President's Budget for Fiscal Year 2009

FTS-HHS-FDA

Moderator: Christopher Kelly
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1:00 pm CT

Coordinator: Welcome and thank everyone for standing by. At this time, I'd like to inform all participants that their lines will be on listen-only mode throughout today's conference call.

Also, today's conference is being recorded. If you have any objections you may disconnect at this time. Now I'd like to turn the call over to Mr. Christopher Kelly. Sir, you may begin.

Christopher Kelly: Thank you very much, (Leann). I'd like to welcome everyone to today's press briefing to discuss the FDA's portion of the President's budget for fiscal year 2009. Please note that a press release and budget summary along with key budget documents are available at www.fda.gov.

Our spokespersons today are John Dyer, Deputy Commissioner for Operations and Chief Operating Officer for FDA and Robert Miller, Deputy Director of Budget Formulation and Presentation, Office of Management, FDA. And I'm pleased to turn the program over now to John Dyer. John?

John Dyer: Good afternoon. Thank you for joining us as we talk about the details of FDA's 2009 budget request. As I think you've already seen in the press materials, if you look at the total number it's $2.4 billion dollars

for 2009. That includes user fees and direct budget authorities – all our funds. And that makes up a 5.7% increase over the 2008 levels that Congress just passed (recently).

When you break it out, the budget contains $50.7 million in budget authority, so it's predominantly the initiative of food protection and import protection and some medical product safety activity.

Also, in these numbers we cite are the $25 million for an increase in the COLA, Cost of Living Adjustments for which (unintelligible) people force, I think as you heard the Secretary talk, in 2009 will be going up over 10,500 government employees.

In the user fee side of the house, it totaled $79 million increase over 2008 for 2009 and again, these increases will be building on the medical side product safety initiative and accelerating getting medical products to market for our consumers and the safety of our population. I'm now going to turn it over to Bob Miller, who's our Deputy Director of Budget Presentation and let him walk you through the details and then we'll get into questions. Thank you, Bob.

Robert Miller: Thank you, John. Let me start by mentioning that some of you may have actually seen – on the call may actually have access to our online version of the budgets, which I believe has already gone up. So I'll be making reference to some of the documents that we have in there.

First, let me begin with the initiatives that make up the $50.7 million that John talked about in the budget authority account for FDA. The first initiative is protecting America's food supply. We have 42.2 million in our budget request for that initiative. That includes $12 million for

those very, very important dollars for the current services takeoff increase and there's also $30 million, $30.2 million precisely, for program enhancement in addition to those pay dollars.

On November 6, 2007, FDA issued its Food Protection Plan. And building on the increases we received from Congress in the 2008 appropriation, this budget will continue to implement that plan and move us forward to the vision of safeguarding America's food supply. There are three core elements to that plan – prevention, intervention and response. And I want to just share with you some of the details that are contained in our business case papers supporting this initiative.

They include funding for preventing food-born illness outbreak, intervening when vulnerabilities surface or problems emerge and rapidly responding to threats when they occur. We also, in the Food Protection Plan are implementing strategies that will tie to the Import Safety Action Plan as well. So I wanted to call your attention to that.

Specifically, in the prevention category of the Food Protection Plan, FDA will be working with corporations that we regulate, both domestic and international, to support their responsibilities and provide best practices and indeed, determine some of the vulnerabilities that we have in our food protection system overall and working with those regulated industries.

We're also moving to establish a greater presence overseas. You've seen the agreements with China that have been worked on by both the Secretary and the Commissioner and we'll be moving forward on that during 2008 and into 2009.

We also intend to expand our science in food protection. Core to the program is a (risk-driven) science-based approach to understanding not only the threats to the food supply, but also in terms of implementing the strategy. On intervention, we will be - in that category of the plan we'll be implementing programs that develop and do audits with the industry. We'll have our inspection work force, which is a major part of this budget request, and the increase is provided by Congress also in 2008.

