Transcript of FDA Press Conference on Global Harmonization Task Force

FTS-HHS FDA

Moderator: Karen Riley
October 2, 2007
11:00 am CT

Coordinator: Good morning and thank you for standing by. All participants will be able to listen only until the question and answer session of today's conference call. Today's call is being recorded. If anyone has any objections you may disconnect at this time. And now I'll turn the call over to your first speaker, Ms. Karen Riley. Ma'am you may begin.

Karen Riley: Thank you. I'm Karen Riley in FDA's Press Office and today we are here to discuss the Global Harmonization Task Force. And with me is Larry Kessler who is the Chairman of the GHTF and Director of the Office of Science and Engineering Laboratories at the Center for Devices and Radiological Health at FDA. Janet Trunzo, the Vice Chairman of the GHTF and she's the Executive Vice President of the Advanced Medical Technology Association otherwise known as AdvaMed.

Also we have the two - the Chairman and Vice Chairman of the GHTF next year. Roland Rotter, he's the Director of the Medical - he will be the Chairman and he's the Director of the Medical Devices Bureau, Therapeutic Products Directorate for Health Canada. And Stephen Dibert, he will be the Vice Chairman and he is the President and CEO of MEDEC.

Also with us is Andrew Whitman. He's the Vice President of the Medical Imaging and Technology Alliance and he's also with the National Electrical Manufacturers Association. So I believe Larry would like to do some opening remarks and then we'll open the phone to questions. Thank you.

Larry Kessler: Good afternoon and thank you for attending on the phone and the few of you who are here at the Reagan Center in Washington, DC where we are holding the 11th conference of Global Harmonization Task Force. And I want to say that I'm only going to make a few very brief remarks to lay a little bit of the background for GHTF and talk about some of the things we have recently accomplished and are accomplishing this week and give you the time for the question and answer period so I don't take a long time droning on.

Since 1992 the Global Harmonization Task Force has worked to develop guidance that moves the regulatory system of its five founding members toward convergence while laying the foundation for emerging regulatory systems throughout the world.

I wanted to point out that the five founding members include the United States, Australia, Canada, Japan, and the European Union and the task force is made up almost equally of regulatory agencies and representatives and the manufacturing industry representing medical device companies. So it's an unusual partnership where it's very even roles between industry and regulators trying to move this forward.

The efforts of GHTF have a dual goal of promoting public health and facilitating international trade. An example of the way in which GHTF and related efforts have facilitated international trade is the

convergence almost entirely worldwide with systems such as the quality system requirements for medical devices. And the closeness of the international standard for quality systems also known as ISO 13485 become a standard worldwide and the U.S. FDA requirements -- although are not exact -- are quite close to this.

And the ability for countries to place products on the market using quality systems, something that was going to allow the increasing ability of products in medical devices and imaging technologies to move from country to country and be approved one place and used elsewhere and potentially auditing of those systems as well which I'll talk about in a second.

A notable example of the public health protection provided by GHTF has been the establishment for the past eight years of the National Conference Authority reporting program. This is supported by Health Canada and we're very thankful for them. They support the underlying electronic structure for us to ship over 100 vigilance reports which represent usually collections of adverse events signaling potential public health problems across the world.

So that a country in Europe or regulators in Japan can be aware of problems in the United States or in Canada and can potentially avoid public health crises in their countries by the rapid exchange through electronic mediums of what we call vigilance reports.

We have some recent examples of those where information shared from the United Kingdom came to the United States and alerted us to problems, in situations where the United States has alerted our

partners in Canada and Japan and Australia and elsewhere about a collection of adverse events we've seen.

Recently as a measure of our success and our reach of Global Harmonization Task Force have been partnerships with the Asian Harmonization Working Party and the Pan-American Health Organization. And I'm very happy to report this summer at meetings in Vietnam of the Association for Southeast Asian Nations, that their ministers have committed them to move their regulatory systems to the GHTF framework by the year 2010.

The Association of Southeast Asian Nations represents 10 countries, that part of the world covering 500 million persons. And they're going to be using the GHTF documents we've been developing over the last 15 years to govern their regulatory system.

At this meeting, the 11th conference of GHTF, we have now moved forward to solidify the basis on which manufacturing audits can be conducted once and used worldwide. We've passed forward a document we're about to go final with the auditing strategy and auditing reports that we believe will be the foundational basis for how audits can be done once.

