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Mark Masselli: This is Conversations on Health Care. I am Mark Masselli.

Margaret Flinter: And I am Margaret Flinter.

Mark Masselli: Well Margaret, big announcement recently from First Lady Michelle Obama. She unveiled the new food labeling design that will be required on all food items sold in this country.

Margaret Flinter: That's right, Mark. The First Lady unveiled the first revision in FDA food labeling design in 20 years. The new design will show the calorie count in much larger bold block letters, and food manufacturers are going to be required to show just how much sugar they added to the food item as well.

Mark Masselli: You know Margaret, most health experts point to the introduction of high fructose corn syrup into processed foods is one of the driving forces behind the nation's obesity epidemic. A majority of the population simply isn't aware of the sugar they are consuming in most of the foods everyday.

Margaret Flinter: Another aspect of the new labeling design will show a very clear portion size and I might say a realistic portion size associated with the calorie count listed.

Mark Masselli: The First Lady has been a staunch advocate for promoting better health across the country with her Let's Move Campaign and her promotion of home gardens and greater emphasis on fresh produce availability. Apparently, her staff worked diligently with the FDA to get this change approved.

Margaret Flinter: And Mark, another new set of rules was recently approved by the FDA, and that's the rules governing oversight of medical mobile apps for the health care industry. Now that's an area as we have talked about often on this show that's just exploded with growth in recent years.

Mark Masselli: Some 100,000 medical and fitness apps now in the marketplace, the FDA has issued new guidelines for the growth industry of medical software and mobile apps to make sure they adhere to safety requirements, something our guest today is quite an expert in.

Margaret Flinter: Bradley Merrill Thompson is a health law expert with a special emphasis on the FDA, and he will break down these new regulations regarding mobile medical apps and take a look at some other policies coming out of Washington that are seeking to regulate this new and perhaps disruptive discipline in the health care arena.

Mark Masselli: Factcheck.org's managing editor, Lori Robertson, looks at false claims that the Affordable Care Act is going to extract hundreds of millions of dollars of new taxes on small businesses.

Margaret Flinter: And no matter what the topic, you can hear all of our shows by going to CHC Radio.

Mark Masselli: And as always, if you have comments, please email us at www.chcradio.com or find us on Facebook or Twitter because we love hearing from you.

Margaret Flinter: We will get to our interview with Bradley Merrill Thompson in just a moment.

Mark Masselli: But first, here is our producer, Marianne O'Hare with this week's Headline News.

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Marianne O'Hare: I am Marianne O'Hare with these Health Care Headlines. The clock is winding down towards the end of open enrolment for folks to sign up for insurance under the Affordable Care Act. Most states wind up open enrollment by the end of March, and while numbers of those signing up are over 4 million, still a long way to go before they reach the target 7 million figure. The President held a town hall meeting to court one group that should qualify for subsidies in big numbers, Latinos, many of whom have stayed away from the insurance exchanges due to lack of access to good information.

Meanwhile, another campaign out of the White House is the First Lady's Just Move Campaign, aimed at getting Americans and especially kids to get more exercise to tackle the growing obesity problem. The First Lady announcing last week that those food labels on the sides of food packages are about to get a whole new look with calorie counts now bolder, the first meaningful change in the food label design in 20 years. The new labels will also make more clear what an actual portion size is.

A disturbing report out of the Department of Heath and Human Services shows one in three nursing home or critical care patients, about a million patients across the country are harmed by the health care workers treating them, either through incorrect doses of medication, the wrong meditation altogether or other accidents in care delivery. The study by the Inspector General of the US Department of Health and Human Services focused on skilled nursing care, treatment in nursing homes for up to 35 days after a patient was discharged from an acute care hospital. The doctors found that 22% of patients suffered events that caused lasting harm, another 11% were temporarily harmed and in 1.5% of the cases the patient died.

I am Marianne O'Hare with these Health Care Headlines.

