

**FDA Media Briefing on the approval of the
first domestic supply of the most commonly used medical isotope in diagnostic imaging**

Feb. 8, 2018 2:30 p.m. ET

Coordinator: Welcome and thank you for standing by. At this time all participants are in a listen-only mode until the question-and-answer session of today's conference. At that time to ask a question press Star, "1" on your phone and record your name at the prompt.

This call is being recorded. And if you have any objections you may disconnect at this time. I would now like to turn the call over to Lauren Smith Dyer. Ma'am, you may begin.

Lauren Smith Dyer: Thank you. Good afternoon and thank you for joining today's call. My name is Lauren Smith Dyer and I'm with the FDA's Office of Media Affairs. This is a media briefing to discuss the approval of the radiogenic system, a unique system for producing technetium Tc 99m which will help ensure a stable and secure supply of this critical radioactive imaging product used to detect potentially life-threatening diseases.

By now the news release for this announcement has been issued and posted to the FDA's Website. Today I'm joined by Dr. Janet Woodcock, Director of the FDA's Center for Drug Evaluation and Research. And Dr. Louis Marzella, Director of the Division of Medical Imaging Product in the FDA's Center for Drug Evaluation and Research.

We are also joined by Mr. Peter Hanlon from the Department of Energy's National Nuclear Security Administration; which was involved in the development of the radiogenic system. Additionally I'd like to introduce Dr. Donna-Beth Howe from the Nuclear Regulatory Commission which oversees

the production, distribution, possession and use of radioactive materials as well as products containing radioactive materials.

Dr. Woodcock and Mr. Hanlon will both provide remarks on today's action. Following their remarks we will move to the question-and-answer portion of the call. Reporters will be in a listen-only mode until we open the call up for questions.

When asking a question please state your name and affiliation. Also please limit yourself to one question and one follow-up so we can get to as many questions as possible. And with that I will now turn the call over to Dr. Woodcock with the FDA.

Dr. Janet Woodcock: Thank you Lauren, and good afternoon to those of you on the phone. I'm particularly pleased to welcome our colleagues from the NRC and NNSA. Without them we wouldn't be here today to discuss a novel technology that not only will improve and possibly save lives, but also contribute to enhanced national security.

I'd like to share some background about the FDA's role in approving the radiogenic system starting with information on the importance of medical imaging. Diagnostic imaging typically uses a drug in combination with a scanner to visualize parts of body or its function. And there are many different technologies are used but you're probably familiar with including (SPECT) PET, MRI, CT or ultrasound.

All this is diagnostic imaging. Healthcare professionals across the world rely on these technologies to detect and treat life-threatening diseases like cancer or heart disease. Nuclear medical imaging is one of these vital detection tools.

More than 80% of diagnostic imaging in the United States relies on nuclear imaging.

But a necessary component of many nuclear imaging procedures, a radio pharmaceutical isotope called technetium Tc 99m commonly used in SPECT scanning requires a – currently a complex chemical reaction and complicated supply chain to produce.

This has led to unexpected challenges such as shortages or unreliable supply. Before today molybdenum 99, the parent of technetium 99m, can only be made from highly enriched uranium by several facilities outside the U.S. Production involved shipping uranium from the U.S. to the international facilities. There the material underwent a physical reaction and several purification steps before shipping the medically useful molybdenum 99 back again.

This complex process left the U.S. vulnerable to possible shortages and supply chain issues. In fact the most severe shortage of molybdenum 99 occurred in 2010. It had a major impact on the ability to conduct standard nuclear imaging procedures. As a result clinicians had to shift to alternative isotopes. It could have exposed patients to higher doses of radiation, especially if they needed multiple imaging procedures.

Patients had to wait to undergo their procedure until the drug was available again or potentially choose a less optimal testing method. To address these challenges Congress enacted the American Medical Isotopes Production Act of 2012. The Act contained provisions to eliminate the use of highly enriched uranium for medical isotope production.

It also encouraged the development of U.S. domestic supplies of molybdenum 99 and associated isotopes. Now many federal agencies including FDA, the NRC as well as the Department of Energy's National Nuclear Security Administration and National Laboratories have been working together with industry to develop a technology that minimizes dependence on highly enriched uranium and brings the supply chain within the U.S.