We're going to be enhancing our ability to test and quickly identify risk signals by deploying new rapid screening tools and methods to adapt by (passage and) quickly and other contaminants include (unintelligible) for that matter. We will be specifically increasing food and feed sampling and testing.

In the response category, we include some money to enhance our partnership with our states in terms of rapid response capacity. We intend to upgrade our (trace back) capabilities and systems and improve our risk communications in the event of a response.

One of the things for FDA that's really important in the 2009 budget and implementing the Food Protection Plan, is integrating both the food safety activities and the food defense activities so the agency, in this budget, does that.

I also want to move and spend a few minutes on our increases for medical product safety and development in the budget authority category of the budget still. There's $17.4 million in that initiative and that includes, again, importantly, $12.9 million for our pay costs that's

included in the initiative. That leaves approximately $4.4 million for specific initiatives -- $1.5 million will go to blood and tissue safety and upgrading our safeguards there. Approximately $1.2 million, $1,256,000 is targeted in a field organization to improve our capability of monitoring the importation of counterfeit drugs into the country. So it's part of the Import Safety Action Plan. In medical devices, we will also be increasing by $677,000 our import activities and enhancing our review of imported medical products

The budget for FDA also includes $8.9 million in management efficiencies and administrative savings. For a number of years, FDA has been investing in improved tools – IT tools, improved facilities and we're capturing some of those productivity gains that we've been able to do in terms of improving our business processes and we're redirecting those to go to these high-priority food protection and medical product initiatives and help us with those.

As John mentioned, we have user fee increases of $79 million planned in this budget. That takes us to a total program level for user fees of – just the user fees – of $628 million. The largest piece of that is, of course, in the prescription drug user fee that was just recently reauthorized under the FDA Amendment Act. And that provides a significant amount of resources for both inflation – approximately 6% I believe is the estimate there for inflationary costs, including the cost of living and current services in the user fee program. It also includes another $10 million on top of the $25 million that was specifically provided for in the 2008 level for prescription drug user fees. So a total of $35 million for drug safety activities within Padupa.

And again, it also includes (director)/consumer advertising user fees. These were authorized in the FDA amendments. However, we did not achieve an appropriation triggering action of those user fees in ’08 and it’s being reproposed in the FY 2009 budget.

For medical device user fees, we have an increase of $4 million. There is a current law level provided for the Animal Drug User Fee Act. As you folks may already know, that act is up for reauthorization in 2009 and we’re working diligently and will be working even later on with the Hill in moving forward on reauthorization of the Animal Drug User Fee Act.

One of the things that, excuse me, an additional item I need to mention to you, is the budget includes $21.5 million for two proposed user fee programs – the generic human drug program is again included in this budget at $16.6 million. We have also included an animal generic drug user fee at $4.8 million. Negotiations on the Animal Drug User Fee Act have gone very, very well. We have a proposal that we’ll be putting together and submitting to Congress. It is included in the President’s budget – official President’s budget policy for FDA to implement an animal generic drug user fee.

I think at that time, we’ve pretty much summarized the budget, so we can move on.

Christopher Kelly: Thank you Bob. (Leann)? Operator? Hello, Operator?

Coordinator: Thank you. At this time to ask a question, please press star, 1. You’ll be prompted to record your name. Please record your name clearly. To

withdraw your question, you may press star, 2. Once again, to ask a question, please press star, 1.

Christopher Kelly: Thank you. I wanted to ask if anyone in the room here would like to ask a question first to start. (Unintelligible).

(Leann), we're going to start our questions here in the building here in the room and that will be with (Nelly Frister) with The Lancet, if you'll please start.

(Nelly Frister): Can you expand – about overseas import safety, the plan to put personnel permanently or core dependently or in other countries? Can you – are there more details on that plan? Money involved? How it's going to work? Where they're going to be?