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Mark Masselli: We are speaking today with Bradley Merrill Thompson, FDA law expert and general counsel for the mHealth Regulatory Coalition, the voice for mHealth technology stakeholders in Washington. Mr. Thompson is an attorney with the firm Epstein Becker & Green, where he leads the Connected Health Initiative. He serves as a member of the work group created by the Department of Health and Human Services and the Federal Communications Commission to identify key considerations in improving patient safety with health information technology and mobile medical apps. Mr. Thompson was elected as a Fellow of the American Bar Association and was included in the 100 Most Notable People in the Medical Device Industry. Mr. Thompson, welcome to Conversations on Health Care.

Bradley Merrill Thompson: Thank you so much for having me.

Mark Masselli: Brad, as an attorney specializing in health laws with a focus on the FDA, you have been a driving force in seeking to create some meaningful guidelines for developers and stakeholders in this rapidly expanding mobile medical app world. And you helped launch the mHealth Regulatory Council to shape policies that will help the health care industry and embrace the benefits of mobile cellular communication products and services. Can you give our listeners sort of the broad overview of the marketplace and talk a little bit about its stakeholders and the impact mobile medical apps are likely having on health care industry and on consumers?

Bradley Merrill Thompson: Well you are exactly right. There are so many different types of apps. But broadly speaking, you can put at least a few of these apps into some buckets that show kind of the trend for where the industry is going. One of them is certainly the wellness and fitness category, and within that, there is just a whole slew of apps that revolve around tracking key aspects of body function or exercise or caloric intake for purposes really of helping you to change your behavior and to become healthier. There is this philosophy that if we do a better job of tracking health information, we can do a better job of managing it. In addition to that, there is a whole slew of apps that really are designed to try and get typically consumers, sometimes doctors, the best available information on a given subject. So whether it’s maybe a rare disease, there are apps that simply help you organize all of the educational materials related to that disease. Then there is a variety used in remote monitoring and so it’s a way to collect information often from a medical device and kind of tether you to your doctor. So if you are a person with diabetes and you need to manage your blood glucose, then it becomes a way to transmit that data back to your doctor.

One of the really exciting areas that's really growing significantly is what's called clinical decision support software, and that's a big name for simply the analytics that are used on data now to help with the diagnosis of disease, help with identifying the most likely or effective treatment. So that's an exciting area. You have a variety of products that are really just physician tools. We really want to figure out a way to make physicians more efficient. There is a physician shortage but there is also frankly just ever-growing need to bring cost out of the health care system. So if we can arm a doctor with a tablet and that tablet can be used to pull up lab values, it simply makes the doctor more efficient as he encounters patients. Even the pharmaceutical industry is getting into the game. I have been reading about apps lately that are used for a variety of things from a SmartPill which simply tells you -- it actually tracks when you take your medication down to the minute in order to help particularly the elderly or anyone who just loses track of whether they have taken their medications. But even more cutting edge, there are apps that help you decide whether a given drug is appropriate for you because the use of the drug can be guided in effect by a mobile app. Clinical trials, mobile health is completely revolutionizing the way they organize clinical trials and medical device manufacturers are all of a sudden realizing that their devices are going to be electronically tethered to every other part of the health ecosystem and that raises a host of issues around interoperability. So it's really affecting everyone.

Margaret Flinter: Well Brad, I want to talk about regulation for just a minute. Your work with the mHealth Regulatory Coalition has come in two phases since forming in 2010, the first one helped facilitate the development of basic guidelines that were passed by the FDA at the end of last year that gave some regulatory framework in the medical app marketplace. So maybe tell us what kind of apps will be governed by this first round of FDA guidelines and what essentially do the guidelines serve to achieve?

Bradley Merrill Thompson: To be honest, one of the big challenges that we have in this space is the investors needing to know is a particular app that is being developed going to be regulated by FDA or not. And the reason they want to know that is quite simple; it dramatically impacts the cost of the development of the product but also the timeline for the development because you have to factor in compliance with FDA before going to market. So knowing what FDA is going to regulate was just pivotal really to a lot of startups getting the funding that they needed. And it addressed typical fashion 80% of the open questions, the basic questions anyway and left about 20% that were still kind of fuzzy. But that 80% was a big win for the industry because it meant that if you were developing an app in that space, you could relatively clearly is FDA going to regulate it or not.

