FOOD AND DRUG ADMINISTRATION

BEHIND THE COUNTER AVAILABILITY OF CERTAIN DRUGS

PRESS BRIEFING ON PUBLIC MEETING

WEDNESDAY, NOVEMBER 14, 2007

Transcript by:
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CHRISTOPHER KELLEY: Pass code is FDA. This is Christopher Kelley calling. I'm the actual conference leader and I'll need to be clued in with the operator.

TRACY: Okay. This is Tracy.

MR. KELLEY: Tracy, hi. Okay.

TRACY: I'll go ahead and join your – (inaudible) – conference.

MR. KELLEY: Okay.

TRACY: (Inaudible) – couple of minutes till.

MR. KELLEY: Okay. Do we have anybody on the line yet?

TRACY: Yes. I have currently right now we have – (inaudible) – from Bloomberg; we have – (inaudible) – from US News; we have Jim – (inaudible) – from National – (inaudible) – we have John (Host ?) from – (inaudible) – Review News.

MR. KELLEY: Good.

TRACY: Jon Rockoff from Baltimore Sun; Steven Reinberg from HealthDay; and Ann Brice from New Jersey Business Magazine, I believe.

MR. KELLEY: Great, thanks. We've got a whole group here as well. That will be good. So if you want to put me on hold there, I'll come back – I'll come back to you – how do I check back in with you when we're ready to go?

TRACY: I'll come into a conference – (inaudible) – cue yet, so I'll come back. – (Inaudible) – conference, and I'll let you know that I'm there.

MR. KELLEY: Okay, I'm going to be stepping out. I'm going to bring my group in in about three minutes.

TRACY: Okay.

MR. KELLEY: Thanks.

TRACY: You're welcome.

(Background chatter.)

TRACY: I'm here, Mr. Kelly.

MR. KELLEY: Hi, Tracy, how are you? Okay. Good. We are – we're ready to go, and whenever you are.

TRACY: Okay. I'll go ahead – (inaudible) – and I'll turn the conference over.

MR. KELLEY: Okay. Thank you.

TRACY: Thank you for standing by. At this time, all – (inaudible) – is listen only mode. During the question and answer session, please Start 1 on your touchtone phone. Today's conference is being recorded. If you have any objections, you may disconnect at this time. I now turn the meeting over to Mr. Christopher Kelley. You may begin, sir.

MR. KELLEY: Thank you very much. Good evening, everyone. I'm joined today by Dr. Randall Lutter, FDA deputy commissioner for Policy; Dr. Charles Ganley, director at the Office of Nonprescription Products; and Dr. Ilisa Bernstein, director of Pharmacy Affairs, all for FDA. And today, they chaired a panel who listened in on the subject of behind the counter medicines. And I'd like to begin the program by having Dr. Lutter speak about what happened today.

Dr. Lutter?

DR. RANDALL LUTTER: Today, we benefited from a very wide ranging discussion and presentation of views from a variety of stakeholders in the healthcare arena about different views about whether or not increase use of behind the counter access could benefit patients in public health. And the meeting was successful in the sense that there were – there was an open, candid discussion. People shared their presentation of a common goal of promoting public health as a generalization, and we heard from a very wide number of stakeholders, pharmacists, medical societies, over-the-counter drug makers, the National Association of Boards of Pharmacy, retail pharmacies, pharmacy schools and a collection of recognized experts and – (inaudible).

Our own stance at this time, as was explained in the federal register announcement for this meeting, is to solicit public views and public input in – (inaudible) – of clarifying circumstances under which pharmaceutical products may be out behind the counter – (inaudible) – access in improving public health. We will review the comments that we receive today – (inaudible) – comments we receive in writing who are open public docket – (inaudible) – November 28th and at that time we'll evaluate appropriate next steps.

MR. KELLEY: Thank you, Dr. Lutter. We'd like to begin the program with question and answer session today with our reporters here in the room. If you'd like to start, identify yourself and your question. Sue, go ahead.

Q: Sue Sutter, with Scriptworld Pharmaceutical News. Does the agency believe that – (inaudible) – legislative – (inaudible) – to create a – (inaudible) – class drugs – (inaudible). And I know there is also an issue raised about whether or not the FDA amendments act gave FDA additional authority in this are. I wonder if you can comment on that.

DR. LUTTER: The question is whether or not FDA believes that we have authority to create a behind the counter class. I think there's been a variety of views expressed on that point today. The word "class" is not one that we've opined on directly – (inaudible) – there are instances in which drugs in this country are already sold behind the counter. In that sense, the track record on this is clear that some drugs are being sold behind the counter. And at this point, we haven't evaluated any sort of authority with respect to the use of – (inaudible) – class – (inaudible).

DR. ILISA BERNSTEIN: Can I answer that? The purpose of the meeting today is to focus on behind the counter availability and how – whether it will benefit patients, how to do it the right way. And so what we wanted to hear – and we've heard and we're expecting to get more from the comments is how can we increase access from behind the counter availability, and then once we hear that, then we can figure out how do you do that right under do we need more legislation, what sort of authority are – (inaudible).

Q: Dr. Lutter, why do you –

MR. KELLEY: Could you please identify yourself and your –

Q: Yes, of course. (Inaudible.) It's the fourth time, I guess, since 1974 that you've visited – that the agency has visited this issue. Why are you revisiting it?

