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EXAMINING THE ROOT CAUSES OF DRUG SHORTAGES:

CHALLENGES IN PHARMACEUTICAL DRUG SUPPLY CHAINS

THURSDAY, MAY 11, 2023

House of Representatives,

Subcommittee on Oversight and Investigations,

Committee on Energy and Commerce,

Washington, D.C.

The subcommittee met, pursuant to call, at 10:31 a.m. in Room 2123, Rayburn House Office Building, Hon. Morgan Griffith [chairman of the subcommittee] presiding.

Present: Representatives Griffith, Duncan, Palmer, Lesko, Crenshaw, Rodgers (ex officio); Castor, Schakowsky, Tonko, Ruiz, Peters, and Pallone (ex officio).

Staff Present: Kate Arey, Digital Director; Sean Brebbia, Chief Counsel; Lauren Eriksen, Clerk; Peter Kielty,

General Counsel; Emily King, Member Services Director; Karli Plucker, Director of Operations (shared staff); Gavin Proffitt, Professional Staff Member; John Strom, Counsel; Michael Taggart, Policy Director; Joanne Thomas, Counsel; Austin Flack, Minority Junior Professional Staff Member; Waverly Gordon, Minority Deputy Staff Director and General Counsel; Tiffany Guarascio, Minority Staff Director; Liz Johns, Minority GAO Detailee; Will McAuliffe, Minority Chief Counsel, Oversight and Investigations; Christina Parisi, Minority Professional Staff Member; Greg Pugh, Minority Staff Assistant; Harry Samuels, Minority Oversight Counsel; Andrew Souvall, Minority Director of Communications, Outreach, and Member Services; and Caroline Wood, Minority Research Analyst.

*Mr. Griffith. The Subcommittee on Oversight and Investigations will now come to order.

The chair recognizes himself for five minutes for an opening statement.

Good morning, and welcome to today's hearing. This morning's hearing will examine the very serious and growing problem of prescription drug shortages.

Americans need more reliable access to lifesaving drugs. According to the American Society of Health-System Pharmacists, we currently have over 247 active drug shortages. Between 2021 and 2022, drug shortages increased by almost 30 percent. It is unbelievable that in our great country there is a shortage of drugs to treat childhood cancer, and that is just one example. It is even more galling when you consider that most shortages are in the generic drug space, where there should be competition. The median price of a drug in shortage between 2013 and 2017 was less than $9 per treatment dose.

Generic drugs account for 90 percent of all prescriptions, but only 17 percent of drug spending. Generics are perhaps the only significant segment of our health care industry where costs have not increased faster than inflation. The generic pharmaceutical industry is plagued with a myriad of issues leading to drug shortages.

We have an economic environment so unappealing to

manufacturers that lifesaving drugs are produced by one or, at most, two companies worldwide, often at unsustainably artificially low prices. There is a broad consensus that the root cause of drug shortages is a profound market failure caused by economic forces unique to the drug market.

Middlemen such as Pharmaceutical Benefit Managers, PBMs, or Group Purchasing Organizations, GPOs, do not care to look for ways to mitigate shortages. By one count, for every $100 spent on a generic prescription drug, $44 goes not to the manufacturer, not to the producer, but to a middleman. The three largest Pharmaceutical Benefit Managers control around 80 percent of the commercial drug sales.

The 4 largest Group Purchasing Organizations control 90 percent of the medical supply market, and have massive market power. They could help end drug shortages by prioritizing generic drugs' availability and quality. Instead, they use their market power to force a race-to-the-bottom pricing without consideration for quality or availability. Their contracts with generic drug manufacturers consist of a take-it-or-leave-it approach, leaving the generic manufacturer with the option of either complying or losing access to the market. Many of them choose to lose that access and just go out of business.

Over the past 10 years, the United States has seen dozens of generic drug manufacturing facilities close, and

this shortage problem isn't limited to just closings. The typical generic drug has just two manufacturing facilities. We currently do not fully utilize the factories that we have. As Professor Sardella notes, we only use about half of our current generic manufacturing capabilities. We now have fewer manufacturing facilities both in the U.S. and globally, and our supply chain has proven to be fragile and vulnerable to disruption. Forty percent of generic drugs are made at a single facility, thus even a temporary shutdown of a single facility triggers a shortage.

We are also far too dependent on foreign countries for generic drugs and active pharmaceutical ingredients, or API, especially China and India. Our dependance on China represents a serious national security risk. China's new interpretation of its national security law may actually make FDA's already anemic inspection program in that country a crime.

As we are holding this hearing, FDA Commissioner Califf is appearing before our Health Subcommittee. All too often his agency has made drug shortages worse, and left us more vulnerable. The FDA's response to shortages is to allow for foreign-made generics and API to come unfettered to the U.S. market. The FDA claims to be focused on collecting information, but it does not effectively use the information that it already has.

We need an FDA that prioritizes applications from U.S. manufacturers and gives companies the flexibility to address shortages with resources based here. Solving drug shortages is going to require an all-of-the-above approach. Purchasers of generic drugs must incentivize quality and reliability in generic drugs, and we must always keep in mind the human toll of drug shortages.

I look forward to hearing from our witnesses today who are working in innovative ways to help solve drug shortages.

[The prepared statement of Mr. Griffith follows:]

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

*Mr. Griffith. I thank you all for being here, and I yield back. I now recognize the gentlelady from Florida, Ms. Castor, ranking member of the subcommittee, for her five-minute opening statement.

*Ms. Castor. Well, thank you, Mr. Chairman, and thank you for calling this critical hearing on the root causes of drug shortages.

These drug shortages are becoming more prevalent due to a warped marketplace. And as a witness Professor Laura Bray in her testimony stated, no patient should have to hear the words, "We do not have medicine to treat you."

Drug shortages in America are at a 5-year high. In 2022 we experienced a 30 percent jump in the number of drugs in shortage. FDA has documented 136 drugs on its shortage list, and health care providers suspect the actual number is far higher. These shortages can last years, and some critical drugs have been in shortage for over a decade. The impacts of these shortages on our neighbors receiving cancer care, children and their caregivers, are incredibly upsetting because when drugs are in short supply lifesaving care can be delayed, can be canceled, patients may be placed on medication that is less effective or more expensive.

The cascading impacts of not receiving appropriate medicine can impair a person's ability to live a full life, to attend school, to work. Plus, it can lead to increased

costs of care and more serious health complications like adverse drug reactions, increased hospitalizations, or even death.

Children and their providers can be hit particularly hard by drug shortages. Children's hospitals often frantically respond to these shortages by scrambling for necessary and appropriate drugs. They have to devote additional staff time and resources to finding ~~a~~ appropriate replacement drugs and determine the appropriate dosage for the replacement drug. Is it safe for children? It takes children's hospitals 50 percent longer to address shortages than other hospitals because of the time needed to compound replacement products into pediatric dosage forms. And it is so costly. One drug in shortage alone can cost a children's hospital north of $50,000 in labor and substitute products.

So we have got to get ahead of these shortages before they happen so that our neighbors and providers are not blindsided and left scrambling to find workarounds.

This past winter's triple epidemic of the flu, RSV, and COVID-19 were exceedingly difficult because shortages of basic medicine like Tylenol and ibuprofen ultimately got so severe that retailers began imposing purchase limits at the counter, sending parents searching multiple locations for medication to take care of their families. FDA took the action it could within its limited authority to ensure that

more products were available for consumers, but the current haphazard approach of addressing crisis episode by episode is not working to give American families the certainty and the quality of care they need and deserve.

So together we need to require greater transparency from manufacturers about where they source raw materials for drugs. We know that 72 percent of manufacturers supplying the U.S. market with active pharmaceutical ingredients, or API, are overseas, mostly in India and China, and the percentage of APIs manufactured in those countries by volume may be higher. I sit on the Select Committee on the Strategic Competition between the U.S. and the Chinese Communist Party, and API manufacturing is another example how over-reliance on raw materials from China creates real-life risks to the well-being of Americans.

Greater transparency will help us better understand where we need to shore up the domestic production and invest in new technologies. But the need to address shortages doesn't end with manufacturers. We need to make sure that the anti-consumer behavior by intermediaries like PBMs and GPOs does not create affordability barriers for patients that magnify the effects of drug shortages for families in need.

And we have a model, Mr. Chairman, for action, for bipartisan action. When faced with a semiconductor shortage, Congress acted to adopt the CHIPS and Science Act and invest

in Americans and our supply chains. Drug shortages will also require a coordinated approach across government, but with manufacturers, providers, and payers to create domestic production, ~~to~~ shore up supply chains, and revitalize scientific research that hopefully will strengthen our economy and our health care system.

I hope that our witnesses today can help us better understand the reasons why shortages occur and persist, and how better and smarter tools would improve insight into the supply chain to better guide strategies to strengthen it. By better understanding the root causes of these shortages, Congress and our public health institutions can enact policies to address them.

I am really looking forward to our witnesses today and covering this topic. So thank you all for being here.

[The prepared statement of Ms. Castor follows:]

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

*Ms. Castor. And I yield back my time.

*Mr. Griffith. I thank the gentlelady for yielding back, and now recognize the chairwoman of the full committee, Mrs. McMorris Rodgers, for her five minutes of opening statement.

*The Chair. Good morning. Our goal today is to examine the complex challenges and root causes that lead to drug shortages.

Just last November, in September -- in Spokane parents were shocked that Amoxicillin, a common antibiotic, wasn't readily available at pharmacies. Parents had to contact multiple pharmacies and talk to the doctor to get alternatives, which is no small effort when your child is sick.