Robert Miller: Well, it's component of both the Food Protection Plan and of course in our medical product safety area it would be part of our plan there as well, building on the base. In terms of creating a greater presence overseas, let me see if I can pinpoint in the food protection initiative. We do have a number – I believe the FY 2009 budget includes. I'll give you that specific as an increase of -- I've got some bullets here to share with you – 50 additional foreign inspections – foreign food inspections, building on the 2008 level…

(Nelly Frister): Inspectors or…

Robert Miller: Inspections. And we'll be doing 20,000 additional food field exams. Now that's field exams that – into – receiving imports into this country. We'll be doing that. It also includes increased sampling and testing that we talked about earlier. And domestically, we'll be doing a significant

number of additional domestic, low-acid canned food inspections. We're doing both for imported and domestic, a cheese program inspection. That’s about 90 for both imported and domestic. So there’s some very detailed specifics in the budget.

(Nelly Frister): But there’s nothing in the budget about actually supporting personnel in different regions who would be…

Robert Miller: Overseas?

(Nelly Frister): Yeah. Is that – because that was something that was talked about a couple weeks ago.

Robert Miller: Right. We are planning on an office in China – establishing that presence. And we’ll be working toward doing that. And we’ve also discussed having a presence in other areas as well based on risk and additional agreements.

(Nelly Frister): But there’s nothing in this budget that specifically supports that activity?

Christopher Kelly: (Nell), you can follow up with me afterwards and I’ll do a double check with you.

(Nelly Frister): Okay. (Leann), we’d like to move now to those who are on the line. Do we have any callers on the line?

Coordinator: Yes sir, we do. Our first question comes from John Wilkerson and please state your company.

John Wilkerson: InsideHealthPolicy.com. There was a proposal in there for a follow on protein product approvals but I did not see any details whatsoever other than one sentence that said that it would be paid for with user fees of some sort. Where are those details going to come from? Is that going to be posted or is that in the budget justification?

Christopher Kelly: We will have to get back to you following the teleconference today. And you can feel free to reach me at christopher.kelly, K-E-L-L-Y, @fda.hhs.gov. I'd like to go back to the room here. Is there a question from within the room? Sir – Alex, if you could state your name and your organization please?

Alex Wayne: Alex Wayne from Congressional Quarterly. I also wanted to ask about the biological proposal, but the question is whether the Administration is going to require clinical testing for follow-on products.

John Dyer: I think the way to put it is we are going to go forward with legislation and that it's going to try to get us the authority so we can begin to work without a developed framework – the path to get there. As you know, we don't have the specifics yet, but we think it's time to sort of get the legislation in place so we have the authority to begin to pursue it.

Alex Wayne: Is there any budgetary impact this year?

John Dyer: Not this year. Not this year at all. And secondly, we'll build into it to think ahead for user fees.

Christopher Kelly: Thank you. That was John Dyer, who spoke there. (Leann) do we have another caller on the line?

Coordinator: Yes sir. Next question comes from Steve Usdin and please state your company?

Steve Usdin: BioCentury, but I was going to ask for the same thing. Is there any way we can get a little bit more detail on the follow-on protein? It's not at all clear. When will we have exactly the (unintelligible) language that's being submitted to Congress on that?

John Dyer: Again, it'll take us a little while to get it drafted and work it through. We have a write up that I'll get to Chris and he can share with you all that gives you some kind of description. (Unintelligible) handle this question. There will be a lot of interest in this.

Steve Usdin: A little while is this today, this week, this month?

Christopher Kelly: Follow up with me, following the press conference today and I'll get that information to you, okay?

Steve Usdin: Okay.

Christopher Kelly: Is there a question from the room here? You have a follow-on question?

(Nelly Frister): No, it's going to be a different question, but the report that came out about FDA, it talked about a – how we need more resources and it, you know, a lot more resources – how does this budget address the concerns that were brought up in the report FDA (unintelligible).