And that will save regulators resources because we're all strapped, in fact save industry from having to go through repeated audits which often shut down the manufacturing line for days or a couple of weeks on end to the disadvantage of not only the manufacturer but their customers, physicians and patients. This is the kind of partnering we think benefits not just the regulators or industry but everybody. It's a win-win.

While those kinds of audits are not a complete reality today they are in fact closer than they ever have been before and in fact those audits are taking place and my colleagues in Health Canada can tell you that those things are happening to certain kinds of countries that are using the underlying structure of the international standards organization, ISO 13485.

That is my prepared remarks and the floor is open. Thank you very much for spending time. Karen?

Karen Riley: Thank you. Now we're going to be taking some questions. We have - Operator we have both press here and we have press on the phone so perhaps what we'll do first is take some questions here and then go to the phone.

Coordinator: Okay.

Karen Riley: If you would, if you're going to ask a question go to the phone so they can hear your question. Who has a question? Yes (Mark)?

(Mark McCarty): (Mark McCarty) with Medical Device Daily. Mr. Kessler I wonder if you would address the professional capacity of some of the others that are going to be participating on this. If they have no infrastructure in the department it sounds like they're going to be (unintelligible).

Karen Riley: If that can't be heard, he's asking about the infrastructure capacity of the developing countries to do this sort of thing.

Larry Kessler: Specifically with regard to inspections, the model that's been largely used in other jurisdictions outside the FDA who are resourced a different way is for countries to recognize or accredit certification bodies. It's the system that's being used for example in Europe where a company has trained auditors to do this and the country who wants to use that system will accredit that body.

So for example we are working with the Thai FDA in Thailand to figure out which bodies could - they would accept the certification of. Rather than establish a new system in Thailand, why do it? There are auditors worldwide who can do those audits for those companies, allow those products to be placed on the market. That's the most likely scenario that will be used.

And in fact we just heard this morning from the International Accreditation Forum, the ones who partner with GHTF to provide international reach, they had - remember how many accredited bodies they had, 70 some? They have over 70 accredited bodies worldwide that accredit certification bodies and maintain that.

And if we can develop -- if -- I want to make sure, we have not yet. If we could develop a relationship they could help countries which don't have the infrastructure, have accredited persons worldwide do the work for those companies. So we're trying to partner with them to make sure - what we're trying to avoid is make sure they don't set up parallel, duplicative, and conflicting systems who audit in a different way. So that's how we're trying to help countries that don't have the infrastructure. Thank you.

Karen Riley: Very good. Who has the next question? Why don't you go? You can get up here faster.

(April Fulton): This is (April Fulton) from (Tunica). Can you talk about the status of the training programs that you have for the countries that are not yet part of Global Harmonization Task Force service?

Larry Kessler: Sure. And by the way, when you - if you guys want to answer too, it's not just me. But on the training program -- very important to us to have active training which does two things. Not only educate emerging - countries of emerging systems on what GHTF is all about but also get a dialog so get them to tell us where this might work for them and where we might need to improve our documents.

So right now we actually have a fairly active training program coming up this week and this year and we're trying to expand it. So this week we have training two days in Washington and we've invited a large contingent from Latin America. Twenty four regulatory participants from Latin America are here attending the GHTF meetings who are going to be trained and trying to take back GHTF documents to their countries.

And the World Health Organization has brought an additional ten to a dozen persons from elsewhere in the world to attend the training sessions which will be all day Friday at FDA facilities and all day Saturday and this is an example of partnership at the AdvaMet facilities downtown.

And for the first time we're actually going to videotape the training with a national (unintelligible) authority reporting program so that these countries can take this back to their institutions, train other people in

their environment, and also when they have change over in personnel be able to have the new people figure it out.

We also partner with the Department of Commerce. Several trainings have already happened but they have just received funding for two training sessions, one in Asia which will occur in Kuala Lumpur in March of 2008 under the chairmanship of U.S. and working with Roland Rotter from Health Canada are going to do a training session in Latin America somewhere. Roland?

Roland Rotter: We believe September, October, 2009 in conjunction with another training that is happening.

Larry Kessler: So what we're trying to do is bring a number of medical device issues to the fore all at the same time.

Karen Riley: Okay Operator, we have some questions here but let's - all right, one more.

(Jennifer Smith): Hi, this is (Jennifer Smith) of FDA Reach. Two questions that kind of flow into each other. The first one is about I guess auditing. I just want to make sure it's auditing adverse events, to double check, or it's not, okay.

