FDA MEDIA TELECONFERENCE
FOOD AND DRUG ADMINISTRATION AMENDMENTS ACT OF 2007
Sept. 27, 2007, 2 p.m. EDT

Coordinator: Welcome and thank you for standing by. At this time all parties are in a listen-only mode. During the question and answer session, please press star 1 on your touchtone phone.

Today's conference is being recorded. If you have any objections, you may disconnect at this time.

Now I would like to turn the meeting over to Heidi Rebello. Ma'am you may begin.

Heidi Rebello: Thank you (Julie). Good afternoon and welcome. My name is Heidi Rebello with the U.S. Food and Drug Administration. This is an FDA teleconference for credentialed media to discuss the Food and Drug Administration Amendments Act of 2007, which was just signed into law today by the President.

It is my pleasure to introduce Dr. Andrew von Eschenbach, Commissioner of Food and Drug; Dr. Randall Lutter, FDA's Deputy Commissioner for Policy; and Dr. Janet Woodcock, FDA's Deputy Commissioner for Science and Medical Programs and Chief Medical Officer.

All three officials will make brief remarks about the law. We'll then move into a question and answer segment.

I will now turn the call over to Commissioner von Eschenbach. Thank you.

Andrew von Eschenbach: Thank you Heidi. Today's a very important day for the Food and Drug Administration. I actually had the privilege a few hours ago to be in the Oval Office to witness the President sign the Food and Drug Administration Amendment Act of 2007.

This bill passed with both the bipartisan support of both Senate and the House. And it really represents an important addition to FDA's authority. As I look back over many, many months, there were many stakeholders including consumers and representatives from industry and other sectors that contributed to the issues that are contained or addressed in this bill.

And FDA's very grateful to all of them for their input and their help. But I'd particularly especially like to thank the leadership of both parties and all the members of the House and the Senate for their diligent work in having crafted and passed this very significant piece of legislation.

I'm particularly thankful to all the colleagues here at FDA who worked so hard over so many months in support of this achievement. And the American people will really benefit from all of these efforts.

It's a great importance that this bill was passed this week and signed by the President today because it allows us to have a continued continuity of very many important programs here at FDA. And it truly eliminates the possibility of significant, potentially very damaging, reduction in our workforce. And for that reason this is obviously extremely important with regard to its timing.

But there are many, many aspects and features of this bill. And I want to touch on just a few key items this afternoon. And recognize that over the coming weeks and perhaps few months, we'll look forward to continuing this dialog with you as we address many of these important and specific provisions.

Today among the many components of this bill of significant importance is the reauthorization of the Prescription Drug User Fee Act or PDUFA and the Medical Device User Fee and Modernization Act or MDUFMA.

These programs and their expansion will ensure that our centers have the additional resources that are needed to conduct the very complex and comprehensive reviews of new drugs and devices.

In addition, I particularly would like to commend Congress for reauthorizing two other very important Acts and parts of this legislation. The Best Pharmaceuticals for Children Act or BPCA and the Pediatric Research Equity Act or PREA; both of these are designed to encourage more research into development treatments for children.

And it's critical to the health of our children that both of these were reauthorized and enable FDA to continue to expand and address this very important element of public health and our mission.

There are many other components of the legislation that also will support our ongoing commitment to protect and promote the public health by assuring the safety of drugs and medical devices while at the same time facilitating their approval.

And I will look forward to continuing to work with the staff at FDA and our many stakeholders and constituents as we go about the process of implementation of this important legislation. And certainly look forward and thank all of you in the media for your interest and look forward to continuing our dialog with you as we go forward.

And now I'd like Dr. Randy Lutter and Dr. Janet Woodcock to touch on some of the specific details in the important components of this legislation that I referred to and then we'll be happy to take your questions and continue the dialog. Randy.

Randall Lutter: Thank you very much. I'm delighted to join the Commissioner of FDA and my colleague, Dr. Janet Woodcock, in commenting on this landmark FDA legislation.

I'd like to focus my remarks on two specific parts of this legislation. These two provisions reauthorized user fees until 2012 for the review of new drugs and new medical devices.

These user fees account for nearly one quarter of FDA's total budget. These programs are crucial for the Agency's ability to efficiently and effectively carry out some of its most essential public health functions.

And above all, they ensure that patients will continue to have access to new devices and new drugs that FDA finds are safe and effective.

