NWX-HHS FDA

Moderator: Irene Aihie
February 24, 2015
1:00 pm CT

Operator: Welcome and thank you for standing by. At this time, all lines are in a listen only mode until the question and answer session of today's call. At that time, please press Star 1 to ask a question. Today's call is being recorded. If you have any objections, please disconnect at this time.

Now I'll turn the call over to your host, Irene Aihie. Ma'am, you may begin.

Irene Aihie: Hello. And welcome to today's FDA Webinar. I am Irene Aihie of CDRH's Office of Communication and Education.

Today's Webinar will provide CDRH's perspective on digital health and will discuss the agency's proposed approach to regulating products that fall under the digital health umbrella.

Our discussion will include clarification of two final guidance documents as well as two draft guidance documents related to this topic.

Today, Bakul Patel, Associate Director for Digital Health in CDRH and Sugato De, Senior Policy Advisor in the Office of the Center Director, will

provide a brief presentation. Following the presentation, we will open the line for your questions.

Other Center subject matter experts are also available to assist with the Q&A portion of our Webinar. Now I give you Bakul.

Bakul Patel: Thank you Irene. With that, let me just extend one other thanks from the team here at FDA, CDRH and to all attendees on the Webinar. Before we start, let me talk about the objective that Irene just highlighted.

We also want to point out to folks that we will not be able to take product specific questions but mostly this Webinar is geared towards, you know, providing or understanding or thinking on the guidance that we published.

And also, give a perspective on our approach to - to digital health and the guidance that we have that were published both final, as well as draft. With that, let me start with the presentation and give you a little bit of background on digital health.

As you can imagine, digital health technologies are continuously leveraging the ubiquity of connectivity, computing power and is setting up a path towards better healthcare paradigm, as well as - and ultimately - as well as public health. With that, today I'm going - I'm going to cover four areas.

First, we'll start off with our - CDRH's vision and approach. And we'll go into the mobile medical app guidance on how FDA has taken an approach towards mobile apps and their growing area and excitement that's happening in this field.

As a result of that, we will also use the approach that I will highlight into how we took into account reevaluating our existing regulations. And lastly, I will end with clarification and overview of our draft guidance as well, on general wellness and medical device accessories.

We will take questions at the end so please hold that, as highlighted by Irene before. Let me share with you, and as you can see, this is our vision for - which stems from our mission to promote and protect public health. And I will not read all of the words on the slide.

But if you were to see -- patient is at the center our thinking. Patient is at the center of our approach. We like to keep patients in the center and have technologies that enable us to advance healthcare, advance public health.

So that led us to - in the area of digital health, where using risk based approach which is not only tailored and functionality focused, that gives us independence from the advances that platforms can take on.

And at the same token, we want technologies to sort of innovate, that will take platforms in a different - to a different level, while promoting patient engagement which - which gets us to a narrowly tailored approach or narrowly tailored functionality focused approach, which leads to protecting patient safety.

So that's in a very - a very high level perspective and thinking of how we have approached digital health technologies. And we want to promote patient engagement, at the same time protect patient safety. We are very cognizant of the fact that technologies will evolve, will become smaller, better, cheaper.

And platforms will also evolve. But focusing on technologies will allow us to promote that innovation, at the same time balance - balance - take a risk based approach. With that, you'll see we had embarked on this - on this - on this thinking in as early as 2011-12.

And we started looking at mobile medical apps. And we proposed our guidance on mobile medical apps. We said we will focus on the traditionally regular functionality that's either cleared, approved or otherwise regulated. We want to provide.

Our goal is to provide users with the same level of assurance of patient safety. While we are thinking about mobile apps as a whole, we also wanted to provide people with - with the clarity that we have been asked for. It's what's considered a medical device or not?

What's considered lower risk when we continue to start focusing on the - this narrow area of our oversight or narrow focus of our oversight? So in the mobile medical apps guidance that was finalized in September 2013, we said - we provided three large areas.

One area which we identified by example, which - which mobile apps are not considered a medical device. And the next layer up is the lower…

((Crosstalk))

Bakul Patel…that meets the device definition but may not be considered as mobile medical apps and not be a focus of our - of our oversight.

That leaves us with a very small area of mobile medical apps that we termed, to represent the areas that we were focused on or areas of apps that we're

focused on. And let me walk through that for a second. So here's our approach.

The role that mobile apps was exploring as we were working through the guidance and preparing our approach, and articulating that in the document, in the guidance we talk about types of mobile apps that are not considered medical devices and have - have no regulatory requirements or no FDA regulatory requirements, let me be clear on that.

Followed with a lower risk types of mobile apps that may meet the definition of a medical device but not considered for our - for oversight. We use the term enforcement discretion. And there are a lot of discussions about what that meant so I'll go over that in a second.

It fundamentally means the FDA has - has laid out a compliance policy which articulates that we would not focus our compliance efforts on those - on those products.

That leaves us with our focus of oversight where that is that if a mobile app that meets the two part definition that we defined in the guidance, would be the focus of oversight.

Very simplistically, let me just share with you that things that were in a different shape, size or form and when I say things, functionalities that were a different shape, size or form that existed before and now happens to be in a mobile - a mobile platform or a mobile way in terms of software or other ways, we would consider them to be mobile medical apps.

So the definitions are - the definition sort of brings that point into play. That's the part about when mobile apps transform a mobile platform into regular and medical device.

The second part of the definition was if a mobile app is now used as an accessory to regulated medical device, we would consider that as a mobile medical app as well. Now we define our world - the world of oversight into this very small area of what we termed as mobile medical apps.

The event in the guidance had highlighted three large principles of what we would consider to be covered in the definition of mobile medical apps. And I've highlighted portions of the first prong or first definition or first principle, with talks about displaying, storing, transmitting specific medical device data.

And I'll share with you the reason why - why I've highlighted that, because later on I see - I talk to the MDDS guidance. I will show that - those factors all come into play.

