to judgment. We think we need to give it the time and we need to give it the collaboration that is absolutely essential to try to get it right. But also, to give flexibility to this community, and allow the marketplace to evolve. What we worry about is locking ourselves into such a great degree, we end up stifling innovation because we really haven't thought through what will happen in the future. We don't know what is going to happen in the future. Do we

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

have the flexibility to account for it as times change, and as technology evolved?

Mrs. Blackburn. I think that one thing we can all agree on is we do not want to stifle innovation, and I would appreciate if we can say that is a shared goal, and something that we would seek to do. For those of us that have rural areas that are dependent many times upon expanding access to certain health care concepts, this, the mobile medical apps plays a tremendously important position in that delivery.

So I like hearing you say let's not stifle innovation. I think that our community of innovators would appreciate hearing that also. I do think it is important that you conduct impact analysis, not only on the industry, but on patients, and as you all have worked through this process, are you conducting that type of impact analysis and looking at the expectation of what that innovation can have on the industry and on individuals, on patients?

Dr. Shuren. So we certainly take into account what the impact when we are looking at regulating, or on the flip side I would say not regulating, particular technologies. We do take that into account. For the framework that everyone has been talking about that we need a new framework for some of these technologies, we are early on for kind of considering what does that look like, and what the impact will be, which is why we think it is so critical to have those collaborative efforts with the stakeholders, to figure out what to do and understand

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

what the implications are.

Mrs. Blackburn. Thank you, I yield back.

Mr. Pitts. The chair thanks the gentlelady. I now recognize the ranking member of the full committee, Mr. Waxman, 5 minutes for questions.

Mr. Waxman. Thank you, Mr. Chairman, I want to follow up, Dr. Shuren, with the questions that Mr. Pallone asked you about the effect of the SOFTWARE Act, the proposed bill, that proposed new law. I am still concerned about the notion that we could successfully use legislation to effectively give FDA the tools it needs to assure patient safety when they use these apps. You know, this is a balance. We don't want to stifle innovation but we don't want patient safety to be at risk. So let me ask you about the two categories that are defined in this bill. One says there is clinical software, and the other part of the bill says there is health software. The bill would completely remove FDA's jurisdiction to even look at both of these newly defined types of software.

Now, clinical software is clinical decision support software that captures, analyzes, changes, or presents patients or population clinical data, but does not directly change the structure or function of the body and is intended only for the use by health care providers. Health software is software that can also capture, analyze, change, or present patient or population clinical data. It can support

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

administrative or operational aspects of health care, but is not used in the direct delivery of patient care. So that is what defined in the bill.

First, let me ask you an overarching question about both of these categories before I get into the specifics about each. Do you see any problems with your existing authority over the apps that these provisions would cover, such that there could be an advantage in putting them into a newly defined categories of unregulated products for which some future regulation would be contemplated?

Dr. Shuren. We think one of the challenges with suddenly carving out areas, writing them down in statute for the moment, is that in trying to figure out what a new framework looks like, you are stuck with those definitions. You are stuck with those categories, and you have to build a framework around those, and it is unclear at this point if those lines are drawn in the best possible way for the most appropriate regulatory framework that facilitates innovation, while also protecting patients.

Mr. Waxman. Well, they define these categories and say you can't even look at them anymore. Let's look at this clinical software category. As I read it, it would seem to cover a large swath of software that the guidance that FDA issued specifically says warrants FDA oversight. For example, it seems to cover mobile apps that perform patient-specific analysis and provide patient-specific diagnosis or

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

treatment recommendations.

I want to know if that is your interpretation. Are there examples of software that the bill would explicitly exempt FDA regulation, but that FDA believes raise patient safety issues warranting oversight?

Dr. Shuren. Yes, it does. And some of those examples we included in our guidance. So for example, computer-assisted diagnostics, or computer-assisted detection devices analyze radiological images for highlighting what may be cancer so they can be used on mammograms to help a radiologist determine if there is cancer or not. And if it is inaccurate, if don't make sure it is safe and effective, radiologists may miss cancers or they may send women for inappropriate biopsies.

Radiation therapy planning which takes patient information, an analyzes their imagining studies to come up with what dose of radiation should be given for their cancer. Very complicated analysis that usually took weeks, several experts, including a physicist now done by software, and then that is uploaded to a machine that can deliver the radiation. If that is not safe and effective, then cancer patients don't get the right radiation to their cancer, or they get radiation to their healthy tissue.

Mr. Waxman. Let me ask you because I have a limited time. There is a category called health software. This seems aimed at excluding software such as electronic health records, which the FDA guidance

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

already describes is not warranting oversight. Let's assume we all agree that FDA should not have authority over electronic health records. But putting aside for a moment whether you think that is a good or bad idea, could you describe the factors one would have to take into account so as not to inadvertently capture things that truly warrant FDA oversight because of patient safety concerns?

Dr. Shuren. Well, certainly in any category, let's say we do talk about electronic health records, I will put it on the table. You have to be very clear about what are we talking about? Are we talking about electronic version of medical records, or are we talking about more, because software is software. You can combine function in a variety of different functions, so can you take what you could call an electronic health record, but I just mentioned computer-assisted diagnostics. That can actually be included. It is software, with any other compilation of functions. So you can call up radiological images and apply that analytical software to it.

So are we saying that computer-assisted diagnostics, because if FDA were to assure it is safe and effective when it sits as standalone program on a computer, if I combine it with other functions suddenly, you don't assure it is safe and effective.

That doesn't make sense. It is the same risk to patients. Why would we do that? Why would we create arbitrary categories like that? That would be a concern.

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

Mr. Waxman. There can be real complexities of what look like simple definitions.

Dr. Shuren. Right.

Mr. Waxman. Thank you, Mr. Chairman.

Mr. Pitts. The chair thanks the gentleman. I now recognizes the gentleman from Illinois, Mr. Shimkus, 5 minutes for questions.

Mr. Shimkus. Thank you, Mr. Chairman, and I appreciate the ranking member of the full committee and the subcommittee in this line of questions. But I also was listening to the chairman talk about a question about when was the first time you provided some technical assistance on legislation -- on this piece of legislation, and my understanding was, following up with staff, was late last night was the first time they had any of these discussions. So I would ask my colleagues to hear, Congresswoman Blackburn, are you willing to work with the FDA to try to clean up some of this language that might be of concern?

Mrs. Blackburn. Absolutely, and that is why we had contacted them in July and continued to seek to work with them. It is about making certain we do not stifle innovation providing certainty and clarity.

Mr. Shimkus. And Dr. Shuren, would you then work with Congresswoman Blackburn and the bipartisan group cosponsoring this legislation, to see if they can reconcile some of these language differences?

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

Dr. Shuren. We certainly would be more than happy to work with you, and I will say in terms of request for feedback on legislation, we did provide some feedback within the agency in July. I don't know whatever came back to you all. And I was on the first version of the bill. The new version of the bill. To my understanding, we were first asked for any kind of feedback late last week. And we did take a look at the bill, and we spoke, I think, with one of your staffers.

Mr. Shimkus. Just reclaiming my time, I think the point being made is, I think you have the author of the legislation, and we have, I think, your commitment to work together because there are issues raised by the ranking member, I think are credible, but it is a good piece of bipartisan legislation that they worked on. Mr. Waxman, would you like to comment?

Mr. Waxman. I thank you for yielding. I am always open to discussing the matters, but it seems to me there is a threshold question of whether we need legislation at all, and I am not convinced of that. But I would certainly be happy to talk to --

Mr. Shimkus. Reclaiming my time, I am going to raise one of those issues of why we might need legislation, and it goes back to Mr. Pitts' other question, based upon this issue of Christy Foreman's testimony, where she basically said that that guidance could change.

Now, Mr. Pitts' question to you was, can that guidance change at any time? And in good bureaucratic form, Dr. Shuren, you said, well,

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

not immediately. Well, that wasn't the question of whether it could change immediately. The question was, could that guidance change?

Dr. Shuren. Yes, it could change.

Mr. Shimkus. Okay, that is the answer we are trying to get out. But I do know that in her testimony, she said could change its mind tomorrow, and I think that is probably where you talked about no immediate response. But the point being that guidance could change, and the importance of codifying is that then the law would have to change, which brings us to the point of why the legislation might be important, and because in the tech industry, they need -- just like any other business -- they need some certainty. And because of the two additional points that I have would be with this, is what would you tell companies who fear the FDA regulation with an imprecise tool like an medical device regulatory tool who fear that regulatory confusion and delay are sure to follow the September 2013 final guidance. You are saying there is none. Is that correct?

Dr. Shuren. Well, I am just saying that we did provide a lot of clarity in the guidance, and we have a mechanism to continue to build on that. So companies who say you know what, I am doing this specifically, I would like to get feedback from the agency, we will look at and quite frankly, no, we shouldn't be dealing with that. We will put that on the Web site so everyone learns.

Mr. Shimkus. Let me reclaim my time. I have got a minute left.

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

There are really small companies, and this is how these folks start as we all know, who are being -- maybe the excitement is being diminished based upon the FDA regulatory regime and so larger companies, not that there is any here in this crowd, might be trying to purchase smaller apps, or proposals, or inventions because of the bureaucratic challenge of getting through the FDA and this process. I only put that on the table because we represent constituents, and this is what has been raised to us.

So I put that just as one of the reasons why certainty might be helpful, more certainty might be helpful than less. And with that, Mr. Chairman, I yield back my time.

Mr. Pitts. The chair thanks the gentleman. I now recognize the gentleman, Mr. Butterfield, 5 minutes for questions.

Mr. Butterfield. Thank you very much, Mr. Chairman, and I won't take the full 5 minutes. I think my colleagues have covered some of the territory that I intended to cover. But thank you, Mr. Chairman, for holding this hearing. I am one of the six individuals who have been referenced here as sponsors for this bill. I think it is important. I have listened very carefully to this conversation, and certainly, I understand the concerns that Mr. Waxman and Mr. Pallone have raised, and I think it is -- they are legitimate concerns and I think we need to work through this as we go forward.

But the reason I have signed on to this bill is just because of

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

the explosion of software in this space. These applications have just exploded over the last 12 to 18 months, and we have got to get some type of regulatory framework to make sure that it does not have unintended consequences. I don't want to discourage innovation. Innovation is the future. And I want to keep us on the cutting edge, and we can do that. And so I pledge to you, to all of you who are stakeholders in this, that I will work with you to try to come up with a framework that we can all agree on.

