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LEGISLATIVE PROPOSALS TO PREVENT AND RESPOND TO GENERIC DRUG SHORTAGES

THURSDAY, SEPTEMBER 14, 2023

House of Representatives,

Subcommittee on Health,

Committee on Energy and Commerce,

Washington, D.C.

The subcommittee met, pursuant to call, at 10:01 a.m., in Room 2123 of the Rayburn House Office Building, Hon. Brett Guthrie [chairman of the subcommittee] presiding.

Present: Representatives Guthrie, Burgess, Latta, Griffith, Bilirakis, Johnson, Bucshon, Hudson, Carter, Pence, Joyce, Harshbarger, Miller-Meeks, Rodgers (ex officio); Eshoo, Sarbanes, Cardenas, Ruiz, Dingell, Kuster, Kelly,

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Barragan, Craig, Schrier, Trahan, and Pallone (ex officio).

Also present: Representative Castor.

Staff Present: Jolie Brochin, Clerk, Health; Seth Gold, Professional Staff Member, Health; Grace Graham, Chief Counsel, Health; Emily King, Member Services Director; Emma Schultheis, Staff Assistant; Lydia Abma, Minority Policy Analyst; Keegan Cardman, Minority Staff Assistant; Tiffany Guarascio, Minority Staff Director; Stephen Holland, Minority Senior Health Counsel; Katarina Morgan, Minority Health Fellow; Avni Patel, Minority Health Fellow; Andrew Souvall, Minority Director of Communications, Outreach, and Member Services; and Rick Van Buren, Minority Senior Health Counsel.

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*Mr. Guthrie. The subcommittee will come to order. The subcommittee will come to order, and the chair will recognize himself for an opening statement.

Today's hearing is focused on the critical topic of finding long-term solutions to prevent future drug shortages of key drugs for patients.

For months, cancer patients, including pediatric cancer patients, have had to scramble to find the drugs recommended or use alternatives because of instability in the markets and supply chains. In 2022 alone there are over _ there were 301 drugs in active shortages, according to the University of Utah.

For over a decade, professionals in the medical and regulatory community have sounded the alarm on the underlying economic causes of drug shortages. Unforeseen circumstances, like a tornado hitting a pharmaceutical warehouse in North Carolina or a manufacturing facility in India shutting down due to quality concerns, can throw a supply chain out of whack and potentially lead to a shortage of vital drugs.

To ensure we are prepared to respond appropriately to these issues, we must encourage strong investments to ensure

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that there are multiple means to develop, store, and distribute drugs. That is why the Energy and Commerce Committee is continuing extensive work to identify the drivers of what can cause the supply chain to be unstable and lead to the shortages we have seen over the last decade.

This Congress alone, we have held an oversight hearing, heard testimony on shortages at a PAPHA hearing, the chair did a request for proposals, all leading to the hearing today on potential solutions that span numerous Federal agencies and players. Through this work a key theme emerged: the fundamental economics of the generic drug market _ specifically, sterile injectable drugs _ must be reformed if we want a more stable pipeline of drugs, including sustained investments in domestic manufacturing.

Earlier this year the New York Times wrote in an article diving into the complex supply chain for generic drugs that, "There is a high cost to low prices.'' From there, the article dives into the frailty of supply chains that operate at low cost, with these low costs often times being driven by artificially deflated prices from government programs like certain Medicare or Medicaid policies. Even Commissioner

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Califf agrees economics are the main driver, which he publicly shared before this committee during a previous hearing.

That is why today we will be considering a discussion draft from Chair Rodgers that aims to improve the systematic market failures of our drug supply chain. This discussion draft includes proposals to reform reimbursement rates for low cost drugs and include new ideas to ensure that FDA is appropriately prioritizing and using regulatory discretion to help get more low-cost generics to the market sooner.

It is also important to note that this is only a discussion draft, and I certainly expect there to be a healthy discussion among all members today on this draft and other proposals to address the issue of supply chains and shortages.

We are also continuing to actively solicit stakeholder feedback, given the complexities of the supply chain.

It is my hope, nonetheless, that after we have had our robust discussion, that we will be able to find common-sense, bipartisan solutions to shore up our generic drug market. Doing so will keep Americans healthy and protect our national

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security by making us less dependent on adversarial nations for medical needs in the event of future unforeseen natural disasters.

I look forward to the discussion today and our continued work to advance long-term policies designed to address this critical issue.

[The prepared statement of Mr. Guthrie follows:]

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*Mr. Guthrie. Thank you, and I will yield back.

The chair now recognizes the gentlelady from California, the ranking member of the subcommittee, Chair _ Ranking Member Eshoo, for five minutes for an opening statement.

*Ms. Eshoo. Thank you, Mr. Chairman, and good morning, colleagues and witnesses.

Today is an important day. After months of pleading by the Democratic members of this subcommittee, we are finally having a legislative hearing on drug shortages in our country. I have been frustrated by our subcommittee's inaction through the spring and summer, as I heard from so many physicians in my congressional district and read about cancer patients, especially children, left behind due to shortages in lifesaving treatments.

A quick scan of the headlines demonstrate the magnitude of the shortages. The New York Times in June: "How the Shortage of a $15 Cancer Drug is Upending Treatment.'' The Wall Street Journal in June: "They Got Cancer, Then Their Drugs Were Rationed.'' STAT in July: "Cancer Drug Shortages Deliver Gut Punch to Patients Unsure if their Survival Odds Will be Undercut.''

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The Food and Drug Administration reports that more than 130 drugs are currently in shortage. A July survey by the American Society of Pharmacy Professionals found that over half of the respondents said shortages of chemotherapy drugs were "critically impactful.''

Long-term structural factors cause drug shortages, including high concentration among manufacturers, swings in consumer demand, complex manufacturing processes, and mismatched pricing. Today we will discuss five proposals that attempt to address this crisis.

First, my Drug Origin Transparency Act addresses manufacturer concentration by providing the FDA with the information they have repeatedly said they need to identify where critical drugs and active pharmaceutical ingredients are made to prevent shortages.

Second, the Bipartisan Drug Shortage Prevention Act by Representative Sara Jacobs of California, requires manufacturers to inform the FDA if there is a sustained increase in demand for a drug or ingredient.

Next, the Ensuring Access to Lifesaving Drugs by Representative Slotkin of Michigan and the Patient Access to

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Urgent-Use Pharmacy Compounding Act by Representative Morgan Griffith of Virginia attempt to mitigate shortages by allowing drugs to be safely used after their expiration date, or through pharmacy compounding.

Finally, we are considering Chairwoman Rodgers's long-awaited proposal, the Stop Drug Shortages Act. This subcommittee delayed action on the drug shortage crisis during the spring and summer with the promise of legislation that comprehensively addresses the issue. But I believe that this proposal mostly studies the problem with more reports.

Where the proposal has actionable policy, I think it is a grab bag of talking points. It weakens the 340B program and chips away at the Inflation Reduction Act by excluding certain manufacturers from the inflation rebate. The proposed inflation rebate policy misunderstands the market failure that caused drug shortages. Many of the chemotherapy shortages were caused by manufacturers choosing to drop their prices in an unsustainable attempt to gain market share.

So I look forward to working with my colleagues to ensure that any final package to address drug shortages contains policies like my Pediatric Cancer Drug Supply Act of

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2023, which I will introduce in the coming days. This bill establishes a program at HHS to create a long-term contract for the manufacturing of essential pediatric cancer drugs to ensure there is a consistent, six-month supply available.

I look forward to finding a bipartisan way to craft a proposal that thoroughly addresses the threat that drug shortages pose to our nation and its patients.

[The prepared statement of Ms. Eshoo follows:]

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*Ms. Eshoo. And with that, Mr. Chairman, I yield back.

*Mr. Guthrie. Thank you. The gentlelady yields back. The chair now recognizes the chair of the full committee, Chair Rodgers, for five minutes for her opening statement.

*The Chair. Good morning, everyone. Good morning, colleagues, witnesses. Thank you, everyone, for being here to address bipartisan solutions to a long-term, decades-long challenge around drug shortages.

We have all heard the heartbreaking stories about children and others that are struggling to get the medication that they need as a result of drug shortages. I visited Providence Sacred Heart Medical Center, including pediatric oncology in their children's hospital in Spokane over the August break, and heard firsthand how shortages are resulting in difficult decisions to conserve and prioritize supply, reevaluate treatment plans for some patients, and identify alternative therapeutics when possible.

The task before us today is to examine the drug supply chain and try to better understand the root causes of drug shortages so our health care providers and the patients that rely on them are not having to change recommended treatments

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due to a lack of supply.

I appreciate the witnesses from across the drug supply chain being here today to help us better understand the problem and provide feedback on the proposed solutions and any new ideas the committee should consider.

Over the last year, Energy and Commerce has committed itself to examining drug shortages that hit a 10-year high earlier this year.

May 11 of this year, the Oversight and Investigations Subcommittee held a hearing where a panel of expert witnesses testified to the underlying market failures that have made it harder for patients and health care providers to get essential medicines.

In June of this year I issued a request for information alongside Senator Crapo to additional stakeholders regarding drug shortages. The robust comments we received highlighted the complex challenges facing low-cost generic drugs, which make up more than 90 percent of the drugs dispensed in this country. Stakeholders submitted comments regarding the consequences of consolidation in the drug supply chain, and how below-market Federal reimbursements for such drugs can

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make it difficult _ a difficult market even worse, leading to a lack of investment in manufacturing and supply chains.

Less than a month later I released a discussion draft to try to put specific solutions forward to address these broad concerns.

Our goal today is to pursue multifaceted and long-term solutions that address the root causes of the shortages. Again, we are hearing from people from across the supply chain to examine this issue.

According to FDA Commissioner Califf, "The economics of this are not favorable for fixing the problem the way it is currently working.''

This committee has a chance to improve the economics for these drugs, potentially facilitating more onshoring and making sure patients have access to the drugs that they need. The challenge is how to appropriately target the incentives and relief from existing government price controls. And I hope there will be a robust discussion on how best to do that.

The discussion draft focuses primarily on generic, sterile, and injectable drugs for a serious disease or

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condition, and getting these drugs out from under mandatory 340B rebates and inflation penalties. We require CMS to launch a model that tests market-based pricing policies for these drugs in Medicare, as well.

The discussion draft also looks into how we can bring transparency to current contracting practices through new 340B guidance and disclosure reporting for group purchasing organizations.

FDA plays a role, as provisions in the discussion draft and other bills noticed today indicate. However, I do not believe FDA authorities would solve these issues and, in some cases, I think FDA may play a role in worsening a shortage through unclear communication.

I am also concerned FDA may not look domestically for production before turning outside the U.S. during a drug shortage.

I look forward to a robust, constructive dialogue about the policies noticed today and any potential unintended consequences, any additional ideas, and I am hopeful that we can work together in this committee to come together on a number of discreet proposals to tackle and turn the tide

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against these drug shortages.

It is clear that each shortage is unique, and there is not one solution that will address all issues.

[The prepared statement of The Chair follows:]

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*The Chair. Thank you. I will yield back.

*Mr. Guthrie. Thank you. The chair yields back, and the chair will recognize the ranking member of the full committee, Mr. Pallone, for five minutes for an opening statement.

*Mr. Pallone. Thank you, Mr. Chairman. I am pleased that after months of refusing to work with Democrats to address the drug shortage crisis, the Republican majority has finally called a hearing to discuss legislative proposals to address this serious ongoing problem for patients.

Democrats put forward three of the bills noticed for discussion in the hearing today during consideration of the Pandemic and All-Hazards Preparedness Act, or PAHPA. We wanted to immediately act because experts, including doctors providing care on the front line, told us drug shortages are an ongoing emergency for their patients and a threat to national security.

They also told us that the Democratic bills could help address the crisis patients are facing by providing new authorities to the Food and Drug Administration. Unfortunately, Republicans refused to work with us to include

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these policies in the PAHPA reauthorization, and instead pursued a Republican-only bill that slashed health preparedness funding and will have difficulty passing the House before PAHPA expires at the end of this month.

After our nation was "unprepared for the worst pandemic in a century,'' and it is inexcusable that Republicans have failed to learn the lessons of COVID-19, and have refused to properly invest in public health preparedness. This failure is putting American lives at risk.

And then, just after gaveling out of session for the August recess, Republicans finally put forward their ideas to address drug shortages. Unfortunately, many of the proposals in the Republican discussion draft may actually lead to more drug shortages and increased profits for the pharmaceutical industry, while raising costs for consumers.

I oppose many of the policies in the Republican discussion draft because I simply do not believe they will help end the drug shortage crisis. In fact, I think they will make it worse. And that is not the approach Democrats want to take. Over the last month we have been highlighting our efforts to expand the middle class, including by making

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drugs more affordable under the Inflation Reduction Act.