Having said that, the guidance actually goes into depth of types of mobile apps that are not medical devices like medical flash cards, finding the nearest medical facility or scheduling hospital room or bed space, are not medical devices or does not belong into FDA jurisdiction.

Things that may be considered medical devices but not the focus of oversight, are allowing people to track their own - own health, track their information, help patients document so they are - communicate that with the provider that condition, are the types of things.

We have - the document is about 40 pages long with - mostly filled with examples for people to sort of take away our thinking behind and our approach behind mobile apps.

We are hoping to accomplish this by when people come up with new technologies or platforms and innovators come up with new technologies. We want people to glean from this guidance, how we would apply and what - what we would regulate versus what we would not regulate.

So as a result of all of this discussion, our work in this area, through FDASIA section 618, we held a (tri-agency) work effort that led to the FDASIA Health IT report which proposes strategies and recommendations for health IT as a - as a whole.

During that process, through extensive public and workgroup feedback, we heard agencies - we heard from the stakeholders that we should, we as agencies, should address ambiguities that exist in our regulations and - and that have cross cutting between other agencies.

We also heard that we should be evaluating current - reevaluating current regulations, specifically in the health IT report.

We responded by saying that we would be providing further clarity on general wellness and disease related claims to health IT and provide more clarity on our approach towards medical device accessories, are the two specific areas.

But before we get into those two specific areas, let me - let me share with you what led us to the reevaluation of the MDDS or medical device data systems rule. So here's what we proposed and we finalized in 2011, February 15.

It's what we call, certain types of technologies that we call the medical device data systems. They're intended by a manufacturer to transfer a storage convert or display medical device data.

And excluding those technologies that were controlling other medical devices, are to be used in active patient monitoring. There is a long process that we went through that sort of - that took public comments on what was activation monitoring, what should be covered under MDDS.

But at the end of that discussion which started in 2008 and - and finalized in 2011, we highlighted what should be the narrow focus of - of the medical device data system rule.

When you look at the approach that we have highlighted in the health IT report, the approach that we have taken in the mobile medical apps guidance, and our philosophy of how to promote patient engagement and protect patients, at the same time promote the functionality dependence and not platform dependent. And take a risk based approach.

We took a harder look at the medical device data systems rule. And here's what we come -and in addition to that, we looked at medical image storage and communication device rules as well.

And we concluded that these types of products or these types of products identified in the regulation were generally considered lower risk and were already classified as class one.

Systems that records share and use medical device data have become very - have become a significant portion of the connected healthcare system.

It also drives toward intercommunication of functionality which is foundational for interoperability of the medical device data and its digital health ecosystem.

Into June 2014, we provided - we proposed a guidance which basically said we will take a hands off approach toward these types of devices that were identified in medical device data systems, medical image storage and communication regulations.

Our intent was to continue to provide the clarity in digital health, narrow our focus on higher risk product. And also more importantly, create an impetus for devices to share data and ultimately become interoperability in this larger health IT/digital health ecosystem.

So fast forward after public comment, here's what we heard back from the - from the stakeholders. Most common - we received about 500 plus comments to the medical device data system draft guidance. Most supported the regulatory policy for MDDS.

So just a specific - and this added to clarify the language. And also asks us to be clear on what we meant by activation monitoring. And some actually did ask us to finalize and make - make a permanent regulation and not just the guidance.

We thought that going down - going further and finalizing the guidance would provide the next level of certainty for folks. And the response of the feedback in the final guidance, we maintain the proposed policy without any changes.

We added additional language in the background section, addressing the comments that we received to explaining to folks what we meant by medical

device data systems. As we said in the final rule. Also, clarified what we - with examples, clarified what we meant by activation monitoring.

So you should find that helpful. We did also propose, in the draft, medical device data system guidance that we would make conforming edits to the mobile medical apps guidance as well so they're consistent with the policy outlined in MDDS guidance. So we made those changes as well.

So here's what the final guidance looks like and then the - the final guidance published on February 9, 2015 clarifies our intent or confirms our intent that we would not enforce compliance with the regulatory controls that apply to the MDDS, to medical image storage devices and medical image communication devices.

We did also say that in the guidance MDDS, as we said in our final rule, MDDS rule, that these products are not intended for our - for activation monitoring or modified - modified medical device data or controlled medical devices. That is - again, consistent with the rule that we have.

The MDDS guidance conforms are the scope of products that MDDS has defined in the rules. The guidance just extends and enforces our compliance policy for that - for these products identified in those rules. So I wanted to make sure that you folks understood that.

So let me share what we did in the mobile medical app guidance as well. As you noticed, I've highlighted a few words in the first principle in the mobile medical apps guidance that we would consider mobile medical apps.

And this is how we edited that language, which is what we had proposed in the draft as well. And we also moved the types of MDDS type functionalities

into the category of - of enforcement discretion or things that we would not enforce compliance towards.

While this was happening, FDA had - CDRH had maintained a Web site and an email address that folks could ask questions on - on specific products. We updated the guidance with those additional examples that we had added to the - to the Web site as well.

And when I mentioned the email address it was the MobileMedicalApps@FDA.HHS.gov, this email address was intended to provide quick triage and sort of clarification on our approach.

And as product specific answers to whether a product would fit into one of this - one of the three categories highlighted in the guidance or not.

As a result of the process that we went through and the extensive public input, we - we have the Web site that we promised to keep it - keep it live, keep it current with the examples and the questions that we get.

But also internally we have - we have set up a committee that would - that would provide coordination to maintain consistent policy decisions related to mobile medical apps.

And that's the email address that we - we used for folks to ask questions to us that - that gets looked over by dedicated team and dedicated staff that - who maintain policy decisions consistent. With that, let me turn over to the two draft guidances that I had mentioned earlier.

Continuing our clarity in the world of digital health and continuing our - our thinking and the approach that we have - that I highlighted in the beginning of

being a risk based functionality focused and narrowly tailored, general wellness guidance was something that - that was requested.