Our committee has exposed the harmful consequences of consolidation, Federal programs, and malincentives that distort the market and make it more difficult for patients to get lower cost medication. Sometimes it is because these medications are not on pharmacy or hospital shelves, or because they are not covered by insurance. These market distortions hinder the adoption of quality generic drugs and weaken the drug supply chain.

The FDA has not been an effective partner in combating drug shortages. Even after Congress provided FDA new authority in 2020 to get more information regarding where

American prescription drugs are made, we still do not have good data on where either finished medications or active pharmaceutical ingredients, or APIs, are sourced.

FDA last testified that around 80 percent of API facilities and 60 percent of finished dosage facilities are overseas, including India and adversarial countries like China. These are countries who limit our foreign drug inspection program's ability to operate adequately. It is an enormous problem if we cannot properly inspect the quality of the ingredients in common drugs Americans rely on.

This situation not only raises concerns over drug quality, but it also poses a significant threat to national security. If adversarial countries were to cut off the supply of necessary APIs to manufacturers, American patients' lives could hang in the balance.

Further, the COVID-19 pandemic taught us that we cannot rely on the Chinese Communist Party, which blocked the export of PPE and other critical supplies, lied about positive case numbers, and has refused to cooperate into any meaningful investigation into the origins of COVID-19.

As we strive to strengthen our supply chain, we must encourage American innovation, increase domestic manufacturing capabilities, and promote the adoption of quality generic drugs. And we need a system that acknowledges and rewards such innovation.

In 2019 HHS programs accounted for 40 percent -- 41 percent of all prescription drug spending. Yet those programs may have unintended consequences leading to unsustainably low prices or incentivizing middlemen to get the best deal at the expense of a secure supply chain. We should look at all Federal programs this committee oversees to help create a more secure and reliable drug supply chain for our nation.

We have gathered a diverse group of witnesses with expertise into the pharmaceutical drug supply chain to help us start to dig into these complex programs and challenges and what potential solutions there are, whether in American manufacturing or in trying to innovate around middlemen in the system.

We will also hear from Laura Bray on why this work to stop shortages is so important. Laura has heard many times what no parent wants to hear, that there is a shortage of medicine needed to treat her doctor's -- or her daughter's cancer.

As I close, I want to note that I am encouraged by the bipartisan approach to this hearing. This is a critical issue that transcends political party lines, and I am confident that by working together we can help ensure more people like Laura's daughter get the lifesaving care and medicines that they need when they need it. Thank you.

[The prepared statement of The Chair follows:]

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

*Mr. Griffith. I thank the gentlelady for yielding back. I now recognize the ranking member of the full committee, Mr. Pallone, for his five-minute opening statement.

*Mr. Pallone. Thank you, Mr. Chairman.

Today we are examining the root causes of drug shortages, which negatively impact the health and well-being of so many Americans. Drug shortages are not a new issue, but unfortunately, they are currently at a five-year high. Shortages can last anywhere from a year to over a decade, with 15 critical drugs in shortage for over 10 years. This past -- this past year alone, we have seen harmful disruptions in the availability of children's pain medication and medication to create or to treat conditions like ADHD. And these shortages can result in delayed care, ineffective treatment, increased hospitalizations, and even death.

So we need to do more to prevent these drug shortages, including building a robust and resilient drug supply chain. This is not only critical to the health and well-being of Americans, but also to our national security. However, we cannot effectively tackle the challenges associated with drug shortages without more information about the current supply chain. Key gaps remain in our understanding of how drugs are manufactured and brought to market.

The Administration for Strategic Preparedness and

Response has shared that there can be up to 20 key materials per pharmaceutical. However, our public health agencies currently do not know which materials are used in the production of each drug, and in what quantity. We also do not know the quantity of active pharmaceutical ingredients used in drugs for the U.S. market that is manufactured overseas. And while we know that 72 percent of active pharmaceutical ingredient manufacturers serving the U.S. market are overseas, we do not know the actual volume of the ingredients that they manufacture, and that number is likely much higher than the 72 percent.

So FDA has some limited tools to examine the supply chain. Recently, as part of the CARES Act, Congress took bipartisan action to start addressing drug supply chain information gaps. The law included a requirement that manufacturers develop risk management plans and annually report to FDA on the amount of each drug they make available for commercial distribution. This is a step in the right direction, providing us more information than we had before. And while it has been useful, it is not enough to fully address drug shortages caused by supply chain issues.

FDA has repeatedly told us that, with its limited tools, it is simply not capable of using its existing authorities to directly prevent or mitigate a shortage. For example, FDA's current reporting requirements don't allow the agency to

determine which suppliers of active pharmaceutical ingredients manufacturers rely on. This makes it difficult to predict how a disruption with one supplier would affect a manufacturer's ability to produce their drugs.

FDA's tools are even more limited when it comes to forecasting and anticipating changes in demand. We have seen how sudden spikes in demand for certain drugs can cause a shortage, most recently in the market for Adderall and children's pain medication. However, manufacturers are not required to report those demand surges to FDA, which means FDA may lack the information it needs to foresee a shortage. Without that information, FDA can't take the necessary action to identify new manufacturers, expedite additional inspections, or review new products that can fill gaps.

So giving FDA these tools will allow the agency to understand why these shortages occur so that we can take action to predict and address them. I would like to hear from our witnesses how greater visibility into the supply chain will help alleviate challenges that drive disruptions in drug availability. And most importantly, I look forward to discussing how more reliable access to important drugs would improve the lives of patients and their families.

So I am pleased the subcommittee is also hearing from experts about what we can do to increase pharmaceutical manufacturing efficiency for greater domestic production.

I especially want to thank Professor Muzzio from Rutgers University in my congressional district for being here today. Dr. Muzzio directs Rutgers Center for Structured Organic Particulate Systems, and he is a national leader in the development of continuous manufacturing methods and technologies, which will help us improve drug manufacturing efficiency and quality.

Dr. Muzzio was also instrumental in supporting passage of my legislation, the National Centers of Excellence in Advanced and~~ing~~ Continuous Pharmaceutical Manufacturing Act, which President Biden signed into law last year. And that law empowers the FDA to partner with universities around the country to further develop continuous manufacturing technology, which will, hopefully, strengthen domestic pharmaceutical manufacturing and help prevent future drug supply chain shortages.

So thank you for being here today, Dr. Muzzio.

Thank you to all the witnesses.

[The prepared statement of Mr. Pallone follows:]

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

*Mr. Pallone. And with that, Mr. Chairman, I yield back.

*Mr. Griffith. I thank the gentleman for yielding back. That concludes the members' opening statements.

I remind all members that, pursuant to committee rules, the members' opening statements will be made a part of the record.

We want to thank all of our witnesses for being here today and take the time to testify before our subcommittee.

Each witness will have the opportunity to give an opening statement, followed by a round of questions from members.

Our witnesses today are Dr. Alex Oshmyansky, CEO/founder of the Mark Cuban Cost Plus Drug Company; Anthony Sardella, chair, API Innovation Center; Laura Bray, founder, Angels for Change; and Fernando Muzzio, distinguished professor of chemical and biochemical engineering at Rutgers University, which I learned is in Mr. Pallone's district.

We do appreciate you all being here today, and we look forward to hearing from you on this important issue. And thank you so much for taking your time.

As you know, and as you are aware, this committee is holding an oversight hearing, and when doing so we have the practice of taking our testimony under oath. Do any of you have an objection to testifying under oath?

Seeing that no one has objected, we will proceed.

Further, you are advised that you are entitled by counsel -- you are entitled to have counsel present with you, pursuant to House rules. Do any of you wish to have your counsel present with you today?

All right, seeing that none have desired to have their counsel with them, would you all rise and raise your right hand, please?

[Witnesses sworn.]

*Mr. Griffith. Recognizing that all responded in the affirmative -- and you all can be seated, thank you -- recognizing that all have responded in the affirmative, I would say that you are now sworn in and under oath, subject to the penalties set forth in title 18, section 1001 of the United States Code.

All right. We got through all the legal mumbo jumbo that we needed to get through. We will now recognize Alex Oshmyansky for his five-minute opening statement.

*Dr. Oshmyansky. Alex is fine.

*Mr. Griffith. All right.

*Dr. Oshmyansky. First, thank you so much to the subcommittee.

*Mr. Griffith. Yes, we need you to turn on the mike and --

*Dr. Oshmyansky. Hear me?

*Mr. Griffith. Yes, maybe pull it up a little bit so you are loud enough. We could hear you, but then nobody at home --

*Dr. Oshmyansky. Oh, but no one else. Got you.

*Mr. Griffith. -- or on C-SPAN can hear you.

*Dr. Oshmyansky. Okay.

TESTIMONY OF ALEX OSHMYANSKY, MD, PHD, CEO/FOUNDER, MARK CUBAN COST PLUS DRUG COMPANY; ANTHONY SARDELLA, CHAIR, API INNOVATION CENTER, ADJUNCT LECTURER & SENIOR RESEARCH ADVISOR, CENTER FOR ANALYTICS & BUSINESS INSIGHTS, WASHINGTON UNIVERSITY IN ST. LOUIS; LAURA BRAY, FOUNDER, ANGELS FOR CHANGE; AND FERNANDO MUZZIO, PHD, DISTINGUISHED PROFESSOR OF CHEMICAL & BIOCHEMICAL ENGINEERING, RUTGERS UNIVERSITY

TESTIMONY OF ALEX OSHMYANSKY

*Dr. Oshmyansky. Well, first off, thank you so much to the committee and the subcommittee for inviting me to speak today. It's an honor and a privilege.