John Dyer: Well, it addresses it in a number of ways. The budget (unintelligible) for protection initiatives. Billing on the increases that we've had in 2008

that were currently implemented. It also provides a substantial amount of support for drug and medical product safety, particularly supported by the user fee increases and the prescription drug use of fee reauthorization. Those are critical resources for us as we move forward on it. So it does move us forward on a core mission – to safeguard America's food and indeed to ensure that medical products that we depend on are safe and effective.

Christopher Kelly: If we can move back to our callers on the line, (Leann), any, our next call, please?

Coordinator: Thank you. Our next question comes from (Laura Bush) and please state your company?

(Laura Bush): Yes, I'm from Biofarm International Magazine. And my question is related to the previous one. Given the focus in the Science Board's report on the need for the agency to modernize its IT systems, is there any specific allocation in this budget request for funds to do so? And also, the (later) question, I hadn't seen anything coming out related to the recent allocations for the 2008 budget indicating that any special allocation has been made in that regard. And is that correct?

John Dyer: You will see and increase for IT 2008 over 2007 level and then 2009 over the 2008 level. If my memory serves me right, we get up to around $240 million in 2009 and I think in 2007 we were running at about $200 million. The money goes across the board to various initiatives – everything from getting MedWatch off the ground, it goes to building a new data operation center as we move to the new White Oak facility, it gets into how to do the registries for the new requirements we have to do for the food protection legislation.

There's a lot of tracking of initiatives that we need to do under (unintelligible) so there's funds in there across the board to do that. It also continues our efforts to move to more of an enterprised approach as we do the IT.

The 2009 budget also specifically includes the increase for surveillance tools and we'll be implementing those both in 2008 and 2009.

(Laura Bush): When you say surveillance tools, you mean inspections?

Robert Miller: I mean, you know, adverse event reporting systems and other signal detection tools.

(Laura Bush): Thank you.

Christopher Kelly: Operator, next caller please?

Coordinator: Thank you. Our next question comes from (Justin Blum) and please state your company. Mr. Blum, please check your mute feature.

(Justin Blum): Hi. Thanks for taking my call. I just have a few more questions related to follow-on biologics. I just want to be clear is what's being proposed in the budget that the FDA would submit proposed legislation to the Hill or is what's being proposed that the FDA administratively would create a pathway that doesn't need Congressional approval to allow follow-on biologics?

John Dyer: It's likely to submit legislation.

(Justin Blum): And has FDA actually written or will FDA write proposed legislation or is the agency simply going to suggest to Congress that this should be done?

John Dyer: I think we'll work with the Congress on this.

(Justin Blum): And who was it that was answering the questions about follow-on biologics a little bit earlier?

John Dyer: It's John Dyer, the Chief Operating Officer.

(Justin Blum): Okay, and can you give us any sense of what the scope is of the proposal that you all would like to see enacted? Would this allow – would the framework that you're describing allow all types of follow-on biologics or only a narrow type of product?

John Dyer: Let me read you the write up since there's so much questions, then we can be precise.

"The legislative proposal will include necessary provisions to ensure the safety and effectiveness of these biological products (unintelligible). The proposal will include a predictable and public guidance process for (unintelligible) follow-on protein products under the PHS act. The proposal will describe the type of data required for FDA to review applications for follow-on protein products and will require labeling for the safety concerns related to interchangeability of these products. In addition, the proposal will include adequate intellectual property and protection to preserve continued robust research into new and innovative life-saving medications. The budget proposed a new authority for FDA to approve follow-on protein

products to a new regulatory pathway that protects patient safety, promotes innovation, includes financing structure to cover the cost of activity through user fee."

And then, as I said, there will also be a user fee provision.

(Justin Blum): So just so I'm clear on that language, what you all are proposing would allow interchangeability with warnings?

John Dyer: You're getting beyond my knowledge base. We'll have to have Chris…

Christopher Kelly: I think we'll have to follow up with you on that Justin. Now if we can move to the next caller please.

Coordinator: Thank you. Our next question comes from Kim Dixon. Please state your company.