For the first time, the Inflation Reduction Act allows Medicare to negotiate the prices of drugs for seniors, institutes a $2,000 cap on out-of-pocket costs for drugs in Medicare Part D, and prevents huge price increases by requiring drug companies to pay a rebate back to the government if they raise drug prices faster than the rate of inflation.

Every Republican voted against lowering drug prices, and now they are trying to eat away at the consumer protections that Democrats created. The Republican discussion draft would allow some drug companies to raise prices on consumers faster than the rate of inflation without paying a penalty to Medicare or Medicaid.

I am deeply concerned that this proposal could unintentionally provide an incentive for drug companies to keep drugs in shortage or near shortage for longer periods of time in order to raise drug prices on the American people. And while it is true that market conditions affect manufacturing and supply issues, two major causes of the drug shortage crisis, the Republican proposal to simply allow drug

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companies to raise prices is not the answer to the problem.

In stark contrast to some of the misguided policies in the Republican discussion draft, the Democratic bills before us today are common sense, and take significant steps towards better securing our supply chain. We should know where our drugs and their critical ingredients are being made so when a drug shortage or other supply interruption happens, FDA and manufacturers can react appropriately.

Ranking Member Eshoo's legislation, the Drug Origin Transparency Act, would require drug companies to report the sources of active pharmaceutical ingredients to FDA, and includes the source of API on a drug's label.

We should also be ensuring that FDA knows that _ the earliest possible time when a surge in demand for a drug is likely to cause a shortage. And that is exactly what the bipartisan bill introduced by Representative Jacobs and Mills will do.

And we should make sure that we are not needlessly throwing away safe and effective drugs that could be used past their shelf life date. Representative Slotkin's bill, the Ensuring Access to Lifesaving Drugs Act, will help

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address that by requiring manufacturers to report to FDA on the longest possible shelf life of their drugs.

So I am interested in hearing more from our panel, and I am hopeful that we can find a bipartisan path forward on these drug shortage policies, as patients and providers are facing life-altering consequences if we don't do more to address this critical problem.

[The prepared statement of Mr. Pallone follows:]

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

*Mr. Guthrie. Thank you. The gentleman yields back. We will now move to witnesses' opening statements.

I will introduce each witness, and then we will call on you individually. I will introduce the witness as a _ witnesses as a panel.

And so first before us is Michael Ganio. He is senior director of pharmacy practice and quality for the American Society of Pharmacy Professionals.

Mr. Todd Ebert, president and CEO of Health Care Supply Chain Association.

Mr. Chip Davis, president and CEO of Health Care Distribution Alliance.

Dr. Melissa Barber, post-doctoral fellow at the Yale School of Medicine, Yale Law School and Yale Collaboration for Regulatory Rigor, Integrity and Transparency.

Mr. Allan Coukell, senior vice president of public policy for Civica.

And Dr. David Gaugh, interim president and CEO at the Association for Accessible Medicines.

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And so each of you will have five minutes for your opening statement. You will _ I think you have _ some of you have testified before. You will have a yellow light when you get close to the end. I think four minutes in you will have a yellow light. And then when _ the red light, we would ask you to wrap up if you haven't finished, get to your final thoughts, and then we will get to questions so we can have some discussion and talk.

And we appreciate it, and first I will recognize Dr. Ganio for five minutes for your opening statement.

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STATEMENTS OF MICHAEL GANIO, PHARM.D., M.S., BCSCP, FASHP, SENIOR DIRECTOR, PHARMACY PRACTICE AND QUALITY, AMERICAN SOCIETY OF HEALTH SYSTEM PHARMACISTS (ASHP); TODD EBERT, R.PH., PRESIDENT AND CEO, HEALTHCARE SUPPLY CHAIN ASSOCIATION (HSCA); CHESTER "CHIP'' DAVIS, JR., JD, PRESIDENT AND CHIEF EXECUTIVE OFFICER, HEALTHCARE DISTRIBUTION ALLIANCE (HDA); MELISSA BARBER, POSTDOCTORAL FELLOW AT THE YALE SCHOOL OF MEDICINE, YALE LAW SCHOOL, AND YALE COLLABORATION FOR REGULATORY RIGOR, INTEGRITY, AND TRANSPARENCY (CRRIT); ALLAN COUKELL, BSCPHARM, SENIOR VICE PRESIDENT, PUBLIC POLICY, CIVICA; AND DAVID GAUGH, R.PH., INTERIM PRESIDENT AND CEO, ASSOCIATION FOR ACCESSIBLE MEDICINES (AAM)

STATEMENT OF MICHAEL GANIO

*Dr. Ganio. Thank you, Chair Guthrie, Ranking Member Eshoo, and distinguished members of the Health Subcommittee. Thank you for the invitation to join today's hearing.

The American Society of Health System Pharmacists is the largest association of pharmacy professionals in the United States. Our 60,000 members, pharmacists, student

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pharmacists, and pharmacy technicians are on the front lines, managing drug shortages in hospitals, ambulatory clinics, community pharmacies, and other health care settings.

ASHP has monitored national drug shortages for over two decades. We collect public reports of drug shortages from clinicians, patients, and caregivers. And through a partnership with the University of Utah Drug Information Service, ASHP maintains a drug shortages list that includes both active and resolved prescription drug shortages. Shortages are added to our database only after the team at the University of Utah has thoroughly investigated each shortage and confirmed details with manufacturers.

We also provide practitioner-focused resources to help the health care community manage drug shortages.

As of July 2023, ASHP and the University of Utah were tracking 309 active ongoing drug shortages, the highest number in nearly a decade. Most of these medications are low-cost generics and many are sterile injectable products used in clinical settings. We recently conducted a survey of ASHP members, and found that 99 percent of our respondents are struggling with drug shortages every day in hospitals and

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health systems, with 57 percent reporting rationing chemotherapy drugs or canceling or delaying cancer treatment.

In recent years, the drug shortage problem has escalated into a crisis that threatens our nation's health care security. Clinicians with less than 20 years of practice experience have never known a world where drug shortages did not exist. Basic critical medications like sterile water, saline, and other electrolytes are chronically in short supply.

Clinical data show worse outcomes when patients are switched to alternative treatments that are less effective or have more side effects than the preferred drug. Medication errors attributed to drug shortages have resulted in patient harm and even death. Shortages can also force clinicians to make heartbreaking decisions about which patients receive a _ prioritized to receive potentially lifesaving treatments and which should receive an alternative.

And of course, the burden of managing shortages is not only on clinicians. Patients have faced frustrating shortages of prescription drugs like EpiPens, amoxicillin, and blood pressure medications. And currently, patients who

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depend on ADHD medications are currently upending their lives monthly as they look for their next prescription for the following month.

The causes of drug shortages can range from raw material availability to natural disasters disrupting infrastructure. Most often, however, shortages are caused by a manufacturing delay or declines in manufacturing quality. And the root causes behind these declines come from a lack of incentive to produce older generic drugs with slim profit margins and from a lack of market recognition of manufacturers who invest in more reliable supply chains and better quality systems.

The current shortage of some injectable chemotherapy drugs was caused by deficiencies in quality manufacturing at an overseas facility. However, these problems are not limited to foreign manufacturing sites. In 2018 manufacturing deficiencies at a domestic facility resulted in severe shortage of injectable opioid medications that we use in hospitals to treat pain and to sedate patients in intensive care units.

The current system of FDA approval and pass-fail inspections does not provide purchasers with any distinction

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among drug products, other than price. This overly emphasizes the cost of drugs in purchasing decisions and contributes to the race to the bottom in generic drug prices. Because purchasers do not have a way to identify manufacturers with strong quality systems, there is no financial incentive for manufacturers to invest in quality management. Providing transparency through a reporting of critical information will allow purchasers to select from reliable sources of generic drugs.

ASHP supports efforts to expand domestic manufacturing, but this will not reduce shortages if it comes at the expense of reliable foreign suppliers. Manufacturing diversity and redundancy are needed to strengthen our supply chain and prevent drug shortages. Without diversity of production, a disruption either domestically or abroad can result in severe shortages, as we have seen recently with Hurricane Maria's impact on Puerto Rico in 2017, and most recently a tornado that recently hit Pfizer's North Carolina facility, damaging 40,000 pallets of finished materials.

ASHP has developed and published detailed recommendations to reduce drug shortages that will be

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submitted for the record. The current status of drug shortages is untenable, and we look forward to working with this subcommittee and with Congress and other policymakers on implementing solutions to solve the problem. Thank you.

[The prepared statement of Dr. Ganio follows:]

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*Mr. Guthrie. Thank you. We thank you for your testimony.

The chair now recognizes Mr. Ebert for five minutes for your opening statement.

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STATEMENT OF TODD EBERT

*Mr. Ebert. Good morning, Chairman Guthrie, Ranking Member Eshoo, and distinguished members of the subcommittee. Thank you for the opportunity to discuss the important role of traditional health care group purchasing organizations in preventing and mitigating drug shortages. We appreciate your efforts to examine this pressing problem, and we look forward to continuing to work with Congress and all stakeholders to preserve patient access to high-quality care.

I have 44 years of experience as a registered pharmacist, and I have seen firsthand the impact of drug shortages on patients and their families. As a former CEO of a national GPO, and now as the head of the Healthcare Supply Chain Association, I have also witnessed the great work that healthcare GPOs do to mitigate and prevent drug shortages so that patients have timely and reliable access to the medications they need.

GPOs serve as the sourcing and contracting partners to hospitals and long-term care facilities, surgery centers, clinics, and other health care providers throughout the

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country. GPOs lower costs for patients, providers, Medicare, Medicaid, and taxpayers. GPOs allow health care providers and physicians to focus on their core mission, which is providing first-class patient care.

GPOs are voluntary, flexible, and clinically driven. Importantly, GPOs take a comprehensive approach to sourcing and contracting that not only accounts for the competitive price offered by suppliers, but also the quality, reliability, and the stability of supply.

We recognize that market conditions change. When they do, GPOs work with suppliers to adjust contracts. GPOs also work to expand the overall number of suppliers, including encouraging new manufacturers to enter the market. GPOs create a vigorously competitive market, both among GPOs and suppliers. Many health care providers maintain membership with more than one GPO at a time, and can shift their purchasing from one GPO contract portfolio to another, or purchase outside-a-GPO contract altogether.

We appreciate the subcommittee's interest in increasing transparency across the supply chain. GPOs already adhere to robust transparency and reporting requirements by GPOs to

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their members and, upon request, to the government.

As the GPO _ as the committee has noted, drug shortages place a significant strain on hospitals, health systems, health care providers, and their patients. The FDA identifies manufacturing quality control issues as the primary cause of drug shortages, along with production delays, lack of raw materials, and supplier business decisions to discontinue product.

Drug shortages are antithetical to the GPO business model. Without sufficient product or suppliers, GPOs are unable to provide the services. HSCA and its member GPOs are committed to collaborating with health care providers and suppliers to bolster the resiliency of the health care supply chain and to ensure that patients and providers have reliable access to the drugs, products, and services they need.

HSCA and our member GPOs appreciate the full committee chair's recognition of the important role of 503B compounding facilities, which are crucial for acute and non-acute health care providers. We strongly support increasing flexibility for 503B compounders to mitigate and prevent drug shortages.

We are concerned about sections 305 and 401 of the Stop

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Drug Shortages Act discussion draft. These provisions will add significant administrative burden facing America's health care providers and exacerbate access challenges for crucial medicines, particularly among small and rural hospitals, without addressing the drug shortage crisis.

In addition, we are concerned that section 307 will change the ASP definition and discourage suppliers from working with GPOs. We respectfully ask that these three provisions be removed.

Solving the drug shortage crisis is a complex task. We have submitted a number of substantive recommendations that will help prevent and mitigate drug shortages, several of which build upon existing congressional authorities. Those recommendations are included in our written testimony.

We appreciate the opportunity to provide our comments, and appreciate this subcommittee's willingness to learn about the GPO industry and how we work, and how we work to prevent and mitigate drug shortages. We look forward to continuing to serve as a resource to Congress and all stakeholders, and I look forward to answering any questions that you may have. Thank you.

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[The prepared statement of Mr. Ebert follows:]

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*Mr. Guthrie. Thank you. The gentleman yields back, and the chair now recognizes Mr. Davis for five minutes for opening statement.

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STATEMENT OF CHESTER "CHIP'' DAVIS, JR.