As I speak here today, there are approximately 200 drug products listed as in shortage on the U.S. FDA shortage database. Many of these medicines are critical lifesaving medications such as albuterol, the treatment for an acute asthma attack. Several chemotherapeutic drugs for cancer are in shortage.

The rates of morbidity and mortality for pediatric cancers in the U.S. have gone up in recent years, as the medications necessary to treat them are increasingly unavailable. The majority of these medications are relatively simple to make, and have been available for decades. How is it that they are unavailable in the United

States, the wealthiest country in the history of human civilization?

The root underlying causes are complex and multi-factorial. However, Mark Cuban Cost Plus Drug Company is working diligently in the background to try to address drug shortages through a combination of innovative technologies and business model innovation.

We have constructed an advanced pharmaceutical manufacturing plant in Dallas, Texas. The facility utilizes robotic fill finish technology optimized by AI machine vision systems that are designed to incorporate single use disposable components. The robotic manufacturing systems installed at our manufacturing facility can transition between making batches of different types of medication within hours, rather than months, with full FDA cGMP compliance. This allows us to very rapidly pivot from making one drug type to another in order to address pharmaceutical drug shortages as they arrive.

In principle, we can have a new manufacturing line up in four hours. In combination with a regulatory strategy as a 503(b) compounding site, we are very rapidly able to pivot from making a shortage drug product with full compliance with FDA regulations.

In addition, within the next few months, we will be launching Mark Cuban Cost Plus wholesale, which will enable

independent pharmacies, clinics, and hospitals to get access not just to our products, but products from any pharmaceutical manufacturer at a true, transparent price. This will enable us to ensure distribution of products outside of the conventional distribution oligopolies.

Our pilot manufacturing facility is currently completing its validation process, and is expected to begin commercial sales later this year. It has an estimated capacity of between one and two million sterile doses of medication a year, either pre-filled vials or syringes. Initial products will include pediatric chemotherapy agents, lidocaine, and essential ICU medications. However, we will be nowhere near meeting the national demand for these products.

Mark Cuban Cost Plus has also drafted preliminary designs for a much larger facility, based on similar technologies, that would hopefully be able to alleviate the majority of acute drug shortage issues in the United States. We believe such a facility would cost approximately $300 million to construct, based on current estimates. We believe that through a private-public partnership or otherwise, through government investment, we will be able to build the infrastructure necessary to ensure pharmaceutical drug shortages no longer affect the health of Americans.

Thank you so much.

[The prepared statement of Dr. Oshmyansky follows:]

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

*Mr. Griffith. Thank you.

And we now recognize Mr. Sardella for his five-minute opening statement.

TESTIMONY OF ANTHONY SARDELLA

*Mr. Sardella. Good morning. I'd like to thank Chairman Griffith, Ranking Member Castor, and the distinguished members of the committee for holding this meeting. And it's a privilege to speak with you. My name is Tony Anthony Sardella. I'm an adjunct professor at the Olin Business School at Washington University. I'm also the university's senior analyst for their Center for Analytics and Business Insights, and also chair a new non-profit that is dedicated to the reshoring of API to the United States, the API Innovation Center.

The economic viability of the generic pharmaceutical industry, which represents over 90 percent of the medications prescribed in the United States, is diminishing and contributing to supply disruptions, drug shortages, with significant negative implications for U.S. health security. Economic conditions indicate that this environment will only worsen, further jeopardizing the quality and the stability of our nation's pharmaceutical supply chain.

COVID-19 revealed the country's over-reliance on foreign production of essential drugs. My research revealed that the United States has no domestic-based supply for approximately 83 percent of the top 100 generic medicines prescribed in America. These are highly prescribed medicines such as

cardiovascular, atorvastatin, and lisinopril that many patients leverage and rely on every single day.

The principal driver to strengthen our health security and keep our nation's drug supply chain secure is economics, not just logistics. We must address the economic instability of the generic pharmaceutical market. We must expand public and private partnerships, and incentivize domestic drug manufacturing.

Generic drugs are commodity products, and because they are substitutable, price becomes the dominant factor in any type of market competition. Since 2016, the generic industry has experienced price erosion greater than 50 percent. An average high-volume 30 count bottle of medicine is now less than $1.50, the equivalent of $0.05 per tablet.

But there is a high cost to low prices. The implications are significant. Reduced earnings lead to cost cutting and reduced ability to invest in new product development, factory maintenance, and innovation. The economic pressures facing generic manufacturers are contributing to increased quality and compliance risks, as they are unable to expend capital to address FDA warning letters, evidenced by greater than 1 in 4 prescriptions in the U.S. are filled by a company that has received an FDA warning letter in the last 26 months.

No single entity can solve this complex problem and

challenge to strengthen our domestic manufacturing. It requires a coordinated approach between the public and private sector. It involves, first, the de-risking of the adoption of advanced manufacturing technologies that will make the U.S. manufacturing globally competitive.

Second, it involves leveraging existing available generic manufacturing infrastructure. In September last year I published a study that revealed that, of the 37 U.S. generic manufacturing sites surveyed in my research, they were producing at just half of their annual production capacity. And by repurposing the existing auto manufacturing base, 57 percent of the U.S. manufacturing sites could be operational in 1 year, and 86 within 2 years, which equates to 30 billion capsules and doses of essential and critical medicines within a 2-year period.

Third, several market-based solutions exist to foster industry investment in domestic manufacturing, and ensure a long-term, sustainable U.S.-based supply. The driver of price erosion for generics is the inability to differentiate on product quality, a dimension of market competition in virtually every other market.

Quality price trade-offs can be addressed by creating transparent quality scores that enables competition on a dimension beyond only price, while incentivizing manufacturers with strong quality.

Leveraging the buying power of the Federal Government, which accounts for approximately 34 percent of total health care spending in the United States, with sourcing policies that favor and incentivize domestic manufacturing or manufacturers with strong compliance records -- which is a practice already employed in Germany, Brazil, India, and China -- is another important instrument to incentivize U.S.-based manufacturing.

Improving provider reimbursements for U.S.-made generics and realigning preferred drug list formularies can also drive incentives.

I'd like to thank the committee for your time and the opportunity to share my research, data, and perspective pertaining to the pharmaceutical supply chain and drug shortages.

[The prepared statement of Mr. Sardella follows:]

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

*Mr. Griffith. Thank you for yielding back.

I now recognize Ms. Bray for her five-minute opening statement.

TESTIMONY OF LAURA BRAY

*Ms. Bray. Good morning. I'm Laura Bray, chief change maker at Angels for Change, a volunteer-supported organization on a mission to end drug shortages. I appreciate the opportunity to speak here today and represent the patient voice.

Thank you for your leadership and bipartisan work to prevent and end drug shortages.

Four years ago my husband Mike and I were sitting in a hospital room when our child, Abby, was diagnosed with leukemia. At that moment we became caretakers while our child began to fight for her life. We were told we were lucky that this leukemia, unlike many other pediatric cancers, has a cure: a miracle protocol, a cocktail of drugs given in certain timeframes, but leading to very successful treatment.

The doctors used these success numbers -- above 90 percent -- to provide assurances, but also to alert us that compliance was the single most effective thing, as her parents, we could do every day for her survival. With our trusted physicians, nurses, care team, and child life specialists we became a team using every tool available to ensure our child's compliance of this cocktail.

When a child doesn't want to take her meds anymore, when

they can't take the pain of being poked and prodded again, when they lose their hair, when it's just too much, we all focus on the importance of the medicine for their survival.

I was sitting in a hospital room with Abby when I first heard the words, "We don't have the drug needed today. It's on shortage.’‘

My Abby, our fierce middle child, caught it right away, and said, "I thought I needed this. Does this mean I die?’‘

Before that moment I didn't know our pharmaceutical supply chain was broken. I had the same questions she had. I told her the only thing I could. "We're going to try to find it.’‘

With no experience, using my background as a business professor, the help of friends and family and Google, we successfully found the medicine. But it didn't end there. Abby's protocol was impacted by a drug shortage again and then again, three lifesaving shortages in nine months, different drugs, different root causes. It wasn't enough that my nine-year-old had to consider her mortality because of cancer. She also had to consider it again because our supply chain was not making enough medicines of the drugs I told her would save her.

This experience haunted me, and I began to ask questions about how common it was for patients to experience something like this. I was surprised by how easy it was to find the

answers. Twenty years of research outlining this drug shortage crisis. There had been calls to actions. There had been hearings like this going back many, many years.

If we had these answers, why did my child and our family have to go through this? It was such a cruel place to find ourselves. I knew no patient should have to go through a search again alone.

So with my friends and family joined in the mission, we launched Angels for Change in 2019, becoming the only patient advocacy organization with a mission to end drug shortages in the United States. And almost immediately, patients began to call. Eventually, hospitals began to call, too. I connected with members of the supply team, the supply chain. We learned from each other. I asked the members to become change makers with me.

The patients stuck in the drug shortage, they are our purpose. But it was the people that make up the supply chain that stepped up and took on collaborative, patient-focused work with us that gave me hope. To date, we have helped patients and hospitals find hundreds of courses of medicine stuck in this broken supply chain during three dozen different drug shortages.

Proactively, we foster stakeholder collaboration to build resiliency, convening members at our summit and helping to launch the End Drug Shortages Alliance, which now has 162

supply chain members ready to do this work. These collaborative spaces have led to innovative pilot programs like our Project Protect.

