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SECURING THE U.S. DRUG SUPPLY CHAIN: OVERSIGHT OF FDA'S FOREIGN INSPECTION PROGRAM

TUESDAY, DECEMBER 10, 2019

House of Representatives,

Subcommittee on Oversight

and Investigations,

Committee on Energy and Commerce,

Washington, D.C.

The subcommittee met, pursuant to call, at 10:04 a.m., in Room 2123, Rayburn House Office Building, Hon. Diana DeGette [chairman of the subcommittee] presiding.

Present: Representatives DeGette, Schakowsky, Kennedy, Ruiz, Kuster, Castor, Tonko, Clarke, Pallone (ex officio), Guthrie, McKinley, Griffith, Brooks, Mullin, and Walden (ex officio).

Staff Present: Kevin Barstow, Chief Oversight Counsel; Jeff Carroll, Staff Director;

Manmeet Dhindsa, Counsel; Austin Flack, Staff Assistant; Tiffany Guarascio, Deputy Staff Director; Chris Knauer, Oversight Staff Director; Kevin McAloon, Professional Staff Member; Kaitlyn Peel, Digital Director; Tim Robinson, Chief Counsel; Nikki Roy, Policy Coordinator; Emily Ryan, GAO Detailee; Andrew Souvall, Director of Communications, Outreach and Member Services; Benjamin Tabor, Staff Assistant; C.J. Young, Press Secretary; Jennifer Barblan, Minority Chief Counsel, Oversight and Investigations; Diane Cutler, Minority Detailee, Oversight and Investigations; Peter Kielty, Minority General Counsel; Ryan Long, Minority Deputy Staff Director; Brannon Rains, Minority Legislative Clerk; Kristin Seum, Minority Counsel, Health; and Alan Slobodin, Minority Chief Investigative Counsel, Oversight and Investigations.

Ms. DeGette. The Subcommittee on Oversight and Investigations will now come to order.

Today, the subcommittee is holding a hearing entitled, "Securing the U.S. Drug Supply Chain: Oversight of FDA's Foreign Inspection Program." The purpose of the hearing is to examine the Food and Drug Administration's ability to effectively oversee the quality of drug products manufactured in foreign countries.

The chair now recognizes herself for purposes of an opening statement.

Today's hearing focuses on an area of longstanding concern to this committee that has taken on increased importance: The safety and effectiveness of pharmaceutical products made in foreign countries. Between 70 and 80 percent of active pharmaceutical ingredients and 40 percent of finished drugs are made outside the United States. In particular, China and India produce a significant portion of the U.S. drug supply.

Because the FDA can't possibly test every new drug that comes into the U.S., inspections of drug manufacturers abroad are a critical way to ensure that manufacturers around the world are following quality standards and producing drugs that are safe and effective for the American public. However, the history of the FDA's foreign drug inspection program is one of challenges and incremental progress. As far back as 1998, the GAO has been raising concerns with the FDA's foreign inspections.

This committee has a long history of oversight in this area. For example, in 2007, we held a hearing about weaknesses in the FDA's foreign inspections program. At that time, the agency was not conducting frequent inspections abroad and did not have reliable data even to know how many firms it needed to inspect.

FDA also struggled to hire inspectional staff, and its inspectors did not have reliable translators to help them conduct inspections in foreign language countries. I remember that hearing because I was there, and it was shocking.

The year after that hearing, the world was reminded why securing the global pharmaceutical supply chain is critical, when it was discovered that tainted ingredients were used to produce heparin, which is a critical drug used in surgery and during dialysis. As a result of that mishap, Americans died, drug shortages occurred, and many lost confidence in FDA's ability to regulate drugs manufactured abroad.

GAO's reports over the years have also noted vulnerabilities in how FDA regulates foreign drug manufacturing. For example, in 2010, GAO found that FDA may never have inspected most foreign firms. FDA was also struggling to staff up its foreign offices, which were intended to make foreign inspections more efficient and effective. Because of these and other issues, GAO placed FDA's foreign inspections program on its high-risk list over 10 years ago.

Now, in response to these challenges, Congress increased FDA's resources to conduct foreign inspections and granted the agency new authorities over foreign firms. As a result, the number of inspections FDA conducted increased overseas, and the FDA implemented a risk-based approach to select firms for inspection, regardless of whether they were domestic or foreign.

Now, these were significant improvements, but here we are back today because FDA's foreign inspection program still has some unresolved challenges. In the GAO's written testimony today, there are reports on the results of its recent travel overseas to evaluate FDA's work. GAO still found some of the same issues, unfortunately, that have been hindering FDA's foreign inspection program for years.

The number of foreign inspections dropped in the last 2 years, after years of increases. Furthermore, when FDA conducts inspections in foreign language-speaking countries, it still relies on the firm itself to provide a translator, raising questions about impartiality. And despite the new resources, FDA continues to struggle to hire enough inspectors, including in the foreign offices, and frankly, there are some real barriers to being able to do that.

These challenges take on real meaning when we see reports of potentially unsafe products in the market. Over the last year and a half, FDA has been announcing widespread recalls of popular medications used by millions of Americans to treat blood pressure and heartburn because of trace amounts of carcinogens identified in multiple versions of these drugs.

Now, I understand each of these recalls involves its own particular causes and factors, but taken together, they raise larger issues, and I'm really -- Dr. Woodcock, I'm very happy you're here today, because I look forward to hearing what the agency's response is to these new GAO findings.

Before I close, I just want to emphasize a couple final thoughts. First, the issues today affect both brand and generic drugs. Many foreign firms provide the active pharmaceutical ingredients used in both brand and generic versions of drugs, so this can happen throughout the supply chain.

And finally, I want to emphasize, this hearing should not be interpreted as an indictment of foreign drug manufacturing generally. Americans should not feel that they cannot trust medicines made abroad, nor should we swear off foreign-made drugs. In fact, we're increasingly reliant on foreign manufacturers, but we do need to make sure that all of these issues which have been persistent for many, many years continue to be

addressed.

And with that, I want to thank both of our witnesses for appearing today. And I'm going to yield to the ranking member of the full Energy and Commerce Committee, Mr. Walden, for purposes of his opening statement, 5 minutes.

[The prepared statement of Ms. DeGette follows:]

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Mr. Walden. Thank you very much, Madam Chair. And I want to thank Ranking Member Guthrie for yielding to me. We've got another hearing I have to get at that conflicts with this one, so -- and I want to thank our witnesses for being here. And, Madam Chair, thank you for holding this really important hearing, because our drugs and drug ingredients more and more are coming from overseas, especially from China and India, and manufacturers have ultimate responsibility for the safety and effectiveness of these products.

But the FDA has an indispensable role to protect public health, which I know you all take very seriously, by ensuring that drug firms are complying with good manufacturing processes and practices. Through this hearing, I hope FDA can further strengthen its ability to fulfill its public health mission and to protect the safety, effectiveness, and integrity of the U.S. drug supply.

Today, we have the benefit of the Government Accountability Office, their analysis, to assist us in our work. Over the years, GAO has provided invaluable work to this committee on FDA's foreign drug inspection program, and not long ago, the GAO reported that the FDA was not conducting enough drug inspections overseas and lacked the resources and authorities to adequately meet this inspection need. This committee responded by enacting the Food and Drug Administration Safety Innovation Act or -- we'll just leave it at that, and the Generic User Fee Act, or GDUFA -- they have all these UFAs and ASIAs and DASIAs and -- well, anyway, FDA now has additional resources and authorities, and to FDA's credit, has addressed the previous disparity between the number of domestic and foreign inspections conducted.

Earlier this year, as you know, the committee again asked the GAO, on a bipartisan

basis, to evaluate the current state of the foreign drug inspection program. While progress has been made in some areas, the GAO's preliminary observations indicate the FDA continues to face persistent challenges in its ability to conduct foreign drug inspections and particularly in India and China. This is concerning because the FDA is identifying serious deficiencies during many foreign inspections.

Now, for years, the FDA leadership has spoken of transforming the agency into a global health organization, particularly in addressing imported drugs. But even with that stated priority and the influx of user fees, FDA has told the GAO and this committee that it can't hire enough inspectors to fill vacancies among staff conducting foreign inspections. Now, having sufficient numbers of inspectors is not a new problem. The need to hire additional inspectors was part of the reason that Congress gave the FDA the authority to collect user fees for generic drugs.

Today, FDA not only has vacancies in its foreign offices, but also does not have enough inspectors in its dedicated foreign drug cadre. The FDA recently received direct hire authority to address this problem, and I have questions today about how this authority will be used to fill these vacancies, as well as about FDA's hiring and retention efforts the past 6 years.

Other challenges to FDA's foreign drug inspection program remain, and unlike domestic drug inspections, most foreign drug firms actually receive advance notice of an FDA inspection. And when the FDA inspectors are traveling from the United States, which is often the case in most foreign drug inspections, the FDA preannounces inspections and foreign drug firms generally get 12 weeks in advance with a notice on when the FDA inspectors are coming to their plants. The concerns raised by recent investigative reports is this system gives plants ample time to clean up evidence of

unsanitary conditions, wrongdoing, or data manipulation.

And I would just say as a side note, having been a licensee of the FCC for 21 years, in the radio business, I always would have liked to have had a 12-week notice in advance when the FCC was coming to inspect our station. We never got a fine, but we would have made sure everything was completely in order. It always was.

In 2014, to address these issues, the FDA instituted an initiative in India, giving plants only short or no advance notice of inspections, and as a result, the serious violations uncovered by inspectors rose by almost 60 percent. So the initiative was discontinued in 2015. FDA told the committee they discontinued the initiative because it lacked protocols and evaluation criteria.

However, the FDA still must believe there's value to short-notice inspections because you do conduct such inspections in for-cause situations and conduct short-notice inspections domestically.

Finally, in about 80 percent of the inspections, FDA sends only one inspector, who is often reliant on the drug firm's employees or agents to do the translation. What could go wrong there? This solitary inspector, relying on the firm for translation and perhaps even travel arrangements, is allocated only a few days for the difficult task of inspecting a drug plant that can be the size of a small city.

Meanwhile, the drug firm has about 3 months' advance notice of the inspection. If the firm's unscrupulous, that's more than enough time to subvert regulations by fabricating records and concealing actual conditions. I think you get the point. So FDA needs to respond to the overall challenges of foreign drug inspections with more vigor. As they said in "Jaws," you're going to need a bigger boat. So we must maintain public confidence and trust in our drug supply chain, and we look forward to working with you

to make that happen.

Madam Chair, thank you for having this hearing.

[The prepared statement of Mr. Walden follows:]

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Ms. DeGette. Thank you so much, Mr. Walden.

The chair now recognizes the chairman of the full committee, Mr. Pallone, for 5 minutes.

The Chairman. Thank you, Chairwoman DeGette.