*Mr. Davis. Good morning, Chairman Guthrie, Ranking Member Eshoo, full committee Chair Rodgers, and full committee Ranking Member Pallone, as well as all esteemed members of the committee. My name is Chip Davis. I am the president and CEO of the Healthcare Distribution Alliance. And on behalf of HDA and our members, we thank you for the opportunity to share the pharmaceutical distribution industry's perspective on this important issue of drug shortages.

Let me begin by applauding the efforts of this committee to examine this issue. We agree that drug shortages deserve attention, and support changes that allow us to preserve the strength and efficiency of the pharmaceutical supply chain while simultaneously tackling this issue.

As a result of that, our comments today will focus in the following areas: first, the role and value of the pharmaceutical distribution industry; second, the role of distributors in mitigating and managing drug shortages; and third, our takeaways from the committee's discussion draft

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that has been referenced that was shared last month.

Distributors truly are the backbone of the pharmaceutical supply chain. We handle approximately 94 percent of medicines that are dispensed in the United States. Our members find the safest and the most efficient ways to get products to where patients need them. Our members work every day to connect approximately 1,400 manufacturers to over 300,000 sites of care on a daily basis, and sometimes multiple times per day. Our members are logistics experts that deliver over 11 million products on a daily basis, and they do it while maintaining a 0.6 percent net profit margin after taxes.

Distributors demonstrated their full capabilities during the COVID-19 pandemic by distributing vaccines and therapeutics, as well as expanding capacity to support specialized requests and partnering with our critical partners in pharmacy and hospital customers as they prioritized patient need. All distributors stepped up to serve patients, our communities, and our country by working collaboratively to ensure the safe and efficient distribution of critical medicines and supplies.

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Simply put, drug shortages occur because the available supply does not meet demand. We align with the FDA's definition of a drug shortage _ we know there is multiple definitions out there _ which the FDA defines as a period when the demand or projected demand of all versions of a commercially available drug exceeds the supply.

Due to our unique vantage point in the supply chain, with upstream partners and downstream partner providers, we see the issue of drug shortages as highly nuanced, categorized by both supply-driven and demand-driven shortages. Unfortunately, there is no single solution that will resolve or prevent drug shortages. Supply-driven shortages occur due to upstream disruptions, while demand-driven shortages are caused by sudden medical surges in which demand outpaces supply.

Distributors support overall supply chain resiliency as a strategy to manage supply chain shocks without significant disruption to patient care. When considering a supplier, distributors consider supplier reliability, quality, historical patterns, and business practices in addition to cost. When shortages occur, distributors employ multiple

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systems to mitigate the disruption and equitably distribute products. Demand forecasting and constant monitoring of supply help our members maintain inventory to meet demand.

When prolonged shortages occur, distributors look for alternative sources. And if demand outpaces supply, distributors employ what we refer to as fair share allocation programs to ensure that all downstream customers have equitable access to whatever product is available.

While drug shortages continue to strain the supply chain, there is also a countervailing pressure, as this committee knows, to constantly reduce costs. The discussion draft includes thoughtful policies to address supply chain shortages.

We support recommendations that encourage competition and supply chain continuity, and to avoid the potential to worsen existing shortages.

We support the proposed Medicaid drug rebate program rebate cap for specified generic drugs, and we encourage CMS to give preferred formulary position to new generics and biosimilars when they enter the market.

We also support the proposal to enhance domestic

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production and provide incentives for U.S.-based manufacturers to address challenges such as continuing manufacturing.

There are multiple positive policy recommendations in the discussion draft. However, there is a provision regarding the narrowing of bona fide service fees that Mr. Ebert referred to that we also believe would have unintended consequences, and could actually unintentionally exacerbate existing shortages.

The bona fide service fees that manufacturers pay distributors actually underwrite the physical movement through the supply chain of the products. These fees cover services such as the safe and secure storage and handling of products; costs associated with cold chain and ultra cold chain storage and delivery; automated inventory management systems to process orders, and select and package shipments; to document and report requirements for regulatory agencies such as the FDA; and the cost of transporting more than 11 million products every day. Our members take on significant risks on behalf of manufacturers, and that fee structure allows them to perform these activities.

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We applaud the committee for the admirable efforts to address drug shortages, and I look forward to answering your questions today. Thank you.

[The prepared statement of Mr. Davis follows:]

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*Mr. Guthrie. Thank you, the gentleman yields back.

And the chair now recognizes Dr. Barber for five minutes for your opening statement.

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STATEMENT OF MELISSA BARBER

*Dr. Barber. Good morning. That is a bit better. Chairman Guthrie, Ranking Member Eshoo, and members of the subcommittee, thank you for the invitation to testify today. My remarks reflect my own views and neither those of my employer nor organizations with whom I work.

Drug shortages are a symptom of a deeper problem in drug markets. I will focus on three themes: first, we need better data to understand the problem; second, we need to address dysfunctional markets with targeted legislation that aligns market incentives with public health need; finally, solutions will require whole-of-government approach.

Today you will hear evidence from many stakeholders. Both here and in my written testimony I will endeavor to report to you as precisely and honestly as I can the evidence from the academic and policy literature on what drives shortages.

As someone who has studied these problems for many years, the first thing I want to emphasize is that there are deep cracks in the information ecology around pharmaceutical

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production, and there is much we do not know because we don't collect data.

Briefly, here is what we know about shortages: first, some types of products, particularly generic, sterile injectables, are in shortage more often than others; second, while any shortage is important to patients, not all shortages are equal in terms of public health importance; third, we know that markets for some products are highly concentrated.

A 2023 study found that approximately one-third of generic active pharmaceutical ingredients, or APIs, produced for use in U.S. markets were manufactured by a single facility. An additional third were manufactured by just two or three facilities.

But there is much that we don't know.

First, we don't even know the cause of most shortages that are reported. As of June 2023, 59 percent of reported shortages in the FDA's database did not have a declared cause because manufacturers are not obligated to give detailed information. Nor does the FDA audit data to ensure accuracy. Thus today, when we discuss the causes of shortages, we are

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only discussing the half where we have data and we are ignoring the half where we do not.

Second, we don't know how many manufacturers there are globally for a given drug, where they are, or how much manufacturing capacity they have. This information is critical to understanding which drugs are most at risk if, to cite some recent examples, a tornado strikes a major pharmaceutical plant in North Carolina, as it did in June this year, or, as I focus on in my own research, when a global pandemic like COVID-19 leads to a shock in production capacity and interruption in global supply chains.

Given what we know about shortages, and with humility on what we don't know, I urge the subcommittee to carefully target legislation to reforms that address the root causes of shortages and not just increase costs.

Provisions in the proposed Stop Drug Shortages Act increase the prices paid for generic, sterile, injectable drugs and drugs in shortage by exempting them from inflationary rebates. There is little evidence that this will be effective. In fact, the FDA has previously found historical price increases have not addressed supply problems

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for drugs in shortage. Rather, these provisions could create more problems than they solve by generating perverse incentives for those companies that have not made needed investments to improve manufacturing quality to nevertheless benefit from price increases that outpace inflation.

More targeted measures would be more effective. For example, case-by-case exemptions where there is clear evidence that supply shocks were the result of external events outside of company's control, rather than under-investment in quality resilience, or by tying financial incentives to a rating system that conditions reimbursement on investments made in supply chain resilience.

Finally, there is no single silver bullet for addressing shortages. It will require coordination across many spheres of government. As a first step, the Agency Drug Shortages Task Force, previously launched by the FDA, should be reconvened as a single point of responsibility so, at the very least, Federal agencies can coordinate efforts.

Stepping back, at the core of this legislation is an understanding that health policy is industrial policy, and industrial policy is health policy. The United States is no

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stranger to targeting subsidies as part of our industrial policy, especially where industries are seen as vital to national security or the economy. The CHIPS Act provided $39 billion in incentives to advance domestic research and manufacturing of semiconductors. Federal programs like the Commodity Credit Corporation were established for stabilizing, supporting, and protecting farm income and prices.

So why have generic medicines not historically also been seen as a strategic focus of our health and industrial policy? Unlike other industries that policymakers have deemed too important to fail, the prevailing wisdom guiding generic drug policy has been that we should trust markets to sort themselves out. We are at this hearing today because this plan is not working for all medicines. Markets are in such a state that I am testifying alongside a non-profit that has had to step up to manufacture essential medicines.

Congress must pass a comprehensive set of targeted measures to address the market that has, for far too long, failed patients. This will require re-envisioning the intersection of health and industrial policy to effectively

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ensure access for medicines for all. Thank you.

[The prepared statement of Dr. Barber follows:]

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*Mr. Guthrie. Thank you. I appreciate your testimony.

Mr. Coukell, you are now recognized for five minutes for your opening statement.

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STATEMENT OF ALLAN COUKELL

*Mr. Coukell. Chairman Guthrie, Ranking Member Eshoo, and members of the committee, thank you for the opportunity to speak with you today on the pressing issue of drug shortages, and on policies to prevent them. My name is Allan Coukell. I am a pharmacist by training, and I lead public policy for Civica, also known as Civica Rx.

Civica is the only pharmaceutical company established specifically to address drug shortages. We are a non-profit, non-stock organization founded by a group of U.S. health systems and philanthropists who, after more than a decade of chronic drug shortages, recognized that the market is not self-correcting, and that a different approach is required.

Civica's mission is to deliver a safe, stable, and affordable supply of essential medicines to U.S. patients. In our first five years of operation, Civica's hospital membership has grown to 55 health systems, 1,500 hospitals. We deliver more than 80 drugs today, 140 million containers to date. And with U.S. Government support, we have just completed construction of a state-of-the-art injectable

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manufacturing facility in Petersburg, Virginia.

The drugs that Civica delivers are not chosen for return on investment. They are chosen by hospitals because they are in shortage or at risk of shortage, tend to be old and low-cost but used in every hospital every day for the care of patients.

Because our mission is to prevent shortages, Civica takes a different approach from the traditional generic drug supply chain. For example, we enter long-term purchase and supply contracts that add stability to the market. We target and maintain a six-month buffer inventory of every drug to ensure continuity of supply. We also emphasize U.S. sourcing whenever possible, with the EU and Canada as our next preference, and we don't source drugs from China, either finished drugs are active ingredient, unless there is no other source.

We perform an intensive quality audit of potential suppliers, along with ongoing review of key metrics to reduce the risk of a failure to supply. And every drug is sold at the same price to any purchaser. Our prices remain stable, and do not increase when the drug is in short supply.

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The success of this model is demonstrated by the fact that 20 of our top 25 drugs are currently in national shortage, yet we are supplying our hospitals without interruption.

When a tornado recently hit a generic drug manufacturing plant in North Carolina, Civica had 21 products overlapping with drugs from that facility. We immediately let our member hospitals know that we could supply double their committed volume for every one of those drugs. And a peer reviewed analysis published today shows net cost savings associated with sourcing through Civica.

So what does this mean for policy? The resilience of this approach may point to Federal policy changes that could help us both respond to and prevent drug shortages.

And make no mistake, shortages now must be understood as a built-in and permanent outcome of the current system. Without change, shortages are likely to get worse in the years ahead.

The immediate cause of most shortages of sterile, injectable drugs is quality problems in the manufacture of the finished dosage form. The root cause is widely

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acknowledged to be low prices, with a vial of medicine often costing much less than a cup of coffee. This reduces the incentive and the ability for manufacturers to invest in quality or in newer manufacturing facilities, and low prices push production offshore to low-wage markets, where quality problems proliferate and the FDA presence is less consistent.

Finally, pharmaceutical production takes time to ramp up, meaning that when one manufacturer leaves the market, a shortage is likely, even if there are other manufacturers making the same drug.

So policy responses to reduce shortages should include measures to incentivize buffer inventory to ensure that generic, sterile, injectable drugs are priced sustainably.

We also need to create market demand for manufacturers that are less likely to have quality problems and to support domestic manufacturing.

My written testimony addresses a range of policy options in detail, but one that I would like to highlight is that Congress could have ASPR make a targeted investment to ensure that high-quality U.S. manufacturers have generic drugs already developed and approved by the FDA ready to go into

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production as soon as a shortage starts. This concept, called ANDAs at the Ready, is discussed in more detail in my written testimony, and would be a cost-effective mechanism to create reserve U.S. manufacturing capacity.

Thank you again for your attention to this important topic, and for the opportunity to be here, and I welcome your questions.

[The prepared statement of Mr. Coukell follows:]

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*Mr. Guthrie. Thank you, I appreciate your testimony.

And Mr. Gaugh, you are now recognized for five minutes.

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STATEMENT OF DAVID GAUGH

*Mr. Gaugh. Thank you, Chairman Guthrie, Ranking Member Eshoo, and Chair Rodgers, and Ranking Member Pallone, and members of the subcommittee. I want to thank you for this invitation to testify today.