Through Prediction, a small manufacturing incentive grant of $100,000, we created gap supply of 2 essential medicines. Those medicines went short, and it was accessed 650,000 times last year for patients in need. This type of multi-stakeholder resiliency work must be supported and scaled.

Building a resilient supply chain will take more transparency, redundancy, and connectivity. Our pathway forward is built on six principles. I've outlined them in our written testimony. Every stakeholder will need to do their part, but together we can ensure no child will ask their parent, "Will I die if I don't get my medicine?'‘

Thank you.

[The prepared statement of Ms. Bray follows:]

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

*Mr. Griffith. Wow, thank you.

Dr. Muzzio, your five-minute opening statement. Thank you.

*Dr. Muzzio. Thank you. Can you hear me?

TESTIMONY OF FERNANDO MUZZIO

*Dr. Muzzio. So, Chairwoman Rodgers, Chairman Griffith, Ranking Member Pallone, Ranking Member Castor, members of the subcommittee, my name is Fernando Muzzio, I'm a distinguished professor of chemical and biochemical engineering at Rutgers University. And I'm the director of CSOPS, which is an NSF engineering research center focused on developing pharmaceutical products and processes. I greatly appreciate the opportunity to appear in this hearing to talk about the root causes of drug shortages, and also share some views on how advanced manufacturing could help mitigate this problem.

I want to make two facts, and I appreciate that my testimony may be a little different than the other witnesses.

The first fact is that we know that the proximate cause of more than 60 percent of shortages is quality issues, whether those quality issues are caused by economic reasons or something else, but quality issues cause the majority of the shortages.

The second fact is that advanced manufacturing methods can improve quality and quality control, and therefore may help reduce the incidence of some of these issues. Let me explain why.

In the traditional batch manufacturing approach, a manufacturer takes a large amount of ingredients, say 500

kilograms, puts that into a process unit, implements the process, then the material moves to another piece of equipment, and another piece of equipment, and after several steps over many hours to make a large number of product units, let's say a million tablets or a million vials. And then they take 10 to 30 samples from that million tablet batch, send them to the lab, get results, assume that those results are representative of the whole batch, and make the decision to release the product based on those results.

The process is time-dependent. Things are changing as you are going through this particular traditional process, and that can affect the quality of the product over time. And this provides also a very limited opportunity to observe product quality. In contrast, continuous manufacturing is capable of much better quality control.

First of all, the ingredients come into the process at a fixed ratio. They move gradually, but continuously from process unit to process unit, but we keep the process very close to steady conditions so that every portion of material experiences the same process. There is only a small amount of materials in the process at any time, but for every small portion of material, we monitor quality in real time. And this allows us to diagnose quality issues in real time, exclude faulty material from what's going to be dispensed to patients, and minimize quality failures.

Where are we in implementing this? Well, we started 17 years ago in our center. There were other efforts at the same time. We established a full ecosystem of industry, government, and academia, attracted over $120 million in funding for this work, and we built and demonstrated the first continuous manufacturing line that operated in a full state of control, and then supported Johnson and Johnson and other companies in commercially implementing these technologies.

In more recent developments -- and I want to give credit to the FDA for this -- the FDA emerging technology teams has accepted 42 proposals for continuous manufacturing review. They have, actually, as of March, approved 13 continuous manufacturing applications.

Direct compression, which is the most common type of continuous manufacturing, has now graduated as an emerging technology. They led the approval by the International Conference on Harmonization of what is called Q13, the global guidance in continuous manufacturing, and we have collectively built widespread consensus, including the U.S. Government through multiple administrations, that advanced and continuous manufacturing could be part of the solution.

Now, this also produces an important opportunity for our country. Given the advantages of continuous manufacturing, we expect that there will be hundreds of billions of dollars

manufactured by continuous manufacturing. We can agree that we would like that manufacturing to happen in the U.S. Now this is feasible, and it can be done in a sustainable manner because continuous manufacturing requires less unskilled labor, which, because that kind of labor is cheaper in other countries, has been one of the reasons why manufacturing moved to those other countries.

However, it's important to recognize that implementation of these technologies requires knowledge, requires training, and requires access to infrastructure.

We expect other developments in the next few years. For example, we expect that we will be able to implement what we would call advanced batch manufacturing, where we will use many of the techniques developed for continuous manufacturing, now adapted for batch, to be able to inspect 100 percent of the product stream so that every single product unit is analyzed in real time, and faulty product is sent to scrap.

We also expect that we're going to expand continuous manufacturing to generics, over-the-counter products, manufacture of active pharmaceutical ingredients and intermediates, as well as injectables, including biologics, and that we will use similar methods to create other advanced technologies such as distributed manufacturing.

All of this is possible, but to achieve this we really

need centers of excellence that will work in a sustained manner in re-energizing the partnership between government, regulators, and academia so that we can create places where all of the workforce can be trained, the know-how is available, and we can support industry, continue to move forward.

As in Public Law 117-328, these centers would also make possible to implement a national strategy in workforce development that is needed to facilitate this.

So in concluding, I would request please that my full written testimony be included in the record, and I will be happy to answer any questions that I may. Thank you.

[The prepared statement of Dr. Muzzio follows:]

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

*Mr. Griffith. Thank you very much for your testimony. Thank you to all the witnesses. At this point, we will begin the questioning process, and I will begin with five minutes of questioning.

Dr. Sardella, can you repeat for us -- I think this was in your testimony -- what percentage of the generic drugs are manufactured in facilities that have received an FDA warning letter?

Yes, turn your mike on.

*Mr. Sardella. One out of four prescriptions in the United States over the last twenty-six months.

*Mr. Griffith. So roughly 25 percent.

*Mr. Sardella. Correct.

*Mr. Griffith. In over how many months?

*Mr. Sardella. Twenty-six, the last twenty-six months.

*Mr. Griffith. And some of those FDA warning letters stay open for years, do they not?

*Mr. Sardella. That is correct. And the industry is less able, due to low margins, to be able to address them. And so their options are shutter, not comply, or continue to operate. And --

*Mr. Griffith. Let's talk about non-compliance, because while some of these warning letters may be on things that folks back home might think are trivial and so forth, but there was an open warning letter on the New England

Compounding Company at the time that they produced a sterile injection which cost -- I believe it was 38, 40 lives, several of whom were in my area. My district was impacted by that outbreak. And that was a warning letter because people were trying to cut costs.

And so I want folks back home -- and I think you would agree with me that when you have 25 percent of your generic medicines being manufactured under a warning letter, most of it is not going to be a big deal, but some of it might be a big deal, and this is a concern that we need to take, as a nation. Would you agree?

*Mr. Sardella. I agree, Chairman. In that spectrum there are very much warning letters that don't imply any type of safety issue, but there's also those that do, and those are significant, and have dire consequences.

*Mr. Griffith. Yes, and that is my concern here, is that, you know, in our race to save a few pennies here and there, we are sacrificing both availability that Ms. Bray talked about and quality.

All right, back to my real questions, the ones that I had prepared in advance. In your white paper, Dr. Sardella, you wrote that it is unrealistic to fully move our API sourcing and manufacturing onshore. Instead, you propose the U.S. API industry should achieve a minimum level of self-sustainability. Explain that for me.

*Mr. Sardella. We've done some research that estimates the cost to bringing the top 40 prescribed medicines and the top 40 essential medicines. We feel this would begin to stabilize the U.S. supply chain, reshoring those productions to the United States.

Our estimates are that that would cost less than $2 billion, which is less than 1 percent of our total spend on pharmaceuticals for those generics, and allow us to have greater certainty and control of our drugs, knowing that the APIs are the clinical part of the drug that allows it to be a great therapeutic. So --

*Mr. Griffith. And would you agree with me that it is likely, if we were to do something like that, that then that would also encourage other folks to maybe make some APIs that weren't in the top 40?

*Mr. Sardella. That's exactly correct. If we can think of them -- we use at the API Innovation Center the construct of critical and essential. If one -- critical being ones that are critical to our national security. Those cardiovasculars that we take, patients take every single day, they're not in shortage, but they're core to our national security.

The ability to incentivize production of those drugs here in the United States will allow for capability to produce the essentials in the United States and, therefore,

solving two of the issues, national security and our drug shortage for our essential medicines.

*Mr. Griffith. All right. You also talked about supply chain challenges and how that is exacerbated by inflexible regulations. Could you expand on that?

And are there lessons we can learn from our experience in moving up the speed on COVID-19 that we should look to extend?

*Mr. Sardella. Yeah. Well, I think on COVID-19 there are some efforts to allow for greater inspections of different facilities to allow for better quality to be produced. I think a couple of the key things that we've learned is any type of expedited approvals or processing allow for faster time to market, allowing companies to have a quicker return on their investment on their capital.

*Mr. Griffith. I have got one more question for you -- and I had some for the others, so I apologize, but I am running out of time -- Group Purchasing Organizations are considered the price setters for generic medications in our pharmacy supply chain, and they seem to create marketing efficiencies. What role have they played in creating current -- the current environment where we have shortages, and what accountability is there for GPOs when shortages occur?

*Mr. Sardella. The GPOs are contributing significantly to the aggregation of profits to them versus the

manufacturers. They're putting the manufacturers out of business, first.

The second -- I would caution -- as we develop policy to address GPOs, recognize that any redistribution of those profits would go to foreign manufacturers, not U.S., because that's where they're getting their supply. If the goal is to create a sustainable, strong economic, U.S.-based supply, that -- those incentives have to be established before the addressing the GPOs concentration of profits.

*Mr. Griffith. All right. I appreciate it. My time is up, and so I will now recognize the ranking member of the subcommittee, Ms. Castor, for her five minutes of questioning.

