HEALTH INFORMATION TECHNOLOGIES: ADMINISTRATION PERSPECTIVES ON INNOVATION AND REGULATION

HEARING

BEFORE THE

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

OF THE

COMMITTEE ON ENERGY AND COMMERCE

HOUSE OF REPRESENTATIVES

ONE HUNDRED THIRTEENTH CONGRESS

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HEALTH INFORMATION TECHNOLOGIES: ADMINISTRATION PERSPECTIVES ON INNOVATION AND REGULATION

THURSDAY, MARCH 21, 2013

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC.

The subcommittee met, pursuant to call, at 9:08 a.m., in room 2322 of the Rayburn House Office Building, Hon. Tim Murphy (chairman of the subcommittee) presiding.

Present: Representatives Murphy, Burgess, Blackburn, Harper, Olson, Griffith, Johnson, Long, Ellmers, Barton, DeGette, Butterfield, Tonko, and Waxman (ex officio).

Staff present: Mike Bloomquist, General Counsel; Matt Bravo, Professional Staff Member; Karen Christian, Chief Counsel, Oversight; Andy Duberstein, Deputy Press Secretary; Julie Goon, Health Policy Advisor; Debbee Hancock, Press Secretary; Brittany Havens, Staff Assistant; Sean Hayes, Counsel, O&I; Robert Horne, Professional Staff Member, Health; Peter Kielty, Deputy General Counsel; Katie Novaria, Legislative Clerk; John O'Shea, Professional Staff Member, Health; David Redl, Counsel, Telecom; Alan Slobodin, Deputy Chief Counsel, Oversight; Jean Woodrow, Director, Information Technology; Tiffany Benjamin, Democratic Senior Counsel; Brian Cohen, Democratic Staff Director, Oversight & Investigations, Senior Policy Advisor; Eric Flamm, FDA Detailee; Elizabeth Letter, Democratic Assistant Press Secretary; Stephen Salsbury, Democratic Special Assistant; Rachel Sher, Democratic Senior Counsel; and Matt Siegler, Democratic Counsel.

OPENING STATEMENT OF HON. TIM MURPHY, A REPRESENTATIVE IN CONGRESS FROM THE COMMONWEALTH OF PENNSYLVANIA

Mr. MURPHY. All right. Good morning, everyone, and welcome to our hearing today on "Health Information Technologies: Administrative Perspectives on Innovation and Regulation." Thank you for being here. Today, we convene the Subcommittee on Oversight and Investigations to discuss development and innovation and these technologies, particularly mobile medical applications or "apps," and how federal regulations may impact this growing industry.

We are joined by two witnesses from the Administration, Dr. Farzad Mostashari, who is the head of the Office of the National Coordinator with HHS; and Christy Foreman, who is the director

of the Office of Device Evaluation in the Center for Devices and Radiological Health at the FDA. Both of these agencies have been leading the government's response to the rapid changes that new technologies are making to our Nation's healthcare system.

On March 4, this committee sent a letter to the FDA on its approach to regulating the rapidly growing market applications used on smartphones and tablets. With this explosive growth, the use of those apps to monitor health information is growing, as well as increasing in accuracy and technological sophistication. News reports indicate that there are as many as 40,000 medical applications on the market for smartphones and tablets.

We are here today to discuss the discretion FDA has an regulating these apps as devices under the Food, Drug, and Cosmetic Act, and over the last few days, we have heard a number of examples of medical apps and concerns from apps companies about whether these apps are devices. For example, where does an app that transmits photos of potential skin cancer or the healing of surgical scars cross the line to FDA scrutiny? If an app that turns a smartphone into an ultrasound can be regulated, what about apps that let you review images from ultrasound or x-rays?

You know, there has been incredible advances in all these things and we expect to see more in not only areas of dermatology in the use of photos, endocrinology with monitoring blood glucose levels, x-rays with radiology and orthopedics, heart monitors with cardiology, mental status tests with neurology. The list goes on and on.

In 2011 the FDA issued Draft Guidance on how the Agency planned to regulate mobile medical applications. The FDA has not yet issued Final Guidance. To our witnesses from the FDA, over the last 2 days we have heard from a variety of witnesses and members of both sides of the aisle, and the message was clear: we need Final Guidance. The developers of these apps and the healthcare industry need certainty.

That certainty is also needed because of the tax on medical devices put in place by the new healthcare law. As we have heard this week, a tax on medical devices can make capital needed to develop these apps and new breakthrough technologies more scarce. This can slow innovation. And we are caught in its cycle of the snake eating its own tail whereby we raise taxes on medical devices, thus increasing the costs, and then use those taxes to subsidize increased costs and offer tax incentives to cover R&D. It doesn't quite make sense but we want to make sure we are not slowing innovation.

So this isn't about scaring people into thinking this tax will apply to their iPhones, Blackberries, or iPads, but this tax could absolutely halt the development of new apps to run on those devices. Everyone here recognizes the need to balance patient safety and innovation. I hope that today's hearing will provide some certainty that regard.

We will also hear from Dr. Mostashari on the efforts that have been made by the Department of Health and Human Services to encourage the utilization of health information technology, and particularly, the incentive payments that have been made to providers to adapt to new healthcare technologies. Recently, HHS announced that for this year they hope to have 50 percent of physicians' offices

using electronic health records with 80 percent of eligible hospitals receiving incentive payments by the end of this year.

While the movement to increased use of electronic health records may seem like an obvious choice as doctors and hospital employees become more comfortable with new technologies, as a supporter of health IT, I am concerned that the promised benefits of electronic medical records have yet to arrive. I have personally heard from physicians in my district who have struggled to adapt or received unclear Guidance from the Agency. Of particular concern are complaints that systems in place aren't able to share information with other systems. I hope our witnesses today will be able to address these concerns over interoperability.

I am encouraged by the work this committee has done this week. We have had a great dialogue on these issues and today I hope we will be able to hear the Administration's view on its approach to innovation and regulation of healthcare technologies.

I also want to apologize ahead of time. I have another hearing that I have to testify, and I will be leaving in a little bit, but it will be taken over by the capable hands of the vice chairman, Dr. Mike Burgess.

[The prepared statement of Mr. Murphy follows:]

PREPARED STATEMENT OF HON. TIM MURPHY

Today we convene the Subcommittee on Oversight and Investigations to discuss development and innovation in health care technologies, particularly mobile medical applications or "apps," and how federal regulations may impact this growing industry.

Today we are joined by two witnesses from the administration: Dr. Farzad Mostashari is the head of the Office of the National Coordinator within HHS. Christy Foreman is the Director of the Office of Device Evaluation within the Center for Devices and Radiological Health at FDA.

Both of these agencies have been leading the government's response to the rapid changes being made to the health care industry by new technologies.

On March 4, this Committee sent a letter to the FDA on its approach to regulating the rapidly growing market for applications used on smartphones and tablets. With this explosive growth, the use of those apps to monitor health information is growing as well. News reports indicate that there are as many as 40,000 medical applications on the market for smartphones and tablets, and it is expected to grow.

We are here today to discuss the discretion FDA has to regulate these apps as devices under the Food, Drug, and Cosmetic Act. I have seen that in today's testimony the FDA is now definitely saying: NO, we will not regulate the general sale of smartphones or tablets-I thank the FDA for providing certainty on this matter.

Yet, over the last few days we have heard a number of examples of medical apps and concerns from apps companies about whether these apps are devices. For example, where does an app that transmits photos of potential skin cancer cross the line to FDA scrutiny? If an app that turns a smartphone into an ultrasound can be regulated, what about apps that let you view images from an ultrasound or xray?

In 2011, the FDA issued draft guidance on how the agency planned to regulate mobile medical applications. FDA has not yet issued final guidance. To our witness from the FDA, over the last two days we have heard from a variety of witnesses and members of both sides of the aisle-the message is clear: we need final guidance. The developers of these apps and the health care industry needs certainty.

That certainty is also needed because of the tax on medical devices put in place by the new healthcare law. As we have heard this week, a tax on medical devices can cause money for the development of these apps and the advancement of medical technology to become more scarce. It can slow innovation. I've heard a lot from my Democrat colleagues about how we're trying to scare people into thinking this tax will apply to their iPhones, Blackberries or iPads, but they don't seem to be concerned that the problem is that it could halt the development of new apps to run on those devices.

Everyone here recognizes the need to balance patient safety and innovation. I hope that today's hearing will provide some certainty on that balance.

We will also hear from Dr. Mostashari on the efforts that have been made by the Department of Health and Human Services to encourage the utilization of health information technology, and particularly the incentive payments that have been made to providers to adapt to new health care technologies. Recently HHS announced that for this year they hope to have 50 percent of physician offices using electronic health records, with 80 percent of eligible hospitals receiving incentive payments by the end of the year. 1A[1]

While the movement to increased use of electronic health records may seem like an obvious choice as doctors and hospital employees become more comfortable with new technologies, this Committee is concerned whether their effectiveness has been oversold. In the last few months we have seen reports indicating that the savings promised by electronic health records may have yet to materialize while doctors struggle to adapt. Of particular concern are complaints that some of the systems being utilized may not be able to share information with other systems—and I hope our witness today will be able to address these concerns over interoperability.

I am proud of the work this Committee has done this week—we have had a great dialogue on these issues and today I hope we'll be able to hear the administration's views on its approach to innovation and regulation of health care technologies.

Mr. MURPHY. And now, I would like to recognize Ms. DeGette for her opening statement.

OPENING STATEMENT OF HON. DIANA DEGETTE, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF COLORADO

Ms. DEGETTE. Thank you very much, Mr. Chairman.

Mobile medical apps and electronic health records are developing at a rapid pace and they have the capacity to transform the patient-doctor relationship, improve healthcare quality, and also to save billions of dollars. And I am looking forward to hearing from the FDA and HHS about the efforts to integrate these new technologies into the healthcare sector.

Dr. Mostashari, I want to welcome you, the national coordinator for Health Information Technology.

The 2009 stimulus bill contained billions of dollars to help incentivize doctors and hospitals to implement meaningful use of electronic medical records. That investment has already made a big difference. Since 2009, the use of electronic health records by physicians has doubled from 20 to 40 percent in the hospital adoption of electronic health records has more than tripled. More than 230,000 healthcare providers have qualified for payments for implementing the use of electronic health records. Ultimately, the adoption of these records will reduce medical errors, save money, and most importantly, improve the quality of care.

Earlier this week, the Premier Healthcare Alliance reported that 333 hospitals in their network had, since 2008, save $9.1 billion and avoided 92,000 deaths by implementing a set of patient-centered quality improvement reforms that was made possible in part by enhanced data-sharing and use of health information technology. But the transition to electronic health records is not without challenges, and Dr. Mostashari, I am glad you are here to address questions about the Agency's roadmap to help us fully implement health IT.

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[1] 1 http://www.hhs.gov/news/press/2013pres/03/20130306a.html

Ms. Foreman, I also want to welcome you to talk about the FDA's role in regulating and improving mobile medical apps.

Mr. Chairman, I have got to admit the discussion of FDA's role in regulating medical apps seems a little redundant. This is the third hearing that is focused on these issues. As we heard during the first two hearings, the other subcommittee heard from 11 different nongovernment witnesses about how the Administration is balancing the need to promote innovation in this field against the need to ensure patient safety. Those witnesses thankfully already debunked some of the biggest myths that we have heard from the outside about the FDA's role. Thank goodness the myth of the iPhone tax has now been put to rest.

We also learned from the witnesses that smartphones and tablets are exempt from the Affordable Care Act medical device tax. We learned that the FDA is not currently and does not intend in the future to regulate smartphones or tablets as part of its regulation of mobile medical apps. We also learned that the FDA does not intend to regulate calorie counters or pedometers or other kinds of similar apps as medical devices. But we also learned about how the Agency has a role in ensuring that other medical devices like monitoring blood glucose or providing other vital medical information are accurate and work the way they are supposed to do, which is exactly what the FDA is therefore.

But the Committee also heard from some industry witnesses expressing concerns about the FDA's regulatory efforts and worrying that they could overreach and limit innovation. These concerns are not new and they are not specific to mobile medical apps. FDA, and frankly this committee, has to constantly address this balance, whether the Agency is regulating food, drugs, traditional medical devices, or these apps. That is part of what we have to do.

The FDA addressed all of these concerns in a letter that was sent to the Committee yesterday and, Mr. Chairman, I would like to ask that the letter be made part of the hearing record. The letter makes it abundantly clear that the FDA will not tax your iPhone and it provides new information that shows for the mobile medical apps FDA has reviewed, those reviews are moving quickly, taking an average of only 67 days. So to me that sounds pretty much like an agency that is trying to foster innovation while at the same time ensuring that patients are safe.

And so, Mr. Chairman, I don't think that the debate over how to balance patient safety and innovation will end any time soon, but I am hopeful that at least we can have a common understanding of the facts with regard to electronic health records and mobile medical apps, and we can continue in our joint effort with the agencies to make sure we balance innovation and safety.

And with that, Mr. Chairman, I yield back and thank you.

Mr. MURPHY. Thank you. And we do have a copy of this letter for the record, but I thank the ranking member for bringing that up again.

I now yield to Dr. Burgess for 5 minutes for an opening statement.

OPENING STATEMENT OF HON. MICHAEL C. BURGESS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. BURGESS. I thank the chairman. And certainly we have heard from a number of qualified and distinguished scientists and specialists in medical technology and the communications industries for the past two hearings, and today, we are going to hear the perspectives of the agencies that wrote the proposed regulations guiding these industries.

The emergence of mobile medical technology does hold great promise not only for lowering the care cost, but most importantly, for improving health outcomes. The increasing availability of these technologies has revolutionized how providers interact with patients. We are at a point now where the number of providers using these devices has increased, almost doubled, from a year ago such that nearly 2/3 of providers are using some type of device. The rapid proliferation of these new technologies also raises legitimate concerns about patient safety, but we also want to encourage important advancements that can improve patients' quality of life. And it is not just the overregulation by the government but it is the uncertainty of pending regulation that also drives some of this discussion.

The FDA struggles to maintain their current regulatory charge, but we need to be assured that they have the experience, that they have the expertise to handle the additional responsibilities of an emerging market.

Ms. Foreman, I would like to thank you and your agency for the rapid response to the letter earlier this week. I hope that sets a new benchmark in the Administration. We are accustomed to waiting years for a response, and this was indeed refreshing that it was only a few weeks in turnaround. And certainly, we look forward to similar quick turnaround for the final regulations of the Draft Guidance, which was issued in July 2011.

And Dr. Mostashari, I have enjoyed visiting with you in the past, and I thank you for being with us as well.

As a provider, I have direct experience using health information technology and seeing the benefits as well as some of the downfalls that it brings to both patients and providers. Artificial barriers do nothing for care coordination, for patient safety, or for provider communication. As a physician, my primary concern is the health and safety of the patient. Inaction is not an option on this issue. However, we must do so in a way that encourages the development of innovative technologies, and we certainly do not want to push them outside of our borders.

I will now yield the balance of the opening statement time to the gentlelady from Tennessee, Mrs. Blackburn.

OPENING STATEMENT OF HON. MARSHA BLACKBURN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TENNESSEE

Mrs. BLACKBURN. And I thank the gentleman for yielding. And thank you, Mr. Chairman, for the hearing. And to our witnesses, Ms. Foreman, Dr. Mostashari, we thank you for being here with us.

The hearings that we have done this week I think are essential. I don't think they are redundant. I do think they are essential to

getting our arms around an issue that we are going to have to deal with on mobile medical apps. And I would say that one of the things that has come forward through the testimony we have received is that a 40-year-old FDA statute is not nimble enough to address the needs that are in front of us with this new innovation sector.

I do think that ONC has a unique perspective on these HIT issues, and along with input from the FDA and from stakeholders that Congress can find a path forward on what a framework would look like. One of the things we have heard from the innovators is the uncertainty that is there within FDA. This big gray area of whether you will or will not be regulated, that is stifling innovation. And as we heard in the hearing on Tuesday, it also does not do anything to provide certainty to investors who are going to be there. So that is of concern to us.

Now, Dr. Burgess mentioned yesterday that these are the tools of today's doctors and future doctors, and 15 percent of these apps that are out there, the 97,000 apps, the mobile medical apps, 15 percent are used by physicians. This is a way for us to achieve efficiency. It is a way for us to expand access, and what we want to be certain is that our innovators know with certainty what their classification would be, how they would be dealt with as an industry.