Speaking of stakeholders, I have in my possession, six letters that I received. Mr. Chairman, I am going to ask unanimous consent to submit these six letters of support for the SOFTWARE Act that we have received from health care industry.

Mr. Pitts. Without objection. So ordered.

[The letters follow:]

******** COMMITTEE INSERT ********

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

Mr. Butterfield. And if I may state for the record, these letters are from Aetna Health, Healthcare Leadership Council, Health IT Now Coalition, Verizon, and IBM, and Applications Developers Alliance. Thank you, Mr. Chairman. I yield back.

Mr. Pitts. The chair thanks the gentleman. I now recognize the gentleman from New Jersey, Mr. Lance, 5 minutes for questions.

Mr. Lance. I thank you, Mr. Chairman, and I will not take my full 5 minutes. It is always a pleasure to be with you, Doctor. Do you know, does the FDA currently have reciprocity agreements with the agencies with which it is working? I know that the Congress has decided that there will be a regulatory framework where no one agency would prevail in all matters. Do you currently have reciprocity agreements?

Dr. Shuren. We have -- we do have MOUs in place.

Mr. Lance. MOUs, you will have to tell me what that is.

Dr. Shuren. Oh, I am sorry, Memorandums of Understanding.

Mr. Lance. Memorandums of Understanding.

Dr. Shuren. And Office of the National Coordinator is part of Health and Human Services so that is actually part of, if you will, one happy family.

Mr. Lance. One happy family. Rather like Congress, one happy family. As an example, if an app developer finds a bug in its software that causes a potential patient safety risk, as I understand it, it will typically issue a patch as quickly as possible to fix the

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

functionality. Since the threshold for submitting a change is whether the change could significantly affect the safety or effectiveness of the device, wouldn't the FDA require that it review the patch before the developer could release it? And if that is correct, wouldn't that mean that a change that actually improves the safety of the app might be held back for months until approval is received?

Dr. Shuren. Yeah, we actually don't generally ask to see those security patches before they may -- in fact, most of the changes in software, we don't look at beforehand. But it is a great point about what you do with software, and you should know that there is currently an international effort underway under the International Medical Device Regulators Forum that you encourage us to be a part of under FDASIA, to develop an international harmonized framework for software as a medical device, because all of these other countries, they have been regulating software medical devices for years. And now it is about do we have a common appropriate framework in place? We have been asked by industry to do that and we are actually working with industry on that.

In fact, the U.S. is chairing that effort, and it deals with what do you do when there are changes in software, and how best to accommodate the business models of companies that make software, but also assure proper patient safety, and that is underway right now.

Mr. Lance. Thank you, Dr. Shuren, and Mr. Chairman. I yield

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

back the balance of my time.

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

RPTS HUMISTON

DCMN ROSEN

[10:59 a.m]

Mr. Pitts. The chair thanks the gentleman and now recognizes the gentleman from Texas, Mr. Green, 5 minutes for questions.

Mr. Green. Thank you, Mr. Chairman. I am proud of the efforts of the group of original co-sponsors of the SOFTWARE Act, and this bill has been supported by the Healthcare Leadership Council, the Bipartisan Policy Center, Information, Technology and Innovation Foundation and several others. It is an important first step toward Congress fulfilling our obligation to provide the FDA the tools necessary to do our jobs.

Dr. Shuren, thank you for being here today. And I am pleased with the guidance issued by the FDA, and I appreciate all your hard work and leadership. Under this guidance, are most electronic records regulated?

Dr. Shuren. Under this guidance, we are not regulating electronic health records.

Mr. Green. Okay. Under this guidance, would mobile apps aimed at diagnosing and prescribing medical care be regulated?

Dr. Shuren. Certain diagnostic apps, but the ones that are, you know, just certain treatment recommendations, no, but certain

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

diagnostics ones, yes.

Mr. Green. Can you distinguish between those for those of us who are not physicians?

Dr. Shuren. Yeah. So what we have said is the kind of functions we have been regulating all along, we have already approved. We have approved devices for that or cleared. Just because they moved to a mobile platform, we would treat them the same. So I mentioned the ECG machine. We have a mobile app for an ECG that doctors can use a smaller smartphone to use to diagnosis patients in their office and help determine if someone is having a heart attack. We want to make sure it is safe and effective. Whether it is a box this big or it is a box that big, it is still the same function.

Mr. Green. Okay. The FDA is using enforcement discretion to establish a risk-based framework for regulating these products. Is that correct?

Dr. Shuren. We are using -- we are actually just using enforcement discretion to clarify the kinds of mobile apps that we are not enforcing any requirements. That is it. It is not creating any new framework at all.

Mr. Green. So future administrations could make different decisions?

Dr. Shuren. So in order to do that, the good guidance practice, the way it works is that there is a very extensive public process to

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

make any changes in it. It is not easily done, it is not done overnight, but the value of it is that things change over time. People sometimes come back and say you know what, we tried this policy for a while, we need new clarity, because things have changed. Guidance lets us do that. When we have statute, we can't do that. We are -- we don't have that flexibility. Guidance does.

And one of the things about changes here, what would change? Well, we also said there are certain things we used to regulate it, we are not regulating anymore. We anticipate over time and more input from the community and more experience, there will be more things we say we used to regulate, we don't regulate. We can do that through guidance. That is what enforcement discretion allows us to do. Statute provides limitations.

Mr. Green. Okay. It appears, though, that virtually all software used in the health setting could be regulated under some administrations and could not under others. I know that discretion helps, but somewhere along the way there needs to be certainty, regulatory certainty, but mostly important could endanger the patient safety in the future.

Dr. Shuren, I commend you and your agency for recognizing your need for clarity and certainty. If clarity and certainty are the goals, why shouldn't we work on legislation?

Dr. Shuren. So as I said before, it is certainly your all

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

prerogative to do so. And if you all want to do that, we are very happy to work with you. I just simply put out, put in place what some of the challenges are with statute. There is a desire for predictability and flexibility. Statute, it can give you predictability, it doesn't give you that flexibility to be able to adapt as technologies adapt, as the marketplace evolves and, as stakeholders say, you know what? We need to see some changes. We are able to better accommodate our stakeholders through a guidance mechanism in many cases than we have with statute. And I am not saying that legislation may not be necessary in the future. All we are saying is it is premature at this point, particularly in not even figuring out what does a new framework look like?

And in that respect, maybe the line's drawn going different places. Maybe at that point there is a need to put something in legislation, or maybe we want something out there and get experience with it first before we have decided whether or not we got it right, because we got it wrong, it is much harder to change statute than it is to change guidance if necessary, but it is not easy to change guidance either.

Mr. Green. Believe me, we understand that, but the concern I have is that we need to have both, we need to have some flexibility with the FDA, but also certainty to industry and everyone else that they know what the FDA's doing. And if FDA should want certainty that comes

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

from updated regular authority through legislation, and if not the right time, how will we know when the right time is to start? After a public health crisis? And, again, our committee just dealt with compounding, because -- and the first hearing did not show very good on the local and, you know, pharmacy agency in Massachusetts or the FDA, and so we have put together a bill that, again, nothing's perfect we do, but that actually gave the FDA that authority, discretion, but certainty in the authority of it.

Mr. Chairman, thank you. I know I am out of time.

Mr. Pitts. The chair thanks the gentleman and now recognizes the gentleman from Florida, Mr. Bilirakis, 5 minutes for questions.

Mr. Bilirakis. Thank you. Thank you, Mr. Chairman. I appreciate it very much. Thanks for holding this hearing as well. Thank you, Doctor, for your testimony.

The first question, Dr. Shuren, under the rules you issued, FDA said it would have enforcement discretion on many commonly-used applications, for example, apps that serve as video conferencing portals specifically intended for medical use and to enhance communications between patients and caregivers; also, apps specifically intended for medical uses that utilize a mobile device, built-in camera or a connected camera for purposes of documenting or transmitting pictures to supplement or augment what would otherwise be a verbal description.

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

This sounds like FDA reserves a right to regulate Skype, Web cams, iPhones and tablet PC's. There are many off-the-shelf software solutions that can be used or adopted into telemedicine, as you know. How do you draw the delineation of a program specifically intended for medical use?

Dr. Shuren. Yeah. So actually the tablets, the tablets themselves and the video cameras and all that, those aren't even medical devices. I don't even view them as medical devices. The issue has come up when someone develops software and they use the smartphone, let's say, the person developing the software that suddenly gives it a medical function. So I mentioned the ECG. Another one is ultrasound. People use sound waves to look at abnormalities in the body, so we have cleared an app that is an ultrasound. It takes kind of a mobile platform and it turns it into a medical device. The maker of that platform is not a manufacturer of medical devices; no responsibility on their part.

The software, though, is the issue. And the challenge there is, and as this bill is currently drafted, the problem for us is we wouldn't be able to assure that that software is safe and effective. And it is used by, sorry Dr. Burgess isn't here, an obstetrician to use on women who are pregnant to look for fetal abnormalities. And in this case, we wouldn't be able to assure that this is going to be accurate technology when a doctor uses it to make sure the fetus is healthy or

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

not healthy. Those are the things that we are talking about, but a basic tablet by itself is not even a medical device.

Mr. Bilirakis. Even if it is used for medical purposes?

Dr. Shuren. No. That itself isn't. The software maker, then, is actually taking that tablet and as part of it is now using it as a medical device. The software maker, then, whoever is putting that together, they are the ones who have now put out a medical device through their software. The person who made the tablet, Apple, is not a device manufacturer, and that is what we have said.

Mr. Bilirakis. Okay. And in the mobile medical app guidance, mobile platforms are defined to include smartphones, again, tablet computers or other portable computers. Is a laptop considered a portable computer?

Dr. Shuren. It is a portable computer. And we don't regulate laptops.

Mr. Bilirakis. What about --

Dr. Shuren. And I have got to tell you, I don't want someone regulated my iPad. I like my iPad.

Mr. Bilirakis. What about a desktop?

Dr. Shuren. A desktop is a computer, right.

Mr. Bilirakis. Not considered a portable computer?

Dr. Shuren. No.

Mr. Bilirakis. Okay.

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

Dr. Shuren. And what you are highlighting is what has changed over time is that you have a lot of the same functions, but you didn't have the capability to make tiny computers. That is the way the world changed. I had things years ago that are on a desktop, and then the laptop came along, we had the PC's, and now they can be on small smartphones. They are computers. And the value is that they can play a variety of different software. Manufacturers don't have to make the hardware anymore, because they now have ubiquitous hardware that a software maker can simply take advantage of.