AAM represents the manufacturers of finished generic and biosimilar pharmaceutical products, and works to expand patient access to safe, quality, and effective generic and biosimilar medicines. Generic medicines make more than 9 out of every 10 prescriptions. Generics and biosimilars provide enormous cost savings _ in fact, $408 billion in 2022 alone.

But these savings are at risk. We face significant threat to the long-term sustainability of this industry, along with potential for future drug shortages unless Congress acts to address these issues today. Business practices by middlemen such as GPOs, wholesalers, PBMs, and health plans are disrupting the economic sustainability of generic manufacturing, shrinking product portfolios, and reducing the availability of resources to counter drug shortages.

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Specifically, these factors include impact of high generic drug deflation and supply chain consolidation. A historically high rate of price deflation has been driven by the consolidation among generic buying organizations. Three GPOs control roughly 90 percent of all generic purchases for hospitals and clinics. As hospitals across the United States seek to remain profitable and look for savings, directors of pharmacies turn to the GPOs for the lower purchase prices.

In the retail market, three distributor retail pharmacy purchasing consortiums control 90 percent of the retail prescription market. As such, fewer buyers mean fewer markets for the more than 200 generic drug manufacturers. And I might point out that, of the FDA approvals, every approval for an ANDA _ 60 percent of those approved never make it to the market because there is no market to make it to.

And the constant downward pressure created by the harmful, most-favored-nation contract terms imposed by purchasers can result in unrealistically low prices. This unchecked consolidation and vertical integration has created an unsustainable take-it-or-leave-it market for many of the

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lowest-cost generic medicines with one-sided terms, maximum downward pricing pressures, but no certainty on the price or the volume that you will get to sell.

To help ensure sustainability for the generic market, we believe Congress, FDA, and CMS can update the generic drug Medicaid inflation penalty to allow with inflation penalty included in the Inflation Reduction Act, expand the drug shortage exemption of the Inflation Reduction Act, speed new generics to market through legislation that enables generic manufacturers to receive key quantitative and qualitative formulation information from the FDA, ensure that Medicare drug plans cover and encourage the use of new generic and biosimilars, amend the 340B program to exempt low-cost generics, or adjust the ceiling price required of generics, empower the FDA drug shortage staff to engage with the Office of Regulatory Affairs and the Office of Compliance during the inspection, planning, and the debrief process, improve transparency regarding the status of applications and inspections, enhance the expedited inspection resolution pathway, review shelf life extension programs for products in critical supply and/or in shortage, and streamline regulatory

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processes to expedite facility review.

Lastly, I would like to say that I have seen this issue at nearly every stage. I am a registered pharmacist, I have been a hospital system director of pharmacy, I have been a GPO director of contracting, and I have led a business for the generic manufacturers. Thus, I fully am aware of the multifaceted front affecting and with responsibility for many entities in the supply chain.

AAM remains committed to working with policymakers, patients, and this committee, and other health care professionals to provide effective _ address _ provide effectively to address the challenges required to improve sustainability of the generic drug industry and ensure patients' savings and access.

Thank you very much, and I will be happy to answer any questions.

[The prepared statement of Mr. Gaugh follows:]

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*Mr. Guthrie. Thank you. The gentleman yields back. That concludes our witness testimony, and will now begin questioning, and I will recognize myself for five minutes to begin questioning.

So thanks for you all being here, and thank you for your testimony.

My good friend, the ranking member, talked about cheaper drugs and cheaper drug prices. And we are not here to _ we all want cheaper drug prices, but we also want access to the drugs that are needed. If the price of the drug is below what creates a supply that is below the demand, that leads to rationing. We have had people _ I think my friend, Dr. Bucshon, talked about his friends in the medical community choosing to ration child cancer treatment. So this is serious for us to be here, and we are not trying to one-up each other politically. We are trying to get to an answer to how we solve this problem because it is real.

And then we have had some comments and _ on provisions of the bill that creates burdens and some other things moving forward. You know, we wouldn't be here if your system was working. The system is not working. We _ it is not just _

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and I referenced the tornado in North Carolina in my opening statement, and we know we have had hurricanes in Puerto Rico, but this is a systemic problem. And that is just _ it is just failing. It is just failing to address the problem.

And we need to shape _ we need to address where the government is involved in this, and has the issues creating the lower prices that aren't created in the marketplace.

And so Mr. Gaugh, we talked about drug shortages in terms of the supply, as I have just talked about. To better understand this dynamic _ and we are _ the government reimbursement creates challenges _ would you specifically talk about how the average sales price calculations affect the shortage?

*Mr. Gaugh. So thanks for the question, and a very complicated question with a very, very long answer.

So as you look across the entire spectrum of whether you are talking about the sale to a distributor, or through the GPO, or through the retail structure, it is different in each and every one of those.

And so what I would ask is that I be able to come back to this committee in writing with a schematic, really, that

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drives through all these issues that are out there, because not one pricing issue _ you can't fix all pricing issues with one solution. There just isn't one that is out there.

*Mr. Guthrie. Okay. Well, thank you for that. And we look forward to your response back.

[The information follows:]

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*Mr. Guthrie. We have seen that a lot of people are leaving the marketplace. I know when I am in _ with the supply chain in the automotive world, and if I contracted to an OEM or an automotive producer to give them a product at the price I am willing to pay for it, and I got to buy product to go into my product to sell to them, then I am just not obligated to give them the cheap price. I am obligated to deliver the product. And it seems like we are having people that are contracting to deliver a product on a _ on _ based on a price, or negotiating a price that is not presenting the product. That is just, from a supply chain background, is what I see with this.

I know on the _ so with the wholesalers, Mr. Davis, I know we have had some feedback already on some of the processes and the bona fide service fee. Can you clarify? I know you addressed a little bit about some concerns that you have with the provision. Like I said, this is a discussion and we are trying to solve the problem, and we are interested in what your _ clarify your concern about moving forward, and we are willing to listen.

*Mr. Davis. Good, thank you, Mr. Chairman. I will be

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brief, because I know this is within the context of the larger discussion around drug shortages.

But I would also say that we respect the fact that this committee and others in Congress over the last several years have focused a lot more attention on the entire supply chain, including many of the stakeholders here and some that are not represented at this hearing, and have begun to question about fees in the channel by different stakeholders.

As I said in my opening remarks about bona fide service fees, they are legitimate fees for a service rendered. And I reinforce that because I distinguish that from what we would refer to as access fees. There are access fees charged by some, sometimes very significant, high-level, high percentage off list-price access fees that impact decisions around formulary access, either in the insurance market or in the hospital setting. That is not what a distributor charge is for. We charge for legitimate fees that CMS requires, have to be at fair market value. It is literally regulatory defined that it must be at fair market value. So by and large, it is a nominal percentage of the list price of the product.

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Our concern about actually shifting it to flat rate would be that, again, we don't know what that scenario would potentially look like, and that system all impacts everybody, from manufacturers to wholesalers. We would have to redo every single one of our contracts. And then it also, perhaps most importantly, impacts the provider community downstream, which is often reimbursed _

*Mr. Guthrie. Thanks. I have only got one more quick question.

So, Mr. Ebert, if I am an automotive supplier, and I negotiate a component for my product that is too low, that the supplier is not going to be able to consistently supply it to me, and I put it into my product and sell it to an automotive, and I can't deliver, then I am held accountable for that. Is that part of your contract, too?

*Mr. Ebert. Our contracting process is an open and fair and competitive process. When contracts are developed, the entire process is one in which the manufacturer is included in the entire process, including the ending, when we determine what the final contract would be. They are part of the entire process, where they understand what the

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deliverables are and at the same time what the expectations are from the standpoint of our customers.

*Mr. Guthrie. Okay, I am sorry. I asked you _ that was not fair to you, I asked the question with not much time remaining, and I have expired. Hopefully, we will get a chance to answer that, and _

*Mr. Ebert. Okay.

*Mr. Guthrie. _ and give you a chance to answer that question. My time is expired. I apologize for that.

And I now recognize the gentlelady from California for five minutes for questions.

*Ms. Eshoo. Thank you, Mr. Chairman.

And thank you to each one of you. I found your testimony to be highly instructive.

And to Mr. Coukell, I think your model is absolutely fascinating, really fascinating, and I think the first in the country, the model that you have established.

And in the coming days I am going to introduce the Pediatric Cancer Drug Supply Act. It is going to establish a program to create a six-month buffer stock of essential pediatric oncology drugs. And I hope to see this proposal

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included as part of any final plan or package to help to address drug shortages.

So I want to ask you, Mr. Coukell and Mr. Ganio, do you support this proposal?

Mr. Ganio.

*Dr. Ganio. Thank you, Congresswoman. Yes, pediatrics are an especially vulnerable population. There are fewer drugs approved for pediatrics. We use many drugs off label, so there are already fewer options for them. I would support that provision.

I would actually expand that to essential medicines for everyone, including adults. But we have seen some very heartbreaking drug shortages in pediatric patients _

*Ms. Eshoo. Yes.

*Dr. Ganio. _ knowing that they are going without _

*Ms. Eshoo. Yes, I have been on this for months.

*Dr. Ganio. Yes, and the heartbreaking part of it is that many of these pediatric cancers are curable with the right treatment.

*Ms. Eshoo. Exactly.

*Dr. Ganio. So that provision would save lives.

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*Ms. Eshoo. Exactly. Thank you.

Mr. Coukell.

*Mr. Coukell. Thank you for that question, Ranking Member Eshoo.

We, as I have said, maintain a six-month stockpile of all of our drugs. So we think that is an important part of creating reserve inventory that can buffer supply interruptions.

What we have found is, for that to work effectively, the size of that inventory has to be directly tied to a predictable demand for the drug. The worst-case scenario would be to build up an inventory, and have all of that product outdated and be expired, and then the government is just out that money.

So I think, absolutely, that it would be a valuable thing to do, and we would be glad to work with your _

*Ms. Eshoo. So what is the ancillary policy that should be a part of this?

*Mr. Coukell. So it needs to be tied to _ directly to purchase commitments for the drug.

*Ms. Eshoo. I see. So how would long-term contracts

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help non-profit manufacturers move into the generic sterile injectables market?

*Mr. Coukell. Well, and not just non-profit manufacturers, but, as you can imagine, if you have predictable demand, then you have more ability to invest in quality upscale facilities, and you know you are in it for the long run. If you are manufacturing drug, but you don't know that you will have market share next year, you can't build up a stockpile, and are unlikely to sort of invest in quality.

*Ms. Eshoo. So in advising our subcommittee, what are the top three things that you believe should be included in legislation to address what we are experiencing in our country, really, placing so many patients in our country at high risk?

*Mr. Coukell. Specific to a pediatric cancer drug stockpile?

*Ms. Eshoo. Mm-hmm.

*Mr. Coukell. So I think, again, ensuring that the _ there is an effective flow through inventory so that you are always selling the older stock and replacing it with newer.

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So it has to be tied directly to demand, so that it doesn't outdate and expire.

And then, you know, thinking carefully about is there such a thing as pediatric cancer drugs, or are those also used in adult cancers, and how do we navigate that?

And then, really, thinking about how do we do it most effectively? Does the government need to pay for the full stock, or is there a way to make the market, you know, pay for that inventory on an ongoing basis?

*Ms. Eshoo. Thank you.

Let's see, Dr. Barber, what has your research into generic sterile injectables shown about the relationship between price and the potential for a drug to be in shortage?

*Dr. Barber. Thank you very much, Congresswoman Eshoo. It is a complicated story. My research in particular looks at markets for upstream active pharmaceutical ingredients, for which _ it is an important component of price for generic, sterile injectables, and the low prices that we have seen are in part tied to a race to the bottom in market consolidation.

To respond to your question specifically on what

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research shows, I am just going to say what the FDA has found, because they have the best data, the most comprehensive analysis, and they found that for drugs in shortage, even when price increases after, supply shocks are not less likely. So price is a factor, but it is not the be-all and end-all.

*Ms. Eshoo. Well, my time has expired, and I will yield back with my thanks to all of the witnesses. This is such an important hearing. And what we do, the words that we write are going to walk right into people's lives. So we have to get this right.

Thank you, Mr. Chairman.

*Mr. Guthrie. Thank you. The gentlelady yields back, and the chair recognizes the chair of the full committee, Mrs. McMorris Rodgers, for five minutes for questions.

*The Chair. Thank you to all the witnesses for being here this morning on this important issue.

Mr. Gaugh, I wanted to start with you and ask a question about some of the reimbursement issues that we see with inflation rebates and the impact on the generic drug market.

If a drug is $0.88 per vial, and the price goes up to

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$1, that is over a 10 percent increase. Current law penalizes the company for any increase in the price that exceeds the rate of inflation. Do we really want to penalize that manufacturer for a nominal increase in the price?