Today, the committee continues its long-time work of conducting oversight of the FDA's foreign drug inspection program. The program is a key piece of our efforts to ensure that the prescription drugs Americans take every day are safe and effective. Under the law, any firm, whether it's basically -- whether it's based domestically or overseas, that seeks approval to market a drug in the U.S., must comply with the FDA's current good manufacturing practice regulations.

Both foreign and domestic firms are held to the same standards which lay out the essential quality controls that ensure drugs are safe for use, and those standards also apply equally to both brand and generic manufacturers. While it's up to the manufacturers to take the necessary steps to implement the CGMP practices, FDA is tasked with inspecting facilities around the world to verify they're in compliance.

In the past, the committee found that FDA was woefully unprepared to take on the challenge of regulating and inspecting foreign drug manufacturers. As part of our ongoing oversight of this program, we found that foreign firms were not being inspected with regular frequency, and FDA had no permanent presence overseas, and its databases could not even tell what firms were actively shipping products to the United States.

And as a result of those disturbing issues, in 2012, Congress passed, and the President signed, the Food and Drug Administration Safety Innovation Act of 2012, and that law changed the way FDA selects firms to inspect, allowing it to focus on more

high-risk facilities including those abroad. It also increased FDA's authority over foreign manufacturers.

Then in 2013, the Drug Quality and Security Act provided FDA with track-and-trace authority to give the agency more tools to counter potentially dangerous drugs in the supply chain. And again in 2017, Congress provided more resources to FDA's foreign inspection program through the Generic Drug User Fee Amendment.

Now, despite these new authorities and resources, FDA's foreign drug inspection program continues to face challenges. For instance, the number in foreign inspections has actually declined the last 2 years. This is troubling because FDA has been making progress in inspecting more facilities, up until 2 years ago, and FDA also continues to struggle with hiring staff to conduct foreign inspections.

Again, this is all disturbing considering that Congress provided the generic drug user fees in part to fund foreign inspections. And I'm interested in hearing from the FDA on why the number of foreign inspections has declined in recent years and what's preventing them from reaching its capacity.

Now, today's hearing focuses on FDA's efforts, manufacturers have the responsibility to guarantee their products are safe and effective. We have to do what we can to ensure that manufacturers continue to produce high-quality drug products, including through innovative methods such as continuous manufacturing. Those methods, not only help control quality, but also enable firms to compete in the global market.

And this one final point I'd just like to keep in mind is that the issues we'll be discussing today affect all kinds of drugs throughout the supply chain. Much of the press coverage has framed these issues as a generic drug issue, but the fact is that the

majority of active pharmaceutical ingredients for both generics and brands come from foreign countries.

Generic drugs have saved Americans billions of dollars and are critical to lowering healthcare costs across the board. FDA must ensure that any company, whether brand or generic, that wishes to market drug products in the U.S. adheres to the same quality standards. That not only provides a level playing field but confidence in American consumers that the drugs they're taking will be safe and effective.

So, again, I look forward to hearing from our witnesses about what's being done to ensure that confidence and what more is needed to secure the Nation's drug supply. And unless anybody wants my minute, I'm going to yield back. Thank you, Madam Chair.

[The prepared statement of Chairman Pallone follows:]

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Ms. DeGette. The gentleman yields back.

The chair now recognizes Mr. Guthrie for 5 minutes.

Mr. Guthrie. Thank you, Chair DeGette, for holding this very important hearing.

The adequacy of FDA's oversight of the U.S. drug supply has been a longstanding issue for this committee. This committee has long been at the forefront of increasing access to reducing the price of drugs in the United States, particular in our effort to expand access to generic drugs.

Over the last three decades, the pharmaceutical industry has been globalized, and drug manufacturing has shifted significantly from the United States to overseas. Today, about 80 percent of ingredients for America's drug supply are manufactured overseas, and roughly 40 percent of drugs in the finished form are imported.

FDA has the responsibility to monitor the safety and effectiveness of drugs through inspections of drug manufacturing. Over the years, the Government Accountability Office has reported that the FDA has been slow to make recommended changes to the foreign drug inspection program in response to a globalized environment.

In 2012, this committee bolstered FDA's foreign drug inspections with additional authorities in the Food and Drug Administration Safety Innovation Act and funding through the Generic Drug User Fee Act. With this support, the FDA has increased the number of foreign drug inspections from 333 in 2007 to 935 in 2018. Through a recent agreement with the European Union on greater cooperation on drug inspections, the FDA has even more resources to focus drug inspections in high-risk facilities.

While important improvements have been made, FDA has persistent challenges. Past GAO reports and investigative reporting have raised concerns about the ability of

FDA to oversee a globalized supply chain when 80 percent of the inspections involve only one inspector. Translation is often provided by the firm to be inspected, and most of the inspections are preannounced with firms getting 2 to 3 months' advance notice.

In contrast, domestic facilities are usually inspected without notice. These conditions are concerning because there have been notable cases of systematic falsification and deception by firms determined to subvert FDA regulations. Putting FDA at this kind of disadvantage against such misconduct is not acceptable, particularly when we're talking about drugs consumed by millions of Americans daily.

The FDA has known for decades about the need to globalize its foreign inspection program and operationalize it effectively. A strategy is needed to change the unbalanced dynamic where domestic facilities are usually inspected without notice, yet foreign facilities are given up to 3 months to prepare.

Despite the additional resources provided by user fees since 2013, it appears the FDA has a deficit of inspectors for several years. For staff based in the United States, FDA management should consider every tool available for creative hiring incentives and consult with other Federal agencies who effectively staff similarly situated personnel.

FDA getting direct-hire authority is a good start, but more must be done to increase hiring, and just as important, retain and promote inspectors who take on these responsibilities. With additional staff, FDA should increase the number of inspections conducted by teams rather than a single inspector and with translators independent of the firm being inspected.

Surveillance inspections are data-dependent, yet the potential for negligent or corrupt business practices overseas is well known. A trust-based inspection system must be closely evaluated to assess the true usefulness of data, information accepted at

face value from the foreign-based facilities.

With the majority of drug ingredients in drugs being imported into the U.S., we are vulnerable to drug shortages, compromises in quality, and reliance on foreign sources. The question for FDA should not be how do we find solutions; instead, the question should be how quickly can we put solutions into action to continue to make sure America's drug supply is safe.

On another note, while I know it's not the direct focus of today's hearing, I want to emphasize that lowering drug prices is one of the top things I hear back home and one of my top priorities as a member of this committee. I am disappointed that this week we are going to go through -- pursue partisan legislation on the floor instead of bipartisan policies that have broad support.

I look forward to working with my colleagues to advance bipartisan reform that will actually lower drug prices while preserving innovative research. The FDA must maintain the public's confidence in America's drug supply by ensuring it has smart, effective foreign drug inspection program strategy that is not just planned or discussed but is both operational and successful. I welcome the witnesses, and I look forward to the testimony.

I yield back.

[The prepared statement of Mr. Guthrie follows:]

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Ms. DeGette. The gentleman yields back.

I ask unanimous consent that the members' written opening statements be made part of the record.

Without objection, so ordered.

I would now like to introduce our witnesses for today's hearing, Dr. Mary Denigan, who's the director of Healthcare, Government Accountability Office. Welcome. And Dr. Janet Woodcock. We usually just have a reserved seat for you at all times, Dr. Woodcock. Thank you for being back with us today. She's the director of the Center for Drug Evaluation and Research at the U.S. Food and Drug Administration.

Both of you are aware that the committee is holding an investigative hearing, and when doing so, we have the practice of taking testimony under oath. Do you have any objections to testifying under oath?

Let the record reflect the witnesses responded no.

The chair then advises you that under the rules of the House and the rules of the committee, you're entitled to be accompanied by counsel. Does either of you wish to be accompanied by counsel?

Let the record reflect the witnesses have responded no.

If you would, then, please rise and raise your right hand so you may be sworn in.

[Witnesses sworn.]

Ms. DeGette. Let the record reflect the witnesses have responded affirmatively, and you're now under oath and subject to the penalties set forth in title 18, section 1001 of the U.S. Code.

The chair now will recognize our witnesses for a 5-minute summary of their

written statements. In front of each of you is a microphone and timer and a series of lights. The timer will count down your time, and the red light will turn on when the 5 minutes has come to an end.

Now I'd like to recognize you, Dr. Denigan, for 5 minutes.

TESTIMONY OF MARY DENIGAN-MACAULEY, PH.D., DIRECTOR, HEALTH CARE, GOVERNMENT ACCOUNTABILITY OFFICE; AND JANET WOODCOCK, M.D., DIRECTOR, CENTER FOR DRUG EVALUATION AND RESEARCH, U.S. FOOD AND DRUG ADMINISTRATION

TESTIMONY OF MARY DENIGAN-MACAULEY, PH.D.

Dr. Denigan. Chair DeGette, Ranking Member Guthrie, and members of the subcommittee, thank you for the opportunity to discuss preliminary findings from our ongoing work, examining FDA's foreign drug inspection program. It is imperative that Americans have access to safe and effective drugs, whether produced here or abroad. Today, the majority of brand-name, generic, and over-the-counter drugs are manufactured overseas, primarily in India and China. However, we have had longstanding concerns about FDA's ability to oversee the increasingly global supply chain.

In 1998, we reported the FDA had significant problems managing its foreign inspection data and conducted infrequent inspections of foreign establishments compared to their domestic counterparts. Since then, we have returned to the topic multiple times and found that many of these problems persist.

In 2008, for example, we determined that, because of inaccurate data, FDA did

not know how many foreign drug establishments were subject to inspection. In addition, we found that FDA continued to inspect relatively few foreign establishments and that when it did, investigators faced unique challenges that influenced how the inspections were conducted.

For example, unlike in the United States where an establishment has no notice that an investigator is coming, FDA routinely gave foreign manufacturers significant notice. Further, FDA investigators had to rely on English-speaking employees of the very establishment that they were inspecting to translate, including key documents that demonstrated compliance with good manufacturing practices.

In 2010, we found that while FDA was conducting more inspections overseas, many establishments had still never been inspected. We also identified shortcomings in the operations of the foreign offices that FDA opened in order to provide the agency with important in-country information and inspection capability. In 2010 and again in 2016, we found that the offices faced persistently high vacancy rates, raising questions about their effectiveness.

As a result of these challenges, we added FDA's oversight of medical products, including drugs, to our high-risk series, citing FDA's inability to ensure the quality of drugs manufactured overseas as an area of particular concern.

This brings me to our current work. While the number of foreign drug inspections increased from 2012 to 2016, inspections have since dropped due to continued inaccuracies in data and investigator shortages. FDA is also still having trouble filling positions in foreign offices, as well as positions for domestically based investigators who conduct the majority of these inspections overseas.

We also found that FDA still provides up to 3 months' advance notice for most

foreign inspections, which gives establishments the opportunities to fix problems before the investigator arrives.