That is the way the world has changed. And all we are saying is the functions, when they stay the same, treat them the same, because the impact and the risk to patients are the same. Simply because it got smaller and I can pick it up and walk out of the room with it doesn't change the risk for patients. Why, for that reason alone, would we simply treat it differently?

Mr. Bilirakis. Okay. I have heard some, including staff at the FDA, suggest that the FDA move to regulate mobile medical apps, will give industry and patients more certainty. Can we really say that enforcement discretion gives health IT developers and investors any certainty or clarity if the FDA can indicate that it may, that it may have the discretion to change its policy? Is that the case? In other words, can we -- instead of -- because the FDA has the discretion, how does that give the industry or developers any certainty?

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

Dr. Shuren. Because there are safeguards in place to actually change that discretion. As I mentioned, there are a lot of statutory requirements for us to go through under good guidance practices with putting out proposals, public comment, and congressional oversight before we can make any kind of changes. So it is not a simple thing for us to do, particularly when there is disagreement on it, but a number of cases, we have our constituents come and ask us to change guidance because the times change and they want updates, and the guidance lets us do that. That is the value of it. And we hear time and time again from our industry how much they want guidance, because it gives them both predictability and flexibility. That is why we have been increasing our guidance production, because we have been asked to do that by our industry. They find it of tremendous value.

Mr. Bilirakis. Okay. Thank you. I yield back the balance. Thank you, Mr. Chairman.

Mr. Pitts. The chair thanks the gentlemen and now recognizes the gentlelady from Florida, Ms. Castor, 5 minutes for questions.

Ms. Castor. Well, thank you, Mr. Chairman. And thank you, Dr. Shuren, very much. I think this is a very exciting area, all of the advances in health information, technology. I have seen it help boost small businesses back home and create business opportunities across my community in the Tampa Bay area. I think that the mobile apps hold great promise in improving people's health, also empowering

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

consumers and individuals and providing more efficient tools for medical professionals.

Now, the 2012 FDA Safety and Innovation Act, FDASIA, directed FDA to work with the Office of National -- of the National Coordinator of Health IT and the FCC to propose a strategy and recommendations on an appropriate risk-based regulatory framework pertaining to health information technology, including mobile medical applications that promote innovation, protects patient safety and avoids regulatory duplication. FDASIA requires the working group of the three agencies to report to Congress by January of 2014.

Dr. Shuren, can you tell us what steps the three agencies have taken so far in developing that report and the extent to which outside stakeholders have had an opportunity to provide input into the development of that report?

Dr. Shuren. Well, certainly. We constituted a multi-stakeholder working group, so representatives from all different parts of the ecosystem under the Office of National Coordinators Health IT Policy Committee, and they spent time and they got a lot of public input along the way, they put out draft recommendations, they got public input on that, and provided it to us. We have gotten a lot of input from the stakeholder community, both from that working group and from other meetings and venues in which we have participated, and that is helping to inform the report that we will make available to Congress

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

and we will make available to the public.

And as I had mentioned, we will get public comment on that before even proceeding to put out proposals for anything that would go into a regulatory framework. So trying to have a very thoughtful process moving forward.

Ms. Castor. And are you satisfied that the participation has been very diverse? Are small businesses adequately represented, are academics represented, the larger corporations? Has everyone had an opportunity? Is there enough balance in what you have heard so far?

Dr. Shuren. We think there has been. I am sure you can always hear from people who said, wow, I wish I am in the room and I am part of a committee. Then you have a committee of thousands. So it is always challenging, but in spite of that, there are publicly available dockets where people provide information, there are meetings where any member of the public could come and to talk, and of course, people can always request to talk to us directly. We talk to lots of people who want to have those conversations, and we do so.

Ms. Castor. So are you still on track for January 2014?

Dr. Shuren. I am anticipating it is going to be a little bit later, in all fairness. We have the recommendations from the working group came in September, and we had the government shutdown, so some people were not around working on things, it adds a little bit more time, that is why I say more likely February, certainly the first

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

quarter, but the final decision after it goes up to review will be made by others, but our goal is to get it as close to that line as we can.

Ms. Castor. And do you think it is important for the Congress to have the benefit of those recommendations before we consider whether or not to legislate in this area?

Dr. Shuren. We do, because we have got a wealth of information to provide back. And like I said, Congress can decide at any moment if you all want to pass legislation, it is your discretion to do so. We would like to make sure that any decisions made are with full information, and then I think there will be value coming from the report. In fact, may even feel that at that point if additional comment, we think there will be need for a lot more input from stakeholders before even sort of figuring out exactly what a framework looks like and what the pieces are, and even then, delving a little bit deeper into the specific aspects of it, because this is complicated.

I mean, it was hard enough even drawing the lines that we did in guidance that is 40 pages long that is just simply about things that are in or out for FDA, nothing about stuff that is out how you treat them, and we knew that was a 2-year process, but how important stakeholders felt it was to have the opportunity to provide input and really think it through.

And all we are sort of asking is sometimes moving quickly to judgment leads to unintended consequences that can be very hard to undo

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

once they are done, and that is all we are really trying to put on the table. We share your desire to promote innovation, and we share your desire to protect patients. We want to see this field flourish. We are jazzed up about a lot of the technology. We want it to happen. We want it to happen right. And that is why we are moving about it in the way that we are doing it and trying to do it in a very collaborative fashion.

Ms. Castor. Good. I look forward to reading your report early next year. Thank you.

Mr. Pitts. The chair thanks the gentlelady and now recognizes the gentleman from Kentucky, Mr. Guthrie, 5 minutes for questions.

Mr. Guthrie. Thank you. Hey, thank you for coming back today. I appreciate you being here. As I have talked to different people who provide apps, and I know you said we do not intend to regulate iPads, it is the apps that go on the iPads, and depends on what that app is that goes in the iPad. And I am not an attorney, but I had one law school class and I know the exams were always not black or white, it is always where in the middle, that is the questions they always asked and where does the gray intersect each other. And so just kind of -- and they would give you scenarios. I was just looking through a scenario that people have brought to my attention. And I will be slow so you can follow, but it says, among the mobile apps for the FDA intends to exercise enforcement discretion are mobile apps that perform

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

simple calculations routinely used in clinical practice. It says, according to the FDA, these apps are intended to provide a convenient way for clinicians to perform various simple medical calculations taught in medical schools or routinely used in clinical practice.

And so the question is, while dosing calculators are not listed among the examples, if a specialist routinely prescribes a certain drug patients, would an app that calculates the proper dose be considered not regulated, or would that app be considered one that performs sophisticated analysis and therefore is regulated?

Dr. Shuren. So we actually think, you know, a lot of those actually would not be regulated. And this is why we kind of ask and why we created this mechanism for people who then have questions, say, well, here is what we are looking to do. Is this the kind of thing that you approve clearcut or something you are not exercising new enforcement discretion to? Because in the past, we regulated that as a medical device. We had a classification for it and now we are saying we are no longer doing it. And those are the cases where, particularly as we expand enforce the discretion, clarity around it, we want people to ask us and we will put those examples on our Web site. But, you know, there are other kinds of --

Mr. Guthrie. So they have pre-clearance if they are going -- because it makes a decision on your investment according to where you think the time is going to take to be approved.

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

Dr. Shuren. Oh, yes. And we have actually provided that for developers for years. They have always had the opportunity to come and ask. Here we are trying to have a much more streamlined mechanism to get feedback to developers very quickly and let them know, and give them the kind of certainty they look for. But when you draw a line, think about even statute, in a few sentences, that is still very brought. The question is, what does it mean? And then even with a bill, we are going to have to move forward and interpret that and provide clarity around that, and then there will be additional questions about, well, what did that mean? And we will go through the same kind of exercise. It will always be these issues of, does this mean I am in or I am out, and we will always be in a position of having to provide that kind of clarity.

Mr. Guthrie. Because that would be very helpful that you are going down that path. And actually I was going to kind of continue that application, but I think that the answer will be the same. You will have to get pre-clearance when you move forward down that path, so --

Dr. Shuren. Yeah. And you don't need pre-clearance, because if you went out there on the market and we strongly said, yeah, you are the kind of stuff we are not touching, that is fine, you don't have do come to us.

Mr. Guthrie. Right.

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

Dr. Shuren. We offer it as a service. If you want to and ask us, we can do that. We provide even an email address to send it in. And I will tell you, for these that are coming in, where there is any kind of question about it, it actually -- it comes up to a group, I sit on that group. We are actually meeting this week. And we have questions that come in, and we are answering them.

Mr. Guthrie. Yeah. I guess I -- I understand on pre-clearance. So I just have an app on my phone that calculates how far -- if I walk to the Washington Monument, it calculates my heart beat and whatever, that type of thing, or if I have an app on my phone that -- I don't have diabetes, but if I have a diabetic pump and it regulates that, that obviously clearly would have to be regulated.

And I guess the question when people start getting, you know, the example, one I had is -- I was going to go through, maybe I should, like, look, you wouldn't regulate it if it was just downloading the Physician's Desk Reference, and I just had that on my phone instead of in a book, because you don't regulate the book -- but I will go through an example, I have about a minute, then. I have an example of Coumadin, a blood thinner that could cause major or fatal bleeding. The full prescribing information in the Physician's Desk Reference gives the list of patient-specific factors that impact the proper dosing of Coumadin. And since this information is being used in the mitigation, treatment or prescription by a facilitating professional

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

assessment of the specific patient, should it be in a different category of apps? And MMA guidance is inconsistent on how the FDA intends to oversee dosing information. So that can kind of blur the lines --

Dr. Shuren. Yeah. And what --

Mr. Guthrie. -- in dosing calculators.

Dr. Shuren. We are kind of moving towards a place of a lot of the dosing information is kind of taking a step back and letting a lot of that happen. That is actually -- we are already doing that. I am anticipating we wouldn't do more. But then we talked about dosing for radiation and how complex a calculation that is, and that is one where it is not so simple. Someone can't figure it out very -- themselves with paper and pencil, if you will, very quickly. That can take weeks. You got a physicist, radiation oncologist. That is the kind of dosing. So if you just blanket any kind of dosing, you would sweep that in. Those are the kinds of challenges.