*Mr. Gaugh. So the easy _ thanks for the question, and the easy answer to that is no, we do not want to.

So if you go back several years, and you look at the intent behind these rebate systems, they were mostly around the brand products, but the generic products got pulled into it. So if you are looking at a brand product _ and I will make up some numbers, but _ that sells for $1,000 a vial, then a 9 percent, 10 percent increase is a significant increase.

But to your point, if you are talking about something that is selling for $1 or less than $1, and you are looking at a $.10 increase, and that is a penalty, it just continues to push the price down lower and lower and lower. Thank you.

*The Chair. As a follow-up, do you believe exempting generic, sterile, injectable drugs with multiple manufacturers from Medicaid's inflationary rebate would improve economics for these manufacturers and help prevent

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shortages?

*Mr. Gaugh. It would be one aspect, yes, of reducing _ preventing and reducing shortages, potentially, yes.

*The Chair. Thank you.

Mr. Coukell, is the inflation penalty exemption in the discussion draft, which is focused on generic, sterile, injectable drugs that have an indication for a serious disease or condition, the right way to target relief for this class of drugs, are there other drugs necessary for patient care that could still be subject to inflation penalties that we should also consider including?

*Mr. Coukell. Thank you for that question. The definition that is in the draft now, as you say, for serious or life-threatening, may leave out some really important drugs that are on shortage. I use the example of local anesthetics like lidocaine and bupivacaine, which have been on shortage for a long time, and I think probably wouldn't qualify for that threshold.

An alternate approach would just be to look at those very low-cost drugs. When we look at drugs we are selling for under $4, some of them have rebates between, you know, 10

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and 80 percent. And as you can imagine, it is hard to have erosion of margin on products that are priced at that level. So just setting that threshold to say below that threshold they are not subject to those rebates and penalties would be helpful.

*The Chair. Thank you. The _ as another question, the 340B rebate exemption is similarly targeted. Could you talk about Civica's experience with 340B, and how those rebates affect the market for drugs often in shortage?

*Mr. Coukell. We participate in that program, like any other manufacturer. And you know, as I was saying, for very low-cost drugs, that can be a significant erosion of margin, which makes it that much harder to deliver the products in a sustainable basis.

When we look at generic spending, spending on generic drugs as a total share of health care spending, it is one percent in total. So you know, removing or reducing the rebates on those very low-cost drugs would be unnoticeable, I think, within the context of the 340B program.

*The Chair. Thank you.

Mr. Gaugh, if one of your members were to sign a

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contract with a wholesaler or GPO, and a new entrant manufacturing outside the U.S. launches at half the price, does your member company lose the contract, or is there certainty about the price and production number for the duration of the contract?

*Mr. Gaugh. Contracts are typically a three-year contract, with a set price and an estimated volume at day one, when you sign, that is good for that day one. The volume is estimated, so you are never guaranteed the volume that you bid on. And if a new price comes forward, typically you have 48 hours to match that price or then you lose the contract.

*The Chair. If a manufacturer loses a contract, are they likely to continue making that drug, or shift to a completely _

*Mr. Gaugh. Depending on how many other contracts are out there.

No, great question. But it is a limited number, as I have mentioned in my talking points, limited number of contracts to go to.

So most often they will just "dump'' their inventory and

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move on to another product.

*The Chair. Thank you.

During August I visited a generic manufacturer in my district, and I learned a lot about the red tape our manufacturers must navigate, including necessary state licenses that bog down the process of building new facilities that could help with this shortage.

There is a provision in the discussion draft that would require FDA to expedite inspections of generic, sterile, injectable facilities in advance of an application being filed so the moment the application is approved, the facility could go forward.

My time is expired, but I will follow up with more questions regarding just the process of trying to get manufacturing plants permitted in the United States. I yield back.

*Mr. Guthrie. Thank you. The chair yields back, and the chair recognizes the ranking member, Mr. Pallone, for five minutes for questions.

*Mr. Pallone. Thank you, Mr. Chairman, and thank our witnesses.

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As I said in my opening statement, I am concerned that the Republican proposal focuses on raising prices for drugs without doing anything to require drug manufacturers to take action to address drug shortages. So let me ask Dr. Barber.

What effect would allowing drug companies to raise prices faster than inflation have on preventing or addressing drug shortages?

*Dr. Barber. Thank you very much for your question.

So increasing the prices of medicines through inflation rebate exceptions may incentivize new manufacturers to enter the market. But the measure is poorly targeted, because manufacturers are nevertheless not incentivized to invest in improving quality and building resilience into their supply chains. On the contrary, they will continue to be incentivized to reduce investments in these areas in order to cut costs and increase their margins. For this reason, increased prices through the rebate exception are not a well-targeted instrument for achieving the intended aim of improved supply chain robustness.

I also want to contextualize why we have price controls, right? Like the Government Accountability Office found that,

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you know, for dozens of drugs there were price increases of more than 100 percent in the year that they were stating _ so, yes, it is important to ensure that prices of medicines are sustainable, that they are _ have healthy margins that allow for quality production, but we also need to be aware that prices were increasing dramatically, and these measures were put in place for a reason.

*Mr. Pallone. I had two more questions I think you kind of answered, but let me just kind of summarize.

I mean, basically note that lower drug prices are not associated with an increase in shortages. So maybe just explain a little more how you came to that conclusion.

And then, could you see a scenario where, if the Republican discussion draft was passed, a drug company may have the incentive to keep a drug in shortage for longer in order to raise prices faster than the rate of inflation without any penalty?

*Dr. Barber. Sure. Thank you very much for your question.

I am sorry, the first question had to do with?

*Mr. Pallone. Well, I mean, how did you come to this

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conclusion that the drug prices are not associated with an increase in shortages?

*Dr. Barber. Sure. I am an academic, so I am going to be very careful and step away from the word "associated.'' It is not strongly associated. And these are not my conclusions. This is the consensus in the literature. These are the findings by the Government Accountability Office. These are the findings by the FDA that point to the root causes of shortages. The majority, I think, was 62 percent being rooted in manufacturing issues, right?

And there is a kind of, you know, put the horse before the cart. Are manufacturing issues existing because prices are too low so manufacturers can't invest in them, or is it the other way around? And I encourage the subcommittee to ensure that they are getting good value for money in terms of extra payments, being sure that they are tied in an accountable way to ensuring that we are paying not just for profits, but for improved quality management.

To answer to your second question, which was asking whether or not there are financial incentives for drug companies to keep certain drugs in shortage, as an economist

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I have to answer yes. That is the effect of the incentive. I wish I lived in a world where such business practices were unimaginable, but unfortunately, there is evidence that, given the opportunity, some companies will create artificial shortages for their financial benefit.

For example, in Italy, competition courts found in 2016 that a pharmaceutical company, Aspen, had intentionally under-supplied Italy with lifesaving cancer medicines to strengthen their negotiation position on price by creating an artificial shortage. The courts ruled conclusively that shortages were not the result of production issues, and internal emails showed that Aspen went so far as they planned to destroy stock of these medicines if they didn't get the higher prices they demanded. I think this context is important. Thank you.

*Mr. Pallone. All right. I am trying to get in one more question here.

There seems to be agreement about Republicans and Democrats that, you know, there is a problem with the API, right? The Republican _ both the Republican discussion draft and Ms. Eshoo's legislation ask drug manufacturers to report

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where the API in their product is coming from. However, one key difference is the Republican discussion draft only requires this of companies relying on 1 API manufacturer for 60 percent or more of their supply chain.

And so let me ask you this. I mean, what steps should we take to better improve our knowledge of API sources and the overall drug supply chain?

And can you tell us whether it makes sense to require only certain drug sponsors to report on their API sources?

*Dr. Barber. Thank you for your question.

No, it doesn't make sense to exclude to only certain sponsors. And to be frank, I think the thing that we should focus on is not where was the API produced for a given drug, but when we think about, you know, public health for the drugs that we need, how many suppliers are there? Where are they? Right?

So at present there is no systematic monitoring of API markets. That is not done by FDA. It is not done by EMA, it is not done by WHO. We don't know, right? So the most central questions for supply chain resilience: how many API manufacturers are there, what capacity can be mobilized in a

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shortage or emergency cannot be answered.

So I hope one outcome of this hearing is a shared understanding of the urgent need to map global and domestic API production, to measure and monitor manufacturing capacity, and to compel manufacturers to share more detailed information on supply chain and manufacturing issues. Promoting quality is a global problem, and I urge the subcommittee to be vigilant in not allowing increasing trade tensions to threaten health.

It is a problem if there is only one factory manufacturing a vital antibiotic, whether that factory is in the United States or China or India. Economies of scale, especially for drugs with small patient populations, are always going to rely on globalized supply chains. But we need more transparency. Thank you.

*Mr. Pallone. Thank you.

Thank you, Mr. Chairman.

*Mr. Guthrie. Thank you. The gentleman yields back, and the chair recognizes Dr. Burgess for five minutes for questions.

*Mr. Burgess. Thank you, Mr. Chairman.

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Mr. Gaugh, let me just ask you a question because price setting, price controls now has come up with _ as a way for _ to hold the prices down. But in other areas of economics we learn that price setting could actually reduce the availability of a product. Is that something that you have encountered?

*Mr. Gaugh. So, yes, thanks for the question. And yes, throughout the contracting process you do find instances where that does occur, absolutely.

*Mr. Burgess. It comes up because I went to a community clinic back home in the district, talked to a doctor who takes care of primarily uninsured, low-income, under-insured patients. And his concern was that he is going to have less availability of some lower-cost products because they are just simply going to be eliminated. Is that a legitimate concern of his?

*Mr. Gaugh. It is. And I actually _ AAM belongs to an international group called the International Generic and Biosimilar Medicines. And in a conference that we had last week, that statement, very similar to what you are making, was made, and that is the prices are pushed down very low,

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but the drugs are not available when they get to that low level, hence drug shortages.

*Mr. Burgess. Okay, and that is a concern because we are seeing more of a reliance _ and I don't mean for this to be political at all _ but we are seeing more of a reliance from the Administration to say, hey, we are just going to limit your expense here on this. All well and good until there is no more of that product to buy. And then that is a serious problem.

Mr. Ganio, let me ask you a question about _ we had some complaints earlier before we had this hearing that we weren't tackling these problems at the FDA. Does the FDA have existing authority to prevent drug shortages?

*Dr. Ganio. Thank you for the question. It gives me a great opportunity to commend the work of the drug shortage staff at the FDA. They do phenomenal work preventing shortages.

I think where there may be some deficiencies, or where the CARES Act, for example, was passed in 2020 with reporting requirements that we are actually talking about today, filing risk management plans, but there is no enforcement authority.

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And the FDA also doesn't have the authority to recall on their own. They _ most of the recalls are voluntary.

*Mr. Burgess. So let me get back to a theme that always seems to recur with me. Has there been an internal analysis at the FDA of what they have got right and what they have got wrong, and how do we avoid some of the mistakes of the past?

*Dr. Ganio. The only insight I can give you into that is the root causes report that was published in 2019. It was an interagency effort, and it has pointed to these _ the low economic incentives for getting into the market and staying in the market, and then a lack of market recognition of quality. Whether there was an internal review within FDA on their role, I can't answer, I am sorry.

*Mr. Burgess. And obviously, 2019 would be pre-pandemic. And I am extremely interested to try to get Dr. Califf to share with us any sort of introspection they have done since the pandemic. But that is a separate issue, we will work on that another day.

How is the FDA working to ensure that drugs on the market meet quality standards of what could be done to further improve the transparency requirements to ensure that

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providers have the tools they need to choose the drugs that work for their patients?

*Dr. Ganio. I think that is the root cause that we really should be talking about, is how do we make sure purchasers have that information to know they are buying from reliable supply chains.

FDA has proposed the QMM Program, the Quality Management Maturity Program. There are some other third parties that have proposed systems to evaluate quality, and I know some of the GPOs are looking at that as part of their contracting. But that really _ we need to find a way to support the manufacturers that are making investments in quality. And right now, the only information we have access to, as purchasers, is the price.

And so that just reinforces this race to the bottom, and we are buying the cheapest product that we can because of the way we are talking about ASP calculations. But these drugs are not separately payable.

So of course, we are incentivized to buy the cheapest product because there is no recognition from payers on which product we are using.

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*Mr. Burgess. So let me ask you another question before my time runs out, and I will have _ I will ask all of you to respond to some written questions that I have, because I just don't have the time.

[The information follows:]

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

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*Mr. Burgess. But you referenced Adderall in your opening remarks. And look, we have trained consumers in _ over the past several years that, if you can't find something, you go online and you get it, right? There is a risk to going online and buying your Adderall, because it may come from someplace you have never heard of, and it may not be pure Adderall, it may be laced with fentanyl. And that is a real risk.