First with respect to the Prescription Drug User Fee Amendments of 2007. The reauthorization provisions for user fees for prescription drugs and biologics provides authority for FDA to collect at least $392 million annually from manufacturers.

This represents an increase of $87 million over the current baseline and a tripling of funding from user fees for post marketing safety surveillance.

The law also authorizes user fees for the following purposes: To review direct to consumer television ads that are voluntarily submitted to the Agency for

reviewing; to help expand FDA's implementation of guidance for our product reviewer; to develop guidelines for industry on clinical trial design; and to help move the Agency and the drug industry toward all electronic environments that's appropriate for the twenty-first century.

The second major provision that I'd like to talk about deals with the Medical Device User Fee Amendments of 2007. The reauthorization of the Medical Device User Fee Program will provide, in addition to funds appropriated by Congress, a total revenue to the Agency of $287 million by October 2012.

The main highlights of these amendments include the following. The law enhances and provides sound footing for the device review program while maintaining predictability in fees for the industry. It streamlines the device inspection program by allowing accredited outside firms to conduct routine inspections for good manufacturing practices. And it helps FDA focus its inspection resources on high-risk products and production facilities.

Finally, it will enhance the development of in vitro diagnostic devices by, among other measures, enabling FDA to issue new guidances and conduct the pilot program.

In the pharmaceutical arena, the FDA Amendments Act reauthorizes two other laws that are also set to expire on October 1. These are the Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act.

My colleague Dr. Woodcock would now discuss each of these Acts and other significant provisions including the establishment of the Reagan-Udall Foundation.

Janet Woodcock: Thank you Dr. Lutter. Like my colleagues, I appreciate the provisions of this new law that are going to enable FDA to do a better job in protecting and advancing the public health.

However, we are still analyzing the potential impact of a number of aspects of the new law. It's a very large and complicated new law. On the whole, we see that this law provides new authorities to aid our mission of promoting and protecting the public health.

As Dr. Lutter indicated, the beneficiaries of this law are the patients for whom we'll be able to continue reviewing and approving new drugs and medical devices more efficiently than we could without the user fees.

In addition, I take particular satisfaction in reauthorization of the pediatric provisions law. The establishment of a new foundation to help move forward the modernization of product development in regulatory science and finally setting up, calling for us to set up, a new electronic surveillance system for adverse events for medical products. And I'm going to cover each one of these.

On pediatrics there are three parts of the new law that increases FDA's responsibilities for protecting and enhancing health of children. The Pediatric Research Equity Act, The Pediatric Medical Device Safety and Improvement Act and The Best Pharmaceuticals for Children Act.

In the medical device provision, they require that certain device applications include a description of pediatric populations, you know, the children who might suffer from the particular disease or condition the device is designed to treat or diagnose or cure.

So there has to be some consideration and discussion of whether children actually would benefit from these devices as well. It also calls for FDA to track and report to Congress on the number and types of devices that are approved specifically for children or for pediatric conditions so we can all get a better handle on this.

And also that FDA report to Congress the approval time for device products on the market for children and for humanitarian device exemptions.

Now as far as the Pediatric Research Equity Act and the Best Pharmaceuticals for Children Act, this reauthorizes an amendment and amends somewhat the provisions that require drug sponsors to conduct pediatric studies. It provides for six-month exclusivity under the Best Pharmaceuticals for Children Act as incentive for studies that are requested by FDA to be done.

Now it also calls for an internal FDA review committee to consider various findings that have been made under these provisions to hopefully advance the study of child health and the role of medical products.

Now the bill, as I said, also calls upon FDA to set up an electronic surveillance system for using the new e-Health records and other electronic health data sources to perform surveillance for adverse events.

And the bill foresees that these records are going to grow over time in the coming years as we all see and gives us a staged implementation requirement as far as the number of people who would be covered by this system. And that would of course enhance its ability to pick up adverse events.

And we are very excited about this and are really preparing now to begin implementing this. This is really the future I think for medical product surveillance.

Now the bill also establishes a foundation for the FDA, the Reagan-Udall Foundation. This is an independent non-profit, independent of Federal Government. However it has its mission is serve the mission of the FDA. And its purpose is to modernize development of products regulated by FDA and to accelerate medical innovation.

So they are charged to identify and set priorities for unmet research needs involving FDA regulated products and forming partnerships with outside scientists.

We also are very excited that we will be able to set up a education and training program as part of this foundation and a fellowship to bring in scientists in all the new scientific fields into the FDA as well as train FDA scientists in advanced scientific disciplines as these fields are currently moving so fast.