But exploring the adverse events because we were talking about that, this is actually a question for Janet and for Andy. With more recent events here with the FDA bill passing without a technical correction passed by the House that would require medical device makers to report adverse events into a database. I just want to know about your feelings on that because they have passed it.

Janet Trunzo: That's specifically related to the clinical trials registry and results database where the information that a company gets developed in the clinical trial would be put into this database. So the adverse event reporting that is required under there - under that provision is not any - there's not much difference there between that and companies report adverse events in their clinical trials as a requirement of the clinical trial.

And so when a company gets a product approved there is a summary of safety and effectiveness in which the results of the clinical trials are discussed and the adverse events associated with clinical trials are discussed. So there's nothing new or unusual about companies reporting clinical trials' adverse events in an open way.

(Jennifer Smith): So in other words -- I'm sorry, I just want to follow up on that. Therefore it doesn't matter that the technical correction did not pass. The bill (unintelligible). Does that address an exemption of (unintelligible) that was written up when the bill came to the House that would exempt medical device companies from reporting clinical trials database. So I just wanted to make sure. See what I'm saying? Like it doesn't matter because you guys report anyway.

Janet Trunzo: Well we report anyway, we don't report in the way in which that clinical trials amendments bind it because it was very much related to how drugs report clinical trials. So that's where the differences are.

Man: But those reports still come in.

Janet Trunzo: But they still come in.

Man: Via the medical device reporting system.

Janet Trunzo: Right, to the FDA, right.

Karen Riley: Did you want to say something Andrew?

Andrew Whitman: No no, that's fine. Janet covered it.

Karen Riley: Very good.

Man: And the auditing just to clarify is about audits for quality systems which is either done post-market like an FDA inspection but it's also done in other jurisdictions sometimes to place a product on the market. Roland?

Roland Rotter: For us it's both a pre-market requirement to have this in place and a certificate issued as well as a post-market requirement that it's maintained on an ongoing basis.

Karen Riley: Great Operator, let's take questions that might be on the phone.

Coordinator: If you would like to ask a question please press Star 1 on your touchtone phone and record your first and last name so that you may be announced. To withdraw your question you will press Star 2. Once again, to ask a question please press Star 1. One moment please. It looks as though there are no questions on the audio ma'am.

Karen Riley: No questions on the audio. Okay what other questions here? All right, (Mark).

(Mark): This is probably sort of going outside the (unintelligible). The (unintelligible) conversions might someday want to be applied toward clinical trial data. I know that the FDA is not that fond about outside U.S. data and for some substantial reasons. But a lot of medical device companies have the products in market overseas that would kind of like to try to combine some of that to get regulatory approval for the U.S. Where do you stand on that?

Larry Kessler: I have two comments but I absolutely want to hear from my industry colleagues here. I would like to take at least slight issue with the phrase we're not fond of non-U.S. data. In fact we use non-U.S. data fairly routinely. I believe that the U.S. FDA has the right to be watchful and careful about data that we use in the U.S.

But I'll give you an example where - and Janet may remember, we used exclusively non-U.S. data to do a Guidant approval a few years ago from their - one of their trials for one of their ICDs to give it a heart failure clearance and it was exclusively non-U.S. So we are quite happy to do so and in fact as I recall the given camera, the camera you swallow that does imaging through your colon, largely data was done outside the U.S.

And we're currently engaged as Janet well knows in a project called Harmonization by Doing where we're trying to use Japan and the United States to do parallel studies so we can use both U.S. and non-U.S. data for joint moving products forward. It's quite a struggle doing it but it's really important.

So I want to take issue. And to read that we don't favor non-U.S. data, part of it has to do with making sure we can ensure the quality of that data which is sometimes a challenge for us. So that's first.

Second, study group five just begun two years ago approximately, devoted to looking at clinical effectiveness data. And what we're trying to do is at this moment harmonize what those reports look like, how clinical studies are conducted, when they are conducted, how that can flow into regulatory agencies.

What will be difficult because of the regulatory structure that we have right now around the world is deciding which products get which clinical data in which jurisdiction. That is not harmonized and I encourage the press and industry to continue to press us on how to do better. But I think that's a distance away. We have a lot of other things on our plate and this is a challenging issue. Andy, please.

Andrew Whitman: No, I mean, I think - this is Andy Whitman for those on the phone. I mean, I think that I would agree with Larry. I think that we have been in certain situations where we have used some international data and also I'm thinking specifically of some combination products issues where we have used some international studies and things to that effect.