*Ms. Castor. Well, thank you, Mr. Chairman.

Professor Bray, I am so proud that a working mother from the Tampa Bay area of three children who grappled with a pediatric cancer diagnosis for her young daughter used her business acumen to start a non-profit to help solve the drug supply shortage. It's a remarkable story, and your voice is very important in this discussion.

So you explained your daughter went to one of the premier children's hospitals in America, Saint Joseph's Children's Hospital in Tampa. And yet they are grappling constantly with shortages of lifesaving drugs. What did you - what did you learn as you dug into it as to the root causes

of the -- of the drug shortages, and why is it impacting children especially?

*Ms. Bray. Thank you. Thank you for addressing me, and thank you for having this meeting today.

So first, pediatrics are uniquely vulnerable to drug shortage because we're a smaller patient population. And when you have a broken marketplace, the smaller samples will always fall out.

And then pediatric cancer is even a smaller niche of that small, broken place. And what we found is that, actually, pediatric cancer is 90 percent more likely to go into shortage, their drugs, and they stay short 30 percent longer. But it's -- compounds because their treatment is multi-layered, and relies on many different drugs and very specific protocols. So one or two drugs, in short, can have drastic problems to their -- to a pediatric cancer diagnosis.

What we have found, both, you know, initially, when we navigated the supply chain for my own child, but then as chief change maker at Angels for Change, we navigate this crisis for patients and hospitals all the time. I like to say, you know, the four P's, we're stuck here at the bottom. That's the physician, the pharmacist, the purchaser, and the patient. We're the consumer of these goods, and we do not have a lot of power during a time of disruption. And so together we can navigate this crisis a little bit better and

be a unified voice.

And so one thing we have found is that collaboration during a time of drug shortage would really help. This marketplace is deeply fragmented. Everyone, I think, talked about transparency today. We do need transparency. There's gaps in knowledge. And until we have a clear picture, we can't address the right solutions for the right problems. And those are the redundant solutions that are -- my other wonderful panelists have talked about.

No one solution is going to fix this. It will be multi-layered and redundant. But to do that we have to be connected as an entire supply chain. All members must be at the table. There is a space for all of us, especially the patient.

*Ms. Castor. So you did this. You mentioned in your testimony you actually initiated something called Project Protect, where you just dived in and tried to actually create a certain supply chain for certain drugs and shortages. How did -- how did that work?

Why did -- why was it -- why was it left to you, without much help from government agencies that should be helping?

*Ms. Bray. Well, I think there's a role for scalability of innovative programs that have been working already, for sure.

So Project Protect, it was -- there's a lot of

discussion about whether prediction can ever fix this, and I believe it can. Any healthy supply chain -- we're in the world of blockchain and AI, that's the stuff I talk about in my business classes and, you know, why wasn't this supply chain, you know, in the new millennia of supply chain management?

And so I was like, we've got to start with prediction. So we got to we got to prove that. So we used prediction and said, what drugs do we think might go short? We picked two. There's a lot of work underway on prediction. I encourage that work to be scaled.

And we then went to a small onshore manufacturer, a 503(b), like Alex talked about, and said, what would it cost you and how much time would it take to ensure this for the American people if it did go short?

They surprised me by saying about 60 days and $100,000. I said, "Each?'' And they said no, for both. So I wrote a grant, and signed an agreement with them, and told them be ready to supply if this -- if it goes short. It did go short, and --

*Ms. Castor. And these drugs were?

*Ms. Bray. Pardon?

*Ms. Castor. Name the drugs.

*Ms. Bray. It was potassium chloride and sodium chloride, and it was accessed 650,000 times last year during

a time of shortage. So it didn't stop the disruption. What it was was gap supply, efficient, flexible gap supply that was incentivized by the marketplace and a private -- public-private partnership.

I think this is a model that can be duplicated over and over and over again to protect the American people during a time of disruption. And then we do need to do all the work to help eliminate some of this disruption that the rest of my colleagues have talked about.

*Ms. Castor. Thank you, Professor.

*Ms. Bray. Thank you.

*Mr. Griffith. The gentlelady yields back. I now recognize the chairwoman of the full committee, Mrs. McMorris Rodgers of Washington, for her five minutes of questioning.

*The Chair. Thank you, Mr. Chairman. I wanted to start with Dr. Alex.

In your written testimony you describe how a PBM will negotiate rebates, and then keep a percentage of the rebate negotiated. How do these negotiated rebates distort the drug market?

And specifically, can you explain how rebates negotiated by PBMs contribute to high drug prices, shortages of essential medicines, or the race-to-the-bottom pricing that undermines our drug supply chain, and the impact that this has on patients, providers, and pharmacies?

*Dr. Oshmyansky. Sure thing. So, you know, the PBMs, I kind of think of them in my head as payment processors, sort of similar to Visa or MasterCard. And many years ago they realized, hey, we're processing all the payments, we can negotiate for drug prices on behalf of the people we're processing payments for.

And the way they decided to go about it was to negotiate a rebate. They wouldn't charge you for this service of negotiation, they would just take a cut of the rebate back off of a list price. And it soon became very readily apparent that the biggest way to make this cut of the rebate as big as possible was to make the rebate as big as possible. So the standard rebate on a generic drug product now is between 85 and 88 percent. And where else in life do you get an 88 percent discount? Like, something's a little off.

So -- and they capture, you know, let's say 10 percent for the sake of talking, percent of that rebate. That serves to, you know, increase the cost of the actual drug by 60 to 100 percent, with none of that actually going to the manufacturer itself.

One of the big misconceptions we have at Cost Plus is that we're able to somehow better negotiate the price of these medications, or we get a better price. We don't. We actually pay more. Manufacturers like working with us, because we're a small entity, as opposed to one of these big

purchasing conglomerates. So they -- we actually pay them marginally more than the competition, and yet we're able to still save patients significant amounts of money.

And that 88 percent discount, let's say, that can be just an average. We've seen much more extreme discounts -- or rebates, rather. Imatinib, the chemotherapy agent, has a list average wholesale price, the generic, of $10,000 for a month's supply. Meanwhile, we sell it at our website with -- and again, paying more than other suppliers -- for $30, about $30, for that same month supply. And the actual adjudicated cost, so the actual price patients pay, we see at the counter at, like, CVS or Walgreens is 2,000, $3,000 for a month supply. And that's not going to the manufacturer. So it's just extreme distortions in the way drugs are paid for.

*The Chair. Thank you. Thank you for that. And I don't think that there is a single, all-encompassing solution for shortage problems.

Would you speak to how transparency, additional transparency, might help?

*Dr. Oshmyansky. Oh, sure. You know, I think if patients, providers, payers just know what these medications actually cost, and what percentage are going to intermediaries in the supply chain, you know, I think if patients learned that most of the money they were spending on insulin went not to the insulin manufacturer, but to the

intermediaries in the supply chain, you know, I think that would incentivize, you know, a change in the way the supply chains work to have, you know, as my colleagues have been saying, more of the revenue going to the people that do the actual hard work of the manufacturing itself.

And forgive me, I didn't answer your last question entirely as to, you know, what are the dynamics that lead to only a few manufacturers getting contracts. Because of the oligopolies at the levels of the purchasers, the sourcing programs, rebate aggregators, GPOs, all of these subsidiary entities of the big purchasing conglomerates, only a couple companies can win that battle for the contract. And say there's 12 manufacturers. If only two or three win the contracts, you know, the others have no incentive to keep their supply chains open.

*The Chair. Thank you.

*Dr. Oshmyansky. So if we just create an open marketplace where, you know, the manufacturers themselves can compete on quality --

*The Chair. Thank you. I am going to -- I am running out of time here. I had -- and I wanted Dr. Sardella -- I am going to have to ask others -- to address you.

I wanted to give -- Ms. Bray, you started talking about the potential of public-private partnerships, and I just wanted to give you my remaining time to talk -- just hear

some more about the potential to help meet -- solve this problem.

*Ms. Bray. Thank you. And I just realized I never mentioned Abby is doing great. She's thriving. She's 13 today, and entered survivorship this spring.

*The Chair. Oh, that is great to hear.

*Ms. Bray. So just -- since I never mentioned that.

You know, any healthy, you know, important supply chain relies on partnership, and every member will need to have a place at this table, especially when we talk about incentivizing the right motives.

The FDA's 2019 root causes, possible solutions report stated in the executive summary, "Enduring solutions will take multi-stakeholder efforts and re-thinking business practices.'' That's basically all I've been doing since we founded.

How do I collaborate with as many people as possible in the supply chain? It includes the FDA, it includes the supply chain members, it includes the manufacturers and the hospitals.

How do we align our incentives to get as many patients the needed drugs that they deserve? And that's, you know, the one message I want to say: we need to be connected and collaborate, but then there needs to be tools of connectivity so we can scale.

*The Chair. Thank you.

*Ms. Bray. Thank you.

*The Chair. Thank you very much, thanks for being here. I yield back.

*Mr. Griffith. The gentlelady yields back. I now recognize the ranking member of the full committee, Mr. Pallone, for his five minutes of questions.

*Mr. Pallone. Thank you, Mr. Chairman. I am still concerned that FDA lacks the information it needs about how pharmaceutical products are produced, and real-time data regarding changes in supply and demand for drugs and their key ingredients, so let me ask Dr. Muzzio.

What gaps remain when it comes to our knowledge of the pharmaceutical supply chain, in your opinion?

*Dr. Muzzio. I'm sorry, I didn't hear you.