But I would say even with statute, you will always have the issues on boundary lines and seeking for clarity, because I will tell you, with the law we have today, on any of a variety of different areas, we are always providing a different clarity to people. It is just a question of do you draw a line that locks you in and still have to provide the clarity, or do you give flexibility to a community that itself is evolving, and we don't know what the future will look like. Shall we tell people, your future is locked in today or do we want to let the

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

community have the ability to let the marketplace evolve. And we would like to see the marketplace evolve.

Mr. Guthrie. Thank you. I yield back.

Mr. Pitts. The chair thanks the gentleman. Now recognize the gentlelady from the Virgin Islands, Dr. Christensen, for 5 minutes for questions.

Dr. Christensen. Thank you. Thank you, Mr. Chairman. Welcome, Dr. Shuren. So we have heard a lot so far about the substance of the guidance FDA recently issued, all that went in to developing it and how you are working with the developers, and that has really been helpful, but I think it would be useful to have some more context. And sort of to follow up on my colleague's last set of questions, I would like to ask you about the background and history of FDA's oversight on software generally.

Your testimony mentions the fact that FDA has been regulating medical device software for decades and medical device software on mobile platforms for more than 10 years. This would, I am sure, surprise many people, because software is not typically thought of as being a medical device. So could you explain to us how software can be a medical device again under the Food and Drug Cosmetic Act? Obviously you don't regulate all software. It would also be helpful if you could give us -- you gave us some examples of where you have exerted regulatory oversight, but some examples of software that you

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

might have begun with decades ago and things you are looking at today.

Dr. Shuren. Yes. Certainly. So, you know, the device definition was written broad, with the idea that it is in place to allow for changes in technology over time. So how it becomes a device is because it is intended for use in diagnosis of disease or conditions or treatment-cure mitigation of disease, and not doing so primarily by chemical action. If it is chemical action, it is a drug, not chemical action. It can be a device. And it is the same approach, by the way, other countries also have that broad definition which allows them to handle new technologies as they come up.

We have technologies now that are moving to mobile platforms. So another one is fetal monitoring. We have now an app for that. And this is typically used on women who have a fragile pregnancy to monitor for uterine contractions, fetal heart rate and determine is the fetus is in distress. It is used in hospitals for that purpose. Our concern is under the bill as currently drafted, we wouldn't be able to assure that is safe and effective.

What is on the horizon? Diagnostics, lots of diagnostics. They are all going to be on mobile platforms. The XPRIZE just put out a challenge to develop a Tricorder. Now, I am a Trekkie. Remember Dr. McCoy had what was probably the first mobile medical app in history. He had a Tricorder, and he would wave this little handheld thing over the body and he would make a diagnosis.

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

Well, the XPRIZE Foundation put out a challenge for that, to actually have technology to diagnose diabetes and stroke and heart disease. And guess what? Today that technology is going to become a reality, because there are ways of measuring things in the blood without taking your blood.

Dr. Christensen. Right.

Dr. Shuren. And they approached us, because they said, these are medical devices. We have got to make sure it is safe and effective. Will you work with us to provide guidance to these developers, and we are doing this. This is a partnership. I would love to see a Tricorder. Can you imagine "Star Trek" in reality? It is like a kid's dream come true. That is the future. But we want to be there to help the future, and we would be concerned on anything in legislation that doesn't provide those assurances for patients.

Dr. Christensen. And so would I. So obviously FDA has had a lot of experience in this space, and that is really very reassuring. And medical devices, they fall into different tiers, Tier I, Tier II and Tier III. Of course, Class I devices are the least risky and III are the riskiest.

Can you briefly elaborate on these three levels of device oversight and the responsibilities the device manufacturer has under each of these levels?

Dr. Shuren. Certainly. So Class I is our lowest. That is low

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

risk. We don't review those going on the market. And about 50 percent of devices on the market today are probably Class I. And they have to have labeling, they have to report certain serious problems to us or, you know, we have some surveillance, and they have to do something called quality systems. Some people call it good manufacturing practices, but in engineering, we call it quality systems, and it is having the practices and procedures in place to assure you make a quality product. And this is actually a linchpin in making good products.

And we believe the future, by the way, in software really focuses much more on quality systems and a post-market approach to many things, and that is what is under discussion in this international effort.

Class II are moderate risk. And in addition to what I talked about for requirements, we do see them beforehand. And that case, we do a comparison of a substantially equivalent to other technologies on the market. That is a 510K.

And the very high risk, Class III, we then ask for studies to show are they, in fact, safe and effective? So we have a very risk-based approach.

As I mentioned, though, all of this is looking at being modified for purposes of software. Exactly. And that is the same we are doing with Europe, Canada, Australia, Japan, China, Russia, and we have the Asian Harmonization Working Party, which if they agree too, will bring

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

in other countries in Asia, the Middle East and Africa into one harmonized framework.

Dr. Christensen. Thank you.

Mr. Pitts. The chair thanks the gentlelady, now recognizes the gentleman from Virginia, Mr. Griffith, 5 minutes of questions.

Mr. Griffith. Thank you so much, Mr. Chairman. And I apologize that I was not here earlier. I am working in another committee as -- or subcommittee as well.

Doctor, I understand your hesitation about setting things in stone, especially considering how quickly this industry is evolving. However, the medical industry as a whole is evolving quickly, as you know. Your comments beg the question whether Congress should ever legislate in this space. Our goal here is to carefully craft legislation that sets your authority in stone, but does so in a flexible manner that provides you the authority for effective regulation of the industry.

My colleague, Mr. Green, in his opening statement mentioned the issues that arose during the meningitis outbreak. Throughout the investigation and legislative process that followed that outbreak, we learned that the FDA felt it lacked regulatory clarity and authority. We all want to make sure that the FDA is in a position to regulate effectively and confidently. I appreciate Mr. Green bringing up this comparison, because it is an incredible lesson we learned about the

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

importance of FDA authority and making sure that the FDA understands what its authority is.

Throughout the hearing, we have heard from everyone the promise of health IT technology. We know this industry is growing and holds enormous potential. You would agree, wouldn't you, that we have an opportunity to set a sound regulatory foundation for such pivotal technology?

Dr. Shuren. For Congress to do that, it is always Congress's discretion to pass legislation, absolutely.

Mr. Griffith. And one of the concerns that I have had, and I am so glad that we have this bill as a vehicle to work on these areas, is that when we had a previous witness in testifying, I brought out my cell phone. I have now got a newer version that does more things by about five-fold than my old one did. And I brought out my cell phone and I said, hey, here is the problem. A group of scientists in Africa working with people in Canada and the United States and Switzerland, I believe, came up with an $8 hack onto a cell phone that allowed them to take high resolution pictures of fecal material, and folks in the United States were then telling them what parasite was affecting the village in Africa.

I said, is that going to be considered a -- if we were to try to use something like that in the United States, would that be a medical device? And the lady said, yeah, I believe it would be, because it

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

is diagnostic. An $8 hack on a cell phone is a way that we can bring a lot of innovation into diagnostics, et cetera, and particularly when -- and I am representing a largely rural district in Virginia, and I had one of my hospitals recently close down, and we are hoping that we can rectify that, but now I have got folks who have to travel 45 minutes to get cardiac care.

It sure would be nice if we had some high tech fixes, and they are on the verge of being there, where my folks could hook up directly with the doctor, if that technology were readily available. And I am just afraid the FDA may slow it down by having too much. So don't you think something like this bill is necessary?

Dr. Shuren. So in all honesty, we don't believe such a bill is necessary, or certainly at this time. And part of the issue, the difference with compounding, in the compounding case, FDA came back and said there is not clarity, to my understanding, clarity in the law, we needed clarity.

Here we think we have the authority. We are using enforcement discretion, if you will, to adapt to changing technology.

I will say that example with stool, no, we wouldn't be regulating that. We just had that with melanoma. If you know, if take a picture of a skin and you are sending it to a doctor, no, we are not touching that, but software that is analyzing that melanoma, we just ran into it with an app developer who sold it to consumers and said, look, use

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

this on your skin lesion, you have a concern, we will tell you if it is high risk or moderate risk or low risk, and if it is high risk, we will recommend you go see a doctor, and if it is moderate or low risk, you just monitor it; not go and see your doctor, monitor it.

And guess what? When researchers at the University of North Carolina looked at it, it was accurate in finding melanoma one out of 10 times. Nine out of ten times it missed it. It was telling patients, don't go see your doctor, monitor it. That is a diagnostic and that is the kind of stuff we should be concerned about.

Mr. Griffith. Well, and I understand that, but I also risk -- there is also the risk that if we don't get things out there onto the marketplace, that people may miss something, because those people who got that test, even with its low accuracy rate, may not have been planning to go see a doctor anyway, and some of them, one out of 10 at least, did go see the doctor. Now, I would prefer it if obviously they didn't have a false read, and that is an issue that has to be taken up.

Dr. Shuren. Yeah. And those folks obviously downloaded the app because they were interested in looking at some suspicious skin lesion. Again, we are not looking to hold up technology.

I will say of the feedback we have gotten on the guidance is, for the most part, you know, you have got the line in a good place. I mean, and we were trying to get to that point of providing the clarity that

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

people are seeking. It is not easy. Whichever way we do it, statute, guidance or whatever, it is not easy to draw perfectly clear lines, and that is why it took 2 years to even get to where we were.

Mr. Griffith. But 2 years is a long time. I do appreciate it.

And I am hearing the signal that my time is up, and therefore, Mr. Chairman, I yield back.

Mr. Pitts. The chair thanks the gentleman. I now recognize the vice chair of the subcommittee, Dr. Burgess, 5 minutes for questions.

Dr. Burgess. Thank you, Mr. Chairman. And again, Dr. Shuren, thank you for being with us today. Back in my opening statement, I talked a little bit about clinical decision support. Back in my day, that meant the Merck manual in the pocket of your white coat as you went down to the emergency room, but now it can be so much more real-time and it can be up-to-date. And it really, in my opinion, is one of those things that could really transform the way doctors practice. Do you agree with that observation?

Dr. Shuren. I do agree with that. And we actually think for clinical decision port, and this is why we have been asked to provide clarity in that area, but we were asked to give more time and do it as part of this other process on a regulatory framework, we do think a lot of those things are not the stuff that FDA would be touching. Even things -- IBM, I am glad they are here, things they are doing with WatsonPaths we have seen and they are going through data import, those

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

are not the stuff that we are touching. We think that is terrific. But the way the people start -- then the question is, how do you define?