This foundation will also conduct research projects in a collaborative fashion related to these new sciences and FDA regulated products.

And then finally, there's a call for an improved clinical trial databases. This is a responsibility that's shared between NIH and FDA. The new law expands the existing government database on clinical trials. And the expansion is foreseen to be in three phases.

First of all, medication and devices, which are new, will be required to provide clinical trial registry information. So they have to register their trials. And this new law goes beyond serious and life threatening illnesses and

requires trials that are beyond phase one trials be registered for drugs and devices.

Second, our sponsors will be required to post basic trial results on the database for approved drugs and devices. So those results will have to be posted so that they'll be transparent.

And finally, it is contemplated the database requirements could be expanded to include adverse event information and even potentially trials of unapproved products but is contemplated that NIH and FDA would engage in the public meeting to discuss many of these additional provisions and potentially engage in rulemaking before they'd be implemented.

So on the whole, this law opens up a very promising chapter in the history of FDA and of medical product regulation and other health related products and food. And we're very positive about it.

At this time, I'd like to turn the call back over to Heidi.

Heidi Rebello: Thank you Dr. Woodcock. So we will now move to the Q&A segment. I just wanted to point out we know that you have multiple questions. Due to time constraints, we ask that you limit your time to one question and one follow up.

Our responses will be broad in nature since the law is quite complex and we are reviewing the provisions and developing our implementation plan. And we're certainly happy to work with you to address your more detailed questions in the days and weeks to come.

With that, (Julie), let's take our first question please.

Coordinator: Thank you. We will now begin the question and answer session. And if you'd like to ask a question, please press star 1. Please un-mute your phone and record your name clearly when prompted. Your name is required to introduce your question. To withdraw your request, press star 2.

One moment please for the first question.

The first question comes from (Jill Welsher). Your line is open.

(Jill Welsher): Oh hi. Thanks for taking my call. I do have many questions, but we'll try and focus.

Heidi Rebello: I'm sorry. Can you speak up? We can…

(Jill Welsher): Sure.

Heidi Rebello: …barely hear you.

(Jill Welsher): Can you hear me. Hello.

Heidi Rebello: Hello.

(Jill Welsher): Yes.

Heidi Rebello: Yes.

(Jill Welsher): Once specific question. The final legislation increased the drug user fees by $225 million over five years. Can you explain a little bit how that's going to be incorporated into the original drug user fee agreement and whether those

fees will be spread out among the three different categories and how that will be calculated?

Randall Lutter: Yes, let me see if I can answer that relatively generally. This is Randall Lutter. It will - the total fees are $392 million annually from all manufacturers. The increase is about $87 million per year over the current baseline. And the increases will be from each of the existing fees, which are for applications for products and for facilities. And the amount of the increase in each of those parts is something that we'd have to get back to you on.

(Jill Welsher): I'm sorry. Does the $87 million increase include the extra say $25 million added on for the first year or is it $87 million plus $25 million?

Randall Lutter: I think we'd have to get back to you on that. I don't know.

(Jill Welsher): Oh.

Heidi Rebello: Next question please.

Coordinator: Next question comes from (Justin Blum). Sir, your line is open.

(Justin Blum): Thanks for taking my call. Dr. von Eschenbach, I'm wondering what you think about some of the new authorities that FDA has been given including the ability to add warnings to labels and require post-market studies. Are these powers that you anticipate the FDA will use?

Andrew von Eschenbach: (Justin) as we are analyzing this bill, we also are committing to an implementation strategy that will enable us to define mechanisms for implementing.

Clearly our ability to now have the authority to address post-market surveillance, to address the kinds of studies that we need to begin to develop when these applications come to us so that we have the opportunity to really gain more information as their applied in larger diverse populations is an extremely important part of our ongoing strategy.

So the simple answer to your question is yes, these authorities are going to be helpful and yes, we are going to now work about the process of appropriately implementing them.

Heidi Rebello: (Justin) did you have a follow up?

(Justin Blum): That does it. Thank you.

Heidi Rebello: Okay. Thank you. Next question please.

Coordinator: Next question comes from AP. Andrew Bridges, your line is open.

Andrew Bridges: Hi. Thank you for taking my question. It's sort of a follow up to (Justin's) question. And that is it seems this bill will tip the FDA's attention more to the safety of drugs once they're already approved and on the market. And I was just wondering how is that going to sit with the FDA? Do you foresee any problems with sort of shifting your focus more to things that are already out the door and on the market?