And we had committed to providing clarity on how FDA/CDRH specifically for devices and technologies, would consider general wellness products and what claims we would - we will be allowed. So let me just walk through some of - some of the highlights of the guidance.

The policy does not intend to examine - we said in the guidance, we don't intend to examine whether products that are either considered lower risk are medical devices and (non-risk).

We are fundamentally saying if there are devices we don't intend to - if general wellness products are devices or meet the definition of the device in Section 201(h) of the FD&C Act, we don't, as FDA, intend to enforce compliance and regulatory requirements.

So what are the products covered? Products intended only for general wellness use are covered in this guidance. Products inherently present are very low risk to user safety. If you look at the guidance it will probably highlight - you understand what we meant by very low risk.

And what we meant by that was not - not have invasive or have an irreversible effect on the human body. So that's one of the - one of the principles in the guidance as well. Products intended for general wellness use, can be marketed.

In other words, can claim without - obviously, without any reference to these conditions, we would consider them general wellness products. But when

such products with a general disease related general wellness (gains) contains references that are well understood.

That a healthy lifestyle may reduce their risk of impact would become - would also be considered as a low risk. So I wanted to highlight that very specific point for people to sort of understand what the policy sort of articulates.

I'm going to pause it right here and I'm going to turn it over to Sugato De which Irene - who Irene introduced earlier. And he's going to talk a little bit about an overview on the accessories guidance. Sugato?

Sugato De: Thank you, Bakul. The draft guidance on medical device accessories was issued on January 20th of this year. This document is intended to clarify the definition of the term "accessory" and to propose a risk-based framework to classify these devices. More specifically, the guidance proposes utilization of the *de novo* classification process to allow manufacturers or other parties to seek risk-based classification of accessories of a new type.

As you can see on the slide, CDRH defines accessories as devices intended to support, supplement, or augment the performance of one or more parent devices. In brief, a device supports performance of a parent device by enabling or facilitating that device to perform according to its intended use. A device supplements the performance of the parent device if it adds a new function or new way of using the parent device without changing its intended use. Lastly, a device augments performance of a parent device by enabling it to perform its intended use more safely and effectively.

Once an article has been determined to be an accessory, the FDA plans to proceed to consider the risk of the accessory when used as intended and what level of regulatory controls are necessary to provide a reasonable assurance of

safety and effectiveness. This risk-based analysis is the same that is used in the classification of any medical device. In practice, an accessory is either classified in the same class as the parent device or is classified in a different classification, either lower or higher. In some situations, an accessory may have a lower risk profile than that of their parent device and, therefore, may warrant being regulated in a lower class.

The last section of the guidance outlines how the *de novo* classification process can be used to request risk-based classification of new types of accessories. This process provides a pathway to Class I or Class II classifications for which general controls, or general and specific controls, provide a reasonable assurance of safety and effectiveness, but for which there are no legally marketed parent devices. The guidance lays out the recommended content of such a *de novo* submission.

I'll now hand it back over to Bakul.

Bakul Patel: Thanks Sugato. I do want to remind folks that the draft of general wellness guidance and the draft accessory guidance are a proposal. And the intent of this Webinar and the discussion that we want to have today is to solicit comments towards those guidances.

And - and suggest if people have ideas on suggesting better - either better clarifying the guidance or make it clear for folks who are implementing or using the guidance, it would be very helpful as we - as you submit comments to the docket.

I do want to remind folks both the general wellness as well as the draft accessory guidance comments, are due by April 20, 2015. So we would - we'd hope folks would actually provide us input so we can turn around and finalize our guidance based on that input.

I want to take this presentation and now summarize where the center is heading for digital health. We believe digital health will be beneficial and drive better health - health outcomes at the end of the day.

We also believe that it will enable patients - patient empowerment and help everybody in the healthcare ecosystem to drive efficient healthcare product decisions.

Our policies, I'll reiterate again, are towards promoting patient engagement technologies, continuing to provide regulatory clarity by using a focused regulatory approach and really working with stakeholders to understanding their needs and expectations so we can better articulate how we as CDRH, can play a role in - in promoting and perfecting public health.

With that let - let me pause right here. This is where we can start the question and answer session. Again, I would like to remind folks that we will be taking questions on clarification on the guidances. We have specific product related questions. We can also connect later on.

We can connect - talk to (DICE) at FDA dot HHS dot gov. Or contact - contact (DICE) through their phone line. So with that, I'll turn it back over to Irene.

Irene Aihie: We'll now take questions.

Operator: Thank you. At this time, if you would like to ask a question, please press Star 1, unmute your phone and record your name when prompted. Your name is required to introduce your question. To withdraw your question, you may press Star 2.

Once again, if you would like to ask a question please press Star 1 and record your name when prompted. One moment for the first question, please. We do have our first question. (Greg Flabakken), your line is open.

(Greg Flabakken): Thank you. Bakul, if you could - if you could just sort of walk everybody through how you see the dividing line between FDA and FTC when it comes to regulating mobile apps.

I ask that question because as you're well aware, FTC seems to be taking a very active role lately, in cracking down on unsubstantiated claims that are made by marketer then manufacturers of mobile health apps.

And it seems almost as if that the FDA is sort of deferring to FTC when it comes to these kinds of actions. So what's your perspective?

Bakul Patel: Yeah. So (Greg), thanks for the question. I - I can definitely talk about FDA but I'm - I won't be able to talk about FTC's role and perspective and their - as you mentioned, they're taking an active role or not. That's definitely not an FDA - on FDA purview.

But the way I can - I can just share with you, we - FDA and FTC have traditionally worked together on - on many, many other products. So FTC has a very defined focus on - on promoting - promotion and advertising.

And we have a very specific role in - in where the lines are for promoting and - promotion and advertising from a public health perspective. So those - that's where the roles are.

I'm - I'm not sure there is - there's a large (oral) lab in terms of the scientific evidence that we requiring for clearing and approving products. That's a different - a different discussion. But that's where we generally focus from a public health perspective.