So we thank you all for the testimony and for being here and we look forward to concluding our series and finding a way forward on the issue.

And I yield back.

Mr. MURPHY. Thank you.

I now recognize the ranking member of the full committee for an opening statement, 5 minutes, Mr. Waxman.

OPENING STATEMENT OF HON. HENRY A. WAXMAN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Mr. WAXMAN. Mr. Chairman, we are here today for the third day in a row to discuss electronic health records and FDA's regulation of mobile medical apps, and I am surprised at the amount of time and attention given to this issue.

I have attended the last 2 days of hearings, and from what I have heard, the members on your side of the aisle seek to answer two basic questions: question one, whether the FDA is regulating mobile medical apps with too heavy a hand; is the Agency impeding innovation and harming this market by regulating too aggressively or approving mobile medical apps too slowly?

This is not a new responsibility for FDA. For over 100 years the Agency has been balancing patient and consumer safety with the need for innovation. In the case of mobile medical apps, the answers that we heard in the first 2 days of hearings indicate little by way of concern. The witnesses told us that they understood the role of FDA and the need for agency regulation and were unable to point out any legitimate examples of apps that FDA was improperly regulating under its Draft Guidance. Although they had some anxiety about it, they had nothing to point to.

Question two is whether FDA will impose a new tax, the Affordable Care Act medical device tax, on your cell phone. The answer to this question is as plain as day. The answer is no. The Affordable Care Act itself contains a clear retail exemption. Even if a cell phone was designated to be a medical device, the Act says that any device that is "generally purchased by the general public at retail for individual use" is not subject to the tax. That exemption would apply to any cell phone you can buy at a retail store. And FDA has been clear that the Agency is not currently regulating and does not intend in the future to regulate smartphones or tablets as part of its regulation of mobile medical apps. The IRS has provided similar indications.

Mr. Chairman, this issue is a non-issue. We did not need to spend 1 day of hearings on this, let alone 3. This committee could have used this time more wisely. I have asked you to hold hearings on the abuse of tax and regulatory loopholes by the tobacco industry and their efforts to undermine the Tobacco Control Act. Ranking Member DeGette and I have asked for hearings on the impacts of sequestration on the agencies of our committee's jurisdiction. We have asked for hearings on the risks associated with antibiotic-resistant bacteria, a very serious and growing public health threat. We have asked for you to hold hearings on Lifeline, the Universal Service Fund's low income phone program. These hearings could examine the expenditure of billions of dollars of consumer funds.

In the last 2 years, I have sent over 20 letters asking for hearings on the impacts of climate change. And we have not held a hearing on a single one of these important issues. Mr. Chairman, I hope you can understand our concern. I don't mean to discount the importance of mobile medical apps and the electronic health records. This is an industry that, thanks to the investment we made in the 2009 Obama stimulus bill, is growing, is creating jobs, and has the potential to dramatically improve healthcare quality and save billions of dollars in healthcare costs.

But there are too many pressing issues before us for this committee and this Congress to get bogged down for 3 days in what amounts to an inaccurate talking point about FDA overregulation and the nonexistent iPhone tax. I hope that in the future this subcommittee can use its time more wisely. I must say, Mr. Chairman, for this particular subcommittee, I thought that the first hearings we have held under your leadership have been very worthwhile and that we can go back to doing things that are constructive and not just talking points for political purposes, which is all these 3 days have been about.

I yield back the balance of my time.

Mr. MURPHY. Thank you very much, Mr. Waxman. I would now like to recognize Christy Foreman. She is currently the director of the Office of Device Evaluation for the Center for Devices and Radiological Health for the FDA. Before being named to the director position, she served as the deputy director for Science and Regulatory Policy in the Office of Device Evaluation.

I would also like to introduce Farzad Mostashari. He currently serves as national coordinator for Health Information Technology within the Office of the National Coordinator for Health Informa-

tion Technology at the U.S. Department of Health and Human Services. Farzad joined ONC in July of 2009.

You are aware that the Committee is holding an investigative hearing, and when doing so, has had the practice of taking testimony under oath. Do you have any objections to testifying under oath?

Both witnesses have said they do not.

The chair then advises you that under the rules of the House and the rules of the Committee, you are entitled to be advised by counsel. Do you desire to be advised by counsel during your testimony today?

Both witnesses have said no.

In that case, if you please rise and raise your right hand, I will swear you in.

[Witnesses sworn.]

Mr. MURPHY. And if someone could work on the volume, I would appreciate that, too.

You are now under oath and subject to the penalties set forth in Title XVIII, Section 1001 of the United States Code. You may now give a 5-minute summary of your written statements. Ms. Foreman, if you would like to begin.

TESTIMONY OF CHRISTY FOREMAN, DIRECTOR, OFFICE OF DEVICE EVALUATION, CENTER FOR DEVICES AND RADIOLOGICAL HEALTH, FOOD AND DRUG ADMINISTRATION; AND FARZAD MOSTASHARI, NATIONAL COORDINATOR, HEALTH INFORMATION TECHNOLOGY, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

TESTIMONY OF CHRISTY FOREMAN

Ms. FOREMAN. Mr. Chairman, Ranking Member DeGette, and members of the subcommittee, I am Christy Foreman, Director of the Office of Device Evaluation in the Center for Devices and Radiological Health, or CDRH, at the Food and Drug Administration. Thank you for the opportunity to testify today. I am pleased to be here to discuss issues related to health IT and to talk specifically about the actions FDA is taking to foster innovation in the field of mobile medical applications, also referred to as mobile medical apps.

The widespread adoption and use of mobile technologies is opening new and innovative ways to improve health and healthcare delivery. Mobile apps, which are software programs that run on smartphones and other mobile devices, can help consumers and patients manage their own health and wellness, promote healthy living, and gain access to useful information when and where they need it.

FDA believes it is important to adopt a balanced approach to mobile medical apps that supports continued innovation while assuring appropriate patient protections. We also recognize that mobile health application developers need a clear, predictable, and reasonable understanding of the Agency's expectations.

While many mobile apps carry minimal risk, others can pose significant risk to patients if they don't operate correctly. In some cases, those risks are identical to the risks associated with an al-

ready marketed medical device. For example, a mobile app that affects the programming of a drug infusion pump or a Computed Tomography scanner could lead to a drug or radiation overdose. And an inaccurate or malfunctioning mobile medical app designed to diagnose skin cancer could delay life-saving diagnosis and treatment.

In July 2011, FDA issued a Draft Guidance announcing our intention to exercise enforcement discretion for most mobile apps. The Guidance also clarifies that the focus of our oversight will be a small subset of mobile apps, which we refer to as "mobile medical apps." These are apps that meet the definition of a device in the Federal Food, Drug, and Cosmetic Act and that are either intended to be used as an accessory to a regulated medical device or transform a mobile platform into a regulated medical device.

What our policy proposes is equally important as what our policy does not propose. It would not regulate the sale or general consumer use of smartphones or tablets. It would not consider entities that exclusively distribute mobile medical apps, such as the iTunes App Store or the Android Market, to be medical device manufacturers. It would not consider mobile platform manufacturers to be medical device manufacturers just because their mobile platform could be used to run a mobile medical app regulated by FDA. It would not require mobile medical app developers to seek agency reevaluation for minor iterative product changes. And it would not apply to mobile apps that perform the functionality of an electronic health record, an EHR system, or personal health record system.

We have received more than 130 written comments on our Draft Guidance. The comment have been overwhelmingly supportive of our narrow, tailored, risk-based approach, and we continue to receive many inquiries from industry stakeholders who are eager to see this Guidance finalized. Some commenters have sought additional clarity on the types of mobile apps that would fall within the scope of enforcement discretion. Our Final Guidance will provide that additional clarity and examples.

Pursuant to Section 618 of the Food and Drug Administration Safety and Improvement Act (FDASIA), the FDA, the Office of the National Coordinator, and the Federal Communications Commission have established a FDASIA workgroup which will provide expert input from a wide range of stakeholders to develop recommendations on an appropriate, risk-based regulatory framework pertaining to health information technology, including mobile medical apps.

It is important to note that FDA has been regulating medical device software for decades, and medical device software on mobile platforms for more than 10 years. We have reviewed approximately 100 mobile medical apps, including remote blood pressure, heart rhythm, and patient monitor apps in addition to smartphone-based ultrasound and glucose meters.

We recognize the importance of using a balanced, transparent approach that fosters the development of innovative mobile medical apps while ensuring appropriate patient protections. We intend to strike the right balance by providing a risk-based, focused approach to the oversight of a small subset of mobile medical apps that present a serious potential risk to patients if they do not work as intended. We believe that focusing the Agency's oversight will

encourage the development of new products while also providing appropriate patient protections.

Thank you for the opportunity to testify today about issues related to health IT, including mobile medical apps, and about the actions FDA is taking to foster innovation.

Mr. Chairman, I commend the Subcommittee's efforts and am pleased to answer any questions the Subcommittee may have.

[The prepared statement of Ms. Foreman follows:]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

STATEMENT

OF

CHRISTY L. FOREMAN

DIRECTOR, OFFICE OF DEVICE EVALUATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS
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U.S. HOUSE OF REPRESENTATIVES

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Release Only On Delivery

INTRODUCTION

Chairman Murphy, Ranking Member DeGette, and Members of the Subcommittee, I am Christy Foreman, Director of the Office of Device Evaluation in the Center for Devices and Radiological Health (CDRH) at the Food and Drug Administration (FDA or the Agency). I am pleased to be here today to discuss issues related to health information technology (health IT), and to talk specifically about the actions FDA is taking to foster innovation in the field of mobile medical applications (mobile medical apps).

Health IT serves as the fundamental infrastructure that enables the management of health information across multiple electronic systems and devices, such as wireless medical devices, hospital information systems, communications infrastructures, and electronic health record (EHR) systems.

The widespread adoption and use of mobile technologies is opening new and innovative ways to improve health and health care delivery. Mobile applications (mobile apps)—software programs that run on smartphones and other mobile communications devices—can help consumers manage their own health and wellness, promote healthy living, and gain access to useful information when and where they need it. Not surprisingly, these tools are being adopted almost as quickly as they can be developed. In fact, industry estimates that 500 million smartphone users worldwide will be using a health care application by 2015,[1] and by 2018, 50 percent of the

[1] Research2Guidance, "500m people will be using healthcare mobile applications in 2015" (Nov. 10, 2010), available at *http://www.research2guidance.com/500m-people-will-be-using-healthcare-mobile-applications-in-2015/*.

more than 3.4 billion smartphone and tablet users will have downloaded mobile health applications.[2] These users include health care professionals, consumers and patients.

FDA believes it is important to adopt a balanced, approach to mobile medical apps that supports continued innovation, assuring appropriate patient protections. We also recognize that mobile health application developers and manufacturers need a clear, predictable, and reasonable understanding of the Agency's expectations.

Mobile apps span a wide range of health functions. While many mobile apps carry minimal or no risk, others can pose significant risks to patients if they don't operate correctly. And, as we will discuss, FDA's proposed guidance takes this variation in risk into account.

Consumers use mobile apps to manage their own health and wellness, such as to monitor their caloric intake for healthy weight maintenance, or like the National Institutes of Health's LactMed app, to provide nursing mothers with information about the effects of medicines on breast milk and nursing infants. Other apps are aimed at helping health care professionals to improve and facilitate patient care, such as the Radiation Emergency Medical Management (REMM) app, which gives health care providers guidance on diagnosing and treating radiation injuries. Some mobile apps can even diagnose cancer or heart rhythm abnormalities, or function as the "central command" for a glucose meter used by an insulin-dependent diabetic patient.

Consumers and health care professionals should be aware of the potential benefits and risks associated with technologies that incorporate mobile apps. In some cases those risks are similar or identical to the risks associated with an already-marketed medical device. As an example,

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[2] Research2Guidance, "Mobile Health Market Report 2013-2017: The Commercialization of mHealth Applications"

mobile apps that affect the programming of a drug infusion pump or computed tomography (CT) scanner could lead to a drug or radiation overdose. An inaccurate or malfunctioning mobile medical app that uses a sensor to diagnose skin cancer or to measure critically low blood oxygen levels in chronic lung disease patients, could delay lifesaving diagnosis and treatment.

FDA's 2011 Draft Guidance and Public Meeting

FDA has jurisdiction over those mobile apps that meet the definition of "device" in section 201(h) of the Federal, Food, Drug, and Cosmetic Act (FD&C Act) and the Agency intends to use this authority reasonably and judiciously. FDA issued draft guidance in July 2011[3] to announce its intention to exercise enforcement discretion for most mobile apps. The guidance also clarifies that the focus of FDA's oversight will be the small subset of mobile apps, referred to as mobile medical apps, that meet the definition of "device" in section 201(h) of the FD&C Act and that are either intended to: (1) be used as an accessory to a regulated medical device,[4] or (2) transform a mobile platform into a regulated medical device.[5] This narrowly tailored approach would not require active FDA oversight of many apps that would otherwise meet the definition of "device." Our draft guidance clarified that a currently regulated medical device would not become unregulated just because it was designed to work on a mobile platform. For example, medical ultrasounds and electrocardiogram (EKG) machines are medical devices subject to FDA review whether or not they are on a mobile platform. We believe that focusing FDA oversight

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(March 4, 2013), available at http://www.research2guidance.com/shop/index.php/downloadable/download/sample/sample_id/262/.

[3] FDA, "Draft Guidance for Industry and Food and Drug Administration Staff - Mobile Medical Applications" (July 21, 2011), available at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm263280.htm.

[4] For example, an application that allows a health care professional to make a specific diagnosis by viewing a medical image from a picture archiving and communication system (PACS) on a smartphone or a mobile tablet.

[5] For example, an application that turns a smartphone into an electrocardiograph (ECG) machine to detect abnormal heart rhythms or to determine if a patient is experiencing a heart attack.

on a narrow subset of mobile apps will encourage the development of new products while providing appropriate patient protections.

Just as important as what the policy proposes is what the policy does **not** propose. FDA's proposed mobile medical apps policy would **not** regulate the sale or general consumer use of smartphones or tablets. FDA's proposed mobile medical apps policy would **not** consider entities that exclusively distribute mobile medical apps, such as the owners and operators of the "iTunes App store" or the "Android market," to be medical device manufacturers. FDA's proposed mobile medical apps policy would **not** consider mobile platform manufacturers to be medical device manufacturers just because their mobile platform could be used to run a mobile medical app regulated by FDA. FDA's proposed mobile medical apps policy would **not** require mobile medical app developers to seek Agency re-evaluation for minor, iterative product changes. FDA's proposed mobile medical app policy would **not** apply to mobile apps that perform the functionality of an electronic health record (EHR) system or personal health record system.

The draft guidance also states the Agency's intent to exercise enforcement discretion for those mobile apps that do not meet the proposed definition of a mobile medical app, even if the mobile app meets the FD&C Act's definition of a "device."

Throughout the development of the mobile medical apps draft guidance and following its issuance in July 2011, FDA has actively encouraged public feedback on how the regulatory approach proposed in the draft guidance would affect the balance between promoting innovation and providing reasonable assurance of safety and effectiveness. In addition to opening the draft guidance for public comment, the Agency has interacted with the stakeholder community, including traditional medical device firms, software companies, health care professionals, patient

advocacy groups, health care facilities, third-party payers, and the health IT community. FDA also hosted a widely attended public meeting to provide a forum for discussion and to encourage additional public comment from interested stakeholders on the issues raised in the draft guidance.[6]

In total, FDA has received more than 130 submissions to the public docket on the July 2011 draft guidance. Respondents have overwhelmingly supported the narrowly tailored, risk-based approach described in the draft guidance, and we continue to receive many inquiries from industry stakeholders who are eager to see the guidance finalized. Some commenters have sought additional clarity on the types of mobile apps that would fall within the scope of enforcement discretion; the final guidance will provide such additional clarity and examples.

It is important to note that FDA has been regulating medical device software for decades and medical device software on mobile platforms for more than 10 years. The Agency has reviewed approximately 100 mobile medical apps, including remote blood pressure, heart rhythm, and patient monitors, and smartphone-based ultrasounds, EKG machines, and glucose monitors.