*Mr. Pallone. Let me get closer to the mike here. Dr. Muzzio, what gaps remain when it comes to our knowledge of the pharmaceutical supply chain?

*Dr. Muzzio. Well, there are many. In addition to the ones I have mentioned, I want to point out that there is an additional factor that I'm very concerned about, which is in reading all the government reports on this issue, you know, on the last couple of years, there is only barely a mention of the chemical building blocks that are needed to make the drug substances.

So the discussion is, you know, who makes the finished product, or who makes the drug substance, but then it turns out that, to make the drug substance, you need to have access to pieces of that molecule. And there is very, very limited knowledge of where those pieces come from, except to say that, for many APIs made in India, which we consider a friendly nation, in many cases the building blocks also come from China.

So we might have to go earlier upstream the supply chain to ensure that we are able to actually make things in friendly shores, including our shore. So I think that's a big gap in our understanding of how -- you know, where shortages come from. There's been instances where key starting materials were found to be contaminated, and that triggered a whole sequence of events, then bringing other problems as we go -- as we went down the supply chain. So I think that those are important issues.

I am aware of efforts at USB, for example, to create a substantial map of the entire supply chain. I don't think they are unique. There is another organization doing something similar. I don't recall their name right now. I think that's a very important effort that also needs to be supported, and strengthened and, you know, completed.

And we need tools that will allow us to update the model of the supply chain dynamically. One important thing is to

realize that it's not a static object, that once you describe it, it remains like that forever. It changes all the time. So we need not only to inventory the pathways, we also need to create methods to update the model of the supply chain very rapidly every time the conditions change. Otherwise, we would be fighting last year's war, so to speak.

*Mr. Pallone. All right, thank you. So let me go to Professor Bray.

Where have you seen FDA work most effectively in its response to drug shortages, and how could additional visibility into the supply chain strengthen that work?

*Ms. Bray. Thank you for asking. I believe the Office of Drug Shortage at CDER is doing a lot of great, patient-focused work, and it's actually led by people who were our health care providers. And I think they're doing great work, we work together often. They're open to communication and feedback, and I'm very appreciative for the work that they do during a time of crisis.

Where we could get better is a lot of the approaches are reactive, and there is missing gaps of information, just like everybody has said. So I would like to do a mindset shift on drug shortages as a crisis, and that mindset shift is to change from a focus of mitigation to ending. And so when you think about the fact that our current strategy for drug shortages is a word called "mitigation,'' mitigate means what

do we do with available supply? And when you ask that question, the answers and next questions are who gets it, and who doesn't. And all you get is disparity and plays for mistrust and power.

The question we need to be asking, it's a full dynamic shift, and it is, how do we end drug shortages? When we ask that question, it's how much supply do we need for the American people? How do we ensure that we have access to that supply, and how do we make sure that supply gets to the people when there's disruption?

And you can see how quickly that mindset shift gets to very different solutions. One is potentially reactive that is repeated over and over again for 20 years, and one is proactive that can work to secure the supply chain for all patients and make a more resilient supply chain. Thank you.

*Mr. Pallone. Well, thank you both, and thank you, Mr. Chairman.

*Mr. Griffith. The gentleman yields back. I now recognizes the gentleman from South Carolina, chair of our Energy Subcommittee, Mr. Duncan, for his five minutes of questioning.

*Mr. Duncan. Thank you, Mr. Chair.

Dr. Sardella, your white paper does a great job in outlining the current state of U.S. API infrastructure and its potential effects on national security. Your paper

discusses the vulnerabilities of U.S. pharmaceutical supply chain. In particular, you highlight our reliance on foreign sources for the active ingredients in our pharmaceutical drugs. Can you please share with the committee the potential risk or consequences that such a dependency poses to U.S. health care system?

*Mr. Sardella. Two real risks that we experienced during COVID.

The over-reliance on foreign manufacturers leave us vulnerable not just to demand shocks like COVID, but also supply shocks due to geopolitical tensions. During COVID, India had to stop any export in order to ensure the safety of their own population, which -- and, in fact, cut off supplies to the United States for critical medicines that we required.

Second, the chief economist in Beijing -- we don't have to think it might happen -- intimated that our drug supply chain was, in fact, a lever to ensure that we cooperated as a country on geopolitical issues ranging from trade to Taiwan.

So we've experienced the risks of being over-reliant already, from a geopolitical perspective as well as from a supply to citizens.

*Mr. Duncan. It points to the need to onshore both pharmaceuticals, microchips, energy sources, because in a time of war or a pandemic like we saw, when the United States of America is reliant on sources for any of those things from

overseas, then systems stop and the ability to provide the medication that our constituents need is important. So the need to onshore that is important.

But when we talk about drug shortages, you have got to keep in mind that in many instances making generic drugs is simply not profitable. So let's shift to generic. In those situations, the manufacture does not have the resources or economic incentive to invest in the manufacturing of those products to keep them on the market, especially if it's a loss leader.

So could you speak -- with the passage of the Inflation Reduction Act, which is a misnomer, is it possible that brand products selected for negotiation have generics in development?

And if a drug selected for negotiation makes it harder or less profitable for generics to come to market, could we see an increase in the shortages?

*Mr. Sardella. Well, first, in regards to the shortages from over-reliance, the strategy should not be to just move the same type of manufacturing to the United States to produce them at economic low profitability or losses. It should be to leverage the advanced technologies, technologies that Fernando mentioned such as continuous flow, that allow for significant cost reductions.

The API Innovation Center is focused on a series of

oncology drugs. We took a crisis in oncology, the drug called Lomustine, built a consortium of innovators who had developed new, novel techniques to produce it using continuous flow, existing manufacturers with capacity to produce it here in the United States on behalf of the Glioblastoma Foundation.

It also engaged with critical entities such as Emerson that makes the control systems. It took numerous stakeholders. The impact of that is a 90 percent cost reduction on a drug that now, all of a sudden, becomes feasible to manufacture in the United States for the Glioblastoma Foundation.

So it requires very much technology to do that, to compete long-term. It also requires changing to incentivize that U.S.-based manufacturer, allowing for changes in formularies and preferred drug lists to, in fact, allow for that manufacturer with advance technologies that are more environmentally favorable, less footprint, as well as economically more favorable, to be chosen in the formulary.

*Mr. Duncan. Is the hang-up to do that the FDA?

*Mr. Sardella. There's numerous instruments that can be brought to bear that wouldn't require significant legislative change in regards to allowing it. So there's an ability to designate on those formularies what the requirements are for preferred drug. And it could be U.S.-made, made from a

facility that has no warning letter. And third, using even advanced technologies, which would allow for more energy efficiency, lower environmental footprint, and as well, higher quality standards, as Fernando had indicated.

This is within our grasp, very reasonable grasp.

*Mr. Duncan. Thank you so much.

Chairman, I yield back.

*Mr. Griffith. The gentleman yields back. I now recognize the gentleman from New York, Mr. Tonko, for his five minutes of questioning.

*Mr. Tonko. Well, I thank the chair and ranking member for the opportunity today, and welcome the witnesses.

Getting ahead of drug shortages will allow us to increase access to lifesaving medications for patients when they need them most. As we have seen this past year, shortages can happen because of unanticipated spikes in demand for drugs. I am thinking today about parents of sick children who couldn't obtain children's Tylenol during this year's confluence of RSV, COVID-19, and influenza, or people with ADHD who could not consistently obtain important medications because of an anticipated surge in demand due to a sharp increase in prescriptions through the pandemic.

One of my constituents from Saratoga Springs shared how she could no longer find her daughter's medication. And she said, "As a mother, I can't believe this, that a child that

needs medication can't get it."/ \ It is a sentiment of both shock and outrage I share along with many of my constituents.

My understanding is that, without more drug information about the demand for drugs, we don't know how much production is required to meet that need. For example, a study in 2022 from Brandeis University found that there was a shortage of -- shortage of naloxone, a critical drug used to reverse overdose in nearly every U.S. state. The study found that the shortage was in part created because there was no comprehensive data on how much naloxone was needed, and who was using it. So I want to be sure our agencies have all the tools they need to be able to accurately gauge demand fluctuations so that we know where we need to fill in gaps.

You noted in your testimony, Professor Bray, that FDA currently has limited visibility into spikes in demand for pharmaceutical drugs. Why is having greater visibility into that demand for prescription drugs so important, and what would having that information allow FDA to do?

*Ms. Bray. Thank you for asking. Well, I think we've spent a lot of time talking about the supply-side issues of this crisis, but there are demand-side issues. And just because we fix the supply-side issues doesn't mean patients are going to get equal and disparity-free access. So we at Angels for Change spend a lot of time making sure available supply onshore is in the right place at the right time,

instead of stuck somewhere in the supply chain.

So it does -- we are blind a lot when we don't know what's happening with spikes of demand. The entire supply chain is. And so when we throw in a potential solution based on old information, what happens is that solution actually works, but then a spike of demand makes it fail, and then it builds additional distrust in the entire supply chain.

So I do think -- I often am flying blind about what's going on with the demand, and where the actual drug is, and it is a very laborious non-economies of scale process built on a painstaking network of American people who care. Like, emails and phone calls, "What are we doing? Where is it?'' This is unnecessary. We could have, you know, not -- but it's not just the information, it's what are we going to do with it? What's the tool we're going to do to make sure people have access?

And then you got to the beginning -- the beginning part of your question was actually about Adderall and amoxicillin. You know, it's the information before then. Those were predictable. There were people who are subject matter experts who knew those things were happening, who tried to ring those bells well ahead. And some of us put in some safeguards because of them. And so we need data that leads to prediction so that we don't have disruption, and that's the key.