*Dr. Ganio. Absolutely. The online purchasing, any kind of pharmaceuticals online, is a discussion we can certainly have. And there are dangers with supply chain vulnerabilities and counterfeit products on the online pharmacies.

*Mr. Burgess. Great. I just thought it was important to underscore that for people who are watching this hearing today.

Thank you, I will yield.

*Mr. Guthrie. That is accurate. Mr. _ the doctor yields back, and Mr. Cardenas is recognized for five minutes for questions.

*Mr. Cardenas. Thank you very much, Chairman Guthrie

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and Ranking Member Eshoo, for holding this hearing and to discuss the shortage landscape. And I also want to thank the witnesses for your insights and your opinions today.

I have said in this committee before that failing to provide FDA with a clear and end-to-end picture of our pharmaceutical supply chains is a mistake with dire consequences. We are now working to address a problem with our hands tied behind our backs.

My Republican colleagues, on the other hand, have brought forth a proposal which clears the way for unchecked price increases that will raise costs for consumers and do nothing to alleviate shortages. Not only is this an inappropriate solution to our current problem, it will limit access even more.

In a previous hearing I asked Dr. Julie Gralow, head of the American Society of Clinical Oncology, what would be the most helpful to avoid and mitigate shortages. Her response was clear: expanding FDA's ability to know where manufacturers source their active pharmaceutical ingredients is critical. This sentiment has been affirmed by experts at the FDA, as well, stating that manufacturing quality issues

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and delays in sourcing raw materials are largely to blame for the current shortage.

Yes, drug shortage issues are complicated, and there are market forces at play. But let's at least build consensus around getting proper reporting and information structures to allow us to monitor and anticipate these shortages.

And most importantly, let's not forget why this matters and what is at stake. We are talking about the lives of every American.

Almost one-third of hospital pharmacists say they have had to ration or delay treatments because of these shortages, with oncology drugs being particularly scarce. This means that the victims of this shortage are very ill cancer patients who can't wait, let alone weeks or months, to get their treatments. For oncology drugs in particular, a delay in treatment for 4 weeks can mean increased sickness and mortality for over 40 percent of common cancers. We need to intervene quickly, and playing with the price points on drugs is not the answer.

Mr. Ebert, your testimony notes that price isn't the only factor that health care providers consider when making

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purchasing decisions. Can you expand on that?

*Mr. Ebert. Yes. Our contracting process relies on three important components in the contracting piece. Price is one, as you have identified.

Number two is quality, we are very keen on analyzing the quality prospects or the aspects of the pharmaceutical company that we are dealing with. We want more information, as your comments made _ have been made. Information is better, from our standpoint, because it helps us make better decisions. So we encourage the FDA's QMM program that has been discussed, or others that give us more information. And then we work really closely with our members relative to their input regarding quality products, as well. It is extremely important to us, and more information is better.

And the final piece is the stability of supply. That is important, as well. And we are using all those aspects to develop stronger contracts for our suppliers to work with our customers.

*Mr. Cardenas. Okay. And what kind of visibility into the drug supply chain do group purchasing organizations, distributors, and health care systems have?

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And how might having the ability to forecast shortages help to avoid similar situations in the future?

*Mr. Ebert. The visibility that we have now is pretty limited. We try to use as much information as we possibly can. We will go on the website to see what 483s are out there. But a lot of that information is redacted, and so we don't have a lot.

The good thing is that we have members that have a lot of experience. They will let us know if there are issues with their products that they use. And as a pharmacist practicing before, you know, you do look at your supplier and determine what are the issues relative to quality.

So we are looking, and we are seeking more information, and that is very important to us relative to the contracting process. And developing a strong supply chain line, that is important to us.

*Mr. Cardenas. Okay, thank you.

Mr. Ganio, what kind of notification processes are in place so that health care settings can anticipate shortages, and providers can put out guidance?

And why is it important to build these systems in?

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*Dr. Ganio. It is actually critical to build those systems in. We don't get a lot of notice of a shortage. And often times you find out that there is a shortage when something doesn't come in from a wholesaler. And then you order it again, and if it doesn't come in then we get a report that there is a potential shortage, and we will investigate.

The transparency information that we are discussing today is critical to improving predictive models. I think anticipating a shortage is very difficult, but there are predictive modeling exercises being done by United States Pharmacopeia, for example, looking at vulnerability. And that vulnerability score can be improved with more transparency, and those are the types of things that we can use as providers to start to develop mitigation plans.

*Mr. Cardenas. Thank you very much.

My time is expired. I yield back.

*Mr. Bucshon. [Presiding] The gentleman yields back. I now recognize Mr. Latta from Ohio for five minutes.

*Mr. Latta. Well, thank you, Mr. Chairman, and thank you to our witnesses for being with us today.

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In the United States we shouldn't be facing a drug shortage crisis. We have the tools, the manufacturers, and the resources. In rural communities in my district I can't tell you how many patients and hospital leaders I have spoken with that have had to take matters into their own hands and use creative ways to overcome these shortages. Unfortunately, there isn't a silver bullet to address these shortages. They are a combination of overreaching government programs and a lack of efficiency in approving new drugs.

Mr. Gaugh, let me start with you. Do your companies tell FDA where API is manufactured as part of the applications, yes or no?

*Mr. Gaugh. Yes.

*Mr. Latta. And can FDA inspect an API facility, yes or no?

*Mr. Gaugh. Yes.

*Mr. Latta. Thank you. Let me continue, Mr. Gaugh. I know that the 340B programs that have been a concern have been reviewed by this committee. Does the 340B program influence the generic drug market? And if so, what can be done to address the impacts?

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*Mr. Gaugh. So yes, it does influence the market. Every hospital has the purchase power to buy under 340B contracting. And so those prices and the price reductions occur on the contract process under 340B. So that is just a continued lowering of the price of the product.

*Mr. Latta. Okay. And so what can we do to address the impacts, then?

*Mr. Gaugh. So there is a couple of things that can be done.

Number one, we look at the pricing in the inflation, and then there is a 14 percent reduction underneath that. We think that 14 percent reduction could be removed in areas of drug shortage. Is that really required, if it is already near zero, from a profitability, to take an additional 14 percent off?

Also could raise the ceiling for 340B on the generic drug prices.

*Mr. Latta. Okay, thank you.

This committee recently worked on the reauthorization of a generic drug user fee agreement, which included provisions to speed up the approval of generic drugs. How does the FDA

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process influence the generic drug market, and do potential delays impact a manufacturer's ability to bring a product to market?

*Mr. Gaugh. So we are now in our third iteration, if you will, of GDUFA and BsUFA. And in both cases we have had major advances in each of the five-year sections. So now we are at a 10-year clock on the approval process, and very tight metrics set around that that the industry can monitor the FDA on. And in general, they are making that mark.

So we either get an approval, tentative approval, or a complete response letter towards the end of those 10 months that we can then turn around and respond to in an additional few months for review and approval.

*Mr. Latta. Okay, thank you.

Mr. Davis, contracting practices between manufacturers and wholesalers can have a large impact on ensuring adequate supply of medicines. Is it typical for commercial wholesalers like your members to contract with multiple manufacturers to ensure supply isn't impacted if one manufacturer encounters an issue that prevents them from manufacturing a product?

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*Mr. Davis. Yes, Congressman Latta, thank you for the question. The short answer is yes.

I think if you actually look for a minute _ and I know the focus of this hearing is on generics and injectable generics, but also recognizing that from our members' perspective, their negotiations on the branded side versus the generic side look very different, right?

If you look at the balance of our system in Hatch-Waxman, on the branded side you negotiate and consider safety, efficacy, and cost. And on the generic side, efficacy and safety have essentially been removed, historically. And the intent of generics originally back to the mid-80s was to compete on price.

So the reality is, in the generic market, what our members are forced to do is actually negotiate with multiple manufacturers simultaneously to build in resiliency to protect against one of them shutting down.

*Mr. Latta. Let me follow up. As far as you know, do your members frequently award sole source contracts for generic medicines?

*Mr. Davis. There might be circumstances where that

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happens. But as I just said, the reality is, particularly in an era of increased shortages, they are looking at things well beyond costs. They are looking at historical reliability, ordering patterns, if they had preexisting business relationships with the manufacturer, has that manufacturer been in short before in certain therapeutic areas, and, if so, how does that inform current negotiations?

And they are also looking at the length of time of their contracts, recognizing there is a desire for greater stability in the market.

*Mr. Latta. Okay. Well, thank you very much.

And Mr. Chairman, I yield back.

*Mr. Bucshon. The gentleman yields back. I now recognize Dr. Ruiz for five minutes.

*Mr. Ruiz. Thank you, Mr. Chairman. As we have heard from experts here today, our nation is facing a critical shortage of medications, and we need to act now.

As an emergency medicine physician, it has always been my top priority in Congress to improve patient access to high-quality, affordable health care. We have made great strides towards this goal, but these efforts are moot if we

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cannot ensure ready supplies of the medications patients desperately need. In the emergency room I have witnessed firsthand the dire implications that shortages of key medications are having on the lives of my patients. For patients suffering from infections or trauma, or fighting against cancer, or needing paralytics to be intubated, this is a matter of life and death.

One factor we have identified that contributes to these shortages are manufacturing challenges. These issues stem from fewer drug manufacturers being based in the United States and little regulation on reporting to the FDA. We need to target our efforts at addressing these problems, which are the source of supply problems to better prevent deadly shortages. Current shortages of vital chemotherapy drugs due to these manufacturing challenges illustrate the urgency of this.

We must increase transparency in manufacturing and increase responsiveness to prevent further shortages in the future. And we need to expand manufacturing, and we need to put reporting mechanisms in place to _ for transparency to ensure reliable supply of safe medications to secure patient

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access to the affordable care that they need. As we saw with the recent baby formula shortage, lack of transparency and limited manufacturing capacity leads to negative health outcomes.

Mr. Gaugh, what are the most effective mitigations we can make to bolster domestic supply and production of medications?

*Mr. Gaugh. To increase domestic?

*Mr. Ruiz. Yes, to bolster domestic supply and production of medications.

*Mr. Gaugh. So it is all really about the expense for doing that. So to your point, we have what we call a blueprint. And in that blueprint we talked a significant amount _ and I can get it to the committee _ about bringing production back, or expanding production in the U.S. And that is going to look at having _ we are now up against, if you will, foreign entities that are a much lower cost for building and labor costs. But we are competing in the U.S. market for a higher price point when you look at the contracting.

So this looks at potential tax relief, if you will,

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grants, but also looking on the back end of a cost point or a price point in the actual contracting of those products in the U.S., because you are still going to be competing with companies offshore in that contracting process. Thank you.

*Mr. Ruiz. Thank you. And thanks for your input towards addressing these solutions.

So, you know, I am going to urge my colleagues to support the five bills before us, and especially the Drug Shortage Prevention Act, which would directly address the concerns I brought up today by requiring manufacturers to notify the FDA when they experience periods of increased demand so that the FDA can step in and respond more immediately to prevent a looming drug shortage.

So thank you and, a gift to the committee, I yield back the rest of my time.

*Mr. Bucshon. The gentleman yields back. I am now going to recognize Mr. Johnson from Ohio for five minutes.

*Mr. Johnson. Thank you, Mr. Chairman, and good morning to all of our panelists.

You know, today we are looking at how Congress can address an issue impacting every single corner of our

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society. From oncology drugs and baby formula to ADHD and generic medications, the current drug shortage is restricting the care that doctors can provide, and it is reducing the quality of patient care nationwide. And all this reduces the quality of life for all Americans.

In some cases, parents are concerned about sending their children off to start another school year without the medications they need. In other cases, doctors are substituting cancer treatments because they are unable to access their preferred treatments. In any first-world country, especially the United States, this is wholly unacceptable.

I am sure each member of this committee can tell a story of someone they represent not being able to get their prescriptions filled or having to change their cancer treatments in order to work around a shortage of a particular oncology drug. That is why this hearing today is so important. We need to fix this, and we need to fix it now.

So, Dr. Gaugh, many of our drug shortages are caused by quality problems. Why do your members seem unable to invest in more modern and upgraded manufacturing facilities that are

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less likely to have quality issues?

*Mr. Gaugh. Thank you for the question, and that question and the process around it, we don't believe, is a totally true statement. We have heard the FDA say that, as well. We do reinvest into our facilities. We do add in new equipment, new lines, building new parts of the facility. So it is not that reduction. It is a combination of FDA inspection processes and the actual facility.