Some have questioned the implications of the medical device excise tax (device tax) enacted as part of the Health Care and Education Reconciliation Act of 2010 in conjunction with the Patient Protection and Affordable Care Act for mobile medical apps. The Internal Revenue Service (IRS) and the Department of the Treasury, not FDA, are responsible for the excise tax imposed on the sale of certain medical devices. The IRS' final regulations[7] pertaining to the device tax define a taxable medical device as "a device that is listed as a device with the FDA under 510(j)

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[6] FDA, "Public Workshop - Mobile Medical Applications Draft Guidance, September 12-13, 2011," available at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm267821.htm*.

[7] IRS, "Taxable Medical Devices, (Final Regulations)," 77 *Fed. Reg.* 72924, 72934 (Dec. 7, 2012), available at *http://www.gpo.gov/fdsys/pkg/FR-2012-12-07/pdf/2012-29628.pdf*.

of the FFDCA and 21 CFR Part 807" and provide a "retail exemption" for medical devices that are "generally purchased by the general public at retail for individual use." Questions about the implementation of this policy should be directed at the IRS.

FDA developed the Agency's draft mobile medical apps policy to protect public health and promote innovation. Because the draft guidance states that the Agency intends to exercise enforcement discretion for certain categories of mobile apps with respect to applicable device requirements, including listing, FDA does not expect such devices to list. FDA plans to provide additional clarity regarding the specific types of apps for which the Agency intends to exercise enforcement discretion in the final mobile medical apps guidance. The Agency intends to maintain a publicly available website with updated information listing those apps which have been cleared or approved by FDA and those for which FDA intends to exercise enforcement discretion, in order to provide continuing clarity on this issue for industry and other stakeholders.

Developing an Appropriate, Risk-based Regulatory Framework for Health IT

Mobile medical apps represent just one component in an increasingly connected health care environment. Three federal agencies—FDA, the Office of the National Coordinator for Health Information Technology (ONC), and the Federal Communications Commission (FCC)—each have unique and complementary responsibilities in the health IT arena. Section 618 of the Food and Drug Administration Safety and Innovation Act (FDASIA), enacted on July 9, 2012, requires the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs and in consultation with the National Coordinator for Health IT and the Chairman of FCC, to prepare a report by January 2014 containing "a proposed strategy and recommendations

on an appropriate, risk-based regulatory framework pertaining to health information technology, including mobile medical applications, that promotes innovation, protects patient safety, and avoids regulatory duplication."[8]

FDA, ONC, and FCC have established a "FDASIA Workgroup" under ONC's Health IT Policy Committee (HITPC)[9], which will provide expert input to ONC's HITPC to inform the development of this report. Like ONC's other workgroups, it will be comprised of a wide range of stakeholders and conducted in a transparent manner with ample opportunity for public comment.

CONCLUSION

FDA recognizes the importance of implementing a balanced, transparent approach that fosters the development of health IT solutions and innovative products like mobile medical apps, while ensuring appropriate patient protections. Like traditional medical devices, mobile medical apps may in some cases present significant health risks to patients. FDA seeks to strike the right balance by providing a risk-based, focused approach to the oversight of a small subset of mobile medical apps that present a potential risk to patients if they do not work as intended. Consistent with this balanced approach, FDA would **not** regulate the sale or general consumer use of smartphones or tablets.

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[8] Food and Drug Administration Safety and Innovation Act, Public Law 112-144 (126 Stat. 993) (July 9, 2012), available at *http://www.gpo.gov/fdsys/pkg/PLAW-112publ144/pdf/PLAW-112publ144.pdf*.

[9] *See* FCC, "Membership Applications Sought for FDA Safety Innovation Act Workgroup," available at *http://www.fcc.gov/membership-applications-sought-fda-safety-innovation-act-workgroup*. The Workgroup is being formed under the ONC's HITPC , a federal advisory committee established by the Health Information Technology for Economic and Clinical Health (HITECH) Act (Title XIII of the American Recovery and Reinvestment Act, Public Law 111-5 (123 Stat. 115) (Feb. 17, 2009), available at *http://www.gpo.gov/fdsys/pkg/PLAW-111publ5/pdf/PLAW-111publ5.pdf*.

In its regulation of medical devices, the Agency strives for transparency, interaction, collaboration, and the appropriate balancing of benefits and risks; ensuring predictable and consistent recommendations, decision-making, and application of the least-burdensome principle; and implementing efficient processes and use of resources. FDA's ongoing actions with respect to the regulation of mobile medical apps, and the tri-Agency collaborative effort on health IT, reflect this regulatory approach.

Thank you for your commitment to the mission of FDA and the continued success of our medical device program, which helps to ensure that patients and health care professionals have access to safe and effective innovative medical technologies. Thank you for the opportunity to testify today about issues related to health IT, including mobile medical apps, and about the actions that FDA is taking to foster innovation. I am happy to answer questions you may have.

Mr. BURGESS [presiding]. The chair thanks the witness. I recognize Dr. Mostashari, 5 minutes for your opening statement, sir.

TESTIMONY OF FARZAD MOSTASHARI

Dr. MOSTASHARI. Dr. Burgess, Ranking Member DeGette, distinguished subcommittee members, thank you for the opportunity to appear today on behalf of the Department of Health and Human Services. My name is Dr. Farzad Mostashari. I am the National Coordinator for Health Information Technology.

In 2009, HITECH was enacted as part of the American Recovery and Reinvestment Act. HITECH provided the resources and infrastructure needed to stimulate the rapid, nationwide adoption and use of health IT, especially electronic health records, or EHRs. HITECH is working. The CMS Medicare and Medicaid EHR Incentive Program, the ONC-led Certification Program for EHRs, as well as the hands-on technical assistance provided by 62 regional extension centers, or RECs, across the country are critical in facilitating unprecedented progress in EHR development, adoption, and use.

There are now over 1,700 unique products produced by nearly 1,000 EHR developers and certified by 1 of 5 ONC-accredited private sector certification bodies. Adoption of EHRs has doubled among providers and more than tripled in hospitals. Electronic prescribing has increased sevenfold. RECs have signed up more than 130,000 primary care providers in over 30,000 practices. As of February 2013, more than 230,000 providers, nearly 43 percent of the Nation's eligible professionals, and over 75 percent of eligible hospitals have earned payments for meeting the initial requirements of EHR Incentive Program.

Recognizing the need to strike a balance between the urgency of modernizing our healthcare system and the pace of change that can be safely absorbed, CMS and ONC have developed the Incentive Program in stages. Each stage is designed to add increasingly advanced concepts. Published in July 2010, the Stage 1 final rules focused on functionality that support the electronic capture of data and its use to improve patient care, enhance care coordination in population health management, and increase patient and family engagement. The final rules for Stage 2 were published in September 2012 and represent an important next step with a focus on increasing standards-based health information exchange between providers and with patients.

Even as we work to bring data and data tools to doctors and hospitals, we have also been encouraged by the pace of progress in the domain of consumer e-health tools. Increasingly, people are literally taking their health into their own hands. Mobile phones can be an incredible tool for empowering consumers to take control of their health, their care, their healthcare finances. And as we all know, more engaged consumers get better outcomes.

ONC's strategy in consumer e-health is to work with partners to increase patients' ability to access their own health data, to increase the use of this data for actionable apps and services, and to shift attitudes around patient empowerment. However, we recognize there are risks as well as benefits to any technology. We must carefully balance the need for the widest possible innovation with protection of patient privacy, security, and safety.

Over the past 4 years, we have worked with FDA and other departmental agencies on a risk-based approach to health IT that promotes innovation and avoids regulatory duplication. ONC advised FDA on the Draft Guidance for mobile medical apps. Where it concerns EHR technologies, FDA has advised us on a health IT patient safety action and surveillance plan, the draft of which was released on December 21, 2012. The draft plan prescribes actions that all stakeholders can take within their existing authorities and resources, including safety requirements related to user-centered design quality management systems and easier reporting of adverse events in ONC regulations, use of ONC-authorized testing and certification bodies to collect complaints and conduct surveillance, working with developers to establish a code of conduct, working with AHRQ and patient safety organizations to improve aggregation and analysis of reported events and working with CMS to train surveyors and use health IT to assist investigations. ONC has received public comments on the draft plan, and those comments have been generally favorable.

On February 20, ONC, FDA, and FCC announced the formation of the Food and Drug Administration's Safety Innovation Act Work Group under ONC's Health IT Policy Committee to provide expertise for the development of a congressionally mandated report on an appropriate risk-based regulatory framework pertaining to health IT broadly, including mobile medical applications that will further promote innovation, protect patient safety, and avoid regulatory duplication. We are now in the process of reviewing nominations.

New technologies, including health IT and mobile applications, offer great promise to improve the quality of care and bring down healthcare costs. This doesn't happen overnight. To truly transform delivery, healthcare providers must also redesigned workflows and reengineer care. Payments must promote value over volume and care that is better coordinated and safe. Implementation of any program of this scale and complexity will inevitably include challenges, but by working within an open and transparent process and in partnership with our public and private sector stakeholders, we can build on this strong start in bringing better care to all Americans.

Thank you.

[The prepared statement of Dr. Mostashari follows:]

Testimony before the Subcommittee on Oversight and Investigations
Committee on Energy and Commerce

U.S. House of Representatives

Statement of

Farzad Mostashari, M.D., ScM.

National Coordinator, Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services

Health Information Technologies:
Administration Perspectives on Innovation and Regulation
March 21, 2013

Chairman Murphy, Ranking Member DeGette, and distinguished Subcommittee members, thank you for the opportunity to appear today on behalf of the Department of Health and Human Services (HHS). My name is Dr. Farzad Mostashari and I am the National Coordinator for Health Information Technology.

In 2009, Congress and President Obama enacted the Health Information Technology for Economic and Clinical Health Act (HITECH) as part of the American Reinvestment and Recovery Act of 2009 (ARRA). HITECH established the Office of the National Coordinator for Health Information Technology (ONC) by law and provided the resources and infrastructure needed to stimulate the rapid, nationwide adoption and use of health IT, especially electronic health records (EHRs). Among other measures, HITECH included the establishment of the Medicare and Medicaid EHR Incentive programs which provide technical assistance and financial incentives to eligible professionals and hospitals that adopt and "meaningfully use" EHRs.

Thank you for the invitation to be here today to discuss how health IT benefits patients and provides the tools that are necessary to transform care. Already, HHS and its partners have made significant progress expanding health information technology use. Since 2009 physician EHR adoption has nearly doubled, growing to 40 percent in 2012, and hospital EHR adoption has more than tripled over the same period, increasing to 44 percent. In addition, I would like to provide a status report on HHS's Patient Safety Action & Surveillance Plan and an update on the progress we have made in the relatively short time since HITECH's passage. Finally, I will conclude with an overview for what we have planned in 2013 and beyond.

Health IT is Transforming Care

Technology is just a tool - but it is a critical tool that can foster much-needed innovation in entrenched industries. Our healthcare system is poised for a transformation in how care is paid for and delivered and how patients engage in their own health and health care. Health information technology supports these transformations.

In the past, our healthcare delivery system based its payments solely on the number of services provided and not on the quality of care. As a result, patients might receive duplicative tests and/or services that might not improve their health. As required by the Affordable Care Act, HHS has launched several initiatives to more closely link payments with quality outcomes and promote value-based care.[1] For example, the hospital readmissions reduction program links hospital payments in Medicare to avoidance of potentially preventable readmissions. These reforms enable HHS to promote value over volume, and patient safety, and ensure that care is better coordinated across the healthcare delivery system.

As both public and private payers take concrete steps to change the incentives for paying providers, health IT can provide the infrastructure for improved care coordination, better quality, and lower costs, as well as the data analytics that providers need to understand the cost of doing business under the new payment models.

[1] See Statement of Jonathan Blum on Delivery System Reform: Progress Report from CMS: Senate Committee on Finance, February 28, 2013.

Federal Advisory Committees: The HIT Policy and Standards Committees

Recognizing that health IT is a complex and quickly changing field, HITECH established two Federal advisory committees under the Federal Advisory Committee Act (FACA). The Health IT Policy Committee was created to make recommendations on a policy framework to support the development and adoption of a nationwide health information infrastructure. The Health IT Standards Committee is responsible for making recommendations on standards, implementation specifications, and certification criteria for the use and exchange of health information.

Both the HIT Standards Committee and HIT Policy Committee include experts from the private sector to help guide ONC and the Centers for Medicare & Medicaid Services (CMS) in developing the rules for meaningful use and the certification of EHR technology. HITECH specified the different stakeholder perspectives that must be represented on the Committees. The law explicitly charged the Comptroller General of the United States with the responsibility of appointing 13 members representing various stakeholder groups to the Health IT Policy Committee. Additional perspectives are provided by the members appointed by the Secretary of Health and Human Services, the Majority and Minority Leaders of the Senate, and the Speaker and Minority Leader of the House of Representatives. HITECH further specified that the Health IT Standards Committee include providers, ancillary healthcare workers, consumers, purchasers, health plans, technology vendors, researchers, relevant Federal agencies, and individuals with technical expertise on health care quality, privacy and security, and health information exchange.

To further enrich the advice they provide, each Committee maintains several workgroups that incorporate the perspectives of additional stakeholders from government and the private sector. Since the creation of the Committees, their members and their many working groups have dedicated their time to meeting an average of once every other day for the past three years. We make each Committee's meetings publicly available through live webcasts. These Committees have informed the development and implementation of all of HITECH initiatives.

Progress on HITECH Implementation

Our goal is to assist clinicians and hospitals in using technology to meaningfully deliver health care that is higher quality, safer, patient-centered, and coordinated. And, we want providers to thrive in the new health care marketplace that puts a premium on value over volume, on coordination over fragmentation, and on patient-centeredness over all.

The CMS Medicare and Medicaid EHR Incentive Programs, the ONC-led certification program for electronic health records, as well as the hands-on technical assistance provided by the Regional Extension Centers (RECs) across the country, are critical in facilitating unprecedented progress in EHR development, adoption and use. There are over 1,700 unique certified products produced by nearly a thousand developers, and certified by one of five ONC-accredited private sector certification bodies. As of February 2013, more than 230,000 providers -- nearly 43 percent of the nation's eligible professionals, and over 75 percent of eligible hospitals -- have earned over $12.6 billion in total payments for meeting the requirements of the EHR Incentive Programs. ONC's Regional Extension Centers (RECs) have

signed up more than 130,000 primary care providers in over 30,000 different practices. This means that roughly 44% of the nation's primary care providers have committed to meaningfully using EHRs by partnering with their local REC. RECs have signed up more than 20,000 Nurse Practitioners (NPs), 48% of all NPs nationwide, to assist them in meaningfully using EHRs. More than 80% of all Federally Qualified Health Center grantees are enrolled with an REC.

Health IT Patient Safety Action and Surveillance Plan

The Institute of Medicine's (IOM's) 1999 landmark report *To Err is Human* raised awareness of the large number of avoidable medical errors harming patients. The report also stated that the use of information technology could improve patient safety through automated order entry, clinical reminders, and drug - drug interaction and drug - allergy checking. While the magnitude of establishing a national infrastructure was hard to imagine in 1999, the Medicare and Medicaid EHR Incentive Program is a realization of that goal. Health IT – which includes EHRs and health information exchange – has already demonstrated the ability to reduce medical errors. For example, EHRs can flag and help providers avoid potential drug-drug interactions and improve the accuracy of physicians' drug ordering. Yet health IT will only fulfill its enormous potential to improve patient safety if the risks associated with its use are identified, if there is a coordinated effort to mitigate those risks, and if it is actually used to make care safer.

Recognizing the need to understand how health IT can promote patient safety as well

as identify and mitigate risks, ONC commissioned an IOM study to determine how government and the private sector working collaboratively can maximize the safety of health IT-assisted care. The IOM report, *Health IT and Patient Safety: Building Safer Systems for Better Care*, was published in November 2011.

The IOM Report included the following three key findings:

- Health IT can improve patient safety in some areas such as medication safety; however, there are significant gaps in the literature regarding how health IT impacts patient safety overall;
- Safer implementation and use begins with viewing health IT as part of the larger sociotechnical system;
- All stakeholders need to work together to improve patient safety.

Based on these findings, the IOM recommended that the market forces are not adequately addressing the potential risks associated with the use of health IT and all stakeholders must coordinate efforts to identify and understand patient safety associated with health IT.

