FDA Media Briefing on Warning About Risk of Inaccurate Results From Certain Lead Tests
May 17, 2017
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Coordinator: Welcome, and thank you for standing by. At this time, participants are in a listen-only mode until the Question-and-Answer session. To ask a question at that time, please press Star, then 1, and record your name when prompted.

Today's conference is being recorded. If you have any objections, you may disconnect. Now, I would like to turn the conference over to your host, Tara Goodin, with the FDA. Thank you. You may begin.

Tara Goodin: Good morning. This is Tara Goodin with the FDA's Office of Media Affairs. I am here to discuss the FDA Safety Communication and CDC's Health Alert regarding blood testing, issued earlier today.

I'm joined by Dr. Jeff Shuren, the Director of the FDA's Center for Devices and Radiological Health, Dr. Patrick Breysse, Director of the CDC's National Center for Environmental Health, and Dr. Sharunda Buchanan, Director of the Division of Emergency and Environmental Health Services in CDC's National Center for Environmental Health.

We are also joined by representatives of the Centers for Medicare and Medicaid Services and HHS' Office of Assistant Secretary for Preparedness and Response.

After their comments, we'll move to the Question-and-Answer portion of the call. Reporters will be in listen-only mode until we open the call up for questions. When asking questions, please remember to state your name and affiliation. Also please limit yourself to one question and one follow-up, so we can get through as many questions as possible.

With that, I will now turn it over to Dr. Shuren.

Jeff Shuren: Well, thank you. And thank you for taking the time to join us. Today, the FDA is warning that certain lead tests may provide inaccurate results for some children and adults in the United States.

The FDA is concerned that Magellan lead tests that use blood drawn from the vein may provide results that are lower than the actual level of lead in the blood. Now, for this reason today, we issued a warning to laboratories and health care providers not to use Magellan Diagnostics LeadCare Testing Systems with blood samples drawn from the vein, called a venous sample.

We've also been working closely with our colleagues at the CDC to issue recommendations for who should be considered for lead retesting, which Dr. Breysse will share with you shortly.

At this time, the FDA's warning is specific to use of all Magellan lead tests with blood drawn from the vein. We have no evidence that Magellan's tests, when used with blood obtained from the finger or heel stick, are impacted. However, the agency is conducting a thorough investigation to provide assurance that these tests give accurate results in these cases.

Finger and heel sticks are frequently used when testing young children. Further information about our warning can be found in the agency's safety communication, issued today.

In addition, while Magellan Diagnostics' LeadCare Systems are the only FDA-cleared tests specifically for lead, and a primary source of lead testing in doctors' offices and clinics in the United States, they are not the only method

of blood-lead testing. We have no reason to believe that the alternative methods of testing are impacted by this issue.

For this reason, and because the majority of Magellan lead tests currently in use in the United States are conducted using blood obtained from a finger or heel stick, it is also important to note that, at this time, we believe most people will not be affected by this issue.

However, we are strongly urging parents of children and at-risk adults who may have been tested, to speak with their health care provider about the CDC's retesting recommendations.

And before I hand the call over to Dr. Breysse, I also want to share that, as a public health agency, the FDA takes seriously our responsibility to identify and inform Americans of any problems that may arise when a medical device — after it comes to the market. And while communicating this information is our first priority, the FDA is also aggressively investigating this issue to determine the case of the inaccurate results.

In fact, we already have inspectors onsite at Magellan and are working with the CDC on conducting testing that will help us better understand the root cause and other relevant issues. Although this investigation is in its early stages, we do not want to delay in issuing this warning, and we look forward to providing updates as we learn more.

I'll now turn the call over to Dr. Patrick Breysse, Director of the CDC's National Center for Environmental Health, who will share more about the CDC's recommendations for retesting.

Patrick Breysse: Thank you, Dr. Shuren. This is Patrick Breysse. I'm here with Dr. Sharunda Buchanan, as well, to respond to specific questions about CDC's Childhood Lead Poisoning Prevention Program.