And just like my colleague said, there is amazing work being done. We have many times worked with USP and their medicines supply map. They are doing unbelievable work mapping the entire global supply chain. It isn't effective until it's used to solve it for the American people.

*Mr. Tonko. Thank you.

And Dr. Oshmyansky, you, in your testimony, share that the manufacturing systems used in your facility can transition between making batches of different medications within hours, when it usually takes months. How would collecting greater insights into unanticipated demand allow facilities like yours to respond in a nimble and agile way to a shortage?

*Dr. Oshmyansky. Oh, sure. So the longest lead time item for our manufacturing is not really switching over to supply lines. It's sourcing the active ingredient.

So our plan is to have a portfolio of active ingredient of the drugs we anticipate will go into shortage, send them to independent laboratories for quality and safety testing. That process takes a few months. Once we've done that process, we don't need to repeat it. But if we can anticipate what the drug shortages are predicted to be ahead of time, we can have that API in our portfolio ready to go.

*Mr. Tonko. Thank you so much.

And with that, Mr. Chair, I yield back.

*Mr. Griffith. I thank the gentleman for yielding back. I now recognize the gentleman from Texas, Mr. Crenshaw, for his five minutes of questioning.

*Mr. Crenshaw. Thank you, Mr. Chairman. Thank you for this hearing, and thank you to our witnesses for being here today. It is an important subject.

You know, in the Houston area, just outside my district, Texas Children's Hospital, 80 percent of their patients are impacted by drug shortages. That is the whole hospital. They currently have 101 medications on back order, 350 medications on allocation, where they are limited in the quantity that they can produce. Eight of these are chemotherapy agents that are used in first-line treatment of pediatric cancer.

So I want to, in as little time as possible, because this is a much longer conversation, but Mr. Sardella, I want to figure out how this supply chain looks with active pharmaceutical ingredients to the -- in the best way that we can. Eighty-five percent of APIs are from foreign countries. Sixty percent of our finished dose forms are from foreign countries. And, you know, a lot of people wonder why.

So what is in an API? Just a variety of other chemicals? Is there -- are there -- is there, like, a top three chemicals that are in APIs? Can you describe that really quickly?

*Mr. Sardella. Yeah, and you bring up an excellent point. The API itself is the chemical that produces the medicinal effect. It is the most important element in that capsule tablet, in that drug.

*Mr. Crenshaw. But the --

*Mr. Sardella. The remaining elements are elements that allow for either the transport through your digestive system or other type of elements to allow it to survive and be effective.

And quite interesting, what you bring up is something that we've seen. It's API, even we've heard capsules or the caps of a bottle will be in shortage and have a supply chain challenge which may prevent -- we always think of just the active -- but all these other areas, the excipients, et cetera.

*Mr. Crenshaw. But I want to focus on APIs for a second. So an API is a chemical, but it is a chemical made up of other chemicals.

*Mr. Sardella. Correct?

*Mr. Crenshaw. Right? And where do those other chemicals come from?

*Mr. Sardella. Oh, yeah.

*Mr. Crenshaw. You know, and --

*Mr. Sardella. So --

*Mr. Crenshaw. Go ahead.

*Mr. Sardella. Yeah. So we are reliant on what would be called starter materials. And these are the original chemicals that allow us to make those APIs. The majority of them are carbon-carbon, carbon-nitrogen, carbon-oxygen bonds. They're the foundational elements.

To build a sustainable API, we need to also allow for the creation of starter materials here in the United States.

*Mr. Crenshaw. And this is -- I do have a point to this. So those starter materials are widely available in the United States.

*Mr. Sardella. Mm-hmm.

*Mr. Crenshaw. Right? They are generally derived from petrochemicals. So, like, benzene, which is like a natural gas-derived chemical, is used to make ibuprofen.

*Mr. Sardella. Mm-hmm.

*Mr. Crenshaw. I didn't know that. We have a lot of natural gas and benzene. Like, these are easy base chemicals to get. So we are exporting these base chemicals to other countries so they can make the APIs, so they can send back those APIs to us to make the more advanced drugs, the final product, and then we complain about our supply chains.

What is stopping us from cutting out that middleman? Is it a policy issue? Is it a market issue? What is happening there?

*Mr. Sardella. It would be having economically viable

domestic API manufacturers that can be the purchasers of those starter materials.

*Mr. Crenshaw. Okay.

*Mr. Sardella. That would be the key to its consumption and use here in the United States.

*Mr. Crenshaw. Nobody just -- nobody has had that business idea?

*Mr. Sardella. Well, the APIs, a majority of the generic ones, are not economically viable to produce in the United States. And so they've been offshored. And so that demand, that U.S. domestic demand --

*Mr. Crenshaw. Why aren't they economically viable? What do they state as their reasons for not opening up shop?

*Mr. Sardella. Yeah, they'll cite lower labor costs as one reason. They'll cite economies of scale, government incentives that these other countries have received to build their facilities. Even right now, India is subsidizing new facilities being built so that they wouldn't be reliant on China --

*Mr. Crenshaw. Well, in a very short amount of time we did we did get a lot out of you, so I appreciate it, but I want to I want to move on, please, to Laura Bray.

Thank you for being here with Mother's Day coming up, and the problem we have with especially cancer drugs for kids. So real quick, what roadblocks are currently in place

at the FDA that really create the problem you are trying to solve? What would be your top three? Or one.

*Ms. Bray. So, I mean, I think part of the problem here is this is a very, very large risk solution for any one member to take on, right? So there are a lot of barriers everywhere. There's not just barriers in one member, there is a lot of risk of any one member taking --

*Mr. Crenshaw. I totally get that. But I -- you know, we have to focus on one thing, and I like to focus on the FDA. So, like, from your perspective, what would change at the -- what would be a better way the FDA would do business that would help what you are trying to accomplish?

[No response.]

*Mr. Crenshaw. It is okay if you are not -- if it is --

*Ms. Bray. I -- you know, I think we all have -- every member needs to come to this table because it is so multi-faceted, and there are true and real reasons for every single policy that has been put in place. But we're -- keep putting policies on top of policies of broken marketplace. And so I think we all need to be at the table saying, here's the solution, here's what my part can do, here's what my part can do.

And so to pick one thing from one member to do, as my colleague said, it's such a dynamic marketplace, it would quickly become extinct, right?

*Mr. Crenshaw. Yes.

*Ms. Bray. We need to all be at the table.

*Mr. Crenshaw. We need solutions. You know, and --

*Ms. Bray. So the --

*Mr. Crenshaw. -- so, you know, one of the things I would point out --

*Ms. Bray. So the solutions are we've got a six-point plan.

It's first, align the incentives and motives. Everybody needs to be at the table, aligning those motives.

It's employing prediction and forecasting, followed by being ready to supply the American people.

Then we have to empower the collaboration of this multi-faceted supply chain.

Patients need to be at the center of the solution, so we're ending shortages instead of mitigating them.

And we need to establish an entrance and exit ramp so that the marketplace can evolve without patients getting left behind.

That's the steps. And it's multi-layered.

*Mr. Griffith. The gentleman --

*Mr. Crenshaw. I appreciate it, I yield back.

*Mr. Griffith. -- yields back, but we may very well have some what we call QFRs, questions after the hearing, and we will get an opportunity to answer at that time.

I now recognize the gentlelady from Arizona, Mrs. Lesko, for her five minutes of questioning.

*Mrs. Lesko. Thank you, Mr. Chair, and thank you for all of you being here. I apologize, I had to go to another committee hearing and come back here.

Mr. Sardella, a key role of the FDA's mission to ensure drug safety, effectiveness, and ultimately, availability includes its foreign and domestic drug manufacturing facility inspections program. While the COVID-19 pandemic effectively halted nearly all overseas inspections for 2020 and part of 2021, the number of inspections conducted both in the U.S. and overseas has been precipitously declining since 2016.

In 2019, in its 2019 report of FDA inspection data, the GAO identified FDA's inability to oversee the global supply chain as a high-risk issue, and concluded with recommendations to the agency to increase the number of inspections of foreign drug establishments.

Unfortunately, GAO's 2022 follow-up report on FDA's inspection capabilities did not conclude that the agency is in any better off -- is any better off in conducting timely and reliable foreign inspections. In fact, GAO found that the share of foreign facilities that have not been inspected in over five years has increased from 30 percent in 2020 to nearly 80 percent in 2022.

Furthermore, GAO shared that the FDA inspected just 6

percent of facilities overseas in 2022. Given that most U.S. drugs and APIs are manufactured in foreign facilities, this raises serious concerns with FDA's ability to ensure the quality and availability of human medical products manufactured overseas.

So my question to you is, how critical are timely and effective inspections of both domestic and foreign manufacturing facilities for ensuring the security of our drug supply chain?

*Mr. Sardella. They're absolutely essential for us ensuring the quality and the safety of the medicines that U.S. citizens consume.

They're also extremely important in ensuring the stability of the market because, through those inspections, the ability to understand which manufacturers are complying, which manufacturers are delivering on quality manufacturing processes.

And then the next element there is incentivizing that, rewarding those that don't have any warning letters for decades and decades, as opposed to those who, in fact, would. The ability to make that distinction on quality is to have a robust inspection, auditing process that allows us to make those distinctions, both to ensure the market is stable and to allow for safety of the medicines.

*Mrs. Lesko. I agree, and I think most U.S. people

would be surprised at the low number of inspections that are going on for the drugs that they are taking each and every day, and foreign drug makers.