Further, investigators face persistent challenges when they travel overseas. As we learned on our site visits to India and China and in conversations with investigators based there and in the United States, lone investigators often had to inspect manufacturing campuses covering acres of land in rural areas. The majority have little flexibility to extend their time at a facility because travel schedules require back-to-back inspections.

In addition, FDA continues to send investigators into establishments without translators. This is particularly problematic in China, Japan, and South Korea. Investigators are left to rely on translators provided by the drug manufacturer that is being inspected, and there can be uncertainties about the accuracy of the information they receive. One investigator we spoke to said he had to resort to a translation app on their phone to conduct their work.

In closing, foreign manufacturers continue to be a critical source of drugs for millions of Americans, and FDA uses inspections as a key tool to ensure the quality of those drugs. FDA has made significant changes to adapt to the globalization of the drug supply chain and has greatly increased the number of inspections conducted overseas. However, the agency continues to face many of the same challenges that we identified in the past, raising questions about FDA's ability to conduct inspections overseas that are equivalent as required by law to those done here in the United States.

Thank you, Chair DeGette, Ranking Member Guthrie, and members of the subcommittee, for holding this important hearing and continuing your oversight. This concludes my remarks. I am happy to respond to any questions you may have.

[The prepared statement of Dr. Denigan follows:]

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Ms. DeGette. Thank you, Doctor.

Dr. Woodcock, you're now recognized for 5 minutes.

TESTIMONY OF JANET WOODCOCK, M.D.

Dr. Woodcock. Thank you.

Well, around the turn of the century, pharmaceutical manufacturing began to move out of the U.S., as people have already stated, but FDA was slow to react to this change. The agency had a longstanding inspectional organization called the Office of Regulatory Affairs, or ORA, that was organized around domestic sites that were called districts, and these districts inspected facilities, whether they had foods, drugs, devices, or whatever, within the boundaries of each district. And then they would volunteer inspectors to go outside of the U.S. from those districts.

FDA also had very poor and inaccurate data systems. So unless a foreign site was part of an application in which it was overtly brought to FDA's attention, then it might not get inspected. And also in the data systems, there was a huge number of incorrect and duplicate sites. So the GAO said we had all these thousands we hadn't inspected, many of them didn't really exist or they were duplicates of another site, but we didn't have data systems that could identify that.

As detailed in my testimony, by 2005, FDA was taking steps to rectify the situation. Center for Drugs began requesting more and more ex-U.S. GMP surveillance inspections, other than just the preapproval inspections that had been going on, using a risk-based model for site selection. Despite this, the ORA, the field organization, was hampered by

the requirement for every 2-year domestic GMP inspections with no statutory requirement for ex-U.S. establishments.

Much of this changed, as people said, in 2012 when Congress passed FDASIA and the generic drug user fee program. FDASIA removed the 2-year domestic requirement and replaced it with a risk-based global approach to inspections. GDUFA provided ORA with additional resources to inspect the generic industry in both domestic and foreign.

At this time, FDA also took major changes in how we regulate pharmaceutical quality. I personally led a major, major reorganization of the Center for Drugs' quality function. And I assumed the role of acting director of an office -- a newly formed Office of Pharmaceutical Quality. We cleaned up the inventory, creating the current site catalog that has lists of the existing firms that import drugs into the United States as well as the U.S. firms that make drugs for the U.S.

We established the Office of Surveillance inside the Office of Pharmaceutical Quality. The whole point of surveillance office is to surveil the inventory, and we can get into that later, but their job is to make sure we're looking at everything and what -- and do trend analysis. And we established clear responsibilities between the Office of Compliance and other offices in CDER.

Subsequently, the Office of Regulatory Affairs undertook a major reorganization, the first in an extremely long time, and they established inspectorates along product lines, so now we have a drug inspectorate, right, rather than having districts that do everything. They developed new SOPs called the Concept of Operations that established a uniform process for doing inspections both foreign and abroad for drugs.

As a result of all these changes, by 2016, foreign surveillance inspections had exceeded domestic, and this trend continues, as shown in the testimony. There had

been a large uptick and warning letters as previously uninspected sites that were identified by the GAO and by our catalog were evaluated. FDA's really currently up to date on our sites. We know there are always new sites coming in. We assign them inspections, and we are on top of all these sites as in the -- documented in the testimony. We expect performance of sites in India and China to improve as they're subjected to continued U.S. oversight.

Despite this, there is much more to do, including hiring inspectors and foreign office personnel -- this is under way -- transforming the site selection model into a true quantitative predictive model, but that will require data, us getting data, rather than PDF, which is what we get now, stimulating advanced manufacturing, and standardization and internationalization of quality standards. And finally, as we put in our shortage report, we're suggesting recognizing quality maturity as an important factor in manufacturers' production.

Happy to answer questions. Thank you.

[The prepared statement of Dr. Woodcock follows:]

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Ms. DeGette. Thank you so much, Dr. Woodcock.

It's now time for members to ask questions, and the chair will recognize herself for 5 minutes.

And one of the reasons why we do hearings like this on a continual basis is so that we can monitor these difficult issues over time. And this committee, as I said in my opening statement, has been working on foreign drug inspections for several decades now.

It seems to me, Dr. Denigan, after hearing your testimony, some of the -- number one, we've made a lot of progress over the years, and Dr. Woodcock talked about some of that progress that we've made, but we still have some sort of stubborn issues that continue. And listening to your testimony, it seems like some of them are, number one, we're giving advance warning to these facilities before we go; number two, we have problem getting independent translators to come, so we don't know about the reliability of what our inspectors are being told; number three, unique challenges of staffing with overseas inspections; and number four, the quality of data.

Are those some of the issues that you had identified?

Dr. Denigan. Yes, that's correct.

Ms. DeGette. And, Dr. Woodcock, what's your view of issues like that that just continue to be difficult to address?

Dr. Woodcock. There are tradeoffs on many of these. Obviously, we'd like to be fully staffed, but the entire FDA has suffered some administrative problems with hiring, and many of the centers are down in personnel. The field has recently received direct hire authority. They hope to bring on 20 people that they're onboarding, and

then we'd hope to hire --

Ms. DeGette. Twenty people to do foreign inspections?

Dr. Woodcock. Well, they will -- first, they'll have to get trained to be inspectors, right?

Ms. DeGette. Okay.

Dr. Woodcock. And then some of them will reach the ability to become foreign inspectors. They hope to bring on 50 in all, because they do have a number of vacancies.

The foreign offices, again, none of these are within my chain of command, but they have explained to me they are really working on hiring. They have vacancies as well.

Ms. DeGette. And to what do you attribute these vacancies? Is it just the vacancies we've seen throughout the agency since 2016?

Dr. Woodcock. There are -- the administrative problems are one problem with vacancies. Another problem with vacancies, of course, is the roaring economy and the fact that people can make more money elsewhere.

The Center for Drugs, for example, we have to hire 400 people to net less than a hundred, because we're losing -- you know, we're so attractive -- our staff is so attractive elsewhere, so -- but we do have administrative problems with hiring.

The foreign offices, it's more complicated. People don't necessarily want to move their family overseas to some area in India for many years. And --

Ms. DeGette. Dr. Denigan, I see you nodding at that. Would you like to comment on that?

Dr. Denigan. Yes, it is correct. I mean, once they even -- through the direct hire

authority, while it's good, it still is going to take 2 to 3 years for that inspector to be able to get the experience to then be able to go overseas, as Dr. Woodcock had mentioned. And plus, if it takes 2 to 3 years, even if they are ready to go, we found that it can take up to 2 years just to get over to the post. And if you're talking about uprooting families, getting security clearances, medical clearances, finding schools, housing, things like that, you can give up in the process. So it is very challenging.

Ms. DeGette. And, Dr. Woodcock, what can we do to try to alleviate some of those challenges and expedite it? Is there something Congress can do to help?

Dr. Woodcock. All right. Well, I think there are many things Congress can help us with. In the hiring area, I believe -- you know, many of the things that were discussed, for example, a single investigator. Well, if we sent a team, then we do half as many inspections. So we're going to need more investigators if we want to have fuller coverage. All right?

Translation, we are working on that. We do have the funding, and we are working on getting contracts for translate -- independent translators per country that, you know, are not related to the firm or any other part of the country.

Unannounced inspections is, again, a tradeoff, because they are very inefficient, because we send people over there and then they aren't operating, and they're in the middle of China and they don't have anything to inspect, for example. So that's -- if we had -- we agree that they would be useful, but we feel that there's a tradeoff there between actually covering the inventory and then how deeply we can cover the inventory, and that should be obvious. So hiring, very important.

The authorities you gave us under CURES is really helping the Center for Drugs in hiring people quickly that are qualified scientific experts. And so those type of

authorities are very helpful.

Ms. DeGette. Thank you. Thank you so much. Lot more questions, but good news, we have a lot more members here.

Mr. Guthrie, I recognize you for 5 minutes.

Mr. Guthrie. Thank you very much. And I appreciate it. And we're kind of going down the same path, I think, with our questions.

First for Dr. Denigan, just to establish the difference in on-site -- or preannounced and unannounced inspections. So do announced or unannounced inspections better enhance the integrity and effectiveness of an inspection, and how does the FDA use both announced and unannounced?

Dr. Denigan. So, generally, the FDA uses unannounced inspections with their foreign offices. They've said that for logistical reasons they need to give up to 12 weeks' notice for those coming from the United States because of the challenges of just doing the logistics. So that's a real value of the foreign offices because they're there, they have the in-country intel, and they can get there for the unannounced inspections.

Mr. Guthrie. Great. Thank you very much.

And it does, Dr. Woodcock, kind of make sense logistically it's easier to do unannounced inspections, easier to send an inspector to Long Island than to interior of China, and I understand the issues with that. Having said that, how do you weigh the risk of maybe we need to do an unannounced inspection even if you -- I know you have to call ahead. How do you weigh the risk of besides? All right, there's one, we're just going to do an unannounced inspection even though we risk of getting there and they're not operating or those types of things?

Dr. Woodcock. Yes. We do, for example, for cause. Say, if we have a

whistleblower or a complaint, we will go in unannounced, even in a foreign country. So we do unannounced inspections both by foreign offices and domestic. But I will say, I mean, it is just a hypothesis anecdotal that the unannounced inspections are so much better, that it's worth all the costs, all the time. Ninety percent of the data integrity problems that have been found recently have been found by our domestic inspectors going and doing announced inspections. And why is that? Because they're very good. Because our regulations under part 11 require them to have computer systems with audit trails. And either they don't have those, or if they have messed around with them, our people can find it. So they have found a lot of the problem -- a lot of the problems have been found by announced inspections.

Mr. Guthrie. Okay. Before I came here, I was in manufacturing. I was a quality engineer. So do you use independent auditors? Is that permissible with you? Because I know when Ford or GM will do auditor, they'll hire -- or the company being audited to sell to them will hire someone to come in that everybody agrees is an independent auditor.