CDC has been working closely with FDA on this announcement. It's important to know that a blood test is the best way to find out if your child has been exposed to lead.

Since Magellan LeadCare Test Systems are used throughout the country to conduct these tests, CDC is now issuing a health advisory recommending that health care professionals retest certain children for lead exposure.

CDC recommends health care providers retest blood lead in children who are younger than six years of age as of today, and had a venous blood test result that was 10 micrograms per deciliter or less from a Magellan Diagnostics' LeadCare Test System.

It's important to note that, at this time, capillary blood, which is collected from a finger stick or heel stick, is not part of our recommendation. This applies only to venous blood drawn from the puncture of a vein.

CDC also recommends that health care providers retest currently pregnant or breastfeeding women who had a lead test performed with blood drawn from a vein, again, using the Magellan Diagnostics' LeadCare Test System.

We developed our public health recommendation to protect young children and provide options on what people and health care providers should do. Lead exposure can affect nearly every system in the body. It produces no obvious symptoms and frequently goes unrecognized, potentially leading to serious health issues.

Lead poisoning is particularly dangerous to infants and young children. Some adults are also at risk for lead exposure, including those who work around products or materials that contain lead.

We understand that parents of children and other people affected by this safety alert might be concerned about what this means for their child's health or for their health. CDC recommends parents and others who are affected discuss with their health care provider or Health Department whether retesting is needed.

We are actively engaging our partners in local communities by providing recommendations and information.

Let me repeat our recommendation. CDC recommends health providers retest blood lead in children who are younger than six years of age as of today, they had a test based on a venous blood draw, and the results were 10 micrograms per deciliter or less, and those tests were conducted using the Magellan Diagnostics' LeadCare Test System.

CDC also recommends that health care providers retest currently pregnant or breastfeeding women who had a lead test performed with blood drawn from a vein and, again, using the Magellan Diagnostics' LeadCare Test System. Thank you.

Tara Goodin: Thank you, Dr. Shuren and Dr. Breysse. At this time we will begin the Question-and-Answer portion of the briefing. As a reminder, when asking questions, please remember to state your name and affiliation. Also please limit yourself to one question and one follow-up, so that we can get through as

many questions as possible. With that, Operator, we will take our first question.

Coordinator: Thank you, and as a reminder to ask a question, please press Star, then 1. Our first question comes from Michele Sullivan. Your line is open.

Michele Sullivan: Hi. This is Michele Sullivan. I'm with Frontline Medical Communications. I have two questions. How did this issue first come to light? And what's the difference in the capillary and the venous blood, as far as the test reading out the inaccurate results?

Jeff Shuren: Thank you for that question. So, our Diagnostics' Review Team discovered that the four LeadCare tests may significantly underestimate the amount of lead during the review of a pre-market submission, or 510(k), that we received from the company, in March of 2017.

And it wasn't until we started to ask more questions of the company, starting to peel back the onion, that we had found that the company had underestimated the amount of risk to the public, and that they did not have adequate data and supporting documentation regarding the cause of the problem or the effectiveness of the mitigation that they had put in place in the past. And that has led to us working with the company to move this to the need for a Class I recall, as well as issuing this warning that we're putting out today.

And now, for the difference between venous and capillary, that's something that we are looking into. Right now, we do have evidence of a problem with falsely lower lead-level reading when using venous blood. And I have to say, based upon the information we have today, we don't know how often we see that in samples, we don't know the full scope of how much lower that amount

is – we have very limited data. It shows that it could have wide variability, and that's why, again, we're just early in our investigation, why there's a need to do further testing to figure out the extent of the problem, how big is the problem, and also get a root cause.

But we also have a limited data regarding the capillary testing. And that data so far shows that there's no problem. We're looking into some of the causes, and there may be differences in how the blood is collected, the tubes that may be used for it, or some of the other processing.