So what do those guidelines say? Well basically it identifies two different apps or two different categories of apps that might be regulated. The first one is where an app is functioning as an accessory to a medical device. So let's say you

make a blood glucose meter and you want to produce an app that will be used maybe to control a blood glucose meter, maybe it will take the readings out of the meter and it will graft them on your cell phone. FDA said if you are making an app to be an accessory to a medical device, the app will be regulated. Well you know, truth be told, that's pretty commonsense. I think we expected that because if the accessory doesn't work, it can mean the whole medical device doesn't work.

The second category is equally intuitive but it was nice that FDA kind of laid it out there and then gave a whole bunch of examples and that is whenever you have an app that does the same thing that historically a medical device has done, you can expect the app to be regulated. There are lot of examples, a simple one being an electronic stethoscope. Stethoscopes have always been regulated so if you take an iPhone and you use the microphone on the phone as a way to listen to the heartbeat and the app basically translates it into a meaningful sound, that's basically an electronic stethoscope and it would be regulated. A little bit more sophisticated would be an example of an app that came out last spring to do laboratory testing on urine. What you actually do is you test urine in a cup. You put a test strip in the cup of urine, you take it out and you use the camera on the phone to basically read and measure blood glucose levels and a variety of other substances that you test urine for. And FDA basically said, "Look, in the past, a cash register size machine used to do that; now it's on a cell phone. That's terrific. But it's doing the same thing as a medical device, therefore it's regulated." So really those are the two buckets. Once they laid that out, folks were able to decide whether or not it was regulated and investors were able to understand what the cost was.

Mark Masselli: I want you to talk to our listeners about this larger role that you all are playing with various regulatory bodies. The Federal Communications Commission is involved; the FDA is involved. And how are you helping shape their thinking about the mobile medical app world and what are some of the concerns that consumers might have, safeguards in terms of security or how are you trying to help shape the regulatory thinking about this new arena?

Bradley Merrill Thompson: Well that's a key question is making sure that we have clarity not just on what the rules are but frankly which agency has the responsibility to make those rules. So FDA's role with all technology is to make sure that the technology does what it says it will do and does it in a manner that is safe and effective. But when you are talking about technology that sits on a cell phone and a key aspect of the functionality then is transmitting those results or information or whatever it might be, you necessarily involve the FCC because they control the airwaves and they control by and large the devices that transmit over those airwaves. So you have simultaneously a cell phone that may be functioning as a medical device and at the same time is functioning as a cell phone, piece of a communication equipment. So it's really important to parse out which agency has responsibility for a given question and to get those agencies

talking with one another, and fortunately they have been. As I understand it, I think they have a standing meeting on Thursday afternoons where they talk about what each of them is doing and making sure that they are coordinating, not frustrating, the industry.

You layer on to that the overall federal policy of trying to encourage the adoption of electronic health records. Mr. Obama committed $20 billion basically to encouraging the "meaningful use" of electronic health records. And a lot of this stuff dovetails with electronic health records because it is data that might get deposited into an electronic health record. So the connectivity to that is very substantial. So you get ONC, Office of the National Coordinator involved as well. The key is that they talk to each other because the worst thing that could happen in my opinion would be agencies working against one another, working in opposite directions, giving conflicting signals. So I do think there is a strong effort within the administration to make sure that they are coordinated.

Margaret Flinter: I also understand it's not just the federal agencies but Congress itself in the House and Senate that is looking to change the oversight of medical mobile apps and I found that somewhat surprising. What are these pieces of legislation and is there a role for Congress in this? Do you think that this will also help or hinder the growth of the use of medical mobile apps?