Building on IOM's recommendations, ONC worked collaboratively with colleagues throughout HHS to develop the *Health IT Patient Safety Action and Surveillance Plan,* the draft of which was released on December 21, 2012. This *Health IT Safety Plan* addresses the role of health IT within HHS' commitment to patient safety. The plan seeks to build upon and strengthen patient safety efforts across government programs and in the private sector – including efforts by patients, health care providers, technology companies, and health care

oversight bodies – to improve knowledge on health IT-related patient safety events.

The draft plan prescribes actions that all stakeholders can take within their existing authorities and resources to promote a culture of safety related to health IT. Suggested actions include:

- Use ONC-Authorized Testing and Certification Bodies to collect complaints and conduct surveillance;
- Work with developers to establish a code of conduct that includes working with Patient Safety Organizations and supporting providers in reporting adverse events;
- Work with Patient Safety Organizations according to the Agency for Healthcare Research and Quality's (AHRQ's) Common Formats in order to improve aggregation and analysis of reported events;
- Include safety requirements related to user-centered design, quality management systems, and easier reporting of adverse events in ONC regulations;
- Work with CMS to train surveyors and use health IT to assist investigations;

ONC received public comments on the draft plan through February 4, 2013, and those comments have been generally favorable. We are in the process of reviewing comments and will publish the final Health IT Safety Plan in the near future.

Consumers – The Most Underutilized Resource in Healthcare

Over the past few decades, we have seen information technology improve the consumer experience in almost every other aspect of our lives, including the way we manage our finances, shop, and book travel. But, health care has been slower to leverage this technology. Most notably, relevant information is not available to patients when and where it is needed.

Increasingly, people are literally taking their health into their own hands—whether that means tracking their health through a Smartphone app or a remote monitor, participating in online patient or caregiver communities, or accessing their medical records online. Changes in consumer technology, such as the growth of mobile phones, are helping to drive this change -- nearly nine out of ten people own a mobile device and nearly half of all Americans own a smartphone.[2] Mobile devices offers several advantages over traditional PCs—they can help remove traditional barriers such as geography and time, breaking down the digital divide in underserved communities, enabling remote treatment, and more continuous monitoring of health make health more convenient and personalized. The mobile devices in our pocket can help us access a world of information at the right time to help make the right health decisions, which is important since 80% of Internet users have gone online seeking health information.[3] Apps like iTriage can help us find a local care facility and Pillbox can help us quickly identify unlabeled medications. iBlueButton – developed pursuant to an HHS-sponsored challenge

[2]Pew: http://pewinternet.org/Reports/2012/Cell-Internet-Use-2012/Main-Findings/Cell-Internet-Use.aspx

[3] Pew: http://www.pewinternet.org/Reports/2011/HealthTopics.aspx).

program – can help us share our medical history, and Ginger.io tracks our level of activity. The Department of Defense has developed apps to help veterans and their caregivers cope with post-traumatic stress disorder. Mobile phones can be an incredible tool for empowering consumers to take control of their health, their care, and their healthcare finances and as we know from the literature, more engaged consumers get better outcomes.

ONC's strategy in consumer eHealth is to work with partners to increase patients' ability to access their own health data, to increase the use of this data for actionable apps and services, and to shift attitudes around patient empowerment.

ONC is also encouraging institutions that have health data to make it easier for patients to get easy, electronic access to their data and to use that information in ways that improve their health and health care. The Blue Button Pledge Program is a voluntary mechanism for supporting consumers' access to their health data. The Blue Button Pledge Program now includes more than 450 organizations that are committed to learning and collaborating in efforts to increase patient access to, and use of, health data. The Pledge Program, launched in 2011, includes "data holders"—such as health care providers and insurers—who pledge to improve the accessibility of health data to patients and other authorized users, and "non–data holders"—such as software developers and consumer advocacy organizations— who pledge to educate consumers about the value of getting and using their health data.

The government is moving forward in this direction. Veterans today can access their full records online, and download their records with a simple click of a "Blue Button"- and more than one million veterans have done so. Medicare beneficiaries can access their full Medicare records online today, and download three years of claims data. HHS is also encouraging

Medicare Advantage plans to expand the use of Blue Button to provide beneficiaries with one-click secure access to their health information. And the Federal Employee Health Benefits program has asked carriers to do the same.

Our regulations and guidance are also encouraging this "data liberation" to patients and consumers. Our partners in HHS's Office for Civil Rights (OCR) recently launched a campaign to build public awareness of individuals' legal right under the Health Insurance Portability and Accountability Act of 1996 Privacy Rule to access their own health information – including an electronic form – if the information is readily producible in the form. In May 2012, OCR released a memo detailing these rights and directing consumers to educational resources.

Meaningful Use Stage 2, as part of the Medicare and Medicaid EHR Incentives Programs, requires eligible providers to use secure e-mail with patients and to provide patients with a way to view, download, and transmit their own health information. Under Stage 2, patients will be able not only to view their health information online, but also to export their data from EHRs in structured and human-readable formats; share those data with others; and use tools and applications to store, analyze, or otherwise make use of their information. Stage 2 also establishes thresholds for the proportion of patients using these functions, which will encourage providers to promote their use.

Privacy and Security of Mobile Technology (including Mobile Applications)

At ONC, we recognize that clinicians want to use mobile technology to access and transmit health information in health care delivery. We recognize the mobile device benefits – portability, size, and convenience in overall care coordination.

However, we recognize that there are risks as well as benefits to any technology. The use of mobile health technology holds great promise in improving health and health care. But the ubiquity and connectedness of mobile devices creates concerns for privacy and security. ONC has developed a number of projects that address the privacy and security of mobile health (mHealth) devices, including convening stakeholders and focus groups to identify concerns and developing technical assistance and education materials to begin to address those concerns.

First, ONC is working with other agencies and stakeholders to identify security issues with regard to mHealth technology, including smartphones, implantable medical devices, and remote monitoring devices. As part of this assessment, ONC hosted the public Mobile Device Roundtable in March 2012 where we gathered public, industry, health care provider, and subject matter expert input on the topic of safeguarding health information when using mobile technology.[4] The Roundtable included participants from various federal bodies that have a role in mobile health, including the Food and Drug Administration (FDA), the Federal Communications Commission (FCC), FTC, and OCR, to discuss the current privacy and security

[4] For more information about the Mobile Device Roundtable, please visit: http://www.healthit.gov/policy-researchers-implementers/mobile-devices-roundtable-safeguarding-health-information

legal framework for mobile devices accessing, storing, and transmitting health information. In addition, through its mHealth Privacy and Security Consumer Research Initiative, ONC identified and explored consumer attitudes and preferences, including underserved populations and different age categories, regarding the privacy and security of communicating health information using mobile devices, including the use of mobile apps.[5] The research initiative highlights the important role that technology developers can play in meeting consumer needs for functionality and improving privacy and security. Results from the initiative may help inform future policy and educational development activities.

Second, based on these assessments, ONC has developed technical assistance materials on privacy and security involving mobile technology. For example, in December 2012, ONC and OCR rolled out a national, multi-prong privacy and security educational initiative targeted at health care providers and professionals using mobile devices such as laptops, tablets, and smart phones in the delivery of care.[6] We developed a set of online tools that encourage health care providers and professionals to know the risks and take the steps to protect and secure health information when using mobile devices. These materials are available at https://www.healthIT.gov/mobiledevices. Although the materials were developed with health care providers in mind, anyone can use the education materials to help them securely adopt and harness the power of these technologies.

Through these projects, ONC has been able to rapidly assess and respond to the growing

[6] A variety of resources, including videos, fact sheets, and other downloadable resources, addressing the privacy and security protections and safeguards can be found here: http://www.healthit.gov/mobiledevices

need for privacy and security policy and guidelines in securing health information as it is being stored and transmitted through mobile technology.

Model Personal Health Record Privacy Notice

As personal health information increasingly becomes stored managed by companies that offer direct-to-consumer technologies, it becomes important for consumers to be aware of these companies' data practices, and to have an easy way to compare the data practices of two or more companies.

The Personal Health Record (PHR) Model Privacy Notice is designed to be a standardized template that a web-based PHR company can use to succinctly inform consumers about its privacy and security policies[7]. The PHR Model Notice was developed by ONC based on consumer testing that identified key issues individuals care about and language that they understand. The PHR Model Privacy Form is meant to be similar to other consumer-oriented "labels" that have been developed for other industries, such as the nutrition facts label for food, and the Model Privacy Notice developed for the financial services industry for compliance with the Gramm-Leach Bliley Act. It is intended to focus only on some important information and does not substitute for more comprehensive privacy policies. Many of the largest PHR companies have agreed to use the PHR Privacy Model Notice. ONC does not enforce use of the tool. However, if a PHR company under the jurisdiction of the Federal Trade Commission

[7] http://www.healthit.gov/policy-researchers-implementers/personal-health-record-phr-model-privacy-notice

(FTC) does not adhere to the privacy and security commitments stated in their PHR Notice, the FTC has the authority to challenge the notices as false or misleading in violation of the Federal Trade Commission Act. [8]

FDASIA Workgroup on Risk-Based Regulatory Framework for Health IT

Throughout the development of the *Health IT Patient Safety Action and Surveillance Plan*, ONC worked collaboratively with other federal agencies such as the Agency for Healthcare Research and Quality (AHRQ), CMS, FDA, and FCC to leverage existing authorities and to add a focus on health IT and patient safety. On February 20, ONC, FDA, and FCC announced the formation of the Food and Drug Administration Safety Innovation Act (FDASIA) Workgroup – under ONC's Health IT Policy Committee -- to provide expert for the development of a Congressionally-mandated report on an appropriate, risk-based regulatory framework pertaining to health IT, including mobile medical applications, that promotes innovation, protects patient safety, and avoids regulatory duplication.[9] FDASIA indicated that if a

[8] For a more complete explanation of how the voluntary adoption of privacy and security practices can result in legally enforceable commitments, see The White House, Consumer Data Privacy in a Networked World: A Framework for Protecting Privacy and Promoting Innovation in a Global Digital Economy, Feb. 2012, *available at* http://www.whitehouse.gov/sites/default/files/privacy-final.pdf. In addition, the National Telecommunications and Information Administration is convening stakeholders to develop a code of conduct to improve transparency in how mobile applications collect, store, and use personal data. *See* https://www.ntia.doc.gov/other-publication/2013/privacy-multistakeholder-process-mobile-application-transparency.

[9] Section 618 of the 2012 FDASIA charges the Secretary of Health and Human Services (the Secretary) (acting through the Commissioner of the Food and Drug Administration (i.e., FDA), in consultation with the National Coordinator for Health Information Technology (i.e., ONC) and the Chairman of the Federal Communications Commission (i.e., FCC) to publish a report by January 2014 that expresses "a proposed strategy and

workgroup was formed, it should be geographically diverse and include representatives of patients, consumers, health care providers, startup companies, health plans or other third-party payers, venture capital investors, information technology vendors, health information technology vendors, small businesses, purchasers, employers, and other stakeholders with relevant experience. The three agencies received applications through March 8th to participate in the Workgroup and are now in the process of reviewing the nominations. The first meeting of the workgroup is expected to be held in April 2013.

The FDASIA Workgroup will build on prior work such as the IOM report, *Health IT and Patient Safety: Building Safer Systems for Better Care and ONC's Health IT Patient Safety Action and Surveillance Plan*; FDA's mobile medical applications guidance[10] and *Medical Device Data Systems Rule*[11]; FCC's *National Broadband plan* and other relevant work. Specifically the three agencies will seek input on issues relevant to the report:

- Types of risk that may be posed by health IT which impact patient safety, the likelihood that these risks will be realized, and the impact of these considerations on a risk-based approach;

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recommendations on an appropriate, risk-based regulatory framework pertaining to health information technology including mobile medical applications, that promotes innovation, protects patient safety, and avoids regulatory duplication."

[10] FDA's proposed oversight approach would limit FDA oversight of mobile medical apps to the small subset that are either used as an accessory to a regulated medical device, or that transform a mobile platform into a regulated medical device.

[11] This is a down classification rule (Class I) that does not require premarket submissions for medical products that are intended to be used in diagnosing, curing treating of a disease and that transfer, store, convert formats, and display medical device data.

- Factors or approaches that could be included in a risk-based regulatory approach for health IT to promote innovation and protect patient safety; and
- Approaches to avoid duplicative or overlapping regulatory requirements.

Like all ONC FACA Workgroups, all FDASIA Workgroup meetings and documents discussed at the meetings will be publicly available and will offer opportunities for public comments.

Conclusion

New technologies – including health IT and mobile applications – offer great promise to improve the quality of care and bring down health care costs. Our progress in moving towards these goals has been steady and deliberate. Working within an open and transparent process with our public and private stakeholders, we have developed a health IT patient safety and surveillance report.

We have worked with other government agencies to help secure the privacy of mobile applications, within existing authorities whenever possible. As technologies continue to advance, we want to work together with Congress to ensure health data is secure.

To truly transform delivery, health care providers must also redesign and reengineer workflow of care. This does not happen overnight. Health IT holds tremendous promise for delivering "smart health" to patients right at their fingertips to help all of us achieve the best possible outcome for each individual. We must carefully balance the need for the widest innovation possible, with protection of patient privacy, security, and safety.

We look forward to continuing to working with Congress to accomplish these goals. I would be happy to answer any questions that you may have regarding my testimony.

Mr. BURGESS. I thank the gentleman for his testimony.

Before we start members' questioning, I do want to stress the importance of the members' questions and the importance of getting direct answers from all of you all. The importance of this questioning is reflected in the fact that the Committee recently changed rules to limit member opening statements to provide more time for testimony and questioning. In order to make the question-and-answer period as productive as possible, I ask that you answer the questions in as a director manner as possible. Some members will ask yes-or-no questions and I ask that you limit yourself to a yes-or-no answer. I thank you in advance for your understanding.

I will now yield myself 5 minutes for the purposes of questions.

Ms. DEGETTE. That is not part of the rules.

Mr. BUTTERFIELD. Will the chairman allow a question at this point? Is that part of our committee rules?

Mr. BURGESS. Stop the clock.

Mr. BUTTERFIELD. Yes.

Mr. BURGESS. Yes, the committee rules as adopted and the Committee was to limit the opening statements.

Mr. BUTTERFIELD. Dr. Burgess——

Ms. DEGETTE. Yes, but not the whole rest of the stuff you said.

Mr. BUTTERFIELD. Dr. Burgess, I have been in this Congress for 8½ years—not as long as you have—but I have never, ever, ever heard of a rule such as that.

Ms. DEGETTE. It is not a rule.

Mr. BUTTERFIELD. Thank you.

Mr. BURGESS. Well, let me direct it as a courtesy then to the members of the committee that we keep our answers direct and to the questions at hand.

I yield myself 5 minutes for questions.

Now, we are here today of course to discuss the issue of the guidance that was produced in July of 2011. Ms. Foreman, the FDA proposed its mobile medical apps policy would not regulate the sale of the general consumer or the use of smartphones or tablets. And certainly, today, we thank you for the certainty. Will the Final Guidance definitively say that the sale or general consumer use of smartphones or tablets will not be regulated by the Food and Drug Administration?

Ms. FOREMAN. No, it is not the Agency's intent to change that position in the Final Guidance.

Mr. BURGESS. But, as everything, there is that possibility. And that is where the uncertainty comes from. And really, one of the things that the last 2 days and today are all about is trying to provide some certainty for the people who work into this space and are making significant investments of dollars and time, and they are doing so because they think they have ideas that are ultimately going to help people. And we would like to provide them that certainty. I think that is one of the reasons these committee hearings have been so important.

Some of the uncertainty we have heard this week relates to the fact that the Guidance issued in July of 2011 is a draft. When can we look for the final draft, the Final Guidance? When can that be released?

Ms. FOREMAN. We have prioritized that Guidance for publication this year. It should be coming soon with the intent of providing clarity to the——

Mr. BURGESS. Is your microphone working?

Ms. FOREMAN. It is on.

Mr. BURGESS. OK. Pull it a little closer then.

Ms. FOREMAN. We intend to finalize that Guidance this year. It is a priority for the Agency. It should be coming out within the next few months. And the point of the Final Guidance will be to seek to provide clarity by addressing the questions received during the comment period, and provide additional examples to clarify the Agency's policy.