Dr. Woodcock. Yeah. If companies get into trouble, all right, and they are having trouble meeting the minimum standards, which are GMPs, we would frequently suggest to them that they use independent consultants who audit them. Sometimes they will give us reports on the progress of the firm.

Meanwhile, the firm won't be able to import into the United States because we do have a very strong regulatory tool for foreign manufacturing, which we can do an import alert, and then they can't send anything to the United States while they're remediating their problems. So we do -- and when we do consent decrees, it may include reports by external auditors.

Mr. Guthrie. Okay. Well, thanks. Just kind of specific questions to make sure we it get on the record. Does the FDA have evaluation criteria for effectiveness of its foreign drug inspection program? If so, what are the criteria? And has FDA conducted any sort of review of the effectiveness of the overall program, and if so, what are the findings?

Dr. Woodcock. Well, I think that's a very good question. I believe that we really need to do more of this. Of course, it's hard to assess the counter-factual, what would have happened if we weren't there, right? And so we do need to, as I said in my oral testimony, we really need to work on standardization of the inspection program, standardization internationally, and then -- then we can put in some evaluations about the consequences or the results.

Mr. Guthrie. Great, thanks. I want to ask a final question. I know we talked this week about nitrosamine and NDMA found in trace elements that if anybody hears that you're more at risk of not take -- you need to take your blood pressure -- you're more at risk of high blood pressure than any risk from nitrosamine. So I want to establish that before we go forward. But have you -- what have you done -- what's the reaction of FDA? Are you testing for NDMA during its foreign drug inspections now?

Dr. Woodcock. Right. No, that's not really possible. That's a different part of the FDA. I think some folks have a misunderstanding what an inspection can actually do. It can look at what the firm does, all right? It can't really -- we don't go and do --

Mr. Guthrie. You're not testing -- you're inspecting, not testing?

Dr. Woodcock. That's correct. So what -- we have some of the best drug laboratories in the world, and they have been doing -- they establish the test first, the benchmark tests that are being used, and we posted them so everyone could use them.

And then we are getting samples. We've tested over 1,500, I think, samples of different drugs for nitrosamines, and we're continuing this testing and getting the manufacturers to do the testing as well.

Mr. Guthrie. I'm out of time. I want to emphasize really quick, but if somebody's taking medicine and they think it's in this category, they need to take their medicine?

Dr. Woodcock. They need to, and what's on the market now --

Mr. Guthrie. I want you to say that.

Dr. Woodcock. -- of the ARBs of the blood pressure medicines is okay. We've recalled the ones that aren't okay.

Mr. Guthrie. Okay, thank you.

Ms. DeGette. I just -- I know the witnesses know this, but I just want to let you know that members are going to be coming back and forth between this hearing and a, unfortunately, co-scheduled hearing with the Health Subcommittee.

With that, I'm going to thank Mr. Tonko for staying here and recognize him for 5 minutes.

Mr. Tonko. Thank you, Madam Chair, on both counts.

As we heard from GAO today, one of the big challenges that FDA inspectors face in certain foreign countries is the language barrier. We have heard throughout the years that FDA inspectors are not usually provided with an independent translator. In fact, GAO's testimony notes that FDA generally relies on the firm itself to provide a translator. According to GAO, FDA investigators stated that this practice, and I quote, can raise questions about the accuracy of information FDA investigators collect, close quote.

So, Dr. Denigan, what type of concerns does the use of nonindependent

translators raise?

Dr. Denigan. Yeah. The use of a nonindependent translator definitely raises concerns about the accuracy of the information that they're receiving, particularly in those countries such as South Korea, China, Japan, where their native tongue would not necessarily be that language. The investigators that we spoke with said that at times people can provide translation that they don't have the knowledge to be doing the translation. It's simply the only person in the company that can speak English and, therefore, is doing it. So it could be inaccurate that way. It can be misinformation on purpose. So there are a variety of concerns that we would have with not having an independent translator.

Mr. Tonko. Well, this isn't a new issue. So does GAO and the subcommittee, as we go forward, need to look more closely at it, since we raised the same concerns over some 10 years ago?

Dr. Denigan, why has this been such a longstanding problem if it was identified 10 years ago?

Dr. Denigan. I don't know that I have the answer to that. I know that FDA has made significant changes, but they have not made progress in this area of providing translators. The China office, however, has taken initiatives to use their foreign nationals that work for FDA to help with the translations, and at times, they have said the company is not interpreting correctly. This is what is really being said.

Mr. Tonko. And, Dr. Woodcock, FDA told committee staff that using translators from the firm puts inspectors at a disadvantage. Are you comfortable with inspectors in a foreign country relying on a translator who works for the company FDA is inspecting?

Dr. Woodcock. No. I think it would be better for us to have our own

translators, and we are in the process of seeking out contracts so that we can do that.

Mr. Tonko. And as you do that, like, what is involved in the exploring of having more independent translators doing these foreign inspections?

Dr. Woodcock. Well, we have to go through the contracting process, which is elaborate, but we can get that done, and there are certainly large number of groups -- because there's a great deal of commerce with China and India -- there are a large number of independent translating groups that exist that one of which could be contracted in each country to provide this type of service to the FDA inspectors.

Mr. Tonko. And, Dr. Denigan, based on your audit and discussions with FDA inspectors, what are the concerns associated with sending a single inspector to conduct a foreign inspection?

Dr. Denigan. There are a variety of different concerns. One can be safety. For example, on one audit over in China, the auditor was actually whisked away to a room and was held because they didn't believe that they were the auditor. And until the Chinese counterpart was able to have conversations, she feared for her own safety. And actually, I think in that example -- sorry, that was a bad example -- there were two there, but even with two, that was of a concern.

The other thing is, these campuses are huge, they're quite large, and it's very difficult to be able to do a complete inspection. And if you're coming from the United States, then you don't have the flexibility, necessarily. You have to get a certain amount of inspections done in 3 weeks. And so if you take more time at one spot to be able to do a thorough inspection, then you're taking away from another inspection.

Mr. Tonko. And, Dr. Denigan, it's reported that 80 percent of its foreign drug inspections -- the FDA's report, that 80 percent of its foreign drug inspections are

performed by solitary inspectors. Do you believe that that number is making a huge impact on the ability to sufficiently inspect these facilities?

Dr. Denigan. I do know that domestic inspections also have solitary inspectors, but they don't have the challenges domestic stateside that they have overseas. And when we go and we visit these plants, I mean, they are in very remote locations and in cultures that are different than our own, and it does raise concerns.

Mr. Tonko. I thank you very much.

And with that, Madam Chair, I yield back.

Ms. DeGette. Thank you very much.

I now am pleased to recognize the gentleman from West Virginia for 5 minutes.

Mr. McKinley. Thank you.

I think, Dr. Denigan, you said in your report and in some of the documents that now that the FDA has opened offices, the GAO has reported that the open offices in China, India, Europe, Latin America, and elsewhere to increase the number of inspections that are taking place, this since 2009. So from an engineering perspective, I want to see from the metrics. Now, so have these increased number of inspectors being on site, have they led to -- are we seeing fewer recalls, better productivity? What are we seeing from the result of having the increased inspection?

Dr. Denigan. So that's one of the reasons that GAO has made recommendations over the years that FDA needs to tie the outcomes of what the foreign offices are doing to results, so that they can better measure their impact. One would think that with unannounced inspections that you could tie, for example, looking at the number of warning letters or the number of serious problems that they find.

Mr. McKinley. So are you testifying that it has been -- it's been cost effective to

do this?

Dr. Denigan. No, I'm not saying that. I'm saying that FDA has not looked at how effective the offices have been.

Mr. McKinley. Okay, thank you.

Now, let me go back, again, Dr. Woodcock, here a little bit on -- I come from the construction industry. We also have some coal mining in West Virginia. Neither one of those industries, neither one of them get an advance notice when there's an OSHA or MSHA coming into their sites. I can't -- I'm still struggling with your idea or your concept of giving advance notice to someone to come in. Can you try that one more time to get it passed me? Because I'm not buying this idea of we're going to let you know, because we know China's gaming the system. Give me a little help.

Dr. Woodcock. Certainly. We -- as I said, we began as a domestic agency, and domestic inspections are not preannounced. However, when we began inspecting overseas, different countries have visa requirements. The travel is -- you know, the location of the site was difficult to ascertain. Now, that's improved over time with various things, and particularly it was difficult to know whether the site would be manufacturing at the time we inspect them. That's very important.

Mr. McKinley. Okay. I'm not buying the thing about the visas, because I would assume that so much of it is taking place in China. We have someone or a group of people over there that they're going to continue to travel the circuit and do their inspection with that.

Dr. Woodcock. No. The number of inspectors we have in China and India are not sufficient to perform the number of inspections that are needed. So most of the inspections need to be done by domestically based inspectors who are sent to other

countries. And those are the ones --

Mr. McKinley. Can you come to the office? I'd like to follow up on this, because I don't think we have enough time to get into that. But I'm not convinced at all that a preannounced -- alerting someone that we're going to come in and look at you is going to get the results we want.

Now, I also -- but I want to follow up also with you on the thing that 90 percent of American prescriptions, from what I understand, are generic, but they only amount to about 56 percent of the recall. So I'm curious, either one of two things, either they're doing a good job replicating them or they need more scrutiny. Which is it?

Dr. Woodcock. I'm not familiar with the figures you're using on the recalls. Could you explain a little bit more?

Mr. McKinley. Yeah. I don't have the source of that, but we have 56 percent of all of the recalls have been generic. If that's not correct, if you don't -- and I can't back that up just at this moment -- what is that? What would you say is the percent? Is it comparable?

Dr. Woodcock. Well, we'd be glad to work with you on this, because I think it's a little more complicated than that. In the first years after a new innovator product is launched, there may be safety recalls and different things that are unrelated to the quality of the product. So first you have to talk about what kind of recalls are you talking about and then where did you get these statistics, because I'm not really clear on this.

Mr. McKinley. Well, the reason I'm saying that -- I only have a few seconds left -- is there are some Members of Congress who have been suggesting that generic drugs are not safe. I'm trying to make a determination whether or not they are safe or

not based on the fact that if 90 percent of us are generic and only 56 percent are recalled, does that mean they're safe, or what's happening? Are generic drugs safe for people to take?

Dr. Woodcock. Yes. We stand behind the generic drugs. I will point out that we do have good safety detection systems, right, and the biggest risk right now we see to the public is from compounding where we have multiple outbreaks that we continue to have of humans being harmed by compounded drugs.

Mr. McKinley. Thank you.

Dr. Woodcock. So we have a system that can detect problems when they occur, and we do not have problems with 90 percent of the drug supply. The generic drug supply is reliable.

RPTR MERTENS

EDTR ZAMORA

[10:56 a.m.]

Mr. McKinley. My time's expired. So before I get yanked, I'll yield back.