And as we may - you may recall, this is not the first time FDA - FTC has - has taken interest in mobile apps specifically. But in other case - previously, in 2011 and - and they have also had taken some actions.

But that has nothing to do with where FDA's jurisdiction stops and where FTC's jurisdiction starts.

Irene Aihie: We'll now take the next question.

Operator: Thank you. And the next question is from Nathaniel Greer. Your line is open.

Nathaniel Greer: Yes, hi. Thank you. So how - can you speak maybe to how this is going to impact such technologies as patient reported outcomes and clinical research?

With the, you know, bringing your own device into deploying apps to - to potential subjects in clinical research and have it - and that - how that interacts with the clinical research space?

Bakul Patel: I - so from my very simplistic perspective, and in the world of digital health, I believe as - as in other - other studies and other research areas, technology has sort of become an enabler towards collecting that information.

From my perspective, I think it's digital health technologies will - will get us to the next level of technology enabling patient reporting outcomes. And that maybe just one part of the research that needs - that will happen.

And sort of bring more information to the table as - as decisions and evidence come together.

Nathaniel Greer: So I guess maybe more specifically then, from a perspective of the - the app itself, obviously we have to look at the perspective of what - the data is being collected and how it's being collected in the mobile app and to what it would fall underneath from a regulatory perspective, from a compliance perspective, from a (main) device perspective?

Bakul Patel: Yeah. So if you're talking specifically about clinical research, when I meant tools there are just different tools that you use in clinical research.

And you may have to look at what those - those requirements are for clinical research, using mobile tools or - or other - other techniques that may end up in the patient reported outcome.

Nathaniel Greer: Okay. Thank you.

Bakul Patel: Thanks.

Operator: Thank you. Your next question is from Bernie Bosley. Your line is open.

Bernie Bosley: I was wondering if FDA is looking to define consensus standards around MMAs like they do for other products and therapies.

The reason I ask is I assume there are - there are still some standards that apply to MMAs, you know, like the HIPAA or - and NAST cybersecurity, the (ISO) risk standards and things along those lines.

Bakul Patel: Yeah. So in general, I would say yeah, this is the (four). And that - so we do work on standards on - on various platforms and various technologies. And when I - when I use the description of functionality focus we - we really want to be ubiquitous on types of platforms and technologies that exist.

And if - if standards exist for what techniques should be using for protecting certain types of platforms and technologies, we would probably rely on those. But, so I guess the answer is, we don't have - I don't have a specific standard there that I can point to or that we are working towards.

But yes, if cybersecurity is valuable and important concentration for a device that's previously existed in other forms, we would expect the same - the same kind of application of that particular consideration in the mobile app as well.

Bernie Bosley: Okay. Thank you.

Operator: And your next question is from (Patricia Bass). Your line is open.

(Patricia Bass): Yes. My question concerns the person who is sitting in the IRV compliance arena. And I'm trying to understand how this will affect our looking at mobile devices or under the - that guidance or under the proposed guidance.

If a device is considered in the enforcement discretion area, does that mean that as an IRV looking at these kinds of devices or not devices that are under development but under clinical investigation, that if a device, all things considered, is going to be under discretion, that an IRV would not have to think about deciding whether something is a non-significant risk device because it's in the enforcement discretion category; is that correct?

Bakul Patel: Let me hand it over to Linda Ricci who is from the Office of Device
                 Evaluation. She can probably also answer this question.

Linda Ricci: Good afternoon. I think your question is getting more at the definition of a
                 non-significant risk study and that's more related to how the technology might
                 be used to help patients. And that's a little different than how we would
                 regulate the device itself.

                 So in terms of from my perspective, about what the IRV would need to do
                 with these devices, we would still need to evaluate the safe use of these
                 devices regardless of the regulatory paradigm that FDA was - would come up
                 with in, you know, those times when we say something's under enforcement
                 discretion.

                 We believe that the use of those devices is low risk. So you can certainly use
                 that as part of your decision making process. But as to whether it's a non-
                 significant risk study, I think that's a different question.

(Patricia Bass): But actually the device itself it says once you make that determination then
                 that's being done in IDE.

                 So I was just trying to think that in terms of making that determination, if it's
                 not going to be considered a device, we would not need to make that
                 determination, apart from its level of risk, as used in the study.

Brendan O'Leary: This is Brendan O'Leary in the Office of In Vitro Diagnostics and
                 Radiological Health. One thing I want to highlight is that none of these
                 guidances redefine what meets the legal definition of a device. They simply
                 discuss our enforcement priorities.

So the determination that a device or that a product is under enforcement discretion does not affect whether not it fits the definition of a device.

(Patricia Bass): Okay. Thank you. That's helpful.

Operator: And the next question is from Robert McCray. Your line is open.

Robert McCray: Yeah. Good afternoon Bakul. I have two questions. I think they're related though - one on MDDS and one on the wellness guidance. And they're related to your - how you can think about risk.

So with MDDS, I'm curious for a little more of your feedback on how you - why you are excluding active monitoring and specifically perhaps, the relevance of the environment where the monitoring takes place, because it's - I think your risk is different in the hospital and at home.

And I'm thinking specifically that, you know, risk of not being monitored for a patient who cannot be in the hospital. It is actually higher than - than - than being monitored by a project or a program that is not perfect. And that we, you know, essentially expect in the hospitals.

Similarly, in wellness, the elimination of any reference to any disease or condition, I'm just wondering how the - the company's promoting these apps and software, can actually gain the attention of customers, you know, without even mentioning, you know, the diseases that the - that the industry believes can be avoided through better lifestyle.

Bakul Patel: Yeah. No, thanks Rob. So let me tackle your first question on medical device data systems. So part one answer to that question is - is fundamentally that we

have - defined MDDS as - in a certain way that excluded activation monitoring as part of the rule making process.

So this guidance fundamentally just says that that particular definition as defined in the medical device data system, which already had excluded activation monitoring, is applicable here for our enforcement priorities as Brendan had highlighted earlier.