So even the bill today which, again, as drafted, draws a line that actually cuts out things like the computer-assisted diagnostics that even the same groups that have said, oh, maybe we would like statute, those are exactly the examples of what they say FDA should regulate. And that is what we kind of mean about we are drawing the lines on this. We want to make sure the kinds of things that we should be looking at, we at least have the ability to do that to assure for doctors and patients are safe and effective, and the other things we are not going to touch. That is our idea.

Dr. Burgess. Well, do you see where there is a concern that as long as there is some ambiguity as to whether or not you might regulate it in the future, it leaves them with the ambiguity of not knowing how to proceed on the development side?

Dr. Shuren. I would say typically for folks who have dealt with us, and understand how we use our policies --

Dr. Burgess. Be careful. I have dealt with you.

Dr. Shuren. I know you have. I know. See, you even caught me off guard right there. Thank you so much.

That being able to make those changes is not something that can be done on a dime. And that is why for folks who have dealt with us understand that, yes, we actually do have a level of certainty. In

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

fact, what they tend to ask for is more guidance and more clarity as opposed to, please don't use guidance to clarify for us.

Dr. Burgess. But, I mean, it is a little bit of a different world than the typical drug device world in which you have historically regulated. Is that a fair statement?

Dr. Shuren. Yes, but one of the things that has happened here in terms of where we are looking, we didn't move out into someone else's space and say, you know what, we are coming out to reach new stuff. What has happened is developers, who weren't making things in the health care space and FDA, typical kind of FDA regulated functions started to say, well, now we are going to go do that. And what they did is they kind of moved into a world we have been dealing with, and for them it became, ooh, we don't know the FDA. We hear of things. We are concerned.

So we didn't reach out to actually expand our universe of anything in our guidance. We have been contracting it. But we have new players. And this has happened before in other times. New people come in, they have uncertainty about us, and that is why we are going through this extensive effort to engage with folks and provide the clarity so that we think over time, the people who aren't used to dealing with us will realize, oh, now we get it, we are good, but that will take time.

Dr. Burgess. That is exactly the point. The developers who have

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

uncertainty about dealing with you, how can we provide them the stable footing they need to proceed with their -- and we want them to proceed with their developments. I mean, this is the golden age of medicine that stretches in front of us, so we want them to proceed. How do we give them the certainty that they can be surefooted in traveling down that road?

Dr. Shuren. By doing what the health IT working group, the multi-stakeholder groups asked us to do: to continue to provide that clarity through guidance in other areas, like clinical decision support, in accessories, on certain claims, and that is what you are likely to see in the report we send up to you all, is saying these are the things that we should do. We should follow up on those recommendations and put out that clarity through guidance as we have been asked to do.

Dr. Burgess. Well, I apologize I wasn't here, but apparently Representative Lance asked you about the updates to apps, that the apps that the FDA does regulate, the up -- you know, it seems like my iPad or iPhone is always telling me I have got to update my apps. So everyone's familiar with the facts that apps have to be updated. Are you regulating the updates to the apps as well?

Dr. Shuren. Yeah. So most of the kinds of updates, we see the software, we don't even look at coming in the door. And I mentioned, too, there is an international effort underway for international

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

harmonization on how software as medical devices approach and that includes modifications. And this is a collaborative effort between government and industry.

So all of this is included. This is an evolving area. It is another reason why, too, some of these things we are not locking in at all because it is evolving. Those discussions are happening. And we want to get to a place where we and Europe and Canada and Australia, China, Russia, Japan and elsewhere are acting in that same way, have harmonized approaches, because we think that ultimately is in the best interests of everybody. That means a technology treated -- a software in the U.S. gets treated the same in Europe. We would love to see that happen and that is what we are working on, and that includes modifications.

Dr. Burgess. All right. I wish I shared your certainty. But thank you, Mr. Chairman. You have been kind. I will yield back.

Dr. Shuren. Well, consider it enthusiasm rather than certainty at the moment.

Mr. Pitts. Okay. The chair thanks the gentleman. That concludes the questions from the members. The members may have follow-up questions. We will get them to you in writing. Ask you to please respond promptly.

To confirm what I heard from you today, Dr. Shuren, you have committed to work with Representative Blackburn and her colleagues,

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

and I would ask that your assistance, collaboration be responsive and timely.

And before I introduce our second panel, thank you, Dr. Shuren, for all of your responses, your testimony.

I ask unanimous consent to include in today's hearing record a letter from AdvaMed, which includes their comments on H.R. 3303 and issues related to regulation and health information technology. Without objection, so ordered.

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

[The letter follows:]

******** COMMITTEE INSERT ********

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

Mr. Pitts. With that, you are dismissed, and I will call the second panel to the table. We have five witnesses, and I will introduce them as they come and the staff sets up.

First, Mr. Mike Marchlik, vice president, Quality Assurance and Regulatory Affairs, McKesson Technology Solutions; Mr. Jim Bialick, Executive Director of Newborn Coalition; thirdly, the Honorable Zachary Lemnios, vice president Research Strategy, IBM Research; fourth, Mr. Robert Jarrin, senior director of Government Affairs, Qualcomm Incorporated; and finally, Dr. J. Leonard Lichtenfeld, deputy chief medical officer of the American Cancer Society.

Thank you all for coming. Your written testimony will be entered into the record. You will each be given 5 minutes to summarize your testimony. And Mr. Marchlik, we will start with you. You are recognized for 5 minutes to summarize.

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

STATEMENTS OF MIKE MARCHLIK, VICE PRESIDENT, QUALITY ASSURANCE AND REGULATORY AFFAIRS, MCKESSON TECHNOLOGY SOLUTIONS; JIM BIALICK, EXECUTIVE DIRECTOR, NEWBORN COALITION; HON. ZACHARY J. LEMNIOS, VICE PRESIDENT, RESEARCH STRATEGY, IBM RESEARCH; ROBERT JARRIN, SENIOR DIRECTOR, GOVERNMENT AFFAIRS, QUALCOMM INCORPORATED; AND J. LEONARD LICHTENFELD, DEPUTY CHIEF MEDICAL OFFICER, AMERICAN CANCER SOCIETY, INC.

STATEMENT OF MIKE MARCHLIK

Mr. Marchlik. Good morning, Mr. Chairman and distinguished members of the subcommittee. My name is Michael Marchlik. I am vice president of Quality Assurance and Regulatory Affairs for McKesson Technology Solutions.

Today I am speaking on behalf of more than 15,000 technology employees. Together, we are transforming health care from a paper-based system to one empowered by interoperable electronic solutions. Our focus is to improve patient safety, reduce the cost and variability of care, and advance health care efficiency.

McKesson strongly supports H.R. 3303, the SOFTWARE Act. This bipartisan legislation recognizes that a 40-year-old statute should be updated to reflect innovation and the importance of health IT.

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

Prior to joining McKesson, I spent 30 years as a quality and regulatory professional in the medical device and nuclear industries. This experience gave me a unique perspective on effective risk-based regulatory frameworks as well as how traditional medical device manufacturing differs from health IT development.

At McKesson, I have faced the challenge of applying a 40-year-old law to technology that did not even exist 4 years ago. FDA rules are designed for physical devices, which undergo slower incremental changes and longer development cycles, where a focus on manufacturing processes makes sense. That environment is markedly different from software, where improvements, updates and patches are made available in a matter of days.

The SOFTWARE Act creates a regulatory framework that acknowledges the difference between medical devices and health IT, recognizes the different categories of health IT, and focuses FDA oversight on the technology that poses a greater potential risk to patient safety. This legislation is the culmination of many efforts to address how health IT should be regulated in the 21st century. Under the auspices of the Bipartisan Policy Center, BPC, I represented McKesson in working with more than 100 hospital, physician and patient organizations to develop recommendations for a new risk-based regulatory framework for health IT.

In a March hearing before this subcommittee, my colleague, Dr.

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

Jackie Midas, testified that health IT is foundational to improving the quality, safety and affordability of health care. She emphasized that a new risk-based regulatory framework distinct from medical device regulation and specific to health IT is necessary. We believe that the SOFTWARE Act is a critical step forward to achieving that vision.

The SOFTWARE Act establishes three distinct categories of health IT: medical software, clinical software and health software. Medical software acts directly on a patient without the ability of a clinician to intervene. Clinical software, by contrast, does not act directly on the patient, but rather informs the clinician's treatment of the patient. Health software is used by clinicians not to treat patients, but rather to schedule appointments, process claims and analyze data.

Under the SOFTWARE Act, medical software would continue to be regulated by the FDA, clinical software would be subject to a new oversight framework developed by Congress and the administration, and health software would not be subject to additional patient safety regulation.

These three software categories are consistent with both the principles described in the BPC report as well as historic FDA software guidance. FDA has little expertise in clinical software development and implementation and does not regulate the practice of medicine, nursing or pharmacy, where software is ultimately customized and used.

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

That is why we believe that clinical software requires a new regulatory framework that reflects first the dynamic nature and rapid innovation of health IT; second, the shared responsibility among health IT vendors and providers who developed, configure and use the systems.

The SOFTWARE Act will update current law to provide clarity on how best to ensure patient safety while promoting innovation and broad adoption of health IT. It replaces non-binding FDA guidance and enforcement discretion with the certainty needed by the highly innovative health IT industry.

In conclusion, we urge Congress first to pass the SOFTWARE Act, which is critically important to setting the guideposts for a new policy; second, to provide oversight to the administration when implementing this policy; and third, to continue to work with stakeholders to establish the effective risk-based framework to appropriately regulate cutting-edge health IT.

On behalf of McKesson, I appreciate the opportunity to testify in support this legislation and commend the sponsors for your leadership. I am happy to answer your questions.

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

[The prepared statement of Mr. Marchlik follows:]

******** INSERT 2-1 ********

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

Mr. Pitts. The chair thanks the gentleman and now recognizes the gentleman, Mr. Bialick, 5 minutes for your summary.

STATEMENT OF JIM BIALICK

Mr. Bialick. Chairman Pitts, Ranking Member Pallone and members of the subcommittee, thank you for the opportunity to testify today on this very important issue. My name is Jim Bialick. 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 safe and effective use of health technologies for newborns.

This hearing is very timely and it is appropriate that Congress takes a deeper look into the many complexities of our regulatory system, identifies the limits of what can be improved administratively, and determines where legislative action is necessary. To argue that Congress does not have a role in reforming the way technology is regulated is to say that regulators already have all of the tools they need to be effective in fulfilling their statutory mandates.