Ms. DeGette. I thank the gentleman.

Now I'd like to recognize the gentleman from California, Mr. Ruiz, for 5 minutes.

Mr. Ruiz. Thank you very much.

This issue is becoming more and more important because of the inability of middle-class families to afford their medications, and they're getting medications from other places, as well as legislation -- legislative ideas to import medications to help lower the cost for people. And as a doctor, I'm concerned because we know what a placebo pill can do to a diabetic's blood sugars. And when patients think that they're -- they need to take a certain drug, they're actually taking a different drug. And then if it's contaminated, then it may make their illness even worse.

So the FDA faces the enormous challenge of inspecting the thousands of firms around the world producing drugs for the United States. Compounding the challenge is the fact that, over the years, some firms have reportedly engaged in fraudulent behavior to cut corners and deliberately conceal failures from the FDA inspectors.

In the past year, for example, press reports have offered disturbing accounts of such fraud. In January, Bloomberg News reported incidents of, quote, computer files found deleted and employees caught on a company's own security cameras shredding documents the night before an inspection, unquote.

In May, NBC spoke to a former FDA inspector and reported that, quote, FDA inspectors struggled to keep up with foreign drug manufacturers that may bury or hide

problems in their production, unquote. In an article in October in STAT News, it was reported that violations of data integrity are persistent and ongoing in overseas drug manufacturing plants.

Madam Chair, I would like to request that these reports be entered into the record.

Ms. DeGette. Without objection, so ordered.

[The information follows:]

******** COMMITTEE INSERT ********

Mr. Ruiz. Thank you.

Dr. Denigan, when you traveled abroad for your audit work and talked to inspectors in China and India, did you hear stories such as these?

Dr. Denigan. Unfortunately, we did. There were instances where inspectors gave 30 minutes' notice they were on their way, and when they got there, they saw documents, bags of documents being disposed of. And they said don't do it, took photos, ran in to show their credentials. In the time that they got back, in the few minutes it took to show their credentials, they blatantly disregarded them and disposed of them.

Mr. Ruiz. Dr. Woodcock, you were quoted in the previously mentioned Bloomberg News story that there were high profile cases of, quote, overt and deliberate fraud, unquote, by certain drug companies. Dr. Woodcock, how should we put these reports in perspective? How pervasive do you think this problem is? And what tools does FDA have to sufficiently root out any cheating or data manipulation, if it is occurring?

Dr. Woodcock. First of all, I should point out that we see this in the United States or in the North America or the Americas as well as ex-U.S. We have seen cases of -- serious cases of data integrity problems.

The second thing I should point out, which gets to --

Mr. Ruiz. So how -- so how pervasive is this?

Dr. Woodcock. Well, that's what I'd like to show here. Slide 12. If I could show -- pull up the slides. No?

Mr. Ruiz. Just tell me if you can, because my -- the time is ticking.

Dr. Woodcock. About -- in the United States, about 93 percent of firms who are inspected pass the inspection, right. In India, 83 percent. So there's a 10 percent difference. That means 83 percent of the firms we inspect are -- fail to be adequate and pass the inspections. They have the lowest percentage. China's percent passed is very close to the United States.

Mr. Ruiz. Do you -- I have about a minute left. Do you feel that unannounced or short-notice inspections could help you better discover manufacturing issues or even data quality issues when they are occurring?

Dr. Woodcock. Certainly. Those are desirable. You just have to think about the tradeoffs in doing that. But no -- no one is opposed to those, and we do them routinely for for-cause inspections.

Mr. Ruiz. Recently, the FDA told the committee that firms were inspected every 2 and a half years, more or less, but given that the reports we have seen about this issue with some firms, including what you yourself have called, quote, overt and deliberate fraud, are you comfortable inspecting foreign firms as the current model and resources allow?

Dr. Woodcock. Well, as I said, 90 percent of this fraud has been detected under the current system in the way --

Mr. Ruiz. So your -- so your acceptable level of error is 10 percent. You're trying to tell me that it is okay to have 10 percent error in inspecting the quality and the safety of our medications?

Dr. Woodcock. We don't know what the error rate is because it's impossible to show a counter factual, as I said earlier. We know that we detect fraud fairly routinely when we go in, even on an announced inspection, because we can look at the computer

records and --

Mr. Ruiz. So do you think that it's working?

Dr. Woodcock. I believe, as I said earlier, that we could use more inspectors. We could do more unannounced inspections. That would be desirable. We could have more team inspections.

Mr. Ruiz. My time is up. Thank you.

Dr. Woodcock. Those things would be good.

Mr. Ruiz. Thank you.

Ms. DeGette. The chair now recognizes the gentleman from Virginia for 5 minutes.

Mr. Griffith. Thank you very much.

Always good to have you all here. Thank you so much, particularly Dr. Woodcock, who is -- always does a great job. But I've got some tough questions today.

So, Dr. Woodcock, according to an article in WIRED in July of 2017, a drug firm in northeastern China, in essence, took an FDA inspector and her translator hostage during an inspection. Dr. Denigan mentioned this earlier. The FDA employees were finally freed after about an hour when Chinese regulators interceded. And the FDA deputy director concluded in an internal email that the firm resorted to appalling intimidation tactics because the inspection was not going well. However, FDA declined to classify the incident as an inspection refusal, which would be grounds for an automatic import ban, because the firm manager wasn't making a specified refusal when he imprisoned the FDA employees.

Why isn't imprisonment of FDA employees classified as a refusal of inspection by

the firm? And let me just say so folks back home understand. It was the conference room that Dr. Denigan mentioned earlier. Imprisoned is a legal term of art as I'm using it here. It does not mean they were placed in a dank cell and only allowed to have food and water, bread and water brought in. But it is technically an imprisonment when you refuse to let somebody leave the conference room.

So, you know, how come that wouldn't be grounds for an automatic import ban? It seems like to me it ought to be.

Dr. Woodcock. Well, that's a legal question that lawyers would have to sort out, whether it met the context.

Mr. Griffith. And I've never had great respect for the lawyers at FDA after NECC, and they refused to get a search warrant after Ohio and Colorado both told them there were problems, and nobody in the FDA legal office thought that was sufficient to get the probable cause to get a search warrant, which might have saved 53 lives.

That being said, you know, it seems to me it would constitute circumstances, you know, of delaying, denying, or limiting inspection or refusing to permit entry or inspection for purposes of section 501(j)(2), little 2, under the Food and Drug and Cosmetic Act.

And, Dr. Denigan, you mentioned some things earlier that were similar to that, not quite as bad as taking somebody a prisoner, but why aren't we being more forceful with these foreign companies and just saying if you don't cooperate, you're out, you won't be selling in the United States?

Dr. Denigan. Well, actually, as part of our ongoing work, I think the inspectors have raised concerns, and they've put them down as serious deficiencies, and there has been times where those concerns have been downgraded. And we plan to look at that in our ongoing work.

Mr. Griffith. And I appreciate that. You know, I was brainstorming on this last night because, to me, this is extremely important, you know. We're working on bringing down prices of drugs, but making sure the drugs actually do what they're supposed to and are not adulterated, don't have harmful products in them is extremely important.

And you talked about the large campuses and how it's hard for people to cover the large campus. So as we were brainstorming, and I want to hear from both of you, as to why this wouldn't be something we ought to be talking about.

You know, we could get young people right out of undergrad to come in there. They don't need 3 years of training. You may need somebody like that to do the big stuff, but you don't have to be a gourmet chef to go into a French restaurant and determine that the bathroom is not clean.

It would seem to me that for pennies on the dollar, lots of young people would love the opportunity to travel abroad and -- and go in and help somebody who's got all that 3 years of training, but help somebody figure out, okay, building A is dirty. I don't know what's going on. You might want to go look at it. It seems to me we could -- we could magnify our inspections and our ability to inspect if we did something like that, and I'm happy to work with you on it.

Dr. Denigan, what do you think of that? And, Dr. Woodcock, I'd like your opinion too. I always respect both of you.

Dr. Denigan. Sure. Well, we certainly heard stories of bathrooms that they -- they were using that were covered in feces. They had to go outside to be able to -- to use the facility, raising questions about good manufacturing practices.

Mr. Griffith. And you don't need 3 years of training to be able to see that, do you?

Dr. Denigan. No.

Mr. Griffith. Dr. Woodcock, what do you think? Is this something we ought to be talking about?

Dr. Woodcock. Well, it -- it raises the question, should ORA, the field organization, change its model somewhat. That's what you're proposing.

Mr. Griffith. That is what I'm proposing.

Dr. Woodcock. And have more of a sliding scale of capacities, translators --

Mr. Griffith. Right.

Dr. Woodcock. -- and so forth. And I think that's worth talking about as far as how -- how we cover the entire range of problems.

Mr. Griffith. Because as we're importing all of these substances, whether they be substances that are used for compounding pharmacies or whether they are actual drugs that go straight to the consumer, it just seems to me, yeah, you want to have your top dog, but you also can use folks who can just go in and take a look at the bathroom. And it doesn't take a genius to figure out or somebody with 3 years of specialized training to figure out the bathroom is dirty and there's feces everywhere. Thank you very much.

And my time is up, and I yield back.

Ms. DeGette. I thank the gentleman.

The chair now recognizes the gentlelady from New Hampshire for 5 minutes.

Ms. Kuster. Thank you, Chairwoman DeGette, for your continued leadership on ensuring the safety and inspection of our drug supply chain. And I want to thank our witnesses for being with us today.

Recently, I heard from a constituent from Nashua, New Hampshire, who was very concerned about his blood pressure medication which has had several recalls. Despite

his concerns, he also acknowledged the balance that must be struck in ensuring that the safety of our drugs but also the supply of drugs. And it's certainly true and something some of my colleagues have mentioned here today.

Outside of the high cost of prescription drugs, one of the other most frequent concerns I hear about is drug shortages. This committee helped to lead the way in working with FDA and stakeholders to ensure that the agency has the additional authorities and flexibilities that you need to inform and respond to drug shortages as they occur. But at the same time, we must ensure that every American has access to safe medication through your quality inspection.

So let me turn to my questions. Dr. Denigan, is it true that staffing in these offices has been a continuous issue since the offices have opened overseas? And if so, why is that? And what is the impact on the foreign inspection program, and if you will, what do you need from us?

Dr. Denigan. Yes. Staffing continues to be a problem, and there were visa problems over in China that have since been resolved so that they've been able to get more staff over there. But overall in the foreign offices, staffing has been -- has been a challenge, and they have critical vacancies of these expert investigators.

Ms. Kuster. Now, I know Mr. McKinley asked a series of questions. This appears to be a very bipartisan hearing in terms of our concerns about the effectiveness of the foreign offices and how you intend to address those staffing concerns. If you are not satisfied that the FDA has fully evaluated how its foreign offices should be utilized and improved, what is it that you need from us? Is this a resources issue? What -- how can we be helpful? I assume that's the point of this whole hearing.