And so - to just give you a little bit of color on what's considered activation monitoring, it is not about location or where the actual patient monitoring is happening. But it could be happening at home or in - or somewhere else, or a clinic.

But it's more about - if you look at the definition - not the definition but the background that we have provided in the - in the guidance, it boils down to - in any device that's intended to be relied upon in the - in deciding to take immediate clinical action, the keywords there are immediate clinical action.

And immediate clinical actions can extend many places. And it's not about in a home setting versus not. It's not about monitoring like people use the word monitoring in a very larger sense.

We actually tried to narrow that down to a very specific application area of monitoring as you would imagine a bedside monitor for example. So think - I would encourage you guys to think about that. On the general wellness part I'm not sure whether I understood the question.

In fact we are allowing the proposal on the table is we are allowing when technologies are - are intended to promote a healthy lifestyle. But also show

through well understood literature or well understood science, that those healthy - that healthy lifestyles are linked to managing diseases or conditions.

Where we are saying that would also be included under something that we would consider low risk devices.

Robert McCray: Okay. Well thanks for the clarification on MDDS. On the wellness, and maybe I missed - misinterpreted the draft guidance in your slide deck, which seem to indicate that any reference to a specific disease would change the - your thinking about the - the product.

Bakul Patel: No. So there are two parts. We proposed that- any general wellness products that are meant to promote healthy lifestyle, without any claims of disease would be a allowed and - would be considered low risk. The part 2 of what we consider low risk is a product that promotes healthy lifestyle.

And when it's known - well known that healthy lifestyle has a correlation to, you know, helping certain types of diseases or conditions. We'd also consider low risk. It's the healthy lifestyle correlative to the disease or condition. It's not the product. So, you know, keep that linkage in mind.

Robert McCray: We just need the (evidence). Okay. Thank you.

Operator: And your next question is from Christina Thomas. Your line is open.

Christina Thomas: Hi. I have a question with regards to the MDDS. In the past, part of the FDA MDDS definition was contained in - the part that information could only flow in one direction from a source medical device through the MDDS to the target location.

And if there's bidirectional information flow it would no longer be considered an MDDS. What I want to know is, is this still the case that it's only one way to, you know, one directional, unidirectional? Or - and if that is the case, can you further clarify bidirectional - bidirectional information flow?

So by that, as an example, I mean coming from the source device through the MDDS, to a destination device. And then back from a destination device, through the MDDS back to the source device?

Bakul Patel: Thank you. So let me - I think you may be referring to the proposed rule that we had done in 2008 where we had talked about the unidirectional mode.

When we finalized the rule after public comment, we changed the - we used the word transfer of medical device data, where we intended to indicate transfer can be in either direction of the data flowing. Very simplistically, you can think of MDDS as conduits that take data from point A to point B.

That's how you would think about it as transfer where they're actually modifying that data.

Christina Thomas: Okay. That makes it clear. Thank you.

Operator: Your next question is from AJ Schreck. Your line is open.

AJ Schreck: Hi. My question may have more to do with what I believed was Robert asked previously, with regards to general wellness. But if an app was specifically targeting a disease condition, would the device manufacturer or manufacturer be able to specify what that condition is?

Or is the draft guidance gearing more towards not allowing a specified condition for these apps?

Bakul Patel: I'm not sure whether you have the guidance in front of you. But I can probably actually point to you the two specific types of products that we - we - we said. We would - a lot of - we are allowing marketing claims to be is may help reduce the risk of certain chronic disease.

Or may help living well with their chronic disease. But it's - the healthy lifestyle may help reduce the risk of - or a healthy lifestyle may help living well with. The key point is the products are promoting a healthy lifestyle, we would consider as low risk.

And if the marketing plan includes a healthy lifestyle, may help reduce the risk of or a healthy lifestyle may help living well with, we would still consider them to be lower risk - lower risk.

AJ Schreck: Okay. Thank you.

Operator: And the next question is from Tracey Fox. Your line is open.

Tracey Fox: Thank you. Bakul, you mentioned that there was a comment on the draft MDDS guidance to permanently update the regulations. Can you tell us if there are any short term or long term plans to actually do that?

Bakul Patel: Right now we did receive some comments about finalizing or updating or crediting some other mechanism to - to either create a new regulation or something else. However, at this time, we thought finalizing the guidance itself provides the immediate clarity that people were seeking for.

And lead a favorite path towards. I am - I cannot discuss at this time whether we have future plans on where - how we would go about doing this or if we were going to go about doing this.

But at this point, our intention was to provide the immediate sort of guidance and final decision for both folks in the industry, as well as our staff, to being able to - or enable FDA to - to implement this policy that we are - we had proposed last year.

Tracey Fox: Okay, thank you.

Operator: And your next question is from Robert Cruz. Your line is open.

Robert Cruz: Hi. My question is with respect to the draft guidance for accessories. So I'm wondering if you could provide additional clarification for the proposed policy and confirm my understanding that this is kind of advocating for an independence of classification between the parent device and accessory.

Now the second part of that question would be has there been considered, given this forum, act on other guidances such as for 510K submissions of software and the software level of (concern)?

Sugato De: This is Sugato De. To answer the first part of your question, you are correct. The guidance is intended to separate the risk based analysis for accessories alone, versus their parent device. The accessory is considered as used with the parent device.

It could be very possible that the accessory might be determined to have a different risk categorization than that of the parent device.

So that is a departure from, you know, what - what's currently done in this space, where most often accessories are usually regulated with their parent devices currently.

The answer to the second part of your question is that for 510(k)s for software accessories, we're not going to differentiate software accessories from accessories. Accessories have their definition as stated in the guidance. You know, it says to support, supplement or augment the performance of the parent device. That would also apply to a software accessory.

Robert Cruz: Okay. Perfect. Thank you very much for the clarification.

Bakul Patel: And so this is Bakul. I just want to add to what Sugato just mentioned. If you have other - I heard you say about the 510K sort of implications of this guidance.