While I recognize that some have come to know the existing regulatory process better than others, the agencies themselves have identified that there are a number of barriers to effectively regulating health information technology that are broken at the level

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

of the written law. This means that even if the agencies wanted to fix the problem, legally they could not, and Congress has to intervene. To me, there is little certainty in doing nothing, especially when doing nothing means not addressing problems that the regulators themselves say they have, and especially when doing nothing is at the expense of those regulators fulfilling their statutory mandate of protecting patient safety, including the stakeholders I represent, which are our newest and most vulnerable citizens.

Technology, such as mobile apps, are playing a central role in transforming our health care system, but their impact will be muted unless there is a concerted effort to clarify how products will be regulated. Efforts across regulators must be coordinated and shift the way we think about medical devices away from discrete products to a focus on the highest risk components of integrated networks and medical devices and consumer products. The line between medical and consumer devices has been blurred by the evolution of this dynamic marketplace, and only Congress can bring the needed clarity to the process.

In my written testimony, I lay out seven recommendations from the Newborn Coalition perspective on action Congress and the administration can now put in place a framework that will scale the needs of the marketplace while keeping patient safety paramount. Among those recommendations are the following: First we recommend

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

that Congress should create a bright line that defines FDA's authority over high-risk medical devices. Enforcement by definition, is discretionary, and will need to be constantly updated to address emerging technologies.

Our disagreement with those who believe regulation by guidance, such as the FDA guidance on mobile medical applications creates certainty, is we believe that that certainty will evaporate as technologies evolve and the process will have to begin anew.

Six members of this committee have sought to address this issue head on with a SOFTWARE Act. We support these efforts for being among the first to recognize that technology regulation should shift away from the assumption that novel use of medical device data constitutes a new device, acknowledge that technology will continue to evolve, and focus on evaluating the components of a system or network that pose the greatest threats to patient safety.

I would argue that the authors recognize placing today's definitions around future medical devices means our sights are lowered rather than focused on the horizon and the innovative technologies we cannot yet begin to imagine.

Second, we recommend Congress require HHS to contract with independent private certification bodies that would certify non-FDA technologies as safe and effective. Newborns are not little adults, but facing limited treatment options, doctors often use the smallest

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

available version of an adult device on babies to fill gaps where newborn-specific products do not exist. We believe, however, that these medical devices can be made more valuable by health information software that supports these tools. 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 health information software. We are engaged in this issue because we have seen health information technology save the lives of newborns, and because in the absence of devices designed for specifically for newborns, data created by adult-focused medical devices will be of only limited utility unless they are paired with health information software that can curate the data to make it more relevant to newborn care.

Health information software is not meant to replace clinicians. Software will enhance the value of the device data, and if it does not adversely impact the function or usability of the clear device it interoperates with, then the software should not be considered a new medical device in and of itself. I would stress that data is not a medical device and does not fit within statutory mandate of FDA. A public-private certification process is a more appropriate means for reviewing these technologies as they come to market.

In summation, there is no magic bullet, but with a level of

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

interest from Congress, the administration and a diversity of stakeholders, it would be a shame to miss this opportunity to reform the system in a way that will foster innovation and improve patient safety for this generation and the next.

I thank you very much for the opportunity to testify and I stand ready to help the committee in any way possible, and I am happy to answer any questions.

[The prepared statement of Mr. Bialick follows:]

******** INSERT 2-2 ********

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

Mr. Pitts. The chairs thanks the gentleman. I now recognize the gentleman, Mr. Lemnios, 5 minutes to summarize his testimony.

STATEMENT OF HON. ZACHARY J. LEMNIOS

Mr. Lemnios. Good morning, Chairman Pitts, Ranking Member Pallone and distinguished members of the Health Subcommittee. Thank you for the opportunity to speak with you today. My name is Zachary Lemnios and I am the vice president of research strategy at IBM Research.

I joined IBM last December and have served in the Obama administration as the Assistant Secretary of Defense for research and engineering. Off script, I will tell you it is a delight to be back before Congress and testifying.

This morning I am going to talk about the innovations in the private sector, but I will tell you that in the defense sector, we saw remarkable progress for our wounded warriors, the technology and innovations that 5 years ago were really just in the research stage, and we should all be very proud of that.

My comments this morning are with respect to technical innovation regarding the private sector and the potential to improve health care, and how Congress and the administration can best work together to promote innovation.

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

IBM invests billions each year in research and development from the first continuous blood separator that led to the treatment of leukemia, to the first heart-lung machine used to keep patients alive during surgery, to the excimer laser that opened up LASIK surgery that many of us use today.

IBM research has a rich legacy of addressing health care's most pressing needs. Today we are collaborating with universities and with medical institutions to help children with -- universities and with medical institutions to help children who would not otherwise have access to intensive care, to simulating the human heart to better understand how genetic variations predispose some patients to arhythmias, and to transform EMR clinical data into user-friendly formats so that patients can better understand and participate with their health care management.

The victory of IBM's Watson on the television quiz show "Jeopardy" revealed how scientists and engineers at IBM and elsewhere are pushing the boundaries of science and technology to create the machines that interact with people in very new ways. This new cognitive era promises a significant shift in the ability of people and organizations to quickly analyze, understand and unlock the insights contained in a torrent of data that is around us.

As this subcommittee knows, health care is one of the most data rich environments today, yet physicians are often working with limited

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

information and shortened timelines. The results can be fragmented care, errors that raise the cost and threaten the quality of health care.

Consider this: Primary care doctors spend on an average of somewhere between 10 and 19 minutes face to face with each patient per visit. An estimated 15 percent of diagnoses are inaccurate or incomplete. Medical information is doubling every 5 years, but 81 percent of physicians spent less than 5 hours a week reading medical journals.

Advanced analytics, combined with cognitive computing, natural language processing, can help doctors efficiently assess and make use of this ocean of information to achieve individualized evidence-supported medicine. In addition, advances in technology could help address disparities of access across our Nation.

Congress can contribute to these advancements by assuring that there is a regulatory environment that encourages innovation while protecting the safety of individuals. Innovation and improved safety are not inconsistent goals. In fact, innovation can enable better tools to continuously promote learning and possibly improve care, to reducing these adverse effects.

The current regulatory framework, largely developed during the decades before the rise of today's sophisticated IT technology, focuses on traditional discrete devices, manufacturing in a single site, and

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

physically shifted distributors and users. While some have embedded software, these are frequently physical articles placed into the commercial environment, modified relatively infrequently, and often do not interact with multiple other devices provided by parties.

With the rise of network ecosystems, and even more sophisticated software, this paradigm simply doesn't encourage tomorrow's innovation. The medical technology field is populated with multiple players who are interconnected through technology that can be rapidly and integrally improved through deep collaboration and through IT partnerships with the clinical end users.

Further, clarity is needed to enable a vibrant marketplace where the paths of bringing collaboratives to market is known. Clarity is really what we are after in this environment, and one area that calls out for clarity is clinical decision support software. This is intended to aid clinicians in making decisions rather than making those decisions directly for patients. It is one of the resources that clinicians can use, not solely rely upon, but use in their decision-making process.

Currently it is unclear whether and how CDS would be regulated, and we urge Congress and the administration to work together to clarify this, recognize that in all health care, in all software in this arena, it is not the -- software is simply not the same. One size fits all is not the right equation. Using the current medical device regulatory

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

framework to determine if and how regulation of the diversity of potential health care software would be used is something that needs to be clarified. Without this, we will quash innovation, we will delay the adoption of supporting tools that can help clinicians better provide health care.

Mr. Pitts. The gentleman's time's expired.

[The prepared statement of Mr. Lemnios follows:]

******** INSERT 2-3 ********

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

RPTS MCCONNELL

DCMN ROSEN

[11:55 a.m.]

Mr. Pitts. The gentleman's time is expired.

Thank you, the chair recognizes, Mr. Jarrin, 5 minutes to summarize his testimony.

Make sure your mic is up. We had a little trouble hearing the last witness.

STATEMENT OF ROBERT JARRIN

Mr. Jarrin. Good morning, Chairman Pitts, Ranking Member Pallone, and members of the subcommittee, earlier this year the Subcommittee on Communications and Technology --

Mr. Pitts. Is your light on?

Mr. Jarrin. Yes. There we go. I thought it was on, my apologies. Good morning, Chairman Pitts, Ranking Member Pallone, and members of the subcommittee. Earlier this year, the Subcommittee on Communications and Technology held hearings during the third week of March on health information technologies and innovations, including mobile medical apps. I was honored to have been invited to participate in the first of those hearings, and I am honored to be here today.

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

Qualcomm Incorporated is number one global supplier of wireless chips and the leading inventor of 3G and 4G next generation wireless technologies. To date, Qualcomm's, chip shipments surpass 11 billion. If a person is using a 3G or 4G device, Qualcomm's technology and ingenuity are being used.

Mobile technology continues to be the largest platform in history. Innovation continues to personalize health care as health apps are more available than ever via sophisticated smartphones and tablets that rely on powerful ubiquitous 3G and 4G mobile broadband networks. In fact, according to MobiHealthNews Research, unique health apps now number over 33,000 in the U.S. After 2 years, the FDA delivered on its promise: A deregulatory and practical roadmap for the mobile health industry. This is significant for solo developers, garage entrepreneurs and established medical device manufacturers, such as Qualcomm's wholly-owned medical device subsidiary, Qualcomm Life. FDA has raised the bar and demonstrated how it can work with industry, be progressive, help speed innovation, and ensure public safety. But more is yet to come as broader issues linger which require the same light touch and flexible approach FDA has now demonstrated it is capable of adopting.

Additionally, the final Food and Drug Administration Safety Innovations Act, or FDASIA report due at year's end by FDA, ONC, and FCC should contain a proposed strategy and recommendations on an

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

appropriate risk-based regulatory framework pertaining to health IT, including mobile medical applications. Qualcomm offers the following recommendations for consideration. Number one, as recommended by the FDASIA external working group report, FDA should utilize current program mechanisms that could enable innovations such as assessing exemption from good manufacturing practices for lower risk health IT, expediting guidance on health IT software and related matters, particularly FDA's 2014 proposed guidance development B list that includes medical device decision support software, medical device accessories, and general wellness products; continue to improve internal coordination on health IT software, and its regulatory treatment; and continue to utilize external facing resources to proactively educate the public about how policies and regulation impact health IT and mobile medical apps.

Number two, FDA, ONC, and FCC should address policy and regulatory deficiencies, ambiguity, and duplication in the final FDASIA report.