And that may account for why there are differences. But again, we're early in our investigation. We're looking into it, and we also doing testing to confirm that there are no problems with the capillary blood test.

Michele Sullivan: Thank you.

Tara Goodin. Thank you, Michele. Operator, we'll take our next question.

Coordinator: Toni Clarke, your line is open.

Toni Clarke: Yes, hi this is Toni Clarke from Reuters. My line went a bit funny when the previous question was asked, so forgive me if it's been answered already.

But yes, again, how did this actually come to your attention? And could you clarify what the chronology was of these products being approved or cleared?

So, if this affects all of these LeadCare devices, then which was the sort of the mother product? Which was the product that got original — with the original PMA product, if there was one? And when, exactly, were the others cleared?

((Crosstalk))

Jeff Shuren: Certainly. So, the very first Magellan test was cleared in 1997. That's LeadCare. The next test, LeadCare II, was cleared in 2005, and this is a point-of-care testing product. So, this is the test that can be used in doctors' offices or clinics and doesn't require well-trained people for using it. It's designed that way.

Then the LeadCare Ultra was cleared in 2013, and the LeadCare Plus was cleared in 2015.

We identified that there is a significant underestimation of the problem through the review of this 510(k) we received in 2017.

The company first became aware that there may be a problem through complaints that they received in August of 2014, and they received a total between August and October.

They did testing at that time, and they concluded that the risk then was negligible. They identified a mitigation, which essentially just is delay processing for 24 hours, and that completely resolved the problem. They communicated with their customers, their customers acknowledged receipt, and that was it. We received some additional information over time, but to date, this was an issue that had been resolved.

In the 510(k) that we received recently, we found information from the company that would indicate that this is a significant underestimation of the risk to the public. We started to ask for the data of what – the mitigation that they used, and did not feel that that data was either adequate regarding what

they thought may have been the cause of the problem, the extent of the problem, or the effectiveness of the mitigation they put in place.

Toni Clarke: Okay, so just so I'm clear — so this affects products. I mean, if the 2017 510(k) had problems, and the 2017 device was predicated on the previous device, which was predicated on the previous one and the previous one, are you going back to look at whether — is it all of these devices that are affected?

And then, again, this one that was cleared in 1997, what was that one based on? So, in other words, what was the original pre-market approval? Or was there never one?

So, I'm just trying to get a sense here of, you know, if this was emerged right now in 2017, and this product is similar to all the other products, you know, what is the nature, technically, of the cause of the misreading in these products, and does it go all the way back?

Jeff Shuren: So, we are currently investigating the cause. However, when those products came on the market, there was testing; there was data that supported the accuracy of those tests coming on.

And the root cause right now – we don't know. It may not be something specific to the test itself. It may have to do with other aspects, including the tubes in which the blood is collected. It may have to do with reactions with the chemicals involved. These are all things that we are looking into as part of our investigation.

Toni Clarke: And that final question about the original PMA; which was the PMA product?

Tara Goodin: Toni, I'm sorry. We have a lot of folks coming on with questions, so we're just going to move on, and we could follow up later.

Toni Clarke: Thank you.

Tara Goodin: Operator, could we take the next question?

Coordinator: Certainly. As a reminder, to ask a question, please press Star, then 1. The next question comes from Roni Rabin. Your line is open.

Roni Rabin: Yes, I'll repeat the question that you didn't have time to answer for her. What was the original PMA product?

Jeff Shuren: The original product is the LeadCare device that was from 1997.

Roni Rabin: And was that a PMA, or was that actually tested and approved — as opposed to cleared? Was it actually…

Jeff Shuren: So, it was cleared, and it was compared to another method already on the marketplace, which we call Gas Furnace Atomic Absorption Spectroscopy.

Roni Rabin: Can you repeat that? Was that also made by Magellan?

Jeff Shuren: No. So, these are instruments that are also regulated by the FDA. They are often used as a comparison to tell how accurate some of the other tests are. And this is one of the methods that's available for testing today. One of the alternative methods that's used, in fact, from the limited information we have, certainly more than half of the testing we see is done by these alternate methods, like atomic absorption.