As - as you look at the guidance and sort of digest it and sort of digest information as of today, if you think there are things that we should consider as part of the finalization of that guidance please - please make sure that you provide that suggestion in the comments.

Robert Cruz: Yeah. I will make sure to do that. More specifically, around the software level of concern were where my kind of questions stem from.

Bakul Patel: Great. Thank you.

Robert Cruz: Thank you.

Operator: And the next question is from Zach Rothstein. Your line is open.

Zach Rothstein: Hi. And thanks Bakul and everyone else at FDA, for your time today. My question relates back to the second category of general wellness products. And that's that make claims based on scientific evidence. You know, I think it's great that CDRH has taken this position.

But my question is have you thought about taking it a step further, like (CFSAN) does in the food space, for qualified health claims? Something like (Hateri) is marketed as good for your heart.

So it seems to me that you kind of had a set of what are essentially preapproved claims based on scientific evidence, both small and large manufacturers when it needs to always research and find and determine whether scientific evidence exists and is sufficient for those claims.

Bakul Patel: Great, great question. And I think we did think through that. And our approach was given our resources and given our workload, we wanted to be very clear upfront and we were not planning on having a separate program that will validate the ability of the scientific claims.

And - and that's an area that we did consider. But again, if you guys have thoughts on how to best approach it without having, you know, CDRH review every single claim that comes through, especially given the volume of mobile apps that may be there that may actually help living - help people with living a healthier lifestyle. That's the condition we had to balance.

And again, back to my foundational principles of being narrowly tailored and focused and, you know, functionality focus is what we were heading towards.

Zach Rothstein: Right. Thanks.

Operator: And the next question is from Troy Jack. Your line is open.

Troy Jack: Good afternoon Bakul. Thank you for sponsoring this today. So we actually have two questions from my side. The first question is surrounding the last page of the MDDS guidance document which is page 8.

                 And in that - on that page it states that FDA does not intend to enforce compliance with the regulatory controls, including registration, we're seeing quality system regulation, etc.

                 So our first question is, are manufacturers still required to comply with these regulatory controls, even if the FDA does not intend to enforce compliance with those controls? You know, I was wondering if you could speak to that.

Bakul Patel: Sure. I - you said you have multiple questions. I was waiting for more. But I'll answer this one. Yeah. So intent here is not to - not to enforce these requirement on people who are in compliance are not - for complying with those regulations.

                 That I can't - I can't tell you whether to - whether to do those things on their own, because we thought at one point in time, for sure, the following quality systems system regulations are generally good for other reasons.

                 So and this only sort of confirms our policy going forward that regardless, we will not be enforcing compliance with regulations.

Troy Jack: Okay. My second question.

(Shelly Astriker): The - hi. My name is (Shelly Astriker). So the second question that we have today, was whether or not the devices that fall in these regulations also on

page 8, are they still considered to be devices if there will not be, you know, if there will not be compliance with regulatory controls in force, are they still considered devices?

Bakul Patel: So I think Brendan may have answered this in previous context. These regulations - we are basically saying these products are medical devices under the section 201H of the FD&C Act. The guidance provides a compliance policy in our enforcement policy.

And they would enforce compliance towards these - these products or not.

(Shelly Astriker): Thank you.

Bakul Patel: And - and just a reminder, if people were asking questions can come closer to the phone. This Webinar is transcribed so it can be clearly recorded.

Operator: Thank you. Your next question - your next question is from Cathy Franklin. Your line is open.

Cathy Franklin: Yes. My question may have just been answered. Is the FDA still requiring an MDDS device to be included in the manufacturer registration and - and device listing?

Bakul Patel: We will not be enforcing a compliance - compliance towards people for that particular requirement.

Cathy Franklin: So if we already have an MDDS that is in fact listed, the determined register - will we be pulling it off? Will that be all right?

Bakul Patel: I will - I will go back to my standard answer. We will not be enforcing compliance to that.

Cathy Franklin: Okay. Thank you very much.

Operator: And the next question is from Sarah Baker. Your line is open.

Sarah Baker: Thank you. I'm sorry. I wanted to - okay. Could you comment on labeling distribution, specifically with reference to patient labeling, as part of the mobile medical application? Would it be acceptable to provide the patient labeling as part of the mobile medical application?

Bakul Patel: I'm not sure I follow the question. But I'll attempt. Now that I'm looking at others to see if they follow the question.

                 But the types of labeling for - for example, if there is a mobile app that is - that would be regulated as a Class 2 medical device and requires review, I think as part of the review you will have to discuss with the branch and the reviewer what format type media is acceptable for patient labeling.

Sarah Baker: Okay. So it depends. It's more on specific circumstances and the scenario, it sounds like.

Bakul Patel: Exactly.

Sarah Baker: Okay. All right. Thanks.

Operator: Thank you. And your next question is from (Edward Wortney). Your line is open.

(Edward Wortney):   You actually answered my question. Thank you thought.

Operator: And the next question is from Kathleen Bacon. Your line is open.

Kathleen Bacon: Good afternoon. I was wondering if on the classification under the triangle, where they're considered low risk but still devices, then because it's part of the software development, do we have to go ahead and translate towards design control if we're already validating through agile processes?

Bakul Patel: Interesting. So the middle portion is what you're referring to in the triangle.

Kathleen Bacon: Correct, sir.

Bakul Patel: Those products - those products are again under the enforcement policy of not for FDA not - are making a very clear statement to not be enforcing regulatory requirements for the - for that type of product that fit in that - in that area.

So the answer is I'm not sure where you're heading with the question but that's really what we are saying. Is we are not going to enforce compliance.

Kathleen Bacon: Okay. Okay. I think that clarifies it a little bit. Because essentially because it is - it is a device and because it does fall under software, the processes for the development of that software is slightly different than the standard linear process of medical device, lifecycle development.

So because the processes are different then that suggests that we don't need to do the - the software definition of say something like design transfer. Because that technically doesn't exist in software development. You are validating the software as you are creating design input.