As a result of this collaboration the U.S. medical community will now have a domestic source of technetium 99m through the use of the radiogenic system which marks the first non-uranium process for the production of molybdenum 99 to prepare the technetium 99m.

So today's approval will help ensure more reliable, clean and secure access to this important imaging agent for nuclear medicine. The FDA worked with the manufacturer to make sure the process of producing technetium 99m meets all the pharmaceutical and microbiological quality standards that we have for all drug products.

FDA nuclear chemists, microbiologists, engineers and a broad range of scientists and medical professionals from both the Center for Drug Evaluation and Research and for Devices and Radiologic Health provided important scientific and technical expertise throughout the development of this innovative technology.

This involved working hand-in-hand with a sponsor to ensure they included the necessary safety and efficacy data in the application to support the product's approval. Because of this collaboration the FDA was able to efficiently review this application and confidently assess that the product met the agency's rigorous standards.

We thank our colleagues across the U.S. government who've made today's action possible. So now I'll turn it over to Peter Hanlon with the NNSA to share more about their role in the development of this technology.

Peter Hanlon: Good afternoon. My name is Peter Hanlon. I'm the Assistant Deputy Administrator for the National Nuclear Security Administration's Office of Material Management Minimization.

Today's announcement is a significant achievement for the U.S. economy, healthcare and national security. For the last seven years the Department of Energy's NNSA has provided critical financial and technical support to NorthStar as they worked to establish production of moly-99 produced here in the United States without the use of highly enriched uranium, HEU.

Today's approval from the FDA paves the way for NorthStar to become the first U.S. company in 30 years to produce moly-99 domestically for patient's use. This is a win for America's infrastructure and innovation. The U.S. patients no longer have to rely solely on moly-99 imported from foreign partners. This is a win for our economy.

NorthStar's new plant in Beloit, Wisconsin brings jobs and opportunity to America's heartland. This is a win for healthcare. NorthStar's entry into the U.S. market will help ensure that U.S. patients get the critical care they need. And finally this is a win for our national security.

NorthStar produces moly-99 without the use of highly enriched uranium, a material that could be used in nuclear weapons.

Thank you.

Lauren Smith Dyer: Thank you Dr. Woodcock and Mr. Hanlon. At this time we will begin the question-and-answer portion of the briefing. When asking a question please remember to state your name and affiliation. Also please limit yourself to one question and one follow-up so we can get to as many questions as possible.

Operator, we'll take the first question please.

Coordinator: Thank you. Again as a reminder if you'd like to ask a question please press Star, "1" on your touchtone phone. Make sure your phone is unmuted and record your name clearly when prompted. If you need to withdraw your question please press Star, "2". Again to ask a question please press Star, "1" and record your name. We'll take a moment for questions to come through. Please stand by.

And our first question comes from (Lynn Peterson). Your line is open.

(Lynn Peterson): Hi. Two and a half years ago – in November of 2015 I actually wrote about this issue. And at the time it looked like there were multiple companies, at least two companies, that were working to do domestic production. Is this just the first of what we expect will be others?

Dr. Louis Marzella: This is Louis Marzella. Yes, indeed. The initial activity was to actually fund four different manufacturers. The NorthStar is just the first of what we hope will be a long list of other producers. And the FDA is currently working with the other, if you will, contenders.

So and in addition I should say that the radiogenics system is envisaged as being a platform really for other isotope production. So it's a very exciting first step.

Peter Hanlon: I would also like to add that NNSA - in addition to NorthStar as you quite rightly pointed out there are two other companies that we are supporting in our efforts to get domestic moly-99 supply. Those other companies include Shine Medical Technologies and General Atomics.

Lynn Peterson: Could I do a follow-up question?

Peter Hanlon: Sure.

Lauren Smith Dyer: Please go ahead.

Lynn Peterson: Okay, thanks. How much of the U.S. demand could NorthStar meet?

Peter Hanlon: NorthStar's early production is – they're just starting out but with time they could be – as they develop their process they could supply about 2/3 of the demand.

Lynn Peterson: Thanks very much.

Coordinator: Our next question comes from Timothy Gardner with Reuters. Your line is open.