DR. LUTTER: I think – the question is why are we revisiting this? And I think implicitly is why are we revisiting this now? There's been a collection of changes over the years, and I think most recently they're really driven by an increased trend toward consumer involvement and consumer patient empowerment in their own decisions and responsibilities, what they paid for healthcare. And that's really manifested in part by the Internet and changes that it has – (inaudible) – about, and these days it's fairly common for patients to go to the hospital – (inaudible) – physician – (inaudible) – pull out a laptop and say, well, let me Google what we know about the safety and effectiveness not only the products that we regulate, but also the medical procedures more broadly, and we're also involved on different fronts with trying to communicate the risk to patients – (inaudible) – from unregulated drug sellers – (inaudible) – gone through any sort of oversight or review by FDA or other appropriate regulatory (body ?).

And what you have, therefore, is a phenomenon with the Internet of increased consumer and patient awareness and need for information about their own decision, given that new technology somewhat appropriate time that has now the – (inaudible) – public health to increase the access – (inaudible).

Q: (Inaudible) – pharmaceutical companies also asked for this – I mean, the point was brought up in the meeting that several drugs most probably statins have gone for OTC, they failed and then they might be looking for another avenue. Have they approach you and asked you to reopen this issue – (inaudible)?

DR. LUTTER: We're – we called for this meeting on our own initiative as a result of – (inaudible) – information that we have, the potential merits and whether – (inaudible) – reading the comments in the docket – (inaudible) – internally – (inaudible). So that's why we called the meeting.

MR. KELLY: Thank you. Any questions? Any questions, sir?

Q: Dr. Lutter, what can you say about the recommendations for a pilot program in the sense of how that might affect what the FDA considers doing? I'm Malcolm – (inaudible)? Thanks.

DR. LUTTER: Thank you. Ilisa, do you want to take that one?

DR. BERNSTEIN: Yeah, that – this is the first time, at least I've heard as a suggestion and then unfortunately, at this point, I don't think we're in any position to comment on that because it is the first time we've heard it, and we do have to consider all the other suggestions – (inaudible).

DR. LUTTER: Let me say broadly that, you know, pilots are potentially interesting. They're a way of collecting a lot more information without necessarily committing oneself fully to full-scale immersion, but having said that, the question of whether – (inaudible) – recent pilots as opposed to other pilots that does exactly what we're – (inaudible) – as Dr. Bernstein pointed out, we've heard this proposal for the first time today. So we have to evaluate, review it internally before making decisions – (inaudible).

Q: Another thing that came up today in – although not for the first time, but many times was a role of the state boards. Has the agency had any collaboration or contact which state boards that are on, looking at a behind the counter issue at this point?

DR. LUTTER: Well, this is the collaboration and the context that you see here in this public meeting. So we have a variety of collaborative efforts with the state boards and with the National Association of Boards of Pharmacy in terms of talking with them about behind the counter. This is the process – (inaudible).

MR. KELLY: Thank you. We'd like to move now to any questions we might have from those on the phone line. Operator, could you go ahead and send them on?

OPERATOR: Thank you. We'll go to question and answer session. If you'd like to ask a question, please press Star 1 on your touchtone phone. Please – (inaudible) – record your name clearly when prompted. Your name is required to introduce your

question. To withdraw your request, press Star 2. Again, press Star 1 if you'd like to ask a question. Our first question comes from Steven Reinberg. Your line is open. (Unintelligible.)

Q: Yes. My question is this: Is there a timetable when something like this might happen?

DR. LUTTER: Well, we haven't committed any particular timetable, and I think it depends a lot on what we – what conclusions we reach internally after reviewing that. Only the public comments that we receive today and – but also, the public comments still – that may come into the public docket, which closes on November 28th. So we understand that we've raised certain expectations about action on our part by holding this public meeting. We understand and we're grateful for the interest that were shown today in the room by the variety of stakeholders who not only came to present but also to stay all day. And you can expect that we will endeavor to make public some next steps in the near future. But at this point, we can't be more specific about that timetable.

MR. KELLY: Thank you. Next question, operator?

OPERATOR: Anyone who would like to ask a question, please press Star 1 on your touchtone phone. Currently, there are no additional question for this time.

MR. KELLY: Any further questions from within our reporters here right now?

Q: Okay. (Inaudible) – some places that have Internet access? (Laughter.)

MR. KELLY: Any further follow-up questions?

Q: Actually one more. And – (unintelligible) – what the gentleman just asked. What – is there a possibility of additional meetings of this type or this process?

DR. LUTTER: We haven't envisioned it at this point. We've already got a lot of public comments and we're grateful for those, and – if – I think with respect to future public input, you know, we haven't decided what next steps might be, but if – for example, it involves us issuing a guidance, all of our guidances are issued – (inaudible) – regulation – (inaudible) – as a proposal for public comment and only after soliciting public comment and taking into account might we finalize any guidance that we might issue on this score – (inaudible) – instead to decide, for example, the issue of legislative proposal. Of course, those were also public – (inaudible). So in that sense, you shouldn't anticipate a final action on our part at this point, but instead the next step – (inaudible) – a specific proposal by us – (inaudible) – to allow other parties – (inaudible).

MR. KELLY: Are there any further questions on the phone line?

OPERATOR: (Inaudible) – question, please press Star 1 on your touchtone phone. Currently, we have no additional question for this time.

MR. KELLY: Thank you. As we conclude, I'd like to thank everyone for participating in this call today, and if you have any further questions, I'd be glad to be of assistance to you and helping you with that. You can reach me by e-mail at christopher.kelly@fda.hhs.gov. Thank you all very much.

(END)