So in theory, you would not have to translate that to medical device design history file. It could stay as agile software development in just - it could essentially be any software.

Bakul Patel: So my recommendation to you would be, is follow the best practice that is good for your business processes to maintain, you know, whatever requirements you have for safety, etc. that makes sense for you, to - for the design process.

But what it boils down to is again, let me reiterate, the triangle is a great depiction of our - our focus in the area of mobile apps.

If you're - if you're trying to figure out what to do in - in the gray area or the middle area where it says the lower risk - where it's not the medical devices area, it's not something that we are saying - we are focusing our energy on.

I think as we get closer towards the line, towards the top of the pyramid or the triangle, where it becomes the mobile medical app, versus under enforcement discretion, I think that's where you can engage FDA to have this conversation.

But - and the - and the email address I provided on MobileMedicalApps@FDA.HHS.gov, is a great place to ask those kinds of questions.

But at the same time I would encourage people to think not to do things because, you know, there are regulations but think what's best for the product and for the patients.

Kathleen Bacon: Okay. I appreciate your time. That clarifies it a lot. Thank you.

Operator: Thank you. The next question is from (Michael Seyes). Your line is open.

(Michael Seyes):   All right, thank you. My question was actually just answered. Thanks.

Operator: And the next question is from Jodi Coleman. Your line is open.

Jodi Coleman: Hi. Regarding the guidance for MDDS medical image storage devices and medical image communication devices, is it correct then to assume that these devices will not be required to be registered in a global unique device identification database?

Bakul Patel: I may have to differ on that. But really on a very broad - you can probably ask the question to (DICE).

                    But at a very high level I would - I would say that since we are not enforcing regulations on - on those devices, we would expect the same - we would probably have the same approach towards other - other regulations such as (UDI).

Jodi Coleman: Okay. Thank you.

Operator: Thank you. The next question is from (Anita Walk). Your line is open. (Anita), please check your mute button. Your line is open. And the next question is from (Lee Lichter). Your line is open.

(Lee Lichter):   Yes. I would like to ask about the use of a - an MDDS or an MMA that is used in conjunction - that is considered a device that is used in conjunction with a drug to record drug values or used by the user in some way in conjunction with their drug therapy.

Does the fact that this is a device used with a drug, make this a product combination product? And if it does, does it in any way, change the enforcement discretion or the application of the regulations as you have described in these guidances?

Bakul Patel: I'm having a hard time thinking on the spot of an example of what you just described. But I think this would also be a great question to ask in the mobile medical inbox.

And like I - like I mentioned earlier, there is a team - a team here of senior leadership that get together on a regular basis, to discuss these kinds of issues. And if this is one area we need to provide clarity, we - we would discuss this and provide clarity.

(Lee Lichter): Okay. Thank you.

Operator: And the next question is from (Sheree Patrick). Your line is open.

Man: Hi. This is (unintelligible). First off, everybody from CDRH and Bakul, thank you very much for your presentation. I - I'm - I mean my question stems from all the discussions that just happened and I'm sort of confused.

The fact that the enforcement discretion mobile apps are considered to be medical devices but FDA is saying they're not going to do enforcement, doesn't preclude them from registering and listening because Class 1 devices also have to register and list. And also have to have design controls.

Am I missing something where - I mean the answers I heard seemed to suggest that that is not a requirement for an app that falls within the enforcement, you know, discretion of FDA.

Bakul Patel: So there's - we can dive down to deep conversation on this one. But fundamentally, what it boils down to, is you may - folks and manufacturers may choose to comply with the regulation.

And what - all we are saying is that's not an area that we will be focusing our enforcement resources on.

Man: No, no. I understand that that's not the area that you guys are focusing on. But what you're saying is coming off of as a manufacturer doesn't have to actually register a list, at least to me. I don't know if anybody else has the same confusion.

But that's how I'm hearing it and I'm not sure if I'm hearing it correctly.

Bakul Patel: So…

Man: It's still a Class 1 device, yes?

((Crosstalk))

Bakul Patel: MDDS is a Class 1 device.

Man: Right.

Bakul Patel: And if there are requirements that are not met by a certain manufacturer and this could include the ones listed in the guidance, we would not be enforcing - we would not be requiring compliance to those.

Man: Okay. I guess I - I guess I have to ask this question to (DICE) because again,
                I'm still hearing that we don't have to register and list and also follow design
                controls, because you're not going to enforce it.

                But that goes against the Class 1 (general) controls requirements that are in
                the, you know, for - for any medical - any device considered to be a medical
                device.

Bakul Patel: Yeah. You can go ahead and ask the question to (DICE) or - or the mobile
                medical apps in email as well, and we can get back to you.

Man: Thank you.

Operator: Your next question is from (Kelly Winn). Your line is open.

(Kelly Winn):   Hi, yeah. Relative to the MDDS guidelines, I think previously it called out
                specifically that plotting data graphically would exclude it form the MDDS
                classification. Is that still the case? Could you speak to that a little?

Bakul Patel: Yes. So MDDS regulations don't include plotting of data. It's the display of
                exact data that's generated by the medical device.

                However, if you take MDDS in combination with the policy described in the
                mobile medical apps guidance, you'd see that combination of plotting the
                data, along with transferring the data is - sort of fits into the same consistent
                approach that's highlighted in - in either the mobile medical apps guidance or
                - and in MDDS guidance.

(Kelly Winn):   Okay. So just to clarify, so if we take that transport from a device and plot it
                graphically, that would fall under the MDDS guidelines?

Bakul Patel: So MDDS guidelines are specifically talking about the definition of MDDS and the MDDS regulation. So MDDS regulation defines an MDDS to do certain functionality.

There are other functionalities like plotting, etc. that the data that the - MDDS which is responsible transferring or storing, were highlighted in the mobile medical apps guidance that we also said would be under enforcement discretion.

So all I'm saying is if you - if you are plotting data but you're taking data and having a functionality that takes data from a medical device, those two functionalities in combination - taken together as a general approach on CDRH, would be under enforcement discretion and they could come from, as a combination of the MDDS guidance as well as the mobile medical apps guidance.