Mr. BURGESS. Did you say it will be coming out in the final month of this year?

Ms. FOREMAN. No, it will be coming out in the coming months.

Mr. BURGESS. In the coming months. And when you say this year, you are talking about the calendar year and not the fiscal year?

Ms. FOREMAN. It should be out before the end of the fiscal year, yes.

Mr. BURGESS. OK. The fiscal year. Well, then let's make a note of that.

Some of the statements made by the FDA either in the Guidance or were made by you today, is the Guidance going to be binding on the Food and Drug Administration? Are there situations where the Food and Drug Administration has deviated from its Guidance when exercising its enforcement discretion?

Ms. FOREMAN. Guidance is not binding. Guidance represents agency thinking, but it is not a regulation. It is not statute. It is on a lower level that represents agency thinking to provide clarity both to staff and to industry.

Mr. BURGESS. And again, I do want to just for the record thank you for your rapid response to that letter. Again, I do hope that sets a new standard for the Administration in replying to letters from this committee. Historically, it can take some time to get questions answered, but these are important questions. These are questions not asked in a partisan manner in any way, shape, or form, and really trying to advance the science of the knowledge.

Dr. Mostashari, I will tell you, again, I do get to travel to a lot of places in the country. I talked to a lot of provider groups. And I will just say there is some concern. You know, the FDA always looks to whether things are safe and effective, well, with the exception of tobacco, but always looks to whether things are safe and effective under its regulatory jurisdiction. I can't recall if we ever saw the randomized clinical trials for electronic health records. Are those trials in existence? Were they done? Do we have that data?

Dr. MOSTASHARI. Dr. Burgess, thank you for your question. There are many, many studies that have looked at whether when you try to improve quality, whether having information helps. And it is not something that perhaps is well-suited to a randomized trial at the policy level, but the overwhelming evidence—and we have commissioned a study of—that looks at every published study on this—and while some of the negative studies, the ones that are counterintuitive, get a lot of press, the preponderance of the evi-

dence is absolutely that when implemented appropriately, health IT is going to improve quality, safety, and efficiency.

Mr. BURGESS. And yet, I just noticed from your testimony—I mean it was the end of last year, December of 2012, when your safety guidelines were published. Our stimulus bill was passed 4 years ago. The implementation began June of 2011 as I recall, and December of 2012 is when you were providing the safety guidelines. And you have stipulated such things as privacy and patient protections.

Dr. MOSTASHARI. We have been—you know, our belief is that—and I think the evidence is that the best thing we can do for safety in general is to get off of paper. And the evidence around computerized order entry, for example, reducing medication errors by 48 percent, is clear. And we have seen an increase in e-prescribing that gets away from my handwriting and perhaps yours, which is a good thing in terms of improving the safety of prescribing.

We just heard from the Premier System just this week about how they have saved $9 billion and 91,000 lives by implementing data-driven processes to improve care that can't be done in a paper-based world. So we believe that really getting healthcare into the data age is critical for improving safety.

Now, as I mentioned, any technology——

Mr. BURGESS. Sir, I am actually going to stop you because my time has expired. In the interest of getting everyone heard, I will yield to the ranking member of the subcommittee.

Ms. DEGETTE. Thank you, Mr. Chairman.

I just have a few questions. Over the last 2 days of hearings before today there was a lot of testimony and claims that app developers face a threat from the FDA and that the Agency is planning to regulate mobile phones on a wide range of apps and then impose a medical device tax on phones. In the chairman's opening statement, I think he implied that he understands that the Agency is not planning to put the medical device tax on phones, but I just want to clarify exactly what the Agency is planning to do, Ms. Foreman. So I want to ask you a couple questions.

Is it within the Agency's jurisdiction to regulate mobile medical apps?

Ms. FOREMAN. Yes, it is.

Ms. DEGETTE. If you can pull that microphone even closer, I think you are a very soft-spoken person. Can you give us some examples of the types of apps that the FDA is trying to regulate?

Ms. FOREMAN. The apps that we are trying to regulate and that we have been regulating for a decade, are similar to what is regulated through other medical device technology, such as a central monitoring station for a nurse that transmits patient data, heart rate, SpO2, other critical parameters for patient care that need to be monitored. We have seen ultrasound technology where there is an app and a transducer that can plug into a smartphone to allow ultrasounds to take place. Those are the types of technology that we are regulating.

Ms. DEGETTE. And why are you trying to regulate those types of technology, Ms. Foreman?

Ms. FOREMAN. Those types of technology pose patient risk. If the device does not perform as intended, there is a potential for patient

risk. Additionally, it is the same as other medical devices we regulate. We regulate based on intended use, not based on platform. Just because a device moves to a mobile platform, it would not be the Agency's intention that that would make it deregulated.

Ms. DEGETTE. So you are not looking at how the app is used; you are looking at what the purpose is, right?

Ms. FOREMAN. Exactly.

Ms. DEGETTE. And this is an ability that the Agency has had for some years; it is just not new under the Affordable Care Act or under the stimulus, correct?

Ms. FOREMAN. That is correct. Our first clearance of a mobile app product goes back to 1997.

Ms. DEGETTE. 1997, oK. And can you tell me what types of apps the Agency will not be regulating and why?

Ms. FOREMAN. There are apps that do not meet the definition of a medical device. The Agency would not regulate those. Those would be, for example, an app that takes an electronic version of a printed textbook. We have said that is not a medical device.

Ms. DEGETTE. OK.

Ms. FOREMAN. There are mobile medical devices that meets the definition of a device, but the risk is low. The Agency would rather focus its regulatory priorities on the higher-risk products. So devices for maintaining a healthy lifestyle that help with——

Ms. DEGETTE. Pedometers——

Ms. FOREMAN. Exactly. We would not put regulatory oversight priorities into those products.

Ms. DEGETTE. OK. Now, in a different subcommittee the other day, members of the industry also agreed with what you are saying. Qualcomm's representative testified at that hearing "the FDA is squarely within its jurisdiction and we took a lot of their initial actions as a very promising indication to the industry at large that they were willing to work with all of us." So Ms. Foreman, I want to ask you, what are you doing to make sure that the Agency doesn't overreach when regulating these devices and using the standards that you have set forth?

Ms. FOREMAN. As I mentioned, for FDA to regulate the product, it must first meet the definition of a medical device. That is what gives the Agency its authority. But for all of the products that technically meet the definition of a medical device, we have narrowed our focus to a smaller subset of those based on risk. We are actually refining our regulatory approach rather than overreaching.

Ms. DEGETTE. OK. So that is good that you are narrowing it down, looking at things that affect patient safety and so on, but we are still hearing concerns about the impact of uncertainty on the mobile medical device market. Can you tell me what the Agency is doing to eliminate this uncertainty for investors and developers?

Ms. FOREMAN. We believe finalizing the mobile medical apps Guidance is the first step in eliminating that uncertainty. That Guidance will provide clear, transparent, and predictable messaging regarding FDA oversight of mobile medical apps.

Ms. DEGETTE. And that is the Guidance that you told Mr. Burgess that you are planning to issue by the end of the fiscal year, right?

Ms. FOREMAN. Correct.

Ms. DEGETTE. Now, also, we have heard concerns about the effects of FDA-induced delays on the mobile medical device market. Now, how do you respond to those?

Ms. FOREMAN. We looked at our performance over the last 3 years, which we believe is a contemporary sample of performance. On average, it takes the FDA 67 days to review a mobile medical app. That is well within our statutory time frame of 90 days for the 510(k) process. All mobile apps we have seen thus far have been in the 510(k) process on——

Ms. DEGETTE. And you are going to continue that——

Ms. FOREMAN. For the most part, yes.

Ms. DEGETTE. Thank you. Mr. Chairman, I had referenced the letter from the FDA in my opening statement and asked for inclusion in the record, and the chairman said he had received it but I don't believe he agreed to my unanimous consent request to put it into the record, so I would renew that request.

Mr. BURGESS. I also received it and I accept your unanimous consent request. So ordered.

[The information appears at the conclusion of the hearing.]

Ms. DEGETTE. Thank you so much.

Mr. BURGESS. The chair recognizes Mr. Johnson from Ohio, 5 minutes, for the purposes of questions, sir.

Mr. JOHNSON. Thanks to our panelists for coming today.

The Meaningful Use Program has made good progress in automating the current system. The first stage was to encourage adoption of current technology and gain automation efficiencies. Of course, Stage 2 addressed connectivity and sharing of information, and Stage 3, the final stage, is where providers and patients have accurate, real-time information in the systems and devices that provide care anywhere.

As an IT professional myself for nearly 30 years, architecture and a roadmap of where you are going is vitally important because, as they say, if you don't know where you are going, any road will get you there. And you can pump millions, billions into these projects. And in today's environment, our healthcare providers simply don't have millions and billions to pump into something that is not working for them.

So what is the gap between today's technology and the architecture of tomorrow to achieve an integrated, coordinated care system? How are we making sure that the data that is being collected people can use? I call it decisional information. How are we making sure that we are connecting the dots?

Dr. MOSTASHARI. That is a terrific question and you are absolutely right that it is the use of data not just the data itself that improves care. And as we found in other IT endeavors, it—particularly—IT becomes particularly important when you redesign the processes to take advantage of the information technology instead of merely digitizing the paper-based or former processes.

Mr. JOHNSON. And I would certainly agree with you. You know, over my 30 years in IT, one of the cardinal lessons is just because something can be automated doesn't mean that it should be automated. It is an issue of business process reengineering, and if you don't do that, you don't have a complete solution or certainly you don't have a solution that is connected.

So who is developing the architecture that tells our healthcare providers in our system how this is all going to fit together?

Dr. MOSTASHARI. We have developed that roadmap that you speak of, and it is an incremental roadmap, as you mentioned, through the stages. And it begins with making sure that we have data because until you have data, you really can't see what you are doing. You can't have accountable care if you can't count. And that is where paper-based systems are today. So in Stage 1, the idea is let's collect the information in a structured way because—yes.

Mr. JOHNSON. Well, that goes back to what I said earlier, and I think this is a discussion between two IT professionals here that everybody else may get bored with. That goes back to the "if you don't know where you are going, any road will get you there." I don't think you know what data you need until you have an architecture and you know what the end stage looks like. You know, in the many, many software and technology programs that I managed throughout my 30-year career, if you don't start with an idea of what the end state looks like, then you waste a lot of money; you waste a lot of time.

Dr. MOSTASHARI. That is right.

Mr. JOHNSON. So I am not sure data collection up front without knowing what data you want to collect makes a whole lot of sense.

Dr. MOSTASHARI. Let me clarify my response.

Mr. JOHNSON. Sure. Because we start with data. Data doesn't become information until it is relevant and until it can be used. And data just for the sake of data, as you know, is——

Dr. MOSTASHARI. That is right.

Mr. JOHNSON. So go ahead. I am sorry.

Dr. MOSTASHARI. Sorry about that. So we start with—in the framework, we actually start with the end in mind. So we said what is it about the use of technology that can—we can expect to improve safety, improve the quality of care, patient engagement, public health. And then we work backwards to say, oK, if we want to reduce deaths—unnecessary deaths, those are associated with better decision support at the point of care, it is associated with quality measurement, and being able to make a list of patients by certain criteria, oK, and taking that a step back, you need to be able to have a list of medications for patients. That is pretty clear. We need to have a list of their problems and diagnoses. You need to know their allergies. You need to know their laboratory values. You need to know their blood pressure and smoking status. And it was those data elements recognizing that as the system evolves, there would need to be flexibility and the ability to extend that framework and add in the next iteration devices, for example.

Mr. JOHNSON. Like I said, people are probably going to get bored. You and I can——

Dr. MOSTASHARI. We would——

Mr. JOHNSON. But how many physicians have been involved in the development of this roadmap and the kind of data that we need to——

Dr. MOSTASHARI. We have one of the, I think, hardest-working and most respected Federal Advisory Committees in government. We—it—there—it is—there are certain statutory representations on that. The house majority and minority leaders appoint members

to the Policy Committee. The Senate minority, majority leaders, the Comptroller General——

Mr. JOHNSON. My time is expired.

Dr. MOSTASHARI. Sorry.

Mr. JOHNSON. The chairman is making that known, so I thank you for your answers. I would love to talk to you more sometime.

Mr. BURGESS. And the gentleman may request the answer in writing, and I hope that he will.

The chair recognizes——

Dr. MOSTASHARI. Will do.

Mr. BURGESS [continuing]. Now Mr. Waxman, the ranking member of the full committee.

Mr. WAXMAN. Thank you, Mr. Chairman.

Ms. Foreman, we have heard a lot of allegations over the last few days that FDA is intending to regulate everything and anything digital or online that has any relation to healthcare. But the facts seem to be very different. I know you have attempted in your testimony, as well as in the 2011 Draft Guidance, to allay concerns about the scope of what FDA intends to regulate. But I would like for the record to go over some of the examples we heard in testimony yesterday or the day before. Is FDA currently proposing or does it intend in the future to regulate ordinary smartphones and tablets?

Ms. FOREMAN. No, it does not.

Mr. WAXMAN. What about mobile platforms in general such as the iPhone, Blackberry, Android phones, tablet computers, or other computers that are typically used as smartphones or personal digital assistants?

Ms. FOREMAN. No.

Mr. WAXMAN. What about the entire mobile network?

Ms. FOREMAN. No.

Mr. WAXMAN. Each new mobile device released on the market?

Ms. FOREMAN. No.

Mr. WAXMAN. All health IT?

Ms. FOREMAN. No.

Mr. WAXMAN. An iPad application to help track the number of steps walked per day?

Ms. FOREMAN. No.

Mr. WAXMAN. An iPad application that reminds one that it is time to refill a prescription?

Ms. FOREMAN. No.

Mr. WAXMAN. Software that enables a physician to search a medical textbook?

Ms. FOREMAN. No.

Mr. WAXMAN. Apps to allow parents to access online services such as personal health records to document procedures that a baby has undergone and drugs their baby was given?

Ms. FOREMAN. No.

Mr. WAXMAN. I don't think you can be any clearer. FDA has established limits on what it can and cannot regulate in the mobile device market, and I appreciate you walking through these limits.

While I know that IRS, not FDA, implements the tax code, I would like to ask you a bit about the recent claims that mobile platforms will be taxed under the Medical Device Act. Under the

new medical device tax, will smartphones and iPads now be taxed as medical devices?

Ms. FOREMAN. The FDA is a public health agency, not a taxation agency.

Mr. WAXMAN. I understand.

Ms. FOREMAN. These questions would probably be best answered by IRS or the Treasury, but my understanding is no.

Mr. WAXMAN. These type of products are exempt from the medical device tax, isn't that correct? Can you explain a little bit about this exemption?

Ms. FOREMAN. As I said, we are public health agency——

Mr. WAXMAN. Yes.

Ms. FOREMAN [continuing]. Not a taxation agency, but they would not be regulated as medical devices, therefore, not subject to the medical device tax.

Mr. WAXMAN. OK. As I understand it, they will be exempt because FDA will not define them as a medical device, and even if you did define them as a medical device, they won't be tax because they will qualify for the retail exemption. The law says that items sold to consumers by way of retail cannot be taxed. Isn't that your understanding as well?

Ms. FOREMAN. That is my understanding.

Mr. WAXMAN. Although we don't rely on you for tax information.

Ms. FOREMAN. You really should not.

Mr. WAXMAN. But we are interested in this issue because it has been brought up so many times, and this committee is not a committee that has jurisdiction over tax.

I thank you very much. It is clear that fears that iPhones and other smartphones are going to be regulated by FDA and taxed as medical devices are unfounded and we can put this myth to rest.

OK. Well, Mr. Chairman, my staff informs me the next question is not for me to pursue and I have asked the questions that I think are important and I think they are good way to end the third day of hearings to allay a lot of the fears that have been raised in the other two. And so unless anybody wants my minute, I will yield it back.

Mr. BURGESS. And the chair thanks the ranking member. It is forever in his debt.

Now yields for 5 minutes to Ms. Ellmers from North Carolina.

Mrs. ELLMERS. Thank you, Mr. Chairman.

Thank you. Thank you. And Dr. Mostashari, good to see you again. We have worked together many times on this issue and there again thank you for coming. Thank both of you for coming to testify today.