So as I said in my opening statement, we think there should be a very important process where the drug shortage staff of the FDA works with the Office of Regulatory Affairs and the Office of Compliance as they go through those inspection processes to make sure that it is an objective, not a subjective process.

*Mr. Johnson. Okay. Do group purchasing organizations, or GPOs, contracting _ do GPO contracting practices play a role in pricing and the stability of the generic market?

*Mr. Gaugh. Yes, they do.

*Mr. Johnson. Okay. All right. While I am with you, Mr. Gaugh, I heard a mention that FDA does not know where API is made for generic drugs. Mr. Gaugh, do generic companies

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tell FDA who their API suppliers are as part of a generic drug application? Yes or no.

*Mr. Gaugh. Yes.

*Mr. Johnson. They do. Can FDA inspect those API suppliers?

*Mr. Gaugh. Yes, they can, and they do.

*Mr. Johnson. Okay, great.

Mr. Davis, what do your HDA members do when there is a shortage and they don't have enough inventory on hand to fill their customers' orders?

How do they decide how much each customer gets, and how do distributors mitigate and manage drug shortages?

*Mr. Davis. Thank you, Congressman, for the question. So I would answer that in two ways.

I think the first thing is they want to define the scope and the severity of the shortage, and they do that through regular communication, active communication with their upstream manufacturing partners, as well as their downstream providers. Often times, going back to my opening statement, we have to define whether or not this is a demand-driven shortage or a supply-driven shortage, because the solutions

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to those things can _

*Mr. Johnson. Okay.

*Mr. Davis. _ and often does look differently.

The biggest thing they do is they will _ once it is confirmed that there is a shortage _ will often put all of their downstream providers on what they call fair share allocation.

*Mr. Johnson. Right.

*Mr. Davis. It is often an algorithmic formula that makes sure that everybody gets a portion of what they like so that no one goes without it completely.

*Mr. Johnson. Okay.

*Mr. Davis. The shortage _

*Mr. Johnson. Continuing with you, Mr. Davis, it seems that distributors are in a unique position to see shortages coming because of their interaction with both the supply and demand sides of the equation. So do distributors communicate to the FDA when they see the potential for a shortage coming?

And is the FDA leaning forward and reaching out to you when they see the potential for a shortage?

*Mr. Davis. Yes, sir, on both of those fronts. I think

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if you go back to last fall, and you look at what was referred to as the Tripledemic, I had direct conversations with the FDA commissioner as well as our team with the Office of Drug Shortages and his office, as did many of our members.

The only thing I would distinguish is I think there is more visibility from us, given the relationship with the provider end, particularly the pharmacy community, when there is demand-driven, because that is coming up through the system. And we don't have as much visibility on supply-driven, because the manufacturers are obviously living with that before _

*Mr. Johnson. Okay, my time has expired. What about the manufacturers? Do they communicate that they are struggling with keeping up with supply and demand, yes or no?

*Mr. Davis. To distributors, sir?

*Mr. Johnson. Yes.

*Mr. Davis. Yes.

*Mr. Johnson. Okay.

*Mr. Davis. Yes, we try to ensure that there is regular communication.

*Mr. Johnson. All right, Mr. Chairman, I yield back.

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*Mr. Bucshon. The gentleman yields back. We now recognize Mrs. Dingell for five minutes.

*Mrs. Dingell. Thank you, Mr. Chairman, and thank you to all of the witnesses today for being here.

As you all are discussing, and all my colleagues are discussing, drug shortages are upending patients' course of treatments across the nation, which is why many of us have been calling for this committee to take action for months. I have been hearing from people who can't get access to the chemotherapy drugs, et cetera.

But during the August recess I held a roundtable at Michigan Medicine, as well as met with a number of doctors to discuss these ongoing shortages. And what was particularly distressing to me was hearing that while FDA is saying we have got a drug shortage of 100-some, for that hospital themselves they have got a drug shortage of more than 500 drugs, and simple things like lidocaine and steroids.

And people say, "Well, can't you do something else?'' But in a baby that is in intensive care, a drop is what is needed. And if the larger is available, that larger amount or that larger _ will kill them. People are dying because of

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this.

My Michigan colleague, Elissa Slotkin, is leading H.R. 3793, the Ensuring Access to Lifesaving Drugs Act of 2023, which I believe would be a meaningful step forward. The legislation would empower the FDA to require drug manufacturers to extend shelf life dates of drugs in shortage based on sound data to ensure we are not unnecessarily discarding valuable products.

Dr. Barber, can you share how extending the longest supported expiration date could help address future shortages?

*Dr. Barber. I am sorry, I just had a bit of a hard time hearing you at the end. The question is extending the expiration date may help address shortages?

*Mrs. Dingell. Yes, can you share how extending the longest supported expiration date could help address future shortages?

*Dr. Barber. Thank you very much.

So the shelf life extension program does exist. This legislation expands it. It was established in 1986, and funded by the U.S. Department of Defense and carried out by

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the FDA, and it regularly conducts shelf life extension studies on medicines deemed to be of military importance. And these sorts of programs have demonstrated their value in terms of ensuring that _ in defense _ access to quality medicines are expanded.

It would be _ one example _ sorry, I am going off notes here. One example where this has been really obvious is on insulin, right? So in terms of shelf life and awareness, manufacturers are not incentivized to tell users what the maximum kind of safe use of a period is.

And the only reason that we know that insulin is heat stable for longer than kind of we previously realized is because a hurricane happened. And in the aftermath, the drug company said, "Okay, actually, here is our internal data. It is safer to use over a longer period of time than we said, okay?'' And then that was further expanded upon by a non-profit organization, Doctors Without Borders.

And so that strange little turn of history has benefited many people with diabetes in knowing that they can use their drugs safely. And so these measures can be expanded across a huge range of drugs so we have less wastage and more access.

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Thank you.

*Mrs. Dingell. So thank you. But unlike the approach in H.R. 3793 of empowering the FDA to work directly with drug manufacturers to extend shelf life, the Republican discussion draft includes a one-month extension of exclusivity for a drug if a shelf life extension study is conducted.

Dr. Barber, is granting an additional month of exclusivity for a shelf life extension study a productive way to mitigate the effects of a drug shortage?

*Dr. Barber. Absolutely not. So the added cost to CMS would be significant if we extended exclusivities by a month. An analysis of additional revenues generated for each medicine _ for something analogous, the pediatric exclusivity, which is six months, found that the net benefit to manufacturers was $134 million per therapeutic receiving this exclusivity.

So scaling this estimate down to one month would suggest average additional cost to Americans of over $21 million paid in profits for each medicine receiving one month of additional exclusivity.

So it has been reported that the cost of these studies

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is only about $350,000, right? So that is maximum. This is just not good value for money. It is not addressing shortages. And those resources could be better used to target the key drivers of shortages in the first place. Thank you.

*Mrs. Dingell. Thank you. I am going to have some questions about compounding I am going to submit for the record.

But since I have only got a minute left, I am going to go to Mr. Davis and ask you, what do your members do when there is a shortage and they don't have enough inventory on hand to fill their customers' orders?

How do they decide how much each customer gets?

How do distributors use fair share allocation to mitigate and manage drug shortages?

*Mr. Davis. Thank you for the question, Congresswoman. They do use, as you alluded to, fair share allocation, with the goal being to make sure that every one of their customers gets some percentage of what their order would have been otherwise.

That is informed by a number of things. Obviously,

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real-time communication between the provider community and the distributor. It is also based upon historical ordering patterns, as well as forecasting as to when the shortage might come off _ or I should say the shortage will become offline so that there is ample supply moving forward.

*Mrs. Dingell. But people aren't getting medicine that they need. Is that not correct?

*Mr. Davis. In a fair share allocation you are correct that each provider is not getting the full allotment of what they requested. But instead of making sure that some get all and some get none, they are allocating as best they can with the supply that they have.

*Mrs. Dingell. Mr. Chairman, I am out of time so I am going to submit questions for the record.

[The information follows:]

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

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*Mrs. Dingell. But I am going to reinforce we have got an obligation to address and find solutions to this crisis because it is real.

*Mr. Guthrie. [Presiding] Thank you _

*Mrs. Dingell. And people are dying. Thank you, Mr. Chair.

*Mr. Guthrie. Thank you. The gentlelady yields back. The chair now recognizes Mr. Griffith from Virginia for five minutes.

*Mr. Griffith. Thank you, Mr. Chairman. I appreciate it greatly.

I am pleased to see my bipartisan bill, H.R. 167, the Patient Access to Urgent-Use Pharmacy Compounding Act, is included on today's list. This bill is intended to create a safe and efficient pathway for patient access to compounded medications when there is an urgent need, or when there is a drug shortage. This bill has support from many members of this committee, especially my friend, Representative Harshbarger, who is herself a compounding pharmacist.

The bill uses 2020 successful temporary FDA guidance as a template to allow pharmacies and other approved entities to

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compound medications to respond to urgent use and drug shortages. During this temporary guidance there were zero adverse events reported from compounded drugs coming from 503A pharmacies.

This bill would create a permanent path for 503A pharmacies to provide urgent use and shortage drugs to hospitals and physicians. It also expands the list of eligible drugs to be included to not just the FDA's shortage list, but also the American Society of Health System Pharmacists' shortage list, which is more local or regional.

Now, I think this is important: expanding the shortage definition to include the FDA's list of drug shortages and shortages identified by the ASHSP [sic] will help capture a wider breadth of drugs facing a shortage. This list is much more up-to-date and nimble than the FDA shortage list.

The bill is not only important, but also timely due to the tornado in July that damaged a Pfizer plant in North Carolina. The damages to that plant have caused some of their drugs to go on the shortage list, and this bill would help mitigate some of those shortages. I hope to see the bill move through the committee and step in the right

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direction.

Now let me address questions that people have not yet verbalized, but I know are floating out there.

How do we protect against another New England Compounding Company problem? As you all will recall, New England Compounding Company, frankly, was a criminal actor, producing medications, sterile injectables or so-called sterile injectables, and they created in the process of being lax their own form of fungal meningitis, and it killed dozens of people, some in my district. And as a part of that, and as a result of that, this committee did oversight work and found out that both Massachusetts and the FDA had not done their job. We had a criminal actor who was not getting proper oversight by state or Federal. We changed the laws. We brought more scrutiny on the compounding pharmacies. DQSA came into being.

We can never completely protect society from a criminal actor. That is why we need our agencies to be prepared to step in. NECC was particularly problematic because the FDA _ and Massachusetts came in and said, "Yes, we messed up'' _ FDA continued to think they didn't do anything wrong, and it

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troubled me at the time. But they did. Both the State of Ohio and the State of Colorado had warned them that there was a problem at NECC. They took no action. They wanted a nice, neat case if they were going to bring any action, all presented to them nicely in a box with a bow on it. That is not the way it works. I practiced criminal defense work. That is not the way it works. You got to go in. Sometimes you have to take the chance.

And I said at the time _ and this is what our agencies need to do, and I think each of our witnesses would agree _ if you see somebody who is creating a problem, and you get warnings from the State of Ohio and the State of Colorado _ Colorado even banned them _ you probably ought to take action, even if you end up not getting a conviction but you save lives.

And I gave the example of the officer on the street who sees somebody who swerves a little bit in the road. May not be a DUI, might be. But that person is headed to a crowded intersection. In the case of NECC, the FDA did not stop that actor who looked like they were doing something wrong. What the officer is supposed to do, like that _ with that drunk _

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potential drunk driver, stop them before they get to the point where they will cause deaths. Go in and investigate. If you find out that the person, you know, was just fiddling around or not paying attention, then maybe you move on. But if you find there is a serious problem, you stop it before it happens.

I believe that this bill, 167, will help us with drug shortages. I believe that we have taken substantial steps with our prior passing of the DQSA to prevent another NECC. But for those who want the world to be perfect, I cannot promise you that we won't have a criminal actor. I cannot promise you that the state agencies who are charged with overseeing medications brought into their states will do their job. And I cannot promise you that the FDA once again will not act negligently in not responding to state concerns. But it is a good bill, and I hope that we will pass it.

I yield back.

*Mr. Guthrie. The gentleman yields back. The chair recognizes Ms. Kuster from New Hampshire for five minutes.

*Ms. Kuster. Great, thank you, Chairman Guthrie. And thank you. I am glad that this committee is dedicating time

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to ensuring that patients can access the medications they need.

I will say I am disappointed that we did not include important policies to respond to drug shortages in the context of pandemic preparedness. But I hope this committee will get to that on another day.

I want to thank our witnesses for your testimony. As you have all explained, drug shortages are driven by multiple factors, and require a sophisticated, thoughtful response.