Timothy Gardner: Oh thank you. Following up on that last question – so at some point NorthStar could supply 2/3 of the U.S. demand. What will it do for, you know, the first year or so. I mean my understanding was it was quite a bit less than that like maybe 10% to start out. Is that – does that sound right? And so it does seem, you know, since there's two other projects that it – at one point that hope – that at some point the hope is to get 100% non-ATU U.S. production of this. Correct?

Dr. Louis Marzella: This is Louis Marzella. If I may point out, the really innovative portion of this approval today is that this is a totally non-fission process for developing molybdenum 99. So it's a – the government – the legislation of – put an emphasis and a premium on shifting from highly enriched uranium to low enriched uranium because of the concerns with diversion of this highly fissionable material.

But the critical aspect of today's approval is that this is a completely non-uranium based process for development. So we are very excited about that for the obvious implications for the broader public health.

Peter Hanlon: But in (consistive) your question you are correct. Over at DOE NNSA our program is to ensure or to support the domestic supply of moly-99 without HEU. And it is – our program is to fully stride to have at least two companies producing moly-99 to ensure redundant, reliable supply of this isotope.

Timothy Gardner: So at first NorthStar would product about 10% of U.S. demand and that will move up to about 2/3?

Peter Hanlon: That is correct.

Timothy Gardner: And if I could – how long will it take to get to 2/3 approximately?

Peter Hanlon: I think NorthStar would have to speak to their actual business plans.

Lauren Smith Dyer: Operator we'll take the next question please.

Coordinator: Thank you. The next question comes from Elizabeth Orr with Medtech Insight. Your line is open.

Elizabeth Orr: Hi, thanks for taking my call. I wanted to check on what kind of FDA approval was this? Did it go through CDRH or through the Drug Center and also how long was it from the first pre-submission meeting until the approval was issued today?

Dr. Janet Woodcock: This is Janet Woodcock. This is a drug approval because this is regulated as a drug. But, you know, there are sort of device components and we worked very closely with the device Center in this.

We can't comment on exact timeline of different regulatory actions but we've been working as I said in my remarks hand-in-hand with the company all along during development and with our other federal partners to make this happen.

So this has been a long and intense process of collaboration over five years or so amongst these various parties, all putting their heads together to try to figure out how we could get this done.

Dr. Louis Marzella: And if I may add, this is Louis Marzella again; the other truly innovative aspect of this approval today is that the separation process for isolating the technetium from the molybdenum is truly, truly a dramatic innovation. And so in order to achieve this there were, you know, without going into details there were a number of experts that had to contribute to talk about, you know, the various fluid paths, the critical aspects related to the associated technology, the use of interface.

So the bottom line is that the innovation aspect related not only to the source for producing molybdenum but also for the separation technology which is truly groundbreaking. And which required the active iterative participation of a lot of FDA experts.

Lauren Smith Dyer: Operator, we'll take the next question please.

Coordinator: Thank you. Our next question comes from David Kramer with Physics Today. Your line is open.

David Kramer: Hi, thanks. My understanding is that this process uses neutrons from the motor reactor; which just happens to be fueled by HEU. So – but leaving that aside does the FDA approval apply only to this neutron capture process and not to the spallation process by accelerator that's also being pursued by NorthStar?

Dr. Janet Woodcock: You know, we're afraid we can't comment on that particular item. As I said – this is Janet Woodcock from FDA. We're kind of – we're limited on what we can talk about with regard to applications before us or potential questions such as the one you might have.

Dr. Louis Marzella: So this is Louis Marzella again. The point to underscore is that the product, the ultimate medically useful product is the same. And it can be prepared using the standard technology or various different innovations. So this particular approval is for a specific process. And any further questions about technical details I would refer you to the company for.

Dr. Janet Woodcock: Yes.

Coordinator: I'm showing no further questions in the queue at this time.

Lauren Smith Dyer: Okay, thank you very much. Thank you again for joining us today. As a reminder, the press release and statement can be accessed on our Website. This concludes today's media briefing. A replay will be available in about an hour and will be up for about 30 days. Thank you.

Coordinator: Thank you. That concludes today's conference. Thank you for participating and you may disconnect at this time.

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