(Kelly Winn): Okay.

Operator: Thank you. The next question is from (unintelligible). Your line is open.

Man: Thank you. I have two questions. One, with regard to patient monitoring, are devices that provide secondary or tertiary alarm notification subject to MDDS or not?

And secondly, if a company only has devices that fall within the spectrum of items that you've mentioned in these guidance documents and nothing else, are they subject to establishment registration and listing, or not? Thank you.

Linda Ricci: Hi. This is Linda Ricci again. I'm only going to cover the first part of your question, with regards to secondary or tertiary systems for monitoring.

If the systems for secondary and tertiary monitoring are used in active station monitoring then they still would be actively regulated as a primary monitoring system. An example of this is - is like a nurse call station in a hospital that is connected to the primary monitoring system at the patient's bedside.

The type of secondary monitors are still actively monitored as they're used for active patient monitoring. Can you repeat the second half of your question please?

Man: Are entities that have devices that fall within these two guidance documents only, required to register as an establishment and subject to inspections?

Bakul Patel: As we - and I'm assuming you're referring to mobile medical apps guidance and MDDS guidance I take it?

Man: Yes.

Bakul Patel: And if - so if a product that is considered a mobile medical app that is the top of the triangle that we would focus our oversight on, they would still be subjected to the same regular rules and enforcement policies that we have today for other Class 1, Class 2, Class 3 devices.

Things below that - that line on the top - the tip of the triangle, are the functionality or types of products are other categories outside of the small triangle, are a system to the medical device - the medical device data system guidance, would - all they're saying is if you fall there, if your product falls there, we would not - we would not enforce.

Which means that includes - enforcement means (infections) as well.

Man: Okay. Thank you very much.

Operator: And the next question is from (Ryan Meyer).

(Ryan Meyer): Yeah. Hi there. So I'll try and ask this so that it makes sense, but I'm kind of hearing a couple of different things and this goes back a couple of questions with the gentleman who had some confusion. And it sounds like there's a set of rules, right, that apply to a medical device.

You know, Class 1, mobile medical device or MDDS, whatever. Are you saying these rules don't apply or are you saying they're just not going to enforce these rules?

Bakul Patel: The latter.

(Ryan Meyer): Okay. So I mean that's kind of - to me that's almost - I mean without it sounding bad but I mean it's kind of like talking out of both sides of your mouth, right? Saying okay, well, you know, this stuff applies. We're not going to come out and make sure that you're doing it.

But, you know, what if something bad happens? Then all of a sudden there's a - like oh wait, you should have been following this to begin with?

I mean it just sounds like you're not taking a proactive approach and going out to enforce but hey, you'd better have a quality system and register and do all of that stuff - design development controls, the whole works, if that's going to be the case.

Sugato De: This is about focusing the resources that we have. I think we're taking the approach that, you know, we're not going to apply active enforcement discretion.

                     This is kind of analogous to maybe a local police department saying, we're not going to issue a ticket for going five miles over the speed limit. The law still says you can't go over the speed limit.

                     You, as a company, in this case as the driver, you have to make the decision if you are going to go over the speed limit or not.

((Crosstalk))

Sugato De: The department is just saying, we won't give you a ticket. It's still your decision. And it's probably in your best interest to do it. It's just we're not going to, you know, actively apply enforcement discretion.

(Ryan Meyer):   Yeah. That makes sense. So is there a scenario where you would enforce it?

Bakul Patel: So as we had articulated in the mobile apps guidance, we have said that we would engage in an open public dialog and feedback, if we've ever changed that decision, in light of other information that we've collected.

(Ryan Meyer):   You're saying if you were to change your decision about not actively enforcing?

Bakul Patel: Correct.

(Ryan Meyer):   So until you guys come back to some public dialog, nobody's getting busted for breaking the speed limit?

Bakul Patel: In Sugato's world? Yes.

(Ryan Meyer):   Okay. Okay, I suppose that adds some clarification. But it doesn't seem to alleviate anything that we need to be doing on this side, if we want to make sure that we're managing our risk.

Bakul Patel: We expect you to manage your risk as you would normally do in other ways or other types - other reasons. All we're saying is from a regulatory perspective, and our compliance perspective, we would be not focusing in that area.

(Ryan Meyer):   Got it. Okay. Thank you.

(Ryan Meyer):   Thank you. And the last question for today's call is from (David Hirschhorn). Your line is open.

Dr. (David Hirschhorn):   Hi. This is Dr. (David Hirschhorn). I'm a radiologist. I noticed that out of the - the mobile medical apps definition you said that you struck your display from there.

So where does that leave us with regard to displaying medical images on mobile devices both for clinical reference and for primary diagnosis?

Bakul Patel: I'm going to turn it over to (Brendan), here.

Brendan O'Leary: Hi. This is Brendan O'Leary again in the Office of In Vitro Diagnostics and Radiological Health. We do have some language in the mobile medical applications guidance on display of radiological images, on page 25.

We say that mobile apps that are not intended for diagnostic image review, and it provides them more specific examples of that. It would be considered medical in these communications devices which the medical device data systems guidance now puts under enforcement discretion.

Does that help answer your question?

Dr. (David Hirschhorn): Yeah. Okay. That clarifies it. Thank you.

Bakul Patel: Thanks (David).

Operator: And there are no other questions in queue at this time.

Irene Aihie: Thank you. This is Irene Aihie. We appreciate your participation and thoughtful questions. Today's recording, along with the slide presentation and transcript, will be available on the CDRH Webinar page at www.FDA.gov/CDRHWebinar, by Thursday, March 5th.

If you have additional questions about the final and/or draft guidance document, please use the contact information provided at the end of the slide presentation. As always, we appreciate your feedback. Again, thank you for participating. This concludes today's Webinar.

Bakul Patel: Thank you.

Operator: Thank you for your participation. You may disconnect at this time.

END