Kim Dixon: It's Reuters. My question was about follow-on biologics also but I guess you've answered that. So - or you tried to answer it or (unintelligible) on answering it. Is this enough? Is the budget increase enough to address many of the issues that were raised by the Science Board?

John Dyer: I think you have to look at the budget request and the (unintelligible) to maintain momentum over the – with the 2008 funding we got. It clearly, since it's an overall tight budget atmosphere is allowing us to target the critical areas that have been identified by the Commissioner and the Secretary, which have been the food protection initiatives.

As you look at some of the medical product area, you'll see it zeroes in on those things that are either key to the import or are areas where we felt that we needed to address some of the blood and tissue issues (unintelligible). So it's a good step that moves us in the right direction that maintains our momentum.

Kim Dixon: What about Drug Safety post marketing? There doesn't seem to be much in there on that, given the issues with Avandia and many other drugs. Is there – are there funds in there for that and I'm just seeing them?

John Dyer: Yeah, there's quite a bit. You have to remember that the FDAAA legislation gave us about $25 million in this year, fiscal year 2008. The 2009 proposes the additional 10 that's authorized in the legislation. It's the funds under the user fees. And there's also built in funds for growth and cost and additional other activities under the (unintelligible).

Kim Dixon: What would be the total proposed marketing then?

John Dyer: We'll have to get it to you broken out. If you give Chris the way you want to see it, we'll break it out. We can walk you across a different way.

Kim Dixon: Okay. Thank you.

Christopher Kelly: Next caller, Operator please?

Coordinator: Thank you. Our next question comes from (Sue Darcy). Please state your company.

(Sue Darcy): The Gray Sheet. Yes, you know, I was at the Congressional hearing last week when they were discussing FDA's budget and (Peter Bartonhut), who is one of those members of the Science Board who wrote the reports that said FDA is in a dire-straight. And he said that it actually needed to have its funding doubled to address some of the problems and that personnel needed to be increased by 50% but when I look at this 2009 budget it's only a 5.7% increase. How are you going to be able to do the things that the Science Board say needs to be done at FDA with this measly increase?

John Dyer: Well again, I think you have to look at the trend has changed I think 2007, 2008 and 2009 that we have been growing exponentially, that the people or staffing will increase by 1,000 over 2007, by the time we are into 2009. It shows a movement of - we are able to see the food protection and import strategy and with the FDAAA legislation, begin to really focus in on those areas where we need to improve our ability to do prevention response and intervention. And so it (unintelligible) gives us a real good start, lays the groundwork of where we need to go.

(Sue Darcy): Did you see 1,000 more FTEs?

((Crosstalk))

John Dyer: Again, you also have to look at the overall budget climate. I think if you saw the departments have taken overall a 3% reduction, FDA is going up 6% over '08.

(Sue Darcy): Could you give me that figure again for how many more full-time employees and can you tell me in terms of percent how many more that is than what FDA has announced?

John Dyer: In simple terms, you're looking at about a 10% increase. And it's about 1,000 people between the end of 2007 till - into 2009.

(Sue Darcy): Okay.

Christopher Kelly: Thank you. Operator, we have time for two more calls.

Coordinator: Thank you. Our next question comes from (Kathy Dembrowski). Please state your company.

Ms. (Dembrowski), please check your mute feature.

(Kathy Dembrowski): Yeah?

Coordinator: Your line is open.

Christopher Kelly: Hello, (Kathy Dembrowski), do you have a question for us? Operator, we'll move to the next caller, please?

Coordinator: Our next question comes from (Karlene Olsten). Go ahead.

(Karlene Olsten): My question was also related to fall-on biologics. I'm going to pass on that one.

Christopher Kelly: Okay. Okay. We took that one. Thank you very much operator. This is going to conclude our call for today. Again, for follow up questions that you might have, feel free to contact me by email. That's christopher.kelly@fda.hhs.gov. Thank you all.

Coordinator: This concludes today's conference call. Thank you for your attendance and participation. You may disconnect at this time.

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