Janet Woodcock: May I answer that question?

Andrew von Eschenbach: Yes, go ahead Janet.

Janet Woodcock: Thank you. I think we have always interested in the performance of medical products when they get out the door. The pre-market evaluation is simply a proof of concept to see how they'll perform once they're out there. The real purpose of the products and the rules around safety and efficacy are to make sure that these products benefit the population.

So I think we welcome the ability to really engage in how those products perform once their out on the market. And for example this new opportunity for electronic surveillance which really wasn't available in the past due to technological limitations, you know, is now a way we can maybe really get a handle on which products are really providing major benefits and perhaps discover performance problems more quickly.

So we are very enthusiastic about the ability to actually find out in a more detailed way how these products are actually doing out in healthcare.

Andrew von Eschenbach: Andrew, this is Andy von Eschenbach again. And I'll look forward to this being one of those areas of the ongoing dialog.

I think what Janet Woodcock and I are saying is that this bill and its provisions are very consistent with what has been our FDA philosophy of being engaged in the total life cycle of these products to ensure their quality on the front end as they come in, in the pre-application process and to continue to stay engaged as they are now being utilized in larger populations that we continue to learn from that experience.

And you will be hearing over the ensuing few weeks the many specific things that we are working on that have tended to enhance out ability to do that.

Heidi Rebello: Andrew, do you have a follow up question?

Andrew Bridges: Yeah. I mean it's sort of a dry as toast subject, but just from a question of organization that most of your time and energy and most of your employees are dedicated to looking at drugs before they're approved. So, I mean, do you foresee any difficulties in sort of changing albeit maybe slightly the course - you're changing course to focus more on things in the post-market arena.

Janet Woodcock: Right. You know, I don't think that's actually the case that most of our effort is spent on the pre-market. We spend a lot of time - we spend at least 50% of our time on safety throughout the product life cycle.

And although we call this an office of new drugs or and office of device evaluation, those people in those offices are looking at the product throughout its life cycle. So I think we're very aware and I think extremely interested in being able to have these new tools to evaluate the performance after the market.

And we think of a continuous life cycle approach where it's very important that you do the pre-market workup correctly and that you're also able to know whether you've predicted the performance of the product right because if you don't have that feedback, then you aren't going to do the pre-market requirements correctly. So it is really one of a piece. It's a continuous process.

Heidi Rebello: Thank you Dr. Woodcock.

Andrew Bridges: Thank you.

Heidi Rebello: Julie, next question please.

Coordinator: The next question comes from Kim Dixon from Reuters. Your line is open.

Kim Dixon: Hi there. On this surveillance system that you talked about, are there new responsibilities, new reporting requirements for drug makers and doctors? Because it - isn't there some - there's some responsibilities now for them to report adverse events but still sort of a piecemeal type system that as of now doesn't collect everything. So, how is this new technology just going to change things?

Janet Woodcock: Would you like me to start?

Andrew von Eschenbach: Yes, go ahead Janet.

Janet Woodcock: Yes, right now what we have, the manufacturers when they discover something, must report; that's mandatory.

Kim Dixon: Right.

Janet Woodcock: And that - but we get the vast majority of our reports from the manufacturers. What changes here is not a new requirement on healthcare professionals, but rather mandate that the FDA work with the healthcare systems and others to get the data that is now available in electronic form and use that. Because that data is much more complete.

We think that only about one in ten serious adverse events are reported to the FDA now, whereas if we were using a healthcare system that really captured all its patients, we could probably find most of them and also know how many people are actually taking the drug or using the device.

So this is actually a totally new approach. We have been piloting this over the last decade or so one healthcare system at a time under contracts that we have

and other mechanisms. But because the electronic records are growing, you know, now there's an opportunity to do this more broadly.

Heidi Rebello: Kim, do you have a quick follow up?

Kim Dixon: Sure. What do you think the most challenging aspects of the law are and what aspects might we see some type of concrete results from most quickly or concrete changes?

Andrew von Eschenbach: Let me just say that as we have received the bill, there appears to be at least 200 specific provisions many of which have timelines that have been identified within the bill itself. And we will be approaching this very systematically and very thoroughly.

And there are clearly some things that we believe we will immediately be able to address; for example, the establishment of the foundation, which is something that the bill requires us to do essentially immediately.