So I think that we're headed that way and so I don't see it as much of - I understand, you know, there's always reservation of using outside data but I think that the FDA has worked with the industry in partnering on this issue.

Janet Trunzo: I agree, I mean as long as the data that are collected are quality data, they're collected according to the rules that have been described by FDA as how all kinds of clinical trials are to be conducted, then I don't think it matters where it's done. If they can support the safety and effectiveness then - and the data are good, reliable, quality data then there should be no problem with where the data are collected.

Woman: I'm sorry, I just want to follow up on everything about the clinical trials as far as you were saying. The way that FDA (unintelligible) clinical trial the way to report is on the (unintelligible). I want to understand the trend of the FDA language essentially. If you don't have to report a claim to (unintelligible) with what the president passed would be (unintelligible). So I'm just wondering about whether or not that's something that you are okay with and that you are opposed to.

Janet Trunzo: Companies are required in clinical trials to collect adverse events during clinical trials. That information is sent to the FDA in a summary format. That information is included in the summary of safety and effectiveness. That information is included in the 510(k) summaries when clinical data are part of the 510(k). There are already those reporting requirements.

The section that you are referring to in the clinical trials portion of the (PDA) is a section requiring very specific adverse event reporting that is very specific to how drugs report adverse events. It is not applicable to how devices report its adverse events associated with clinical trials in the summary format in which we currently do.

Karen Riley: Yes Operator, are there any questions from the phone?

Coordinator: There are no questions on the phone at this time ma'am.

Karen Riley: Okay, very good. Larry maybe you could say, if no one else has any other questions, give them a flavor of what's going to happen the next couple of days.

Larry Kessler: Okay thanks. So tomorrow we'll have all day at the GHTF conference, and it's the planning part of the conference so there will be presentations about what we did in the steering committee and there will be a couple of very different presentations which I'm kind of excited about.

We have contracted with (Beth Peterson) who's actually from Health Canada, a former chair of the Global Harmonization Task Force, to do what we've called a retrospective assessment of the GHTF -- where we've had successes, where we've run into some obstacles, and to help guide us into both what we have succeeded in to try and build on those but also the challenges we face for the future. She's going to present that which I think it's going to be quite exciting and quite novel.

We're going to present the accomplishments of each of the study groups as well as a separate presentation by the steering committee on implementation of the guidance documents. One of the things that industry has asked the FDA and the other regulators around the table is gee, you guys have been developing a lot of documents. You haven't adopted very many. Why not?

And that is going to be a presentation led by the FDA but will have all the regulators, what we have adopted and have not and why not and where we're headed. I think that's going to be, you know, an open and

lively debate because it's an important question. If you've done all this, you know, where's the beef?

We'll also have comments from the Asian Harmonization Working Party and the Pan American Health Organization, our regulatory partners. So that's tomorrow.

Karen Riley: Don't forget about (Al Mann).

Larry Kessler: Oh I'm sorry. I'll let you mention that. The primary speaker is …

Karen Riley: (Al Mann) who is - has a long history of being an innovator and inventor plus a number of patents and he is going to provide a keynote address at the primary session tomorrow going through some of the innovations that he has been involved in over his long career. And I think it will be very exciting to hear about that.

Larry Kessler: And that bookends, and that's the (Al Mann) beginning part of the bookend. The other end of the bookend for tomorrow's presentation will be a presentation by the Commissioner of the FDA, Dr. (Bon Eshenbach) and he'll talk about not only his view of FDA and its overall vision but for how international cooperative efforts fit into that. So they will begin with (Al Mann), an inventor, and will end with our Commissioner and hopefully a lot of stuff in between.

Thursday will be a full day of workshops and this is where we actually get to the nitty gritty of what's going on in harmonization in certain areas. So there will be presentations along the lines of combination products. There are going to be presentations on medical device

software. They are a very interesting set of - what's the title of your session Roland?

Roland Rotter: Clinical trials conducted in countries that do not currently have a regulatory system.

Larry Kessler: Yeah and that's a real challenge. Oh yes. It's going to be a little controversial we think because it's a challenge for us. So I think there's going to be some excitement on the workshop day. And then as I mentioned, they're not open sessions but Friday and Saturday will be the trainings that we'll perform and (unintelligible).

Karen Riley: Okay and that is it and we thank you for participating in today's briefing and please contact me. I'll pass out my card and whoever is on the phone can give me a call at (301) 827-6244 for some additional materials. Thank you for participating.

Coordinator: This will conclude today's conference call. You may now disconnect.

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