Roni Rabin: Okay. So, you're saying this was cleared, not approved, but it was cleared even though it wasn't really a similar product on the market made by Magellan. It was a different instrument.

Jeff Shuren: Yes, so the – you don't need another product made by Magellan. There was another test out there. Magellan was now making a test for other kinds of…

((Crosstalk))

Roni Rabin: …to do a 510(k), you don't need another very similar — isn't the 510(k) process based on having a very similar product already on the market?

Jeff Shuren: Yes. We had another testing method out on the market, which was this atomic absorption method that has been out there for a long time. So, Magellan then makes products now for different settings, looking to move into other labs that may not be using this other kind of technology.

That's a comparison, then, to the other method that's on the market. In addition, as part of a 510(k), they provide a lot of testing data on the performance of that test. What's its accuracy?

So, we get a lot of data in the door to look at these tests to make sure they are performing well.

Tara Goodin: Thank you, Dr. Shuren. Roni, we are happy to follow up with you with some information…

Roni Rabin: Yes. I don't know what the comparison is. I don't understand; is that an actual trial? Is that actual data from a study? Or is that just…

Jeff Shuren: Yes. So, this is actual data from a study.

Tara Goodin: And we'll follow up with you, Roni, with more information offline.

Roni Rabin: Okay.

Tara Goodin: Thank you. Operator, can we queue up the next question?

Coordinator: Next question comes from Lynne Peterson. Your line is open.

Lynne Peterson: I think we all have the same questions. And so, if you're going to send something to Roni, send it to everybody that's on this call, because we're all uncomfortable, I think, with what we're hearing.

So, my specific question, though, is – so for three years this has been going on. So, a lot of people have been tested in those three years, and if they're uncomfortable, who's going to pay for it? Who pays for these tests now? Is Magellan paying for it? Or does the parent of the patient or the health care system have to pay?

Tara Goodin: Thanks for your question. Actually, we have a representative from CMS on the phone who is going to address this.

Tim Hill: Right. And this is Tim Hill from CMS. From a coverage perspective, for those – particularly for those kids on Medicaid, we would expect that the Medicaid programs in those states would be covering and paying for the retesting, just as a normal course of business.

For folks who are covered privately, we would encourage folks to consult with their health plan.

Lynne Peterson: And for the — okay. So, I have a follow-up. So, how, if this test has been inaccurate for three years, you approved in 2015 another test. And at that time, did you not go back and look and see this glitch from 2014? Did you not see that?

Jeff Shuren: So, the answer is no. When we were reviewing the 510(k) for the latest test, for the Ultra — rather, for the Plus — we had received data regarding the performance of that test. The data supported that this was an accurate test, and hence, we cleared it on the market and put it on the market.

One of the issues for us is the fact that while this was under review, and the company had identified another issue with the Ultra — which essentially is the same as the Plus, but designed for just different lab settings — that information was not conveyed to us during the 510(k) by the company, in spite of repeated interactions.

The company viewed this as low-risk, fully resolved with their mitigation, and did not convey this at all. This would have been, from our perspective, a material fact, which would go to the performance of the test. This was actually put into labelling as a minor change during the review — no indication regarding the issue going on. And so this is also one of the aspects of our active investigation right now.

Tara Goodin: All right. Thank you, Lynne. Operator, could we queue up the next question.

Coordinator: The next question comes from Steve Reinberg. Your line is open.

Steven Reinberg: Yes, a couple of things. One, how common is using venous blood for lead testing?

Jeff Shuren: Yes, so we have not firm data, but remember too, we're talking both the Magellan tests and the other testing.

So, in the case of Magellan testing, most of the testing is performed on heel stick or finger stick blood. And then we have the other tests — which probably make up more than half of the tests that are performed — are unaffected by this at all.