You know, one of the things—and I know we have discussed this in the past—is really the cost to physicians who are small business owners, and as important as we all know health information technology is, the cost being passed on to them, you know, there are estimations of 15,000 to $70,000 for the cost of implementing IT. And also, there is the issue of the physician really being taken away from the patient at the bedside to implement the information. And there is of course that learning curve that everyone has to go under.

Now, one of the points that is being made is how this is helping eliminate errors and actually thereby improving healthcare. However, when limited time is given to the patient directly, hands-on, and eye-to-eye contact with that patient, don't you think that subsequently it could actually have a bearing on the ultimate outcome of the patient, maybe something being missed, possibly tests being over-ordered as a result of not an adequate time with the patient?

Dr. MOSTASHARI. Overall, the—we actually have data from the National Center for Health Statistics where providers report that EHRs have, in their estimation, produced clinical benefit for their patients. It is 79 percent. And if you look at those who are using the modern systems and who have been using it for more than 2 years—and this is important because it takes time——

Mrs. ELLMERS. Yes. Yes. Sure. Sure.

Dr. MOSTASHARI [continuing]. To get used to the systems, that rises to 92 percent. Now, providers believe that in their practice the electronic health records are providing clinical benefit to their patients.

Mrs. ELLMERS. OK. Now, that leads me to my next question because a lot of the software is incompatible with other facilities, so software that one physician may be using may not be the same software another physician or the physician in the hospital not using the same. So getting back to again considering errors, considering the possibility of information not being exchanged adequately, but also considering cost, which of course ultimately gets passed on to the patient, and we are always looking for good quality of care, what is going to happen when we are trying to integrate all those systems? Is this cost then going to be passed on to the physician again and, you know, having to bear the brunt of that expense?

Dr. MOSTASHARI. Making sure that the patient information is available when and where it is needed is one of our top priorities. And we could have, as some countries have done, have said we are going to solve that problem by the government is going to buy the EHR system for the whole country. That is not the way we do things——

Mrs. ELLMERS. Yes. Yes.

Dr. MOSTASHARI [continuing]. Right? We said the people who are best suited to make those purchasing decisions are the hospitals and doctors who have to live with the systems. But in order to make sure that they can talk with each other, then we need to have some standards. We need to have a certification program and to evolve that certification program and to create consensus, industry consensus——

Mrs. ELLMERS. Yes.

Dr. MOSTASHARI [continuing]. Private sector consensus around how we can have one doctor choosing one system, the other choosing a different system that meets their needs but having those systems——

Mrs. ELLMERS. Be able to communicate.

Dr. MOSTASHARI [continuing]. Be able to talk to each other. That is the approach we have taken, and the certification criteria for 2014 put a big step up in those requirements.

Mrs. ELLMERS. OK. Thank you.

Ms. Foreman, I do have a couple questions. I know we continuously are talking about, one, the FDA regulation issue, which is very important, but also the tax on the medical devices. Has the FDA looked at this as an issue that it might actually be stifling some of the innovation moving forward with having the tax on medical devices?

Ms. FOREMAN. As I said, we are public health agency. Our decisions are governed by public health. Our decision-making is based on balancing innovation and public health.

Mrs. ELLMERS. Yes. Yes.

Ms. FOREMAN. We identified a large subset of devices that could be under enforcement discretion without our regulatory oversight.

Mrs. ELLMERS. Yes. Yes.

Ms. FOREMAN. As it happens, those devices may not be subject to the device tax.

Mrs. ELLMERS. OK.

Ms. FOREMAN. As was mentioned, there is a retail exemption as well——

Mrs. ELLMERS. Right.

Ms. FOREMAN [continuing]. Meaning products available for retail—even declared to be a medical device—is exempt from the tax—FDA does is a public health organization, not a taxation agency.

Mrs. ELLMERS. Thank you. Thank you. My time is expired. Thank you both.

Mr. BURGESS. The chair recognizes the gentleman from North Carolina 5 minutes for purposes of questions, sir.

Mr. BUTTERFIELD. I thank you, Mr. Chairman.

And I thank both of you for your testimony here today.

Over the course of the last 2 days of hearings, and actually in Ms. Foreman's testimony here today, we have learned that FDA has proposed regulating only a very small subset of mobile applications. FDA's Draft Guidance states that the Agency will only look at those mobile apps that are essentially acting as a medical device or as part of one. The Guidance also explicitly exempts many of the apps that my colleagues on the other side have been trying to scare people into thinking FDA was going to take over, things like electronic PDRs and electronic health records. That seems like a very reasonable approach to me.

But I want to learn more about exactly what kind of regulatory burden we are talking about even with this small subset of applications that will be regulated as devices. I know that an FDA-regulated medical device may fall into one of three tiers. We have heard about that. Class 1 devices are the least risky devices while Class 3 devices are the most risky.

And so let me start with Ms. Foreman. Ms. Foreman, can you briefly elaborate on these three levels of device oversight and explain what responsibilities a device manufacturer has under each of these levels?

Ms. FOREMAN. Certainly. I will start at the bottom and work up. If the device is a Class 1 device, and this small subset could include devices that would meet the Class 1 definition of a medical device, they are not subject to agency premarket review. They are subject to meeting registration and listing requirements, as well as

the quality system regulation, which ensures that the devices are manufactured properly.

Moving up to Class 2 devices, these must meet those same criteria—registration, listing, quality system—but they also need what is called a 510(k) or a premarket notification. That application would allow the Agency to review and clear the device as equivalent to another device on the market. There is a user fee associated with that. It is just under $5,000. However, if it is a small business, it is half of that. If the sponsor makes significant modifications to the device, they would need a new 510(k), but as I mentioned, we planned many of those iterative changes to not require new submissions of 510(k)s.

If we move up to the next level, Class 3, those devices require a premarket approval application. To date, we have not found a mobile app that would fit into that category. I am not saying that in the future it wouldn't be possible, but we have not seen one yet.

Mr. BUTTERFIELD. So essentially, what you are saying is that a Class 1 or 2 device doesn't have to do all that much in terms of premarket clearance, while Class 3, if there is one, sounds like it may be subject to more stringent requirements if one evolves——

Ms. FOREMAN. Correct.

Mr. BUTTERFIELD [continuing]. Is that correct?

Ms. FOREMAN. Correct.

Mr. BUTTERFIELD. OK. Now, which level of regulatory oversight will most of these medical applications fall under?

Ms. FOREMAN. Class 1 or Class 2.

Mr. BUTTERFIELD. Class 1 or Class 2. And you don't know of any Class 3 existing at this moment?

Ms. FOREMAN. I do not.

Mr. BUTTERFIELD. All right. Now Ms. Foreman, there were also some assertions yesterday that FDA lacked the expertise to regulate mobile applications. Your testimony states that you have regulated medical device software for decades and mobile apps for more than 10 years. Can you elaborate on FDA's experience regulating in this area?

Ms. FOREMAN. Absolutely. This is not a new area for the FDA. We have been regulating software and mobile apps for some time. When we do our review, we actually bring together two different sets of expertise. There is the software expertise, we have software engineers who will review the software information to make sure that it was developed properly, coupled with a clinical review because the app is intended for a medical application. For example, if you take an app to view a radiology image on a smartphone, the software reviewer can make sure that all of the technical specifications happen properly on the smartphone. And we will ask the clinical reviewer for an evaluation to determine if, for example, we view an image on a smartphone, can we actually detect cancer with the same level of sensitivity and specificity that we would on the large view station? You can zoom the image, you can pan, you can look at it that way, but is there a difference between looking at the whole image versus pieces of the image to make sure that patient safety is not compromised? Because you don't want somebody to have undergone radiation for a diagnostic purpose and then—realize there is a false negative or a false positive.

Mr. BUTTERFIELD. Can you finally address how you plan to keep up with the world in which so many apps are already on the market and so many new ones are coming out every day? How are you going to keep up with all this stuff?

Ms. FOREMAN. As I mentioned, part of keeping up with it is prioritizing our focus, and we are prioritizing our focus on the small subset; within that subset we receive about 20 applications a year. Right now, we are getting less than 20 a year. That is actually in our 510(k) inventory. That is about .5 percent of the medical device applications that we review. And keeping up with technology is something that we are always faced with, so that is why we add on competent staff and we make sure to provide training opportunities for those staff so that they can continue to stay abreast of the latest technology.

Mr. BUTTERFIELD. Thank you. My time is expired.

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

I am advised that votes have been called. We will try to go over and get through as many of the panel as we can.

I recognize the gentleman from Missouri 5 minutes for questions.

Mr. LONG. Thank you, Mr. Chairman. And thank you all for being here today.

Director Foreman, I have a question for you. As far as current FDA Risk Evaluation and Mitigation Strategy, REMS for short, their Guidance requires, doesn't it, that medication guides upon first dispensing of the medication and then for every subsequent refill you have to have the medication guides printed out. Is that correct?

Ms. FOREMAN. So I am going to apologize because REMS is a provision implemented by CDER, or Center for Drug Evaluation and Research. So that is really outside of my area of expertise in the Center for Devices and Radiological Health.

Mr. LONG. OK. Who should I go to to answer that question? Who should I——

Ms. FOREMAN. CDER is headed by Dr. Janet Woodcock.

Mr. LONG. OK. OK. Because that was my intent was to ask if on a refill prescription if that could be able to be handled through a mobile device as opposed to trying to mail a stack of how to retake your medicine every time that it is prescribed. So with that—and I know we are short on time—Mr. Chairman, I yield back.

Mr. BURGESS. The gentleman yields back.

The gentleman from New York is recognized for 5 minutes for questions.

Mr. TONKO. Thank you, Mr. Chair.

Dr. Mostashari, there is a broad consensus that the increased use of electronic health records and health information technology ultimately leads to better patient care and a bending of that cost curve and savings, but there is also a concern that the adoption of these EHRs also provide an increased opportunity for fraud by exaggerating the intensity of care or severity of patients' conditions on their Medicare claims. We have, I guess, labeled this as up-coding and it is often facilitated by software programs that prompt billing for additional services that were not provided and maybe only tangentially related to the care received. Many of our health

IT vendors are developing these systems to promote their products as a way to increase the bottom line.

So my question is can you discuss what your office is doing to develop guidance and technological standards in electronic health records software that will help to prevent this type of fraud?

Dr. MOSTASHARI. Yes, thank you for the question. I want to make one thing very clear, which is that if there is documentation of care that did not occur, that is fraud. And CMS and the Attorney General and the Secretary of Health have made it very clear that we will not tolerate fraud. And the electronic health records provide increased tools also on our side to be able to better investigate and prosecute fraud should it occur. There are always those who will attempt to defraud the system and I think this Administration in particular has been very successful and has had record prosecutions and recoveries under that.

But I think your question gets to also issues where it is not explicit fraud, and those are more complicated situations. I think some of the analysis has been done looked at patterns of coding intensity over the past decade. Before the first meaningful use payment check ever went out, for a decade there has been this creep towards higher intensity codes. CMS—this is not a new issue for CMS and they have ways of dealing with shifts in these patterns. But the electronic health records that were formally predominantly used for documentation and billing purposes before meaningful use, that may have been part of the business case for them. I think that our challenge is twofold. First, to make sure that we get the broadest possible input on ways that we can mitigate any possibility of the records systems themselves inducing inadvertent violations.

The second is to make sure that the systems meet the needs of the future, which is, as I think there is broad consensus, means moving away from paying fee-for-service based on documentation and more towards outcomes and value.

Mr. TONKO. Thank you. And what lessons can be drawn from the implementation of EHRs nationwide from the VA's long successful track record with VISTA, their Veterans Health Information Systems and Technology Architecture program, specifically in terms of interoperability and usability of records?

Dr. MOSTASHARI. It is interesting, following on your previous question, one of the groups that had the most experience with the perils of copy-and-paste was the VA, which, even though there was no billing incentive, it was convenient to carry forward notes from before, and it resulted in not—it is not a billing issue. It is a clinical documentation issue where it wasn't easy to understand. If you practiced at the VA, sometimes you saw notes that were copied forward and forward and forward, and it wasn't good for clinical care. You couldn't understand what was really going on with the patient in this visit. And the VA has done a lot working with clinical leadership to say how can we improve the quality of the clinical documentation and the usability of the systems?

The VA—there is very strong evidence that they have saved billions of dollars by implementing IT and by continually improving the systems that they have. And if there is one lesson I would take from the VA it is that, that no system is perfect the day it is implemented. And it becomes improved over time through the polishing

of that stone to the application of clinical judgment, improved usability, improved interoperability, and that is what we are engaged with here. This is not a, you know, one-and-done process. This is going to be a continual process of refinement, optimization, improvement, and redesign.

Mr. TONKO. Thank you, Dr. Mostashari and Ms. Foreman, for appearing before us.

And Mr. Chair, with that, I yield back.

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

The chair now recognizes Mr. Griffith for 5 minutes for questions, sir.

Mr. GRIFFITH. Thank you.

And I apologize to the witnesses in advance. I have to move fairly quickly so I am cutting through a lot of the explanation because I think you all know where we are heading with the questions as we get to it. But if you need further, let me know.

Ms. Foreman, your testimony notes that questions about medical device tax should be directed to the IRS, but clearly, they are going to need help in figuring out what is a medical device at what you are regulating as a medical device if it is the purpose of it and not the platform. And so I would ask, have you had any discussions with the IRS about this tax, if they have asked for your input on that?

Ms. FOREMAN. We provided technical input to the IRS on the interpretations of our laws. The way it was implemented is that if a medical device lists, it would be subject to the tax.

Mr. GRIFFITH. And can you provide us with a copy of what you gave the IRS so we can take a look at that to the committee? Not today, but subsequently?

Ms. FOREMAN. I can look into that.

Mr. GRIFFITH. OK. Thank you. And has the FDA done any analysis on the impact of the tax either in dollar figures or the number of manufacturers it will have an impact on?

Ms. FOREMAN. FDA is a public health agency. We are not involved in the taxation. We receive no direct benefits.

Mr. GRIFFITH. In regard to the questions, the list of examples that Mr. Waxman listed out, while the FDA does not currently have any plans, do you believe that the FDA could if it so chose to do so regulate those examples down the road if it had a change of heart?

Ms. FOREMAN. If the device meets the definition of a device as defined in the Food, Drug, and Cosmetic Act, we could. We have no intent to. The only thing that would change our mind is if there was a strong safety signal that we became aware of related to a device that we were not regulating appropriately under enforcement discretion. By not regulating it, that would cause us to reconsider our position. But absent strong safety signals, no, we would not change our mind.

Mr. GRIFFITH. All right. And then the practical question that I would have is if somebody is currently developing an app of a medical nature, how does anybody know if they are supposed to be contacting the FDA? And, you know, I am just an old country lawyer and I got on my tablet here—it is an Android—and found an article yesterday and there was lots of; I just chose this one because it

sounded interesting—that the iPhone is now a handy tool for detecting and diagnosing parasites, and the article says "using little more than an iPhone, strips of double-sided tape, a cheap ball lens, and a battery-powered flashlight, a workable model was assembly to determine whether or not a child had parasites." Are you all regulating that or not?

Ms. FOREMAN. To my knowledge, we have not regulated that. It has not come before us. A diagnostic device, though, would meet the definition. That would——

Mr. GRIFFITH. So if the Canadians, the Bostonians, and the Swiss who worked this up to help in other countries decided that it might be helpful in rural parts of the United States, they would have to come to you first, and instead of costing $8, it would cost what? Hundreds of thousands?

Ms. FOREMAN. We are not involved in the pricing of medical devices.

Mr. GRIFFITH. No, no, no, I am not talking about with the price is. I am talking about how much it costs to get it approved.

Ms. FOREMAN. So, as I say, a 510(k) fee is just under $5,000. If it is a small business, it would be half of that.

Mr. GRIFFITH. OK.

Ms. FOREMAN. So $2,500.

Mr. GRIFFITH. But you would want all kinds of tests and studies, not the fact that they have been out in the field and made it work with double-sided tape, am I not correct?

Ms. FOREMAN. I am not inherently opposed to double-sided tape but——

Mr. GRIFFITH. I understand. I think I have made my point, and I yield back my time, Mr. Chairman.

Mr. BURGESS. I thank the chair. The chair yields to the gentleman from Texas, Mr. Barton, for questions.

Mr. BARTON. Mr. Chairman, I appreciate the time. I want to yield it to you to use as you so decide.