Bradley Merrill Thompson: So there are two pieces of legislation that have been introduced, one in the House and one in the Senate. The House bill is called the SOFTWARE Act and the one in the Senate is called the PROTECT Act. Overall, the thrust of both pieces of legislation is removing from FDA regulation a whole variety of health information technology, including a variety of mobile apps. I think basically they want to avoid FDA regulation. That's what the legislation does. So it seems that must be their intent. I have publicly honestly come out against both of those bills because I think they would be bad for the industry, and I have a few reasons for that. The first is they take some very important and frankly, risky software and remove it from FDA regulation. I will give you an example.

Let's say you wanted to develop an app for detecting melanoma, and there is this technology being developed. You basically would take picture of a mole on your skin and then maybe six months or a year later you take another picture and the software compares the two pictures and then offers a view on whether there are any changes to the mole such that it might indicate melanoma and you ought to go see a doctor. The legislation would deregulate that and I can't for the life of me understand that. And it's not just that. That's not good for patients. I think patients need to have greater confidence that an app that they rely on not to seek medical care actually works. But it's also bad for industry because the worst thing that could happen to industry is patients getting hurt. It is terribly important that both patients and doctors believe that the apps that are out there will do what they say they will do. I saw just last week a study results that were

released. I think 250 physicians were surveyed and 42% of them say that they don't prescribe mobile apps because they aren't regulated and they therefore have concerns about whether they work or not. Well that's a big limitation. If you are trying to convince users that an app has value and they are concluding that because it's not regulated it may have dubious value, that will hold back the development of the more important side of the app spectrum. You will still be able to develop games no problem but if you really want to move the needle on public health, you need that pubic confidence.

Mark Masselli: We are speaking today with Bradley Merrill Thompson, FDA law expert and general counsel for the mHealth Regulatory Coalition, the voice for mHealth technology stakeholders in Washington. Mr. Thompson is an attorney with the firm Epstein Becker & Green where he leads the Connected Health Initiative. Brad, I want to sort of pull the thread on that thought that you had there about the need for having regulatory engagement and you have decided to take it down the road, you have got a road show coming up, the mHealth Educational Outreach Tour to various institutions to better educate clinicians and developers at some of the top research and teaching hospitals around the country. So tell us a little bit about when you will be going out and where you will be headed.

Bradley Merrill Thompson: We have already been several places. We have been to Stanford and the University of Illinois and we are going to be at MIT and we are also going to be at a place called The Innovation Center in Cleveland, Ohio and we are also going to Berlin. There is a big program over there, mHealth Summit in Europe. And basically the objective is to create a community around people in the mHealth space who are basically dealing with FDA regulation. And at this point, there are well over a hundred companies that have navigated the FDA process for a mobile app. And so we are drawing on those people who have the expertise of having been there, done that and we are organizing panel discussions where they can basically share their experiences good, bad or indifferent, the lessons that they learned frankly in order to keep from making mistakes in their future, really in the hope number one, of developing best practices, how exactly do you get through the FDA process most efficiently but also to learn frankly some of the benefits of having done so.

Some of the companies talk about what it cost, what the investment was and what they perceive the benefit to have been. And ultimately the goal is to sort of foster mentorship, to get some of these experienced entrepreneurs connected with those who don't have the experience so that they can form kind of informal support networks and help one another as they try and navigate this. So it's been exciting to watch, to see these folks come together and help each other. The universities have been great. There are about a dozen national and international organizations that are sponsoring it, professional societies. And the discussions that we have had with these entrepreneurs have just been fascinating to find out what they are working on and what their challenges are.

Margaret Flinter: We have been speaking today with Bradley Merrill Thompson, FDA law expert and general counsel for the mHealth Regulatory Coalition. You can learn more about Mobile Medical Apps Roadshow and his work by going to www.mhealthregulatorycoalition.org. Brad, thank you so much for joining us on Conversations on Health Care today.

Bradley Merrill Thompson: Well thanks very much for having me.