Number three, FDA should continue its commitment to consistency, predictability, and transparency by coordinating internal and external efforts through a single dedicated office of mobile health within FDA.

Number four, interoperability is a critical concern for reliable data exchange and secured health communications to and from mobile devices.

The FDA should collaborate closely with ONC in supporting the

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

direct messaging exchange standards and the direct trust security and trust framework.

Number five, privacy data use rights and identity management issues have unique concerns in relation to mobile health devices. Close collaboration between the FDA, ONC and FTC are essential to the establishment of consistent standards and requirements for industry health care providers and the public.

Qualcomm underscores the importance of FDASIA's work and encourages the involved agencies to utilize existing program mechanisms to enable innovation immediately. While they explore how to improve and modify existing frameworks, or if needed, develop recommendations for Congress to consider a new risk-based regulatory framework, what the public and industry don't need is a situation where innovation suffers as a result of regulatory confusion on health IT software, which is why existing program mechanisms are vital policy tools that can be employed promptly.

The end goal should be for a regulatory framework that allows new technology to flourish, promotes innovation, avoids regulatory duplication, and above all, protects patient safety. Thank you. I look forward to your questions.

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

[The prepared statement of Mr. Jarrin follows:]

******** INSERT 3-1 ********

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

Mr. Pitts. The chair thanks the gentleman and I any recognize Dr. Lichtenfeld, 5 minutes for opening summary.

STATEMENT OF J. LEONARD LICHTENFELD

Dr. Lichtenfeld. Thank you, Chairman Pitts, Ranking Member Pallone, and members of the subcommittee. I am Dr. Len Lichtenfeld. I am Deputy Chief Medical Officer for the American Cancer Society, and I thank you all for the opportunity to testify before you today.

Software applications play an increasingly integral role in the care of patients, including and especially patients with cancer. So I applaud this committee's bipartisan attention to providing a proper level of oversight for these products.

As we all know, cancer care has changed significantly in the past 40 years when it might have been enough for a physician to manually assess a tumor size, determine the appropriate diagnosis, and the recommended treatment for a patient with cancer. We are now moving into an era where everything from sending patient appointment reminder emails to analyzing genetic tests are all done using software, and software applications have increased our ability to quickly and accurately diagnose patients and develop the most effective treatment plans as mentioned earlier today.

Continued innovation in this space is an urgent priority for

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

cancer patients, survivors, their families, loved ones, and of course, their health care professionals. At the same time, the power of software applications to improve patient care must be tempered by potential dangers that come with any new medical intervention. We consider it unethical to administer new drugs as part of a patient's treatment without first understanding both the safety and the efficacy of those medications, and similarly, we need to understand the safety and efficacy of integrating software applications directly into patient care.

In terms of the appropriate calibration of oversight for software applications, you will find nearly universal agreement, the lowest products do not merit FDA oversight, while high risk ones do. The real challenge lies in how to create oversight for the space in between that may include clinical software, mobile apps, similar products.

Rather than commenting on specific proposals, I would like to offer several broad design criteria for your consideration. First, and foremost, patient safety and privacy are paramount to all of us. It is the first duty of medical professionals, the relevant oversight agencies and policymakers to ensure that patients are not subjected to dangerous, ineffective, or misleading treatment and that their information is secure.

Second, any information oversight system should be fluid. Technology is advancing at a speed challenging our ability to provide

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

effective oversight. And some technology in use today was, as we know, almost unheard of 5 years ago, and so any new oversight structure should not be so rigid that it cannot quickly adapt to new realities.

Third, details matter. The changes are enacted to create new categories of medical software applications with differing levels of oversight, then the definitions of those categories must be very clear and not create loopholes, ambiguities, or unintended consequences.

Fourth, focus the solution on the actual problem. Innovation software mobile apps can be promoted through regulatory certainty and the relief of regulatory burden on software sectors where it is not appropriate. This may be possible with narrower policy changes aimed at targeted sets of software rather than the full spectrum of software and mobile apps.

In closing, let me reiterate. The innovative new software will be crucial to making progress against cancer, and ensuring patient safety. We need a risk-based oversight paradigm for this software that does not impose a heavy regulatory hand that might otherwise stifle innovation. But we must never allow the pursuit of innovation to displace patient safety and privacy as our primary considerations. Wherever software is involved directly in patient health, oversight is not only appropriate, but it is necessary. I thank you again for the opportunity to share our views and I look forward to your questions. Thank you.

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

[The prepared statement of Dr. Lichtenfeld follows:]

******** INSERT 3-2 ********

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

Mr. Pitts. The chair thanks the gentleman. That concludes the opening summaries. We will now begin questioning. I will recognize myself 5 minutes for that purpose.

Mr. Lemnios, so why, in your opinion, is it important that Congress address regulating medical apps?

Mr. Lemnios. I am sorry?

Mr. Pitts. Why is it important that Congress address regulating medical apps in your opinion.

Mr. Lemnios. We think the key issue here is one of clarity and it goes back to comments that several Members made in their questions in the opening statements. For the private sector to make investments in developing new technologies and transition those technologies, that involves decisions on partnerships, it involves strategic decisions on where we will make those investments, all of which is -- all of which must be framed --

Mr. Pitts. Pull the mic a little closer, sir. They say they are having trouble hearing.

Mr. Lemnios. Let's try this.

Mr. Pitts. There you go, that is good.

Mr. Lemnios. You know, you guys really ought to get an IBM mike. This doesn't say IBM.

Mr. Pitts. All right. We will start over.

Mr. Lemnios. The question was why should Congress, why should

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

this committee make a recommendation and pursue this? Look, I think it is an issue of clarity, and in fact, that will help our business decisions, and I think it will help decisions of small innovators as well. And that is really what we want. Not to compromise patient safety. But to build that environment that encourages innovation in this field.

Mr. Pitts. Thank you. Mr. Marchlik, do you think the FDA has the regulatory structure to appropriately regulate medical apps?

Mr. Marchlik. I believe that they have certain structures that they have been able to use for embedded software very effectively. Where we have questions is around clinical software, where implementation and use of the software is just as important as the development, and there what we see is that FDA doesn't have the oversight models necessary to ensure patient safety across that continuum.

Mr. Pitts. Mr. Bialick, do you think that the regulation of medical devices is best addressed through agency guidance, legislation, or a combination of both?

Mr. Bialick. I think it is most likely a combination of both. I think in hearing Dr. Shuren's testimony that there is -- it is quite clear that there is an effort within FDA to do the right thing, to figure out how to fix the process. But I also think that it is important to note that through the FDASIA working group that he mentioned and so

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

did Mr. Jarrin mention, the external working group as well as those that will make the report, I guess, in the first quarter of next year, there were a number of issues that were identified by not only stakeholders that were part of that external group, but actually representatives from the agencies, FDA, FCC and ONC that identified that there were some issues that got, like we said before, broken at the level of the written law. And if that is the case, then you are very well going to need a hybrid of both.

Mr. Pitts. Mr. Lemnios, one of the main themes in this hearing is how quickly technology is evolving. Some may argue that because the industry is changing so much so quickly, we should just continue to releasing guidances. Why do you think we should address this legislatively, and how do you suggest we incorporate enough flexibility to make sure the agency is equipped with the flexibility to adapt to this evolving industry?

Mr. Lemnios. So that is a tension in the dialogue. The tension is how much flexibility and how much certainty will there be in this environment? And I think what the bill has done, and I would compliment the Congressman, the Representative for drafting this -- what the bill has done it has laid out three imperatives that, in our view, sort of lay the structure. Whether there is direct change in function, or structure of the body, whether there is an involvement of a health care provider, and whether the software is marketed to individuals or to

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

health care providers. I think those are three key elements that you could build on.

Now, there is going to be a lot of discussion about the eaches, there will be a lot of discussion, does this particular software fit under this category or that? But I think the basic structure that was put in place really provides a way to build on this.

Mr. Pitts. Let me ask each of you to respond to this question. We will start at the other end. Dr. Lichtenfeld, can you discuss the impact health IT can have on the personalization of medicine as well as the potential to lower medical cost?

Dr. Lichtenfeld. You know, obviously, it is a world that I live in in a lot of different ways, and there is no question whatsoever that health information technology is going to have a huge impact on patient care, is going to have a huge impact on directing personalized medicine, precision medicine, and making sure that it works right is critically important. We have to have the certainty that we need not only as health professionals, as patients. We need to make certain just as we do with our medications, that what people say something is going to do, is, in fact, going to do it.

Mr. Pitts. Okay.

Dr. Lichtenfeld. We are adjourning a discussion with the early part of that discussion as we are here today with obviously much more to come in the not too distant future.

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

Mr. Pitts. Mr. Jarrin.

Mr. Jarrin. Health IT has and will continue to have a huge impact on America, especially things like cost savings. I would only point out that 330 million subscriptions in America right now for mobile devices, yet one out of two adults according to the CDC -- one out of almost -- one out of two adults in America, has at least one chronic illness and chronic disease is about 75 percent of our health care cost. I think will you start to see that go down as the ubiquity of health IT continues.

Mr. Pitts. Briefly, Mr. Lemnios.

Mr. Lemnios. Again, I view the impact both from the private -- on the patient side, but also on the provider side. If I look at the enormous growth in information that a health care provider can access, a doctor can access, software that translates that complexity into something that provides some insight is going to have a significant value. So in fact, it will, I think in both cases, there will be a significant improvement.

Mr. Pitts. Mr. Bialick.

Mr. Bialick. I absolutely do believe health IT will have a huge impact on the personalization of medicine. We often talk about personalized medicine like it is a single thing, like we can go buy personalized medicine, but personalized medicine is the consequence of a health technology-enabled health care system where we are able

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

to communicate between devices, between providers, between patients, and have that information created in a way that it is valuable to the individual at the point of care.

Mr. Pitts. Mr. Marchlik.

Mr. Marchlik. Yes, I would agree that the will and, you know, the data is there and the opportunities to find applications which actually can unlock that data and help with personalization.

Mr. Pitts. Thank you. My time is expired. The chair recognizes the ranking member, Mr. Pallone, 5 minutes for questions.

Mr. Pallone. Thank you, Mr. Chairman. My questions are of Dr. Lichtenfeld. You note in your testimony that it is necessary to ensure that any new definitions enacted into statute be very clear and not create loopholes, ambiguities or unintended consequences. You also note that many software applications contain multiple functions and each individual function in isolation could conceivably fit into a different regulatory category. So clarity is needed about where in the regulatory scheme these multifunctional applications fit. Those points argue, at least for me, that this is not an area that could be easily addressed through legislation. In FDA's recently issued guidance, it appears to me to have been well received by many stakeholders who have indicated that it provide the necessary clarity to allow innovations to flourish. As you say in your testimony, any oversight structure should not be so rigid that it can't quickly adapt

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

to new realities.