So I think to answer your question, the complexity and the challenge is in the comprehensiveness of this bill and its many important provisions. And so where we're challenged is we will have implementation strategy that will address that in a comprehensive kind of way and in an orderly kind of way. And that clearly is something that's going to get a lot of our attention immediately.

Heidi Rebello: Thank you. Operator, next question please.

Coordinator: The next question comes from Matthew Herper from Forbes. Your line is open.

Matthew Herper: Just a quick question on the clinical trial reporting, both in terms of listing trials and of listing results. Is there a timeline for getting those results submitted and up?

And do you have any kind of system for making sure they go up or is it just up to the manufacturers to do it because they're supposed to? Is there come kind of monitoring to see whether they're submitting listings when they're supposed to? Kind of how do you actually implement this? It sounds like a lot more data than is there now.

Janet Woodcock: This is Janet Woodcock. It's quite complex. This is actually - NIH is going to be operating the posting and so forth. So we will have to get with NIH and discuss with them, you know, the various implementations.

There are different timelines and requirements within here. And they're different for different parts of these provisions. So I don't think it's something I can explain. In fact, I actually couldn't explain it at the moment.

But we will perform an analysis and as Dr. von Eschenbach said, we'll be getting back to everyone with some clarity on all of this once we've had a chance to go through this extremely carefully…

((Crosstalk))

Janet Woodcock: …timelines.

Heidi Rebello: Thank you. Next question please.

Coordinator: The next question comes from Anna Mathews from Wall Street Journal. Your line is open.

Anna Mathews: Hi. I just wanted to ask - I don't know how much you can say at this point. But in terms of the new authorities or new powers that were given specifically in the drug area, I was wondering if regulatory action is needed to implement those.

In other words if you're going to have to do rulemaking or guidances running them or if they just sort of kick in right away. And if you do have to do guidances or rulemaking, what your - if you have any sort of rough timeframe either set by the bill or that you'd aim for?

Heidi Rebello: I think Dr. Lutter is going to address that.

Randall Lutter: We're right now in the middle of reviewing the bill and trying to figure out answers to questions just like that. A complicated question is whether the provisions are self-implementing or whether they need clarification in the form of a reg or a guidance.

All of our regulations and guidances would go through the normal procedure of public comment, which we do for guidances as well as regs. But we're going to have to answer the specifics about what would be need to implement any of those new authorities or related provisions a little bit later on after we've figured out more details about an implementation plan.

Heidi Rebello: Anna, did you have a quick follow up?

Anna Mathews: I'm not sure where to go with that.

Heidi Rebello: That's okay.

Anna Mathews: All right. So…

Heidi Rebello: You can get back to me.

Anna Mathews: On the specific questions on authorities then, you don't know yet whether they'd have to be implemented through rulemaking or other actions or they just kick in.

Randall Lutter: We're in the middle of looking at it.

Anna Mathews: Okay. Thank you.

Heidi Rebello: Okay. Operator, I think we have time for just one more question I'm afraid.

Coordinator: So the next question, or the last question, comes from (Anna Edney) from Congress Daily. Your line is open.

(Anna Edney): Hi. Thank you. I was wondering as far as the provision on the (rems), is there something - have you guys been talking with pharmaceutical companies helping them to repair if they think they might have something in, you know, the pipeline kind of that might be coming out when this needs to be implemented? Is there something that they should be doing that you're talking with them about?

Heidi Rebello: It's just a little hard to hear you. Would you mind repeating it or rephrasing it a little bit?

(Anna Edney): Sure. I'm sorry. I was wondering about the - what you guys might be telling the pharmaceutical companies to prepare for the (rems) provision when that is

implemented if they might have a drug that is, you know, coming down the pipeline when that would be started.

Heidi Rebello: Okay. Dr. Lutter will address that.

Randall Lutter: I think that's very closely related to the earlier question by Anna Mathews. It's related to how we would be implementing the new authorities with respect to drug safety broadly and whether we can do these with regulations or guidance or whether they're self implementing. And the answer is we're still looking at that.

Heidi Rebello: Okay. Well thank you very much. This concludes our media availability. If we didn't get to all your questions, we apologize. But I'd be happy to take any follow up questions. By the way, this is Heidi Rebello. You can call me or email me, heidi, H E I D I dot rebello, R E B as in boy E L L O at fda.hhs.gov.

Thank you very much and have a good afternoon.

Coordinator: Thank you so much for participating in today's conference call. You may disconnect at this time. Thank you.

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