Dr. Denigan. Well, I think what's concerning is that the data of understanding

the number of establishments is challenging to get, and you have firms over there that are registering with FDA that don't necessarily have to. Unlike medical devices, there's no charge to register because it looks good, right. You're registered for FDA overseas, and so that creates noise in the database. And if you don't know the universe of those that you need to be inspecting, I think it's very hard to be able to come up with a strategic workforce plan to know the number of folks that you need to be able to -- to carry out the inspections.

Ms. Kuster. So couldn't we do something about that? If we're giving them permission to send these -- this medication into our country for sale, somebody's making a profit. Can't we link that more clearly to where has this been made and be much more specific about this? I mean, they have an incentive to want to bring this medication in.

Dr. Denigan. Right. I think that that's what FDA wants to do is to be more strategic about their workforce planning and more risk-based, which GAO appreciates, but they should put their limited resources at the places with the highest risk.

Ms. Kuster. Dr. Woodcock, do you want to respond? I mean, do you need legislative authority to make this a much more direct link? Why don't we just say if you want to send medication into our country, you need to tell us precisely where it's being made, and we're going to come out and look at it.

Dr. Woodcock. All right. They usually have to do that now, all right, for application products. So if you send in an application for a generic drug or an innovator drug, you have to tell us where it's going to be made. And we do preapproval inspections before we even let that product on the market.

Ms. Kuster. So, presumably, you know where they're being manufactured?

Dr. Woodcock. Well, not only do we know where, we go there, unless we've

been there recently. However, for -- there's some loopholes for compounding and for over-the-counter monograph drugs that don't have applications. That's a very large segment, and that's many of the never being -- been inspected that were --

Ms. Kuster. Do you need us to close those loopholes?

Dr. Woodcock. It would be -- I think we would be interested to work with you on the issue that they can ship to the United States without ever being inspected right now, because all they have to do is register.

Ms. Kuster. Right.

Dr. Woodcock. And there are other data points, as I alluded to in my verbal testimony, that would be very useful for us to receive as data. For example, we don't know the volume. We know -- you said maybe 20 percent of APIs made in the United States, but it may only be an infinitesimal fraction of the actual volume, because we only know the facilities, not how much they're making. And they tell us --

Ms. Kuster. Well, I hope you -- my time is up, but I hope you will work with our committee to tighten this up, because these loopholes sound dangerous to the American people. Thank you.

Dr. Woodcock. We would be delighted. Thank you.

Ms. DeGette. The gentlelady from India is recognized for 5 minutes.

Mrs. Brooks. Thank you, Madam Chairwoman. And thank you both for being here and for focusing on this critically important subject.

I want to stay focused a little bit on the staffing issues. And I'm curious, Dr. Woodcock, has the FDA ever used outside consultants to study this in-depth problem rather than GA -- you know, and I appreciate GAO's recommendations and ideas, but this is very complex. Have you used outside consultants, and what have been the results?

Dr. Woodcock. We used outside consultants to look at the administrative hiring problems we had, and we even had a public meeting on that that went over all the different problems. The direct hire should help some of that.

As far as an outside consultant to think about the workforce in ORA and how it's deployed, and actually, the people in the foreign offices actually report to a different component, a third component of FDA that's not the Center for Drugs and not ORA. And so I don't know whether they've done a study or not, but we can get back to you on that, and it is a good idea.

Mrs. Brooks. Were there recommendations that were made that have not been implemented, if you know, and if not, why not? Were they not given, you know, sufficient credit in the recommendations?

Dr. Woodcock. I believe in the recommendations that were made on our administrative problems, there's been a stupendous effort to try and turn this ship around and to get the hiring process to something that can actually bring people on board in a timely manner. And as I said earlier, CURES helps us for positions that are CURES eligible.

So yes, we have acted on those recommendations, but the hiring so -- was so problematic, it's going to take us a long time to recover from that.

Mrs. Brooks. It seems, even if you were able to hire enough people, one of the things you said that I'm very concerned about is the lack of, unless I didn't write this down properly, standardized inspections, and this is an example.

Earlier this year, the committee sent FDA a bipartisan letter asking about the FDA's India pilot program and why the program wasn't extended. In response, FDA told the committee that the drug inspection initiative was not extended, quote, based on lack

of protocols and evaluation criteria. No formal report or evaluation was completed.

How is this possible? How is it possible that we've got pilot programs with no evaluation, no protocols, no standardized inspections? I mean, who would want to come work for you if you're -- if there's no roadmap and there's no standardization of what their work product's supposed to be?

Dr. Woodcock. Well, there are two separate issues. There is standardization that ORA has for what its inspectors do and how they document it, and that is written down. And we are working on what we call the new inspection protocol program which is changing to a more modern, more standardized inspection process and protocol. We've already completed that for sterile products, but we have to go through all the different kind of products.

Mrs. Brooks. Do you need more people, Dr. Woodcock, to help get this process? I mean, you've just mentioned sterile products. I can't even imagine how many other products. Do you need more people to be focusing on protocols and the standardization of inspections?

Dr. Woodcock. If we had more people with doing analysis, as you've pointed out, doing analysis and actually working on these projects rather than, you know, doing the work -- the day-to-day work of trying to inspect all these firms, of course, that would be very helpful.

And I will add, there's another component of this since we did the Mutual Reliance Agreement with the EU and all those countries, okay. They do their reports in all different languages, naturally. And so all of us would benefit from a very standardized report document that we could all read without having to translate it into different languages.

Mrs. Brooks. I was actually going to ask you about the EU reli- -- can you please talk with us about what that means and how long will it take us to realize the benefits from the Mutual Reliance Agreements with the EU? And who else should we -- and what does it mean? Can you go into a little more detail on that?

Dr. Woodcock. First of all, what it is, is we've agreed with all the EU countries that their inspectors are qualified to inspect the plants within their country boundaries, because each country has different inspectors, right, and that we will accept the results of those inspections, and they'll -- they'll send them. And then they don't have to come over to the U.S. and inspect facilities that are here, because they -- they accept the results of our inspections. It doesn't extend to their inspections in other countries, but it does free us up to go send more people to India and China.

Now, that trend has been abrogated, as people pointed out, by the loss of staff in ORA, the loss of people in the inspectorate in the foreign offices, and so we haven't had the capacity, and our number of foreign inspections has actually gone down because of capacity problems, even with the MRA in operation.

Mrs. Brooks. Well, I certainly hope our Mutual Reliance Agreements can extend, and maybe we can look at other countries as well. Thank you.

I yield back.

Ms. DeGette. Doctor, would it be possible to get a copy of that independent report you're telling Congresswoman Brooks about?

Dr. Woodcock. Absolutely. We can get that back to you.

Ms. DeGette. I think that'd be really helpful. Thank you.

The chair now recognizes the gentlelady from Florida for 5 minutes.

Ms. Castor. Thank you, Chairwoman DeGette. Thank you both for being here

today.

I know we've focused a bit on the challenges in staffing, and I'd like to focus a little bit more on the quality of FDA's data. FDA's foreign drug inspection program relies upon having quality data that allows FDA to know which firms to inspect and to review those firms' inspection history. However, GAO has long identified problems with the data FDA relies on for its drug inspection program. In testimony today, GAO states, quote, data challenges were -- we identified in our 2008 report continue to make it difficult for FDA to accurately identify establishments subject to inspection.

Beyond staffing, Dr. Denigan, what are your main concerns with the way FDA is collecting and using data relating -- related to its foreign inspection program? How do these data collection concerns impact the effectiveness of the foreign inspection program?

Dr. Denigan. Yeah. So as I mentioned before, the establishments -- they have establishments in there that are registering that don't need to, and that creates the extra noise. And while it's true that 40 percent of those establishments didn't need an inspection, and therefore, FDA was able to say that they went through their backlog, it still creates an inefficiency. They have to take the time to clear out to find out which one of those didn't.

And so the foreign offices can add value. For example, like over in China where they're actually matching up to see does that establishment really still exist. Because as Dr. Woodcock said, they -- they do change. They -- they go in and out, so it's a snapshot in time. And further, their active pharmaceutical ingredient could be produced in China, for example, and if they ship it to Germany, then it's not subject to an inspection. I know that FDA is very clear of that loophole.

Ms. Castor. Okay. Let's talk about those two. And FDA told committee staff that some firms on its foreign drug facility list were, quote, washouts. Is that what -- what you were referring to?

Dr. Denigan. Correct. Those are the washouts that didn't need to be inspected but were on their list.

Ms. Castor. Okay. Meaning that these firms were not actually subject to inspection for various reasons, including because they were no longer exporting to the United States.

Dr. Denigan, what is the difference -- what is the significance of these washouts previously included in FDA's data? Do you have -- you said you had concerns about it. I guess this is a really good question for -- for Dr. Woodcock.

Dr. Woodcock. Yeah. Well, you know, we have various thoughts about this. It's easy for people to register. You just can register, and then you have a -- a sort of branding. You can say I'm registered in the United States, and you never have to ship anything to the U.S. And so we have to go to the trouble, as Dr. Denigan was saying, of figuring out where that firm is, figuring out is it shipping anything into the U.S., what's its status, and then crossing it off the list.

It's possible that some small barrier like a modest fee or something might -- might help with that. I don't -- I don't know where -- how we could do that, but it is possible right now for a lot of firms every year to register with the -- with the U.S. and actually not be shipping drug into the U.S. But it's also possible for them to register and then ship without being inspected if they are one of these loophole firms.

Ms. Castor. And then you -- you also raise the -- the problem with facilities. You don't -- FDA does not have a firm handle on the volumes being shipped out.

Why -- why is that the case, and what are you doing to address that?

Dr. Woodcock. Well, we're thinking of doing a regulation, which would be a very long process. The companies have to tell us in what's called right now the annual report. Remember, these -- many of these regulations are very old. But my understanding at least, I recognize I'm under oath and I don't have total grasp of the details, but they have to tell us that kind of stuff for the past year. And then they -- eventually, they submit that annual report at some time in the next year. So it's a really lagging indicator. And it isn't data; it's in a PDF of a document that they send us.

And what would help, if you all wanted to know the volume being shipped in the United States, we would need something like quarterly data reporting as data in a database rather than -- you know, a fillable form rather than sending us a PDF a year later about the volume that was shipped. If we had that type of data, then we could really put together a more complete picture of what's coming into the United States.

Ms. Castor. And you -- you need legislative authority to -- to move towards a quarterly data report?

Dr. Woodcock. We think we could do that under regulation, but it might take us 7 years.

Ms. Castor. Why 7 years?

Dr. Woodcock. Because it takes a very long time to do regulations. I know I'm under oath.

Ms. Castor. Yes.