Mr. BURGESS. Well, I thank the chairman emeritus.

Dr. Mostashari, I just have to ask you here as we conclude today, I hear a lot of stuff about interoperability. I mean you are the head. Why don't you just fix that? Why don't you just make that happen?

Dr. MOSTASHARI. We are using every lever at our disposal to increase the sharing of information, and that includes not just the data standards and getting industry together to help us. We don't want to be the ones to say, you know, we will choose the standards. We really want to work with industry to get consensus and to accelerate this.

Mr. BURGESS. But, you know, in the interest of time, we do hear about this a lot. Even anecdotally, hospital systems in the same city that have the same operating system aren't talking to each other. It seems like you could make that happen.

Dr. MOSTASHARI. We—the 2014 certification criteria, Dr. Burgess, I—we—I would be happy to go into great detail with you, but they are a big step forward, and I believe that hospitals and doctors around the country will see a palpable difference once those certification criteria are in place.

Mr. BURGESS. Well, I want to thank both of our witnesses for being here today and for bearing with us. I apologize about votes cutting the hearing short. Dr. Mostashari, I look forward to having you back at either the Health Subcommittee or this subcommittee in the future. You are a fascinating witness. We have learned a lot this morning from both of you, and I appreciate your time.

I want to thank the members for their devotion to the hearing today.

The committee rules provide that members have 10 days to submit additional questions for the record to the witnesses. I also failed to ask for unanimous consent that all members' statements that wish to be entered in the record be entered.

Hearing no objection, so ordered.

The hearing stands adjourned.

[Whereupon, at 10:25 a.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

MAR 20 2013

The Honorable Tim Murphy
Chairman
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
House of Representatives
Washington, D.C. 20515-6115

Dear Mr. Chairman:

Thank you for your letter of March 1, 2013, cosigned by six of your colleagues, regarding the requirements of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and the Patient Protection and Affordable Care Act (PPACA), and how these laws are applied to the manufacturers of smartphones, tablets, and individualized applications (apps). Your letter poses several specific questions concerning the activities of the Food and Drug Administration (FDA or the Agency) regarding the regulation of wireless medical devices (also referred to as "mobile medical applications" or "mobile medical apps").

We have restated your questions below in bold, followed by FDA's responses.

1. **When will the FDA issue final or updated guidance with respect to the July 19, 2011, request for input on its oversight approach for mobile medical applications designed for use on smartphones or other mobile computing devices?**

   FDA issued a draft guidance document regarding mobile medical applications on July 21, 2011.[1] That guidance announced FDA's intention to exercise enforcement discretion for most mobile apps. The draft guidance proposed regulatory oversight of only a small subset of mobile apps (referred to in the guidance as "mobile medical apps") that meet the definition of a device in section 201(h) of the FD&C Act and are intended for use as either: (1) an accessory to a regulated medical device, or (2) to transform a mobile platform into a regulated medical device.

[1] FDA, "Draft Guidance for Industry and Food and Drug Administration Staff - Mobile Medical Applications" (July 21, 2011), available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm263280.htm*.

FDA received more than 130 submissions to the public docket on the draft guidance. Many commenters sought additional clarity on the types of mobile apps for which FDA intends to exercise enforcement discretion. FDA will seek to provide this clarity in the final guidance.

Commenters overwhelmingly supported the narrowly tailored approach FDA described in the draft guidance. FDA has since received many more inquiries from members of industry eager to see the guidance finalized. The mobile medical apps guidance is currently in the final stages of Agency review. The Agency has previously indicated its intent to publish the final guidance this year.

2. **Has the FDA discussed, prepared, or analyzed the effect of the medical device tax on smartphones (as well as tablets or similar devices) or the creators or distributors of applications for those products? If so, please provide all documents analyzing or relating to this issue.**

FDA has not analyzed the effect of the medical device tax on creators and distributors of smartphones, tablets, and similar devices but is aware of concerns about the effect on innovation if novel technologies become subject to the tax. FDA developed the Agency's draft mobile medical apps policy to protect public health and promote innovation.

Although the definition of a "taxable medical device" is tied to the FD&C Act, it is the Internal Revenue Service (IRS) and the Department of the Treasury that are responsible for the excise tax imposed on the sale of certain medical devices, not FDA. Moreover, as indicated by the IRS's definition of "taxable medical device," not all medical devices regulated by the FD&C Act are subject to the tax—only those that are required to list with FDA. Because the mobile medical app draft guidance states that the Agency intends to exercise enforcement discretion for many mobile apps with respect to applicable device requirements, including listing, FDA does not expect those devices to list.

Questions about the implementation of this policy should be directed to the IRS.

3. **Will the actual use of a smartphone, tablet, or app be a factor in whether the FDA chooses to regulate the device or app as a medical device? Has it been a factor in any analysis by FDA already completed?**

The answer to both questions is no.

As stated in FDA's draft mobile medical apps guidance, FDA's mobile medical apps policy will not regulate the sale or general consumer use of smartphones, or tablets even when such sale or use is in a health care setting (e.g., in a doctor's office or hospital). FDA's proposed mobile medical apps policy does not consider entities that exclusively distribute mobile medical apps, such as the owners and operators of "iTunes store" and "Android market," to be medical device manufacturers.

Instead, FDA's draft mobile medical apps guidance focuses on the intended use of the mobile app and proposes oversight only for those mobile apps that meet the definition of a "device"

under section 201(h) of the FD&C Act, and are either intended for use as an accessory to a regulated medical device or to transform a mobile platform into a regulated medical device. This analysis is typical of how FDA has handled various products that might be devices that serve multiple purposes. FDA looks to the intended use of the product to determine whether the product is a device. The intended use of a product is typically determined by how a product is marketed; that is, by labeling, advertising, and promotional claims.

We note that products that are not intended for use in the diagnosis of a disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, including smartphones, tablets, and apps, even when used in a health care setting, would not be considered to be medical devices.

4. **How many mobile medical apps have sought approval from the FDA before entering the market? What was the processing time for each of these apps? How many mobile medical apps have been subject to oversight by the FDA after introduction to the market? How many apps have either been changed or removed from the market by FDA oversight, and why?**

It is important to note that FDA has been regulating medical device software for decades and medical device software on mobile platforms for more than 10 years. During the past 10 years, the Agency has reviewed more than 30,000 premarket medical device submissions, including approximately 100 for mobile medical apps. However, FDA traditionally has not categorized or tracked premarket submissions based on the specific underlying technology of a medical device. Rather, our systems have been focused on capturing devices that generally fall within device classifications that are grouped by medical specialties (for example, radiology; ear, nose, and throat; toxicology; dental; ophthalmic; etc.). We are currently exploring methods to better capture the number and types of mobile medical app submissions.

For 2011 and 2012, the average time for FDA review of medical device submissions that were identified as containing a mobile medical app was 67 days and the average total time from submission to FDA decision was 110 days. These numbers represent review of not only the mobile medical app, but also review of any relevant attachments or accessories included in the submission. For example, review of a submission of a glucose meter included evaluation of both the mobile medical app and the blood glucose attachment.

In general, manufacturers often voluntarily correct their products that may either be in violation of the FD&C Act or experience a malfunction that could result in serious injury or death. We are aware of one voluntary recall involving a mobile medical app that could miscalculate an insulin dose potentially resulting in dangerously low or high blood glucose levels in diabetic patients. In addition, the app was unintentionally made available in the United States by the manufacturer. The manufacturer voluntarily notified all users worldwide and removed the app from the Global App Store.

As requested in your letter, appropriate FDA representatives briefed staff of the Committee on Energy and Commerce and discussed these issues by telephone conference on Thursday, March 14, 2013.

Thank you, again, for contacting us concerning this matter. If we can be of further assistance, please let us know. The same letter has been sent to your cosigners.

Sincerely,

Michele Mital

Michele Mital
Acting Associate Commissioner
for Legislation

cc: The Honorable Henry A. Waxman, Ranking Member

The Honorable Diana DeGette, Ranking Member
Subcommittee on Oversight and Investigations

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

The Honorable Tim Murphy
Chairman
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
House of Representatives
Washington, D.C. 20515-6115

MAY 10 2013

Dear Mr. Chairman:

Thank you for providing the opportunity for the Food and Drug Administration (FDA or the Agency) to testify at the March 21, 2013, hearing before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, entitled "Health Information Technologies: Administration Perspectives on Innovation and Regulation." This letter provides responses for the record to questions posed by certain Members of the Subcommittee, which we received on April 9, 2012.

If you have further questions, please let us know.

Sincerely,

Michele Mital
Acting Associate Commissioner
for Legislation

cc: The Honorable Diana DeGette
Ranking Member
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce

We have restated each Member's questions below in bold, followed by our responses.

The Honorable Tim Murphy

1. **The testimony submitted by the FDA strongly states that the FDA's proposed mobile medical app policy would not apply to mobile apps that perform the functionality of an electronic health record (EHR) system or personal health record system. Has the FDA had any discussions or conducted any analysis on how this will apply to the coming health insurance exchanges that will debut on January 1, 2014 as part of the Patient Protection and Affordable Care Act? Will any mobile apps related to the exchanges be subject to this same statement?**

FDA's proposed policy would focus its regulatory oversight on only a subset of mobile medical apps that meet the definition of a device in section 201(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and are intended to be used as an accessory to a cleared/approved medical device, or to transform a mobile platform into a cleared/approved medical device. We are not aware of any mobile apps related to health insurance exchanges under the Patient Protection and Affordable Care Act that meet that definition.

2. **During your testimony you indicated that FDA had provided technical guidance to the Internal Revenue Service to implement the Medical Device Tax created by the Patient Protection and Affordable Care Act. Please provide this for the record.**

We are in receipt of the April 9, 2013, letter to FDA on this issue from Chairman Fred Upton, House Committee on Energy and Commerce, Chairman Tim Murphy, Subcommittee on Oversight and Investigations, and Rep. Morgan Griffith. We will respond to this request under separate cover.

3. **Both your written testimony and responses to questions at the Hearing indicated that FDA will utilize its enforcement discretion in determining whether a mobile medical app will be regulated more carefully (and ultimately become subject to the Medical Device Tax). Are there ways in which that discretion will not be necessary? If a previous or future FDA guidance indicates that manufacturers should automatically register with the FDA or otherwise notify the FDA of their intentions, could that trigger increased scrutiny? Will the use of your enforcement discretion occur on a case by case basis or will there be certain actions that guarantee a mobile medical app requires increased oversight, outside of the triggers listed in the July 2011 guidance?**

FDA's draft guidance, issued in July 2011, proposes our intent to exercise enforcement discretion for most mobile apps. As stated in our guidance, FDA is focusing its regulatory priorities on those mobile apps that meet the definition of device and are intended to (1) be used as an accessory to a cleared/approved medical device, or (2) transform a mobile platform into a cleared/approved medical device. FDA typically makes its enforcement

decisions on a case-by-case basis and these decisions will be guided by the principles set forth in the final version of this guidance.

To help clarify the Agency's policy for mobile medical apps, FDA intends to post on its website new examples of mobile apps on which FDA is focusing its priorities.

The Honorable Morgan Griffith

1. **With the thousands of medical apps that are currently being developed, what plan does FDA have to approve the majority of these medical apps in a timely fashion?**

FDA has been reviewing medical device software for almost as long as FDA has had premarket review authority for devices. Further, although there are thousands of mobile apps on the market, relatively few have required FDA review. FDA has reviewed approximately 100 mobile medical apps over the last decade. All of these apps have been reviewed as premarket notification (510(k)) submissions, rather than premarket approval applications (PMA).

Even with the recent increased growth and availability of these mobile apps, in the last two years FDA has received for clearance no more than 20 premarket notification (510(k)) submissions per year for mobile medical apps. For 2011 and 2012, the average time for FDA review of medical device submissions that were identified as containing a mobile medical app was 67 days. Under the FD&C Act, medical device 510(k) clearances are to be completed within 90 days, and our data show that the Agency is well within that time frame in reviewing mobile medical app submissions.

FDA does not anticipate a substantial increase in its premarket review workload due to an increased number of submissions for mobile medical apps. Under FDA's proposed guidance, most mobile apps will fall outside of FDA's regulatory focus. The approach proposed in the Agency's July 2011 draft guidance on mobile medical apps states that FDA's oversight will focus on a small subset of mobile apps that are similar to medical devices that are cleared/approved or that may affect the functionality of cleared/approved medical devices.

2. **Has FDA considered a 3-tiered, risk-based oversight framework for health information technology, including medical apps, as discussed by McKesson in testimony before the Energy and Commerce Health Subcommittee on Wednesday, March 20, 2013 and by the Bipartisan Policy Center in a February 2013 study titled "An Oversight Framework for Assuring Patient Safety in Health Information Technology"?**

As required by section 618 of the Food and Drug Administration Safety and Innovation Act (FDASIA),[1] FDA is working with the Federal Communications Commission (FCC) and the Department of Health and Human Services (HHS) Office of the National Coordinator for

[1] Public Law 112-144, 126 Stat. 992 (July 9, 2012).

Health Information Technology (ONC) to develop a report containing a proposed strategy and recommendations on an appropriate, risk-based regulatory framework pertaining to health information technology that promotes innovation, protects patient safety, and avoids regulatory duplication.

The three agencies are convening a workgroup of external stakeholders and experts, as suggested in section 618 of FDASIA, under the Department of Health and Human Services Health Information Technology (HIT) Policy Committee. This will allow for diverse stakeholder groups to provide input to the HIT Policy Committee on the proposed strategy and recommendations for the risk-based regulatory framework for health information technology. The working group will be charged with providing input on a tiered, risk-based regulatory framework that appropriately addresses patient safety and innovation and avoids regulatory duplication. We intend to consider all suggested proposals, including the approaches that were described in the testimonies before the Health Subcommittee of the House Committee on Energy and Commerce during the March 20, 2013, hearing entitled "Health Information Technologies: How Innovation Benefits Patients."

3. **If so, does the FDA need legislation to facilitate the agency's adoption and implementation of a 3-tiered, risk-based oversight framework for health information technology, including medical apps?**

Please see response to Question #2 above.

The Honorable G. K. Butterfield

1. **The world we live in is filled with resources for everyday folks to self-diagnose their symptoms by using popular medical advice websites, and countless medical-related apps. I am a big proponent of consumers having direct access to information, but do you have any concerns about individuals using these apps to self-diagnose and not seeing their doctor or other healthcare professional? Can you talk for a moment about the impact these medical apps have had on consumer actions?**

Certain health-related mobile apps can improve the care and quality of life for many people, giving them the freedom to conveniently access health-related information that can help them make important decisions about their care. Mobile apps that motivate individuals to lead a healthy lifestyle (for example, by exercising and eating a healthy diet) by providing information and education are good examples of how mobile technology has enhanced people's lives and helped them manage their conditions. We encourage consumers of these types of apps to consult their physicians and other health care professionals before making any lifestyle changes that could potentially affect medical conditions.

For other types of mobile apps that are designed to help individuals diagnose illnesses, there is always the risk that consumers would not seek treatment when they should. We believe that consumers should make informed decisions and so instead of solely relying on

technology to diagnose a disease or health-related condition, they should also consult a licensed medical practitioner, as appropriate.

Mobile medical apps that allow consumers to self-diagnose a disease must be shown to be safe and effective so that consumers can rely on them as they would rely on a blood glucose meter or an over-the-counter blood pressure cuff.

FDA intends to focus its regulatory oversight on these types of mobile medical apps, to ensure that this technology, which enables consumers and patients to diagnose serious diseases or conditions or that may be used to make important treatment decisions, is safe and effective.

2. **Many mobile applications update frequently when their creators or consumers notice problems that require correction. How will the FDA keep up with new generations of web applications and help ensure consumers are using safe and accurate mobile health applications?**

FDA's proposed mobile medical apps policy would not require mobile medical app developers to seek Agency re-evaluation for minor, iterative product changes that do not significantly affect the safety and effectiveness of the mobile app. Even for the small subset of mobile medical applications that FDA would actively regulate, such changes could be made without notification to FDA, provided that the manufacturer complies with applicable Quality System requirements in making such changes.

For changes that significantly affect safety and effectiveness of the mobile medical app, FDA would take a risk-based approach that primarily relies on manufacturers to have Quality System processes in place. Significant changes made to higher-risk regulated mobile medical apps may be subject to certain additional oversight by FDA, in order to ensure that such changes do not adversely affect the safety and effectiveness of the device.