This past December the President authorized $10 million for a pilot program to increase the number of foreign inspections at the FDA. However, the agency has cited challenges in the agency's ability to recruit and retain investigators as a major factor in the delay or dereliction of timely foreign inspections.

Again, Mr. Sardella, how confident are you that this pilot program will close the gap in the share of overseas establishments that remain uninspected, while there remains a fundamental challenge within FDA to retain investigators and prioritize foreign inspections?

*Mr. Sardella. Yeah, I feel FDA is no dissimilar to any organization in its struggles to develop talent, recruit talent to conduct its efforts. I feel they, like all organizations, will be challenged to be able to allow for the right workforce that enables them to go overseas as well as globally to do their inspections.

I also feel that there's other opportunities to allow for understanding the quality of medicines that are more technical in nature versus only inspection in nature.

Modernizing the monitoring systems. Fernando had talked about the new emerging advanced manufacturing technologies,

control systems that monitor the productions every second as these medicines are produced. Those will allow inspection and observation without being at the facility, only through data transport in real time, every second. Those will be very transformational capabilities that we should look into and enable the FDA to utilize and leverage.

*Mrs. Lesko. Thank you, and I yield back.

*Mr. Griffith. I appreciate the gentlelady yielding back. I now recognize Dr. Ruiz of California for his five minutes of questioning.

*Mr. Ruiz. Thank you, and thank you all for your testimony today.

Drug shortages have serious impacts on quality and safety of patient care in this country. Before Congress I practiced as an emergency physician at Eisenhower Medical Center in California. I have seen firsthand the effects that drug shortages can have on patients, their providers, and their families by causing delayed care or second-choices treatments, especially when I want to intubate a patient and we don't have s~~S~~uccinylcholine, ~~and~~ I have to use another paralytic that is not used very often. Okay?

Professor Bray, how have you seen shortages play out for patients seeking emergency care?

*Ms. Bray. Thank you for asking. There is severe patient impact happening every day, and not just in missing,

skipping, or changing doses. Ninety percent of oncologists state that drug shortages have led to patient harm up to death.

We also can't forget the emotional trauma that you're putting on a family in a medical crisis. Patients deserve access to these medicines. The patient -- the physicians and nurses and care team who are trying to solve these crises and save them deserve easy and equal access to these medicines.

*Mr. Ruiz. Thank you. Generic drugs are particularly vulnerable to shortages: 40 percent of drugs -- 40 percent of drugs -- have only one manufacturer, and most generic drugs have only one competitor per drug. Having limited sources for essential drugs or medical supplies is dangerous, particularly when an emergency strikes.

So, for example, when Hurricane Maria devastated Puerto Rico in 2017, a major saline manufacturer was damaged. This caused a shortage for hospitals throughout the country of this very basic and critical lifesaving medical supply.

Dr. Muzzio, can you -- how can the government support more diversified drug manufacturing that is less susceptible to supply chain disruptions?

*Dr. Muzzio. Thank you for the question. We've been looking at this very carefully because, as my colleagues mentioned, there are a number of economic constraints. And we have also a 30-year history now of offshoring and losing

manufacturing shares. So the reversal of that process is going to take sustained plan over many years with, you know, a lot of insight into not only how to make it profitable again, but also how to regain the know-how that we have lost, and how to build better systems that are more nimble, able to do more flexible manufacturing of a larger number of products. I'm very encouraged by some of the things that I've been hearing.

One way the government can do it is by recognizing the following. There are reasons why the generic manufacturers are having trouble implementing the newer technologies, right? They cost a lot of money, they take a long time, and they don't have access in-house to people with the knowledge. So this is the perfect opportunity to create, again, centers of excellence, places where we have the knowledge, we have the people, and we have the equipment needed to implement the solutions, working closely with contract manufacturers that can then very rapidly pick up the required manufacturing tasks --

*Mr. Ruiz. Thank you.

*Dr. Muzzio. -- like 503(b)s or other manufacturers. It will take a network --

*Mr. Ruiz. Thank you.

*Dr. Muzzio. -- to solve the problem.

*Mr. Ruiz. Center of Excellences [sic].

Mr. Sardella, in its July 2021 Report on Supply Chain Resiliency, the White House proposed several recommendations to strengthen the generic market. The report recommended providing greater predictability in production costs, pricing, and volume sold to manufacturers, as well as increasing government and private sector flexibility in contracting and sourcing. How would enacting these recommendations help strengthen the generic market and help prevent future shortages?

*Mr. Sardella. The ability to have certainty in your demand, from a business perspective, would drive economic investment and production of these.

A common instrument of contracting in the United States government is what's called the IDIQ, Indefinite Demand, Indefinite Quantity. There's no ability to have certainty in your investments if you have an indefinite demand or an indefinite quantity. Solidifying those quantities, the years of demand, will allow for businesses to make investments and understand their return to their shareholders or to their owners.

*Mr. Ruiz. Thank you.

So drug shortages caused severe adverse health outcomes, and are an urgent problem. We need to support policy and resources that help address supply chain vulnerabilities so that shortages are less frequent and can be quickly

addressed. Stat.

I yield back.

*Mr. Griffith. I thank the gentleman for yielding back. I now recognize Mr. Palmer of Alabama for his five minutes of questions.

*Mr. Palmer. Thank you, Mr. Chairman. Thank you for holding the hearing, and for the witnesses' testimony today.

Dr. Sardella, one of the things that I am concerned about is the FDA's role in the shortages. And in your testimony you mentioned the expensive and complex compliance challenges that so many drug companies face.

In a previous Congress, we had had a number of hearings related to drug manufacturers and the massive increase in cost, and one of the things that we discovered was how regulations had forced a lot of companies either out of business or into being sold to other companies so that the company that bought them basically became the sole manufacturer. We saw that with drugs like insulin and EpiPens, things like that.

I just want your thoughts, a little more clarity from what you said in your testimony about how this is impacting the cost and availability of these drugs.

*Mr. Sardella. Yeah. So, as a manufacturer, if we start with the understanding that their profitability is already low, when they have a warning letter from the FDA

there is therefore an expense that they have to incur to bring the facility up to standards to meet that. Sometimes the businesses cannot afford -- their return on their capital is so low already, less than five percent -- I mean, in business school we teach if you're anywhere below 20 percent you should be out of business.

So then when you couple the request to have to comply, the facility will shutter. They will not make the investment. Only 4 percent in recent data, from numbers in the 2020s, only 4 percent of the FDA warning letters are now being addressed, a drastic drop, and that's a result of their inability economically to resolve them. So the facilities shut down. Akorn, a facility, just recently shut down.

*Mr. Palmer. Right, I saw that.

*Mr. Sardella. Nesher, as well.

*Mr. Palmer. Yes. And then, when you combine that with the need to upgrade the manufacturing processes with newer equipment and things like that, and the stranded cost that's involved in that, plus for newer drugs the stranded costs involved in that, it really becomes an economic issue in many respects that we have to address.

And again, listening to your testimony and reading your testimony, you make excellent points about the order of magnitude increases in drug production if we -- if the companies had the ability to upgrade their equipment.

Would you think that incentives or tax credits, things like that, would be helpful to companies?

*Mr. Sardella. Incentives, very much. One we are -- we have an example.

The API Innovation Center is working with the State of Missouri. The State of Missouri is funding the de-risking of their adoption of new technology. So what we've done, as a non-profit, we've procured the new advanced manufacturing technology, developed it, and are placing it in existing Missouri manufacturing, manufacturers that have been there, some for 100 years, some new ones for 30 years, and some for just 10 years. And that now is being able to bring supply for cancer drugs like Lomustine and a suite of an additional six.

In some respect, those incentives de-risk the adoption, very effective. The one element of the tax incentive is when you have an industry with such low profitability, tax incentives are less effective than creating certainty of demand by changing formularies.

*Mr. Palmer. Well, you set me up perfectly for where I want to go with this.

And this is a little different direction, Mr. Chairman, because in 1996 the Clinton Administration repealed section 936 of the U.S. Internal Revenue Code, which provided tax incentives for drug manufacturers, and it had a devastating

impact on the pharmaceutical industry in Puerto Rico. And what people don't realize is that, of U.S. territories, including the States, Puerto Rico even today still manufactures more pharmaceutical products than any state, including Indiana.

But after the repeal of 936 we saw an exodus of drug manufacturers to other countries. In a number of respects I remember Horizon Pharma out of Chicago moved enough of their production and headquarters to Ireland because if they reached a certain percentage of foreign ownership they were not subject to U.S. taxes, and their tax went down to 12-and-a-half percent.

So what do you think about reinstating section 936, and particularly in how it would impact our ability to produce the drugs that we need?

*Mr. Sardella. Yeah, I don't know the regulation or legislation well enough to comment, but I do believe tax in that case would be a strong instrument to incentivize manufacturing in the U.S.

*Mr. Palmer. Well, it was a huge industry in Puerto Rico. It was -- obviously, the problems were compounded with Hurricane Maria years later. I think it was eight years later, that.

Mr. Chairman, I think that is something that we need to explore. We might not be the right committee for that since

it is a tax issue, but I do think it is part of the solution.

I yield back.

*Mr. Griffith. I thank the gentleman for yielding back.

Seeing no further members wishing to ask questions, I would like to thank each of our witnesses for being here today. Thank you all so much.

In pursuance of committee rules, I remind members they have 10 business days to submit additional questions for the record -- that is the QFR, questions for the record -- and I ask that witnesses submit their responses within 10 business days upon receipt of those questions.

Without objection, this committee is adjourned.

[Whereupon, at 12:09 p.m., the subcommittee was adjourned.]