Dr. Woodcock. I can't say -- you know, I can't predict. We could say maybe never, right, or maybe we could do it a little faster, I don't know, but it takes a long time to write, propose, get comments on --

Ms. Castor. Gotcha. Yeah. We -- we, you know, understand.

Dr. Woodcock. I'm sorry.

Ms. Castor. Thank you very much. Thanks for making that recommendation.

Ms. DeGette. The chair now recognizes the gentleman from Oklahoma for 5 minutes.

Mr. Mullin. Madam Chair, you forgot to say your good friend from Oklahoma.

Ms. DeGette. My best friend.

Mr. Mullin. Best friend. There you go. Thank you. Thank you.

Dr. Woodcock, thank you again for being here. I sure appreciate your demeanor and your ability to answer the questions the best you can.

I've got just a few questions I'm going to go through here. How many drug inspections can the FDA conduct per year in India and China? Currently.

Dr. Woodcock. Currently. We do have a slide on this. Does anybody know what number that is?

Mr. Mullin. Everybody likes slides and PowerPoints, don't we?

Dr. Woodcock. Yeah. Sorry. It's slide No. 4. So if we can get --

Mr. Mullin. We don't have to get it up. We can just -- you can just tell me.

Dr. Woodcock. Okay. So in -- well, this doesn't --

Mr. Mullin. While they're looking for it -- let's let them look for it. I'll go on to another question.

Dr. Woodcock. Okay.

Mr. Mullin. How many would you like to be able to inspect in China and India?

Dr. Woodcock. Well, if you don't mind me pushing back on you a little bit.

Mr. Mullin. Sure.

Dr. Woodcock. What I would really like to have is a predictive risk model that tells us based on a lot of data who we should really go to next, who's the highest risk.

Mr. Mullin. Well, the last time you were here, we brought up corruption in China and asked if that could bring up issues. When you start thinking that 45 percent of all of the ingredients in our drugs today made inside the United States come from India and China, huge concern for all of us. And -- and so when you start talking about risk data, you can't get the risk -- you can't understand what it is you're looking for unless you put your hands on it. I tell all my foremens and superintendents that used to work for our companies when I ran them that, you know, the best way to get the information is to be in the field.

So once again, how many would you like to be able to inspect? If you could -- if you could have your druthers and you could -- staffing wasn't an issue, what's our current level at now, and where do you think we should be?

Dr. Woodcock. Well, it looks like we inspect about -- in China? Foreign, we inspect about under a thousand, 966. In China, it looks like maybe about 400. I think it would be higher. I think there would be more unannounced, as was said. There would be more team inspections. I mean, those things all would be desirable.

Mr. Mullin. So when you go inspect these other 40, what -- what percentage of violations do you find in these facilities?

Dr. Woodcock. Well, in the previous slide I showed, 83 percent of China -- India passes, 90 percent of China passes, and 93 percent of the U.S. passes.

Mr. Mullin. Do you think that the 90 percent in China and the 80 -- what did you say?

Dr. Woodcock. -3.

Mr. Mullin. -- 83 percent in India is actually accurate, or do you think the -- that's not an accurate number because they're -- they're changing things before you walk in the door?

Dr. Woodcock. I believe there's always some -- an inspection is only a snapshot in time. They don't inspect every single system --

Mr. Mullin. Sure.

Dr. Woodcock. -- in the facility. We have lots of cases where we had inspections that were okay, okay, and then all of a sudden, everything was wrong.

Mr. Mullin. So do you -- so do you believe it's easier for FDA to inspect our drug manufacturers inside the United States or in India or China?

Dr. Woodcock. It's obviously easier to inspect in the U.S., and there's a long history. Back in the nineties --

Mr. Mullin. Sure.

Dr. Woodcock. -- there were many problems and many consent decrees and things, but the intensity of the oversight brought the level of performance up in the U.S.

Mr. Mullin. So what's the biggest barrier? Why do we have 45 percent of our drug ingredients made in China and India and not here in the United States, if that's where the drugs are coming to anyways?

Dr. Woodcock. The reasons that we discussed at the previous hearing are cost of personnel, the lax environmental regulations, which are very -- it's a very important issue in other countries compared to the U.S., and, you know, the cost of doing business is lower.

Mr. Mullin. So we've basically regulated these manufacturers out of the country?

Dr. Woodcock. Yes. Well, we feel that advance manufacturing, which is what FDA has been trying to bring about in this pharmaceutical sector for the last 20 years, would -- you could bring manufacturing back to the United States, because it's not -- it doesn't have a huge environmental impact. It has a smaller footprint, and it's very cost effective, but there is a cost of doing that.

And Sanofi has built a plant in Framingham that they recently announced has successfully completed all its test runs and is one of these plants of the future in the United States.

Mr. Mullin. We'd love to work with you moving forward on that because we'd love to see the manufacturing come back, and so anything our office can partner with the FDA on, consider us a friend.

Dr. Woodcock. We would be happy, because we're very excited about this.

Mr. Mullin. Thank you. I yield back.

Ms. DeGette. The gentlelady from New York is now recognized for 5 minutes.

Ms. Clarke. Thank you, Madam Chairwoman, and I thank our Ranking Member Guthrie, for convening this timely oversight hearing on the Food and Drug Administration's inspection program for foreign drugs. I'd like to thank you both as well, our witnesses, for being here today to testify on behalf of the FDA and the GAO.

The fact is that our drug supply is becoming increasingly global. Many of the drugs that Americans rely on every day are produced around the world. As such, FDA must adapt to this new reality to ensure that our drug supply remains safe and that the manufacturers are held accountable.

So let me start with you, Mrs. -- Dr. Denigan. Why should we be concerned that FDA's inspections of foreign manufacturers might not be equivalent to its inspections of

domestic manufacturers?

Dr. Denigan. Well, that equivalency is important. They don't announce inspections here for a reason, and so you want -- for the same reason, you want to see -- I know it's a snapshot, but you -- that's your best chance of being able to see what the process actually looks like, not what it looks like after 3 months of working with a contractor, for example, to -- to get into compliance.

Ms. Clarke. One of the committee's longstanding concerns is FDA's ability to get out and inspect the thousands of firms around the world. After Congress gave FDA more authority and resources, FDA was able to conduct more inspections. However, after 2016, the number of inspections went back down.

Dr. Denigan, why did the number of FDA's foreign inspections decrease in recent years, and what does this mean for the FDA's ability to oversee the Nation's drug supply?

Dr. Denigan. Well, and I -- I think, as Dr. Woodcock has pointed out, the staffing shortages have been a tremendous strain and have made it very challenging to conduct. In addition, we do have concerns about the accuracy of the data to understand the denominator of those that they need to inspect.

Ms. Clarke. Very well.

Dr. Woodcock, FDA has made improvements over the last decade in its ability to inspect more foreign firms, and we are appreciative of that work. But as we just heard, there's more work to be done on hiring inspectors and getting better data.

Dr. Woodcock, what is FDA doing about all the remaining unresolved issues that GAO has identified in its recent work? And we've been talking about these same issues for two decades now?

Dr. Woodcock. Well, we have brought about a lot of change. We're doing

more foreign inspections now than we're doing domestic inspections. We are working on hiring. The FDA has just received direct hiring authority for the field inspectors, and so they have 20 that they're onboarding. They expect to hire a total of 50 by the end of this upcoming calendar year. So that would be an addition in the pharmaceutical inspectorate.

We've done what we can on data, and we're very interested in working with the Congress on better data sources so that we can have a better understanding of the firms that are shipping drugs into the United States.

As far as cleaning up the registration database, that's -- there are a variety of techniques we could use to do that. I mentioned one, perhaps a modest fee for listing might discourage some of these foreign entrepreneurs from listing with never having an intent to ship into the United States, but there might be other ways to do this, and we could talk about that.

And then, you know, better data that we could make a true predictive model instead of our site selection model that we have, but a true predictive model based on data would be a tremendous advance.

We also are working on advance manufacturing, which could actually bring manufacturing back into the United States, or if it were outside the U.S., it would be much better controlled. We would know even remotely with that kind of manufacturing if things were going wrong.

Ms. Clarke. Well, Dr. Woodcock, that sounds -- that sounds promising. I'd like to encourage us to -- to really move in that direction, because our reliance on foreign manufacturing, I believe, is only likely to increase as we look at the sort of aging of Americans, the boomer generation and the young folks coming up who, you know,

unfortunately, may need some pharmaceuticals to make sure that their quality of life is preserved.

So, Dr. Denigan, overall, do you believe the FDA is where it needs to be to effectively regulate the drugs coming from overseas, and if not, what more needs -- does the FDA still need to do?

Dr. Denigan. Well, they certainly have made great strides since 1998, and I know I'm going to run out of time. But clearly, they need to work on getting folks on board, keeping them on board, perhaps looking at other models. You know, the Foreign Service, they're now a global agency, and they weren't designed to be a global agency originally.

Ms. Clarke. Very well.

Thank you, Madam Chair. I yield back.

Ms. DeGette. Thank you very much.

The chair now recognizes Mr. Walden for 5 minutes.

Mr. Walden. Thank you very much, Madam Chair, and again, thanks for having this really important hearing. To our witnesses, thank you both for being here.

Dr. Woodcock, FDA in January of 2014, the FDA began a pilot program in India of no-notice and short-notice inspections of drug manufacturing plants instead of customary preannounced inspections. And over the course of 18 months, I'm told, the unannounced inspections revealed some troubling conditions from a bird infestation at one plant to a plant that entirely faked its environmental monitoring data, purporting to have screened for micro bile and contamination when it had not.

Under the India pilot program, the rate at which FDA inspectors recommended the most serious findings of official action indicated an increase by almost 60 percent.

Yet in July of 2015, the FDA discontinued the program and resumed preannounced inspections.

So considering the high rate at which inspectors found serious violations, why did FDA discount -- or discontinue, I'm sorry, this program?

Dr. Woodcock. Well, this program was done by the India office, is my understanding, okay, which reports through a different structure. And apparently, it was simply -- it wasn't really a program; it was an initiative of the India office, and they decided to conclude it after a certain amount of time. And so --

Mr. Walden. Do you have any idea why, though?

Dr. Woodcock. No.

Mr. Walden. Because it would seem to identify a better path forward if you're trying to uncover problems at these facilities.

Dr. Woodcock. Well, there were resources involved. The India office and other personnel had to do a lot of additional work to arrange this travel and enable the inspectors to kind of show up in a surprise. The foreign offices currently do unannounced inspections when they have inspectors resident in the foreign offices. They do unannounced inspections.

Mr. Walden. Do we have them in India and China?

Dr. Woodcock. Yes. We do have inspectors there.

Mr. Walden. But do they do unannounced inspections?

Dr. Woodcock. Yes, they can do unannounced inspections.

Mr. Walden. And do they?

Dr. Woodcock. Yes, uh-huh.

Mr. Walden. Yeah.