So my questions are: Are you concerned that legislation will not provide the requisite flexibility here? Do you agree that guidance is an appropriate way to oversee this kind of technology?

Dr. Lichtenfeld. Far be it for me to say to Congress whether or not you are able to legislate something. That is in your purview, and I understand that the America Cancer Society understands that. I mentioned a moment ago there are substantial conversations that are currently ongoing, and I believe that this legislation begins the process within the legislative branch, but certainly within the private sector and within the advocacy sector, and with interested parties, we have had a lot of discussions surrounding these issues.

So our concern is that the FDA guidance meets a need at the present time that listening to the testimony today reinforces, in my opinion, that they have the flexibility and the direction that we need today. But we are going to be having a different conversation even within the next several months. And that definitions do matter, not that they are not appropriate, not that they are not important, but they do matter. And putting something into legislative language today to codify something when even in a couple of months we may be having a different discussion, or a more informed discussion among all of the parties, both governmental, legislative, private sector, advocacy, this may not be the right time for us to do that as opposed to, number

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

one, seeing how the FDA guidance works, and number two, listening to the reports and discussions that we are going to be having as I mentioned in the not too distant future, hopefully.

Mr. Pallone. Well, thank you. Let me also say, FDA indicated on the first panel that the Blackburn bill would exempt from all FDA oversight such apps as radiation therapy planning software, and mammography detection software, to name a couple. I have no doubt that the sponsors of the bill had no intention of exempting such apps from oversight, but these examples generally illustrate the difficulty deriving the perfect language for legislation. Would you be concerned about legislation that permanently removed FDA's jurisdiction over certain types of software that might ultimately pose patient safety risks?

Dr. Lichtenfeld. Well, it is not a question so much of opposing the legislation, but making sure that we understand the potential risk of unintended consequences and definitions, as I mentioned, definitions matter. Getting those definitions right in legislative language is an art. It is difficult. It has to be done properly. If we don't do it properly, we do run the risk of having -- we do believe we have issues of oversight difficulties and what we would call unintended consequences so the definitions are critically important.

Mr. Pallone. You make another important point in your testimony that we are still awaiting the report that Congress requested in last

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

year's FDASIA legislation from FDA, from the Office of the National Coordinator for Health Info Technology and the FCC. So do you agree that any legislation that we consider here should be informed by that report?

Dr. Lichtenfeld. I do. As you are well -- as you are probably aware, there have been several reports, one from the Bipartisan Policy Center that came out recently, another one from the Office of National Coordinator. We are awaiting the report from the working group as was mentioned. And I think that in the -- what I think is an appropriate place, is to say we need to have that information. We need to be able to understand that information. We need to have the input of all of the relevant stakeholders before we advance a legislative remedy -- before we advance the legislative remedy, I should say.

Mr. Pallone. All right. Thanks a lot. And Mr. Chairman, I am not convinced there is a problem that needs to be fixed here, and if there is, that it should be addressed by such a broad piece of legislation that virtually rewrites FDA's oversight of what is a fast-moving technology. But I think it is important that we had this hearing today. Thank you, Mr. Chairman.

Mr. Pitts. The chair thanks the gentleman. I now recognize the gentlelady from Tennessee, Ms. Blackburn, for 5 minutes of questions.

Mrs. Blackburn. Thank you, Mr. Chairman. You all have been very patient with us, and I hope I don't take my whole 5 minutes. How

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

is that for starters?

Mr. Marchlik, three quick questions, and thank you for your testimony. I want you to just kind of give a brief concise overview, the difference between health IT, and medical devices, why they need to be approached differently. You argued in your testimony that the FDA is not well-suited for regulating the software. I want you to expand a bit on why, and then going back to the FDASIA work group recommendations that were presented to the ONC policy committee earlier this fall, I want to know what you thought about that.

Mr. Marchlik. Thank you. I think it is important that we believe that the legislation and we agree that the FDA would still be well-suited to regulating certain types of software. Some of the applications that we expect would still be regulated would be, for example, are perinatal care, you know, monitoring type of software. Some of our cardiology products would meet those definitions, would still be regulated by the FDA.

What I testified to and what we believe is that in a clinical software space, it is not just a development. And it is not just a manufacturer, which has standard, is regulated by the FDA, but it is implementation and use. We deliver products that actually require input, and configuration of the practice of medicine for it to actually be fully functional. And the FDA oversight doesn't extend that far. What we would be looking for is the new oversight model which would

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

be able to expand and address that whole segment of that.

On the FDASIA report, I believe that a lot of the findings that came out of FDASIA report were consistent with the BPC report. Maybe, I think it is interesting is that we talk about, you know, the need for legislation or not. Partly, I think what happened is that in parts of the report, they were constrained because the only oversight was FDA oversight, and therefore, if there was a need for oversight it pointed to FDA versus nothing else. And there is a gap there and that is where we think the bill was very good about laying out that there should be an alternative for type of clinical software.

Mrs. Blackburn. Excellent. Thank you, for that. Mr. Bialick, does the FDA currently require changes to existing drugs or devices on the market to go through an FDA review process before they go to the patients?

Mr. Bialick. So you are asking if there are changes to existing devices?

Mrs. Blackburn. Yes.

Mr. Bialick. As someone who has never put a device through the process, I unfortunately can't answer that.

Mrs. Blackburn. All right. Okay, let me move on then. I was asking that in relation, Dr. Shuren, during his answer to Congressman Lance said that patches, or updates, to the apps that could improve or harm patient safety would not have to go through the FDA approval

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

process. So does that concern you?

Mr. Bialick. The question in my mind is really how those errors or how those bugs are coming to people's attention. I think that what really we should be trying to do here is foster an environment where there is a transparent nature, a combination of punitive and non-punitive mechanisms and levers that would allow both vendors, maybe through the protections of something like patient safety organizations as well as providers, and really patients to have a way to redress their grievances to say there is a problem. We want to figure out what it is, and fix it as fast as possible. Now, depending on if this is the world of the SOFTWARE Act or if this is the world of FDA now, whether that goes through the FDA, whether that goes back through a certification process, whatever it is, I think just the real take-away there is that we need to have a system of transparency so if there are patches we know why they were needed.

Mrs. Blackburn. Okay, so I guess what you are saying that enforcement discretion rather than certainty, could have some unintended consequences on patient safety, especially with the very delicate patients that you all focus upon, is that fair?

Mr. Bialick. I think in certain circumstances, absolutely.

Mrs. Blackburn. Okay, thank you. I yield back.

Mr. Pitts. The chair thanks the gentlelady. I now recognize the gentleman from Florida, Mr. Bilirakis, 5 minutes for questions.

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

Mr. Bilirakis. Thank you, Mr. Chairman, I appreciate it very much. In the 1970s, Congress wrote the statute giving the FDA the authority to regulate medical devices. As is often the case, technology will outrace the law, and government is forced to use outdated laws to deal with emerging situations. When the Medical Device Statute was created, we did not have personal computers, cell phones, the Internet, or cloud computing. Yet, these things are part of our daily lives. We need to modernize the law in my opinion, to provide clarity to the FDA, and the medical software industry, on the regulatory framework for their respective industries. And I want to ask Mr. Marchlik, a question, Mr. Marchlik. You have suggested in your testimony that different types of health IT should be regulated differently. Isn't that exactly what the FDA is doing using their discretion?

Mr. Marchlik. I believe that what they have attempted to do within the boundaries of the current legislation is to use enforcement discretion to carve out those products which they are not going to actively enforce. I think that what is needed is actually to take a fresh look at that, and also to expand that, like I have been, you know, like I have discussed, is expand that across the platform including clinicians, including the way we implement and use, we need to have a framework that works across and that is why we support the legislation is it calls for that, which would be in addition to what the FDA is

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

doing with the higher-risk products.

Mr. Bilirakis. Thank you, I appreciate that. Mr. Lemnios, IBM has proposed that Watson, your supercomputer, could provide medical assistance to doctors. That is very exciting. It has the ability to review medical records, the latest in medical research, and provide recommendations or options to physicians during the diagnosis process. Would this be regulated like a medical device by the FDA in your opinion?

Mr. Lemnios. Well, Congressman, I can't comment on Watson as a particular product. The discussion here I think is a much bigger than that, and that is really about how decision support software would be regulated. And I will come back to the comments that I made earlier. I think in framing the arguments, in framing how this regulation could be structured, the distinction between whether that software is provided to the patient, or the clinician is a key one; the distinction of whether that software is used to support a decision, or to make a decision, is a clear one; and the distinction of whether that is -- whether the result of that software, the conclusions are interpreted by an individual or interpreted by a clinician is a key thing. I think those are the key, as we view it, those are the key structural elements of how to think about this. And I think the bill clearly outlines that.

Now, Watson is a technology that we are developing. We are training it. We are training it in many fields. It is in the financial

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

sector. We are training it in the medical community. We have other areas that we will train systems like that, but I will simply tell you that the field of analytics, and the field of cognitive computing, where humans interact with data in a very natural way, that field is exploding. We see that across the VC community. We see that in other areas. And I think that will be a key element of this field going forward.

Mr. Bilirakis. Okay, if it were regulated by the FDA, why don't you tell me, maybe you can elaborate a little bit. What kind of implications would that have? Would it raise the cost of the computer system? Would it make it slower to provide updates and improve the system?

Mr. Lemnios. So updates, updates on any software is a key cost issue, it is a risk issue, and it is a delivery timeline issue. I mean, we really need to see the clarity and the reason we support the bill is because we need clarity in this space.

Mr. Bilirakis. Thank you very much. I appreciate it. I yield back, Mr. Chairman.

Mr. Pitts. The chair thanks the gentleman. That concludes the questions of the members here. We have two hearings going on at the same time, so I am sure some of the Members will have follow-up questions. We will send them to you. We ask that you please respond promptly, if you would. This is very, very important hearing. Thank

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

you very much for the information, for coming today. I remind the members they have 10 business days to submit questions for the record, and members should submit those questions by the close of business on Thursday, December 5th.

Without objection, this subcommittee is adjourned.

[Whereupon, at 12:25 p.m., the subcommittee was adjourned.]