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Mark Masselli: At Conversations on Health Care, we want our audience to be truly in the know when it comes to the facts about health care reform and policy. Lori Robertson is an award-winning journalist and managing editor of FactCheck.org, a nonpartisan, nonprofit consumer advocate for voters that aim to reduce the level of deception in US politics. Lori, what have you got for us this week?

Lori Robertson: Well Republicans have claimed for years that the Affordable Care Act taxes small businesses and families. Most recently, Senator Tim Scott of South Carolina made the claim that the ACA's taxes of $800 billion hit those two groups, small businesses and families. But that's misleading for several reasons. First, the claim overlooks the tax credits available to those groups. Second, there are few taxes directly affecting small businesses. And third, the 10 year figure Scott gave mainly affects individuals earning more than $200,000 a year. The $800 billion number is an estimate from the Congressional Budget Office and Joint Committee on Taxation on how much government revenue would be lost over a decade if the ACA were repealed. So keeping the law in place would increase government revenue by the same amount. But the law also includes about $600 billion in net government spending over the same time period, and included in that, is $519 billion in premiums and cost sharing subsidies that would go to families. Hundreds of millions of dollars more paid for Medicaid expansion also benefiting families and even small businesses whose employees may gain insurance coverage that way.

Now the families getting subsidies aren't the same ones getting hit by the ACA taxes. A family of four earning up to $95,400 qualifies for subsidies or Medicaid for lower income earners. About 40% of those $800 billion in taxes however affects families earning more than $250,000 a year or $200,000 for individuals. That's subject to higher Medicaid payroll taxes and a new 3.8% tax on investment income. Those folks are certainly families but they represent less than 2% of taxpayers. And that's my fact check for this week. I am Lori Robertson, Managing Editor of FactCheck.org.

Margaret Flinter: FactCheck.org is committed to factual accuracy from the country's major political players and is a project of the Annenberg Public Policy Center at the University of Pennsylvania. If you have a fact that you would like

checked, email us at www.chcradio.com. We will have FactCheck.org's Lori Robertson check it out for you here on Conversations on Health Care.

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Margaret Flinter: Each week, Conversations highlights a bright idea about how to make wellness a part of our communities and everyday lives. During the school year, some 21 million American children receive free or reduced price lunches through their schools, often the healthiest meal these children eat during the school day. Yet, when school is out, only 10% of these children participate in the free meal programs during the summertime, and studies have shown that many of these kids tend to gain a significant amount of weight over the summer as a result. A group of researchers at the University of South Carolina sought to tackle that issue with a program they developed called the Healthy Lunchbox Challenge. They deployed the program at a number of large community-based summer day camps, and lead researcher Dr. Michael Beets says they relied on a simple known fact about kids, they love competition.

Dr. Michael Beets: Staffers during the first snack period would ask kids to hold up the fruits or vegetables or water that they brought and then at the end of the week they announced the winner of the Healthy Lunchbox Challenge for that week.

Margaret Flinter: Dr. Beets says the simple competition and group rewards system created a dramatic shift in the average camper's lunch box from chips, cookies and sugary drinks to more fruits, vegetables and bottled waters.

Dr. Michael Beets: So kids are not just bringing additional fruits, vegetables and water, they are substituting these healthier items for the less helpful items.

Margaret Flinter: The study published in the Journal of Nutrition Education and Behavior showed a dramatic shift in the kids' homemade lunches with this really simple and inexpensive incentive program. They see this as a model for summer day camps across the country, which serve some 14 million children per year often in underserved areas. The next phase of their study will look at the actual weight and body mass index of kids in the next round of campers to calculate the impact on lowered weight gain. The Healthy Lunchbox Challenge, a simple competitive challenge and rewards system designed to get kids to switch out high fat, high sugar, high calorie foods from their diets in favor of healthier snacks and beverages, now that's a bright idea.

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Margaret Flinter: This is Conversations on Health Care. I am Margaret Flinter.

Mark Masselli: And I am Mark Masselli, peace and health.

Conversations on Health Care, broadcast from the campus of WESU at Wesleyan University, streaming live at www.wesufm.org and brought to you by the Community Health Center.