Dr. Woodcock. It's the domestic people who travel over and make these long trips where they're, for 3 weeks, they're going to inspect three different silos. They want to make sure they're operating and so forth that are the preannounced.

Mr. Walden. So rather than discontinue due to -- I've been told it was also a lack of protocols and criteria that may have led to this discontinuation. Do you think they should have developed evaluation criteria or undertaken a formal review of the program?

Dr. Woodcock. Well, again, I don't know enough about it.

Mr. Walden. Okay.

Dr. Woodcock. It's not in my chain of, you know, responsibilities. Certainly, we're being urged today to evaluate -- to develop and evaluate such a pilot.

Mr. Walden. Which is -- and I'm sure you -- you know that it raises issues for us. I mean, we look at that and go, wow, something -- they were uncovering more when they did that type of inspection.

Dr. Woodcock. Well, that -- that isn't clear. And with all due respect to my GAO colleague, all these ideas are anecdotal. We know that 90 percent of the fraud and so forth that we uncover in our inspections is by -- in foreign countries is by domestic-based inspectors who go over there and do unannounced inspections, and they still find this fraud and so forth. And a tremendous amount has changed over this period, even from 2014, but nobody is denying that unannounced inspections, team inspections, more inspections in the foreign area wouldn't be a good idea.

Mr. Walden. Dr. Denigan, do you want to comment on any of this?

Dr. Denigan. Sure. Based on the data that we have, the whole value of the foreign offices is to provide -- not the whole value, but one of the major contributions of the foreign office is to be able to get local intel. And based on the local intel that the

India offices -- office found, they had lapses in integrity of quality, production, laboratory data, significant GMP deficiencies, and firms were found to have been creating records. And so with their initiative, they did 16 unannounced inspections. And of those 16, 15 of the firms ended up with serious problems. Now, mind you, they targeted firms that they knew were high risk --

Mr. Walden. Okay.

Dr. Denigan. -- but that's the value of using your resources.

Mr. Walden. Yeah. Dr. Woodcock?

Dr. Woodcock. So some of this is still going on, because part of this program was to develop this intensive intel and brief the inspector about all this before they go in. Now, the Office of Surveillance that we formed in Office of Pharmaceutical Quality with our reorganization, now provides site dossiers for inspectors before they go into a site, and that pulls together all sorts of information. It's probably not as good as the local intel, but we try to get the foreign offices to add that. But that's my point, you know, you're comparing a little bit apples and oranges.

Mr. Walden. Right.

Dr. Woodcock. I mean, we do all the for-cause inspections we do if we got intel, and we were going to go because of a whistleblower, we would do unannounced.

Mr. Walden. All right. My time has expired. Thank you, Madam Chair, and thanks to both of you.

Dr. Woodcock. Thank you so much.

Mr. Walden. We all want to get this right and make sure we have a safe supply chain, so thank you.

Ms. DeGette. The chair now recognizes the gentlelady from Illinois for

5 minutes.

Ms. Schakowsky. Thank you so much, Madam Chairman.

There's so much going on today, and so I was in all kinds of other places, and I missed your opening statements, and I apologize for that. So I'm trying to figure out what to worry about or not to worry about. And, for example, I received a -- where did it go? -- a letter. Oh, okay. There it is.

I received a letter from a constituent, Chris Collins is his name, in September. And he wrote to me about his belief that, quote, offshoring of generic drugs has made the United States exposed to potentially unsafe and ineffective medicines and deprives us of a domestic supply of critical medicines in case of a national emergency. And then he quotes from a book, which may be totally a scam, I don't know, "A Bottle of Lies," that suggests in a quote that generic -- quote, generic drugs are poisoning us.

So there are two issues here. One is offshore, that so much of our supply is coming from overseas. What it says in our memo is that FDA estimates that nearly 40 percent of finished drugs, drug products, and 72 percent of active ingredients come from overseas. So I'm trying to divide out --

He's also -- he's complaining about generics and he's also complaining about overseas. So first of all, is there a difference in imports? We import brand name as well as generics? Is that the case, Dr. Woodcock?

Dr. Woodcock. Yes. Those figures include both.

Ms. Schakowsky. And is it about even number of generics, brand names, or --

Dr. Woodcock. That I -- I could get you.

Ms. Schakowsky. Okay.

Dr. Woodcock. We have all these figures cut many different ways. But,

certainly, a large number of brand names source their API from India or China or elsewhere. And forever, a lot of brand names have been made in Europe.

Ms. Schakowsky. So I'm -- I'm trying to understand, Dr. Denigan. So from the GAO, what am I to be worried about? What -- what is the problem?

Dr. Denigan. Well, it's true that the majority of our drugs, whether it's generic, over-the-counter, or brand name, are coming from overseas. And I think the concern is ensuring that the current tools that FDA has at its disposal are being used to their maximum. It would be great if we could move towards advanced manufacturing and be able to enhance our capacity here, but the fact of the matter is these are the tools that they currently have, and they need to staff up these offices and they need to ensure that the inspections are as equivalent as possible to here in the U.S.

Ms. Schakowsky. So it's something about minimum standards. I'm looking for the -- the language. It says the -- the Current Good Manufacturing Practices regulation, CGMP regulation, lay out minimum requirements for the methods, facilities, et cetera. Is -- is that what we want? What is -- minimum doesn't feel good to me.

Dr. Woodcock. Well, I just spoke to a large group of manufacturers yesterday, many of them from brand name, and they agree. All of them aim at this minimum. That's one of the problems. That quote, I believe, or something like it comes from a report on shortages which points out that having true reliability of a supply requires quality maturity. GMPs make sure that if you make a product, it'll be fit for purpose that day. It doesn't say that 6 months later, you're going to be able to keep making the product at the same level.

So we feel that we would like to have a positive program as well where we recognize excellence wherever it occurs so we can incentivize manufacturers and

purchasers to recognize quality, high quality.

Ms. Schakowsky. Is part of the problem, Dr. Denigan, we have to staff up, there has to be more resources to do the number of inspections that would make a difference?

Dr. Denigan. Well, I'd be concerned at just staffing up, because there's concerns on being able to not only through the direct hire authority to get them on board, but to keep them on board. And there are problems that, indeed, they go over on 2-year rotations in the overseas offices, and they come home, and they don't have a good way of integrating them back like they do with other offices that are more familiar with how to do that.

Ms. Schakowsky. Thank you. I appreciate this.

I yield back.

Ms. DeGette. The chair now recognizes the chairman of the full committee, Mr. Pallone, for 5 minutes.

The Chairman. Thank you, Chairwoman DeGette.

As has been mentioned today, this committee has been examining FDA's foreign drug inspection program for nearly two decades. And without question, the FDA has made progress thanks, in part, to new legislation. But I mentioned in my opening statement, over the years, Congress has taken various steps to improve FDA's ability to conduct foreign inspections. But despite this, FDA's foreign drug inspection program continues to be challenged by the same longstanding issues that have persisted for years.

For example, as we heard from the GAO today, staffing continues to be a constant challenge for FDA's foreign drug inspection program. To assist, Congress reauthorized GDUFA, which allowed FDA to collect generic drug user fees which could then be used to hire additional inspectors.

So, Dr. Woodcock, the 2016 GAO report found that only 8 percent of GDUFA inspectors were actually doing foreign inspections. How has FDA used the GDUFA resource to increase its foreign inspection capacity, if you will?

Dr. Woodcock. Well, the field has -- the field organization, ORA, has gotten what they call a cadre or group of people who strictly do foreign inspections, and then they qualify the other investigations to also be able to do foreign inspections. So the goal is to probably increase the number of people who do primarily foreign inspections. But we're challenged by the fact the entire field force is way under capacity, and they need to hire up.

The Chairman. Okay. We focused on FDA's role with these drug products overseas, but we know that domestic importers also play a role, and these companies have a responsibility to conduct due diligence to know where they're getting their drug products from and what kind of quality controls are used before the drugs arrive here.

So, again, what role do U.S. companies play in ensuring that the drug products they import are manufactured in accordance with the quality standards?

Dr. Woodcock. Companies are required as part of good manufacturing practices to validate their suppliers, to test incoming APIs or excipients or other ingredients that they'll put into their product if they're making them in the United States to make sure they are fit for purpose. And that same is true if, say, the finished dosage form is in Europe or in India or wherever it is. There are requirements that you qualify your raw ingredients and -- and your suppliers to make sure that they are the quality needed. So that's a requirement that has been in place for a long time.

The Chairman. But in the FDA's Safety and Innovation Act, Congress required that the commercial importers register with the FDA, as you said, and that the agency

should work with Customs and Border Protection to issue regulations to establish good importer practices for drugs. But can you provide the committee with an update on this work? And what more do you think domestic firms, especially those sourcing raw ingredients from abroad, should be doing to ensure that the products are safe?

Dr. Woodcock. Well, the Custom and Border Patrol, that is within -- under -- the work with them is under ORA. I know significant progress has been made, but I can't give you the details. We can get back to you on that.

The API manufacturers and finished dosage form manufacturers are supposed to qualify all the ingredients that they may use and do tests that are applicable, safety tests or quality tests, to make sure they're using the proper ingredients, and that's their responsibility wherever they're located.

The importers, it's more a matter of the data to make sure we're getting the correct information about what's coming across our border. Now, the agents are right at the border to make sure that we are notified if an ingredient crosses the border or a drug or whatever.

The Chairman. All right. Let me just add one more thing. The retail chains, they have a different role, as illustrated by the case of Dollar Tree. In that case, FDA conducted inspections of multiple foreign drug manufacturers and found significant violations, such as not testing raw materials and falsifying test results. So in addition to taking action against those firms, FDA also issued a warning letter to Dollar Tree and they stated, quote, you're responsible for ensuring that the drugs you distribute are manufactured in compliance with all relevant CGMP requirements for drugs.

So how are retail chains informed of unsafe products in its supply chain? And what more can they do to ensure the safety of the products that they offer for sale?

Dr. Woodcock. Right. Well, it depends on what role they have. If they are a distributor, they have a certain role under the GMPs. If they repack and relabel, then they have another level. We can get back to you on the details of what requirements are for every stage in that distribution chain, but they do have requirements.

And you're pointing out one of the loopholes I talked about earlier that OTC drug manufacturers can register and then ship without having an inspection. And so that's something that allows this type of thing to -- to go on.

The Chairman. All right. Thank you. And I know through the chairwoman, if you could get back to us in those cases where you said you would, I'd appreciate it. Thank you.

Dr. Woodcock. We certainly will.

Ms. DeGette. The gentleman yields back.

I really want to thank both of our witnesses for participating today. These are obviously important issues that the committee remains interested in.

And I want to remind members that pursuant to the committee rules, they have 10 days to submit additional questions for the record to be answered by the witnesses, and I ask that the witnesses would agree to respond promptly to any such questions.

With that, the subcommittee is adjourned.

[Whereupon, at 11:51 a.m., the subcommittee was adjourned.]