3. **Certain mobile applications do not work properly with an incompatible mobile device. How can we assist in communicating to consumers which applications are appropriate for their individual mobile devices?**

The mobile apps industry plays an important role in establishing standards in areas such as device compatibility. Some industry groups have already begun activities in developing open architectures and standards with regard to expectations for compatibility. FDA can also play a role, by participating with health care professionals, industry, and standard-setting organizations in standard-setting activities.

QUESTIONS FOR THE RECORD: Farzad Mostashari, National Coordinator for Health Information Technology, U.S. Department of Health and Human Services

"Health Information Technologies: Administration Perspective on Innovation and Regulation" – March 21, 2013

Committee on Energy and Commerce, Subcommittee on Oversight and Investigation, U.S. House of Representatives

Chairman Murphy

Question 1:

Page 7 of your testimony notes that a November 2011 IOM report reported that "market forces are not adequately addressing the potential risks associated with the use of health IT." Has ONC experienced this? Does ONC believe that market forces are not adequately addressing patient safety or other risks?

ONC believes that on the whole, the adoption of health IT has greatly improved patient safety by reducing medical errors and helping to standardize the way that care is provided, but we are mindful of the need to ensure that new systems are built and used in the safest possible manner. We believe market forces have already motivated a high level of safety in the industry, but there is opportunity for improvement. For instance, in 2014, certified EHR technology developers will be required to publicly identify a method of incorporating user-centered design that has a high likelihood of helping to prevent medical errors. Certified EHR technology developers will also be required to provide transparency regarding their approach to quality management systems.

In our draft Health IT Patient Safety Action and Surveillance Plan, we encouraged the industry to draft and enforce a voluntary code of conduct to improve safety practices, among other things. We will continue to monitor the industry's progress in addressing potential safety risks going forward.

Question 2:

Page 8 of your testimony notes that ONC's draft plan on Health IT Patient Safety will recommend the inclusion of "safety requirements related to user-centered design ... and easier reporting of adverse events ... " Can you elaborate on the authority given ONC to either compel or recommend that these items be included? How will this be enforced, if ONC chooses to endorse this approach?

The draft Health IT Patient Safety Action and Surveillance Plan (the Safety Plan) restates ONC's commitment to patient safety through the safe use of health IT. Prior to the Safety Plan's release, ONC had already adopted through rulemaking two safety-related 2014 Edition certification criteria for EHR technology. The first certification criterion requires that EHR technology presented for certification to any one of eight specific medication-related capabilities must have had user-centered design processes applied to them in order to be certified. The second certification criterion requires the identification of the quality management system followed and used in the design of the EHR technology. Given that these requirements are part of ONC's HIT Certification Program, they will be primarily enforced by the certification bodies ONC has authorized to perform certifications and, generally, by ONC in providing its overall program oversight.

Question 3:

One of the main concerns about the push for the meaningful use of health IT is that we may be encouraging doctors and patients to rely more heavily on computers or the internet than face-to-face interaction. Do you have any evidence that the use of health IT is better or worse than interaction between a doctor and patient? Have any studies been done on the possibility this could decrease patient safety?

Meaningful Use does not replace appropriate physician-patient interaction or in any way encourage virtual interaction when face-to-face is best warranted. Its application encourages more productive interactions by enabling physicians to make more fully informed point-of-care decisions and recommendations. Just as the advent of the telephone did not preclude, prevent, or disable the need for face-to-face interaction between the patient and his/her doctor, health IT and Meaningful Use provides yet another timely conduit for information exchange.

One of the most recently published reports by David Radley, et. al., describes how the use of computerized provider order entry (CPOE), a central component of Meaningful Use, decreases the likelihood of prescribing error by 48%.[1] ONC believes the application of this tool has tremendous potential to improve patient safety.

Question 4:

Many complaints have been made about the problem of interoperability – health IT systems that cannot communicate with each other – in fact you were asked about this during questioning. What does ONC plan to do to finally solve this problem?

Health IT and the secure exchange of information across providers are crucial to reforming the system. In 2014 EHRs will be significantly more interoperable because providers will have to demonstrate that they can exchange clinical information with other providers.

More specifically, starting in 2014 hospitals, doctors, and other eligible professionals that use certified EHR technology in Stage 2 of Meaningful Use will be able to share summary records across providers, send electronic prescriptions, electronically report clinical quality measures, and allow patients to view, transmit and download their health information. These advances, combined with the ongoing work ONC is doing to develop standards for health information exchange, will continue to drive increasing levels of interoperability over the coming months and years.

In addition, we are currently considering which policy levers might be able to strengthen the business case for the exchange of health information by making sure that different providers and vendors have the strongest possible incentive to share information. In March, ONC and CMS jointly issued a request for information (RFI) seeking public input on this issue. We have received over 200 comment letters from a wide variety of stakeholders, which we are reviewing.

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[1] Radley, D. C., Wasserman, M. R., Olsho, L. E. W., Shoemaker S. J, Spranca, M.D., Bradshaw, B. *Reduction in medication errors in hospitals due to adoption of computerized provider order entry systems. J Am Med Inform Assoc* 2013;20:3 470-476 Published Online First: 20 February 2013 doi:10.1136/amiajnl-2012-001241 (available at http://jamia.bmj.com/content/20/3/470.long) (last accessed 4/15/2013)

We are also encouraged that others have increasingly recognized the progress that is underway. At a recent hearing on HIT standards and interoperability that took place on November 14th, 2012 before the House Committee on Science, Space, and Technology, Subcommittee on Technology, all five witnesses stated that progress is being made on interoperability. Similarly, in an October, 2012 report on information sharing, the Bipartisan Policy Committee stated that a business case for electronic health information sharing is beginning to emerge, and also that the Meaningful Use Stage 2 requirements that take effect in 2014 largely address a majority of the information sharing needs that have been identified in clinician surveys.

Question 5:

Does ONC see a problem with information sharing among psychologists or behavior health workers? Were Health IT incentives offered to this group? Why or why not?

ONC has worked with the HHS Substance Abuse and Mental Health Services Administration (SAMHSA) to clarify the federal protections over substance abuse information in the context of health information exchange.[2] These efforts led to the publication of FAQs "Applying the Substance Abuse Confidentiality Regulations to Health Information Exchange (HIE). Further, in September 2012, in partnership with other components of the Department of Health and Human Services (HHS) and with the Department of Veterans Affairs (VA), ONC, through its Data Segmentation for Privacy Initiative (DS4P) demonstrated that with proper standards in place, existing privacy laws and policies can be implemented appropriately in an electronic environment. Using standards identified in the DS4P Initiative, SAMHSA and the VA safely and securely transmitted a mock patient's substance abuse treatment records tagged with privacy metadata from one EHR to a different EHR system after electronically verifying that the mock patient had consented to the transmission.

Health IT incentives were not offered specifically to psychologists or behavioral health workers, and only mental health professionals who meet the definition of an eligible professional (EP) could qualify to receive EHR incentive payments under Medicare or Medicaid. The specific criteria for Medicare or Medicaid EPs can be found at the following link: http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Getting_Started.html.

Question 6:

The Health Insurance Portability and Accountability Act (HIPAA) protects the privacy of an individual's health information. How does ONC balance the requirements of HIPAA with the benefits of Health IT? What conflicts or barriers exist? In particular, are there any specific barriers or problems related to mental health records that ONC has encountered? Has ONC done any analysis or identified any problems related to HIPAA and the coming health insurance exchanges established by the Patient Protection and Affordable Care Act?

ONC recognizes the importance of protecting the privacy of patient health information while at the same time encouraging greater use of health information technology (Health IT) in order to achieve significant improvements in areas such as health care quality and cost control. ONC works closely with other Health IT stakeholders to create a culture where ensuring the confidentiality, integrity and availability of electronic health information is seen less as a barrier to health information exchange than as a valued, shared cultural norm.

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[2] http://www.samhsa.gov/about/laws/SAMHSA_42CFRPART2FAQII_Revised.pdf

With respect to HIPAA, ONC is not aware of any specific problems related to mental health records and the use of Health IT. For the most part, the HIPAA Privacy Rule treats mental health records in the same manner as any other protected health information (PHI). Under the Rule, a health care provider generally may use and disclose protected health information, including mental health records, for the key health-care related purposes of treatment, payment, and health care operations without obtaining the patient's express written authorization. While the Rule generally does require patient authorization for a covered health care provider to disclose psychotherapy notes (i.e., notes recorded by a mental health professional documenting the contents of a private or group counseling session which are maintained separately from the rest of the medical record), such notes are subjective to and for use by the originating provider and thus, access to the notes is rarely needed by other health care entities for treatment or other purposes.

Finally, with respect to the coming health insurance exchanges, ONC reviewed and contributed to the Patient Protection and Affordable Care Act (ACA) regulations, to help ensure that privacy, security, and data stewardship policies were appropriately incorporated into the final rules governing the new modes for exchanging and analyzing health information under the ACA. This effort addressed regulations governing: 1) accountable care organizations; 2) qualified entities that provide performance measurement services, 3) and the health insurance marketplace.

Representative Johnson

Question 1:

As an IT professional for 30 years, I understand the vital importance of IT architecture and having a roadmap to achieve the end state. As they say, if you don't know where you are going, any road will get you there.

When ONC and CMS together published the original set of rules setting up the Electronic Health Record Incentive Program in 2010, we articulated long-term goals for the program that continue to serve as a useful roadmap as the program evolves over time (see 75 FR 44321). We continue to believe that certified EHR technology used in a meaningful way is one piece of a broader HIT infrastructure that will ultimately help reform the health care system and improve health care quality, efficiency, and patient safety. We look forward to working with you as we continue to pursue this vision.

Question 2:

With regard to the Meaningful Use Program currently in place to guide implementation of electronic health record (EHR) systems, how is HHS ensuring that we aren't just collecting and digitizing data? Were the stages of Meaningful Use crafted with an IT architecture in mind that spans all stages to achieve a specific end? If so, then how?

Starting with the first proposed rule on Meaningful Use Stage 1 issued in January 2010, HHS laid out its vision for what Stages 1, 2, and 3 would look like and focus on. With that vision in mind, we worked backward and charted an ambitious yet incremental course for the industry. We also took care to ensure that each Meaningful Use stage would build on the next. Thus, as an eligible provider progresses from one stage to the next they are asked to use the data in their EHR technology (and the technology itself) in specific ways that will help enhance care delivery and improve patient engagement. As we consider policy for Stage 3, we will continue to work toward the vision we laid out with a careful interest

in making sure that the experience eligible providers' gain through Stages 1 and 2 can be applied in Stage 3.

Question 3:

Information must also be relevant and functional for the end user. How have you involved health care providers in the development of this road map to ensure that the time, money, and effort put into these systems will be worth their while and create an integrated, coordinated care system that streamlines their work? What concerns have these providers had with regards to EHR and Meaningful Use stages and how has HHS worked with these individuals to address them?

Health care providers and other health professionals have been involved at every step of HHS's policy development processes for Meaningful Use. The HIT Policy Committee, which has made policy recommendations regarding Meaningful Use, includes healthcare providers that participate in the EHR Incentive Programs – for instance, the Committee's Meaningful Use Workgroup includes 8 medical doctors (including both co-chairs), 2 registered nurses, and a variety of other stakeholders who represent the health care industry more broadly. ONC and CMS openly solicit feedback from provider organizations during our rulemakings, and HHS employs several staff with significant clinical experience working with electronic health records. In both our Stage 1 and Stage 2 rulemaking processes, we introduced significant new flexibilities for providers into our final rules in response to public comments.

Some provider concerns are unique and specific to their practice/setting while others are more general. To educate providers about program requirements, HHS has produced a significant amount of downloadable education materials, increased the number of webinars and education sessions, and regularly communicated with provider associations to help spread the word. We have also devoted a considerable amount of resources toward the 62 Regional Extension Centers (RECs) that have been established across the country through cooperative agreements funded under the Health Information Technology and Clinical Health (HITECH) Act. The personnel that work in the RECs are local experts and work hand-in-hand with health care providers along every step of the way – from selecting an EHR to getting to meaningful use. We have also established a virtual infrastructure of communities of practice to enable healthcare providers to share best practices with each other and to communicate feedback directly to HHS.

Representative Butterfield

Question 1:

Many rural parts of my congressional district are desolate and where the nearest primary care doctor can be an hour or more drive away. East Carolina University located in my district in Greenville, North Carolina has been operating a telemedicine program since 1992 – making it one of the oldest telemedicine programs in the world. Recognizing that there is a clear link between access to care and improved health, what other resources in addition to telemedicine are available now to link the rural elderly and indigent populations to healthcare providers like primary care doctors and physician's assistants? What is on the horizon?

Medicare pays for certain telehealth services to beneficiaries in rural communities. Medicare pays for these services when they are furnished at specified originating sites that include physicians' offices, critical access hospitals, rural health clinics, and federally qualified health centers, and when those sites

are in either a rural Health Professional Shortage Area (HPSA) or a non-Metropolitan Statistical Area county.

In addition to telehealth, there are a number of programs available to help link the rural elderly and indigent populations to health care providers. HHS administers the Rural Health Outreach program, which provides grants to rural communities to test out new ideas and develop models for improving access to care. This program includes funding for rural health networks that help rural providers work together to build better systems of care.

As authorized under Section 3026 of the Affordable Care Act, HHS is also partnering with community based organizations and acute care hospitals under the Community-Based Care Transitions program to improve transitions of beneficiaries from the inpatient hospital setting to other care settings, to improve quality of care, to reduce readmissions for high risk beneficiaries, and to document measurable savings to the Medicare program. One of these partners, Access East Community-based Transitional Partnership, is located in Greenville, North Carolina.

Question 2:

Recently, Congress passed legislation that requires the Department of Defense to expand telemedicine opportunities to service members regardless of whether they are on a base or in a home, and regardless of where the doctor is licensed. Are there ways we can use this model in other federal programs like Medicare to better expand access to care via telemedicine?

The Center for Medicare and Medicaid Innovation is testing several projects related to increased use of telehealth. A project in Hawaii received a Health Care Innovation Award for telehealth-based home monitoring for very high risk patients with complex health care needs in order to prevent hospitalizations. A project in Wyoming received a Health Care Innovation Award to improve care coordination and communication with practitioners in ten rural Iowa counties using telehealth and web-based personal health records.

In addition, under the Affordable Care Act, accountable care organizations (ACOs) participating in the Medicare Shared Savings Program agree to coordinate care for beneficiaries, such as through the use of telehealth, remote patient monitoring, and other such enabling technologies.

Question 3:

The VA has moved to mostly eliminate cost sharing on telemedicine, recognizing treating veterans at home is less expensive than treating them in a VA facility. For example: The Veterans Administration's home telehealth program has resulted in a 30 percent reduction in hospital administration and a 20 percent decrease in hospital stays. How can Congress build off this model and achieve similar outcomes in other federal healthcare programs?

The Veterans Administration has long been a pioneer in the use of telehealth technology. In addition, the Health Resources and Services Administration has awarded funding for using tele-home care services. The CMS Center for Medicare and Medicaid Innovation (Innovation Center) has also funded a number of new models using telehealth technology. The Innovation Center is testing innovative payment and service delivery models that have the potential to reduce expenditures while preserving or enhancing the quality of care provided to Medicare, Medicaid, and CHIP beneficiaries. Participants in the testing of all of the models are encouraged to use health information technology, and we understand that they are using a variety of different technologies.

Currently, under the fee-for-service Medicare benefit, Medicare has the authority to pay for telemedicine services for beneficiaries in specified rural communities provided by specified providers. Section 1834(m) of the Social Security Act authorizes Medicare payment for telehealth services. The statute requires that the originating site for telehealth services be in an area designated as either a rural health professional shortage area, or a county that is not included in a Metropolitan Statistical Area. The statute lists certain services that are considered telehealth, but also allows for the addition of other telehealth services. CMS annually evaluates whether to add additional services to the telehealth benefit, and last year in the final rule for the CY 2013 Physician Fee Schedule, a variety of new services were added. Some of these new services include: alcohol and substance abuse and intervention services; annual alcohol misuse screening; annual depression screening; intensive behavioral therapy for cardiovascular disease; and intensive behavioral therapy for obesity.