Which is why, again, most of the testing that has been done for lead in the country would not be subject to the recall or the recommendations that are being made by CDC.

Steven Reinberg: Any idea of how many children or adults are affected?

Jeff Shuren: We don't. What we do know is that for young children, finger sticks and heel sticks are the more common way of testing. And again, even if that is used on the Magellan System, we have no evidence at the present time that there's a problem with those results. That’s why it's so important that parents, adults, talk with their health care provider to find out if they need to be retested and just to follow the CDC's recommendations.

Tara Goodin: All right. Thank you, Steve. Operator, we'll take the next question.

Coordinator: Certainly. As a reminder, if you'd like to ask a question, please press Star, then 1.The next question comes from Tom Burton. Your line is open.

Tom Burton: Hi. Just following up on that question about numbers, do you have any idea how many of these tests have been sold in the United States — that is, the venous tests?

And also, how many of them, or what's the scope of the problem, in places like Flint, Michigan, or Pittsburgh, or other places where either the Municipal water system, or schools like in Newark – to what degree would this affect those situations?

Jeff Shuren: So, the information we have right now is that since the beginning of 2014, there are — and again, these are estimates — probably 8 million tests that were used with the Magellan System to the present time.

The majority of those were for capillary blood – the finger sticks and the heel sticks. We do not have absolute firm numbers. What we do know is the majority of those were finger stick and heel stick.

And I'll turn to maybe CDC to talk about Flint.

Patrick Breysse: Yes, so this is Patrick Breysse. So, we're fortunate, because of our ongoing involvement in Flint, and response to the water crisis there, that we have pretty detailed information on testing in Flint. And in 2016, CDC recommended that all children less than six years of age in Flint get retested as part of the response to the crisis.

And when we look at those data, we've determined that less than 1 percent of the children who were tested from 2016 going forward, which represents the overwhelming majority of children in Flint, were done with tests that were not impacted by the Magellan Test System — so in venous blood.

So, the vast majority — less than 1 percent, perhaps — might be at risk for being underestimated because they were a venous draw that were tested on the Magellan System.

Tom Burton: And again, what about places like Newark or the Pittsburgh water system? School systems that have discovered problems – any sense of the scope of how they may be affected?

Patrick Breysse: So, we just don't have the level of data specificity that we did for Flint for those communities. However, when we're asking people to go talk to their health care provider, their health care provider will know where their lead tests were sent, and knowledge of that will help determine whether children need to be retested or not.

Tom Burton: Okay. Thanks.

Tara Goodin: Thank you, Tom. And I think this – we'll get to our last question, Operator. Can you share the next…

Coordinator: Certainly. The next question comes from Linda Johnson. Your line is open.

Linda Johnson: Hi. Most of my questions have been answered already, but I want to go back to this thing about who is paying for this. So, Magellan screwed up, and they're expecting people to pay for retesting? What about all the people who pay out-of-pocket? And why should insurers and the taxpayers, through Medicaid, be on the hook for the retesting?

Tara Goodin: CMS, Mr. Hill, can you help with this question?

Tim Hill: I can answer from — our first priority, obviously, right now is to make sure that folks get retested if they need to get retested. It's up to the Medicaid program. And kids, we want to be sure that happens and don't want reimbursement necessarily to hold up the retesting from occurring.

It's my understanding that the sort of conversations with Magellan are ongoing, in terms of what happens next, and so speaking as to whether or not Magellan has liability or not is not something I can speak to. I don't know if somebody from FDA can speak to that.

Tara Goodin: All right. Well, we're happy to follow up on that question with you, Linda, and as I mentioned, this is – that brings us to the end of our session, concluding today's media briefing.

Thank you for joining us. A replay will be available in about an hour, and it will be available until June 30th. And please remember to check the FDA's website for our press release and safety communication, as well as CDC's website for the health alert. Thank you again for your participation.

Coordinator: Thank you for your participation in today's call. Participants, you may disconnect. Speakers, please stand by.

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