I am concerned, however, with some of the proposals before us, particularly the notion that 340B is a program that has any relationship with drug shortages. It does not. The 340B program allows patients to help pay for the lifesaving care and treatment they need. It does not skyrocket drug use or prescriptions. To claim otherwise is a disservice to the very real factors contributing to the drug shortages, and lets manufacturers off the hook for raising prices. We can and must pursue a better approach. Instead of blaming patients for accessing the drugs that they need, we should address manufacturing problems, supply chain bottlenecks, and the mismatch between supply and demand.

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Today I want to focus on how generic and biosimilar drugs can balance supply and demand. Generics are a low-cost alternative for patients making up around 90 percent of prescriptions in the U.S. However, they also make up two-thirds of drug shortages at any given time. That is why I was proud to introduce bipartisan legislation with Congressman Dunn to increase transparency between the FDA and manufacturers to help bring generics to market faster.

Today I am also introducing bipartisan legislation with Representatives Miller-Meeks, Matsui, and Dunn entitled the Ensuring Access to Lower Cost Medicine for Seniors Act, which would ensure that generics and biosimilars on Medicare Part D formulary are available to seniors.

Dr. Gaugh, can you describe how these two proposals could help address generic drug shortages?

*Mr. Gaugh. Thank you for the question and, yes, you are trying to expand the access, if you will, for that. And so that is another customer base, if you want to look at it that way, from a manufacturing standpoint.

The problem is still in the contracting processes between the manufacturer and the patient. And so there is

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that stream in between that still needs to be addressed.

*Ms. Kuster. Thank you. Are there additional policies that this committee should consider to specifically support lower-cost generic and biosimilar drugs, in your view?

*Mr. Gaugh. So in my testimony I talked about the sustainability of our industry, and I am going to go back to what I just said. It is really about the in-between, if you will, so between the manufacturer and the patient. If I am a manufacturer selling a product, the $.88 price that was talked about earlier, but as a pharmacist and as a patient that I go to my pharmacy counter and know that I have to pay a co-pay of $10 for that, there is more behind that in the insurance than the $0.88 that my manufacturer got for selling that product. That needs to be researched further.

*Ms. Kuster. And with the minute-and-a-half that I have left, is there anyone else that has any comment on how we can lower the cost of specifically lower-cost generics and biosimilars?

Anyone want to comment? No?

Yes, go ahead.

*Dr. Barber. Thank you very much. That is a very

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important point.

When drugs come off patent, they generally decline in cost by, you know, between 99 and 95 percent. And then we reach an equilibrium. And the concerns in this committee are is that equilibrium too low to support cost of manufacture?

So the two things I would say is, one, we are tossing around a lot of numbers. Like, is $0.88, okay? Is $1.50 okay? Like, we should know what the cost of manufacture of a medicine is so we can then build in appropriate margins to ensure quality. That is the first thing I would say.

The second thing I would say in terms of ensuring access to generics, I think that there have been many actions recently in terms of acting on competition policy to ensure that we don't have collusion among generic suppliers. There have been some cases brought forward by ADGs. And so I think that is _ competition regulation and vigilance is an important element of a healthy generics policy. Thank you.

*Ms. Kuster. Great, thank you.

Would you like to comment?

*Mr. Davis. Just briefly, Congresswoman, thank you for your leadership on this issue.

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I would just say, again, in the modern framework of the balance between the innovative ecosystem where the U.S. leads and, actually, the lowest cost generics, where the U.S. also leads, if we don't have a system where once that follow-on competition comes to market it is less expensive for the patient, then you can legitimately ask the question, "Why is there follow-on competition to begin with?''

So we are very supportive of making sure that, as generics come to market, as biosimilars come to market, they are put in preferred positions on formularies to ensure that level of lower-cost access.

*Ms. Kuster. Great, thank you.

My time is up, and I yield back.

*Mr. Guthrie. Thank you. The gentlelady yields back. The chair recognizes Mr. Bilirakis for five minutes.

*Mr. Bilirakis. Thank you, Mr. Chairman. I appreciate it. Thank you for the panel's testimony today.

Mr. Coukell, I have concerns about the shelf life extension legislation noticed for today. It seems to allow FDA at any time for any reason to require manufacturers to conduct studies to lengthen the shelf life of a product and

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turn those studies over to the FDA, or else face a _ civil or criminal penalties.

My understanding is manufacturers already currently collaborate with FDA to discuss expiration data. And in last year's end-of-year package, Congress required FDA to issue guidance on how to conduct shelf life extension studies that are scientifically supported. But we have yet to see a draft from this Administration.

Could you comment on how stability data is currently generated, and whether extending it would reduce drug shortages?

In your view, would requiring these studies help mitigate shortages?

What are the current incentives around shelf life, as well, please?

*Mr. Coukell. Thank you for that question, Congressman.

A sterile injectable drug typically comes to market with a shelf life of two to three years. Much beyond that and you start to get concerned that you are going to get breakdown and impurities. So generally, going beyond that is not desirable.

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Manufacturers do that study when they _ prior to first making the FDA submission, and then they continue to conduct stability studies on an ongoing basis as they go forward. The _ if the market is working well, and a drug is coming to market with a two or three-year shelf life, then that drug is not expiring on the shelf. And indeed, expired drugs is not really a driver of the drug shortage problem we are discussing today.

So if the government is looking to have dating, you know, beyond three years on a product, probably what they should do is do what was referenced in the DoD program earlier, which is buy the drug, do their own studies, and they could own that risk. But otherwise, the shelf life system works pretty well right now.

*Mr. Bilirakis. Thank you very much. The next question, again, for Mr. Caukell. Can you provide some specific examples of products you worry could go into shortage, based on their price, and why, please?

*Mr. Coukell. So we have had reference today _ thank you, sir, for that question _ to drugs selling for $0.88 a vial. You know, there is a drug called Lorazepam. It is

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used as a sedative in surgery. It is used to interrupt epileptic seizures. It sells for less than $1 a vial. It has been in shortage, been on the shortage list for 15 years. And, you know, you _ pretty hard to buy an empty vial and fill it with sterile water for under a dollar. So I think that illustrates the sort of instability in the market when you are making a complex product that is priced at that level.

There are other drugs. There is a drug used for nausea in cancer that is selling for well under a dollar. It is not in shortage now, but, you know, at a price like that, it will be someday, probably. And so, you know, it is relatively easy in one sense to predict shortages. The best predictor of a drug shortage in the future is whether that drug has been in shortage in the past.

And so we can look at the portfolio of essential drugs, which ones are low cost, which ones have been in shortage in the past, and really create a pretty strong priority list for where we need to invest to ensure resiliency.

*Mr. Bilirakis. Thank you for that answer. I appreciate it. I have got a couple _ one more minute.

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Mr. Gaugh, how has the generic drug market changed over the last five years?

Could you speak specifically to the number of genetic _ excuse me, generic drugs getting approved and then marketed, as well as any recent bankruptcy announcements by generic drug companies, and if you believe drug shortages are improving or getting worse over the next year or so?

Please, Mr. Gaugh.

*Mr. Gaugh. Yes. Thank you for the question.

To kind of address all of that at once, it is getting worse, and it is going to get a lot worse, in our opinion.

So to your point about foreclosures, we know a company that closed in March, chapter 7, closed their doors, had to recall 75 products from that. Six of those were sole source products.

At the same time, if you look at the number of manufacturers, somewhere between 250 and 350 _ I mentioned 200 in my talking points because that is what we are able to validate, but per FDA it looks more like 350 companies. Of those, as I have said earlier, in the approval process 60 percent of those approved by the FDA never make it to market

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because there is no market to go to. So they typically, as we would say, dump their product and move on to another product, which can lead to shortage.

*Mr. Bilirakis. Thank you very much. Yes, thanks for the direct answers.

*Mr. Guthrie. Thanks.

*Mr. Bilirakis. Very knowledgeable. Thank you very much.

And I yield back the balance _

*Mr. Guthrie. Thank you. The gentleman's time has expired. The chair recognizes Ms. Kelly for five minutes.

*Ms. Kelly. Thank you. Chair Guthrie and Ranking Member Eshoo for holding today's critically important hearing.

Health systems, providers, and patients have all felt the strain of the most recent wave of drug shortages. Providers and hospitals, while still recovering from the effects of the COVID-19 pandemic, have seen several financial burdens and staff strain as workarounds are attempted to fulfill the patient need.

Furthermore, many patients have received inferior

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treatment regimens, or even delayed treatment altogether, which has impacts on both mortality and morbidity. Numerous explanations for the shortages have been proposed and identified. Despite this, the lack of transparency about drug supplies from drug manufacturers persists as a critical factor.

Dr. Barber, a lot of the focus today has been on the generic, sterile, injectable drugs. Is there any reason why we should limit demand notifications to only generic, sterile injectables, or should this requirement apply to all drugs?

*Dr. Barber. Thank you very much for this question. Yes, there is no reason to limit.

We talk about generic, sterile injectable drugs because they are the drugs that are more likely to be in shortage than other drugs. But other drugs are also likely being shortage.

If I may, I would like to very briefly counter a misconception that has come up a lot in this hearing about API transparency. On the one side, some people have said we don't have access _ the FDA doesn't have access to API data. And on the other, folks have said, okay, API is reported.

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Both of these are true. The issue is companies are obligated to report the source of their API, but we don't necessarily know if that is the original source.

So for example, I may be manufacturing a finished generic, sterile injectable drug, and I am buying my API from a company that then buys it from another company, right? And so you may have a situation where four companies are manufacturing the finished product, and they are all buying API from the same two companies that are all, in fact, buying the same API from the same single factory.

So if you looked at the mapping from the FDA's data, you would say maybe there is four companies, maybe there is some redundancy, but we don't actually know that. And for drugs that have gone into shortage where we have done deep dives, we have found that there is, in fact, often times only this one single source. So I just wanted to clarify that because that has come up quite a bit. Thank you.

*Ms. Kelly. Thank you.

And is it Mr. Ganio or Ganio?

*Dr. Ganio. It's Ganio.

*Ms. Kelly. Ganio?

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*Dr. Ganio. Yes, thank you.

*Ms. Kelly. Thank you. Some of the testimony we have heard today suggests that the FDA is getting incomplete data on drug shortages. Under current law there is no requirement for reporting shortages caused by spikes in demand. One of the bills before us today, H.R. 3008, the Preventing Drug Shortages Act, would change that.

How can earlier notification help FDA address drug shortages?

*Dr. Ganio. Thank you. That is a great question.

And right now the FDA is receiving reports of supply interruptions. But as we saw over the past winter, there was an increase in demand for amoxicillin and other antibiotics. That increase in demand would give the FDA drug shortage team more time to do their work, be an earlier signal.

The other way that would be beneficial is if another manufacturer is having supply issues and does not report to FDA, and other manufacturers begin seeing an increase in demand. It would give the FDA a little bit more notice that something is out of balance, and maybe there is a supply issue somewhere.

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*Ms. Kelly. And additionally, the 340B program plays a pivotal role to meet the health and social needs of marginalized populations, as well as the broader community, many of which would not otherwise be financially sustainable. I have facilities in my district of Illinois that rely on this program to provide quality health care to those that are in their service area.

Some have claimed that the 340B program contributes to shortages. Did you see any evidence of this in your tracking of drug shortages?

*Dr. Ganio. We are unable to find any link directly between the 340B program and drug shortages.

I can tell you that generic, sterile injectables are about 7 percent of overall purchase volume of 340B, and if you are looking specifically at drugs that are in short supply, those drugs make up less than 1 percent of 340B price savings.

Where my co-panelist, Mr. Coukell, earlier said that that one percent would go unnoticed, I disagree that our hospitals and health systems that are providing care for underserved patients would notice that.

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*Ms. Kelly. Thank you so much. Thank for your response.

I yield back.

*Mr. Guthrie. The gentlelady yields back. The chair now recognizes Dr. Joyce for five minutes for questions.

*Mr. Joyce. Thank you for yielding, Chairman Guthrie, and to our panel for appearing here today on such an important topic.

Over the August break I heard from health care providers in my district as large as UPMC and as small as individual practices about the acute shortages of both carboplatin and cisplatinum [sic]. We all recognize this as a serious issue with the potential to cause delays in care for patients which are ultimately detrimental to the outcomes, specifically when it comes to treating cancer. It is important today in this hearing that we are working on both short-term and long-term solutions to these issues, as I fear they will not be going away any time soon.

I would like to thank my colleagues, Representative Griffith, Carter, and Harshbarger for their work on the use of pharmacy compounding to help solve some of these issues in

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the near term. These shortages are not a new phenomenon, and have [sic] caused by decades of poor policy decisions that have hollowed out the generic manufacturing capacity.

One of these occurred in 2015, when the Bipartisan Budget Act applied a brand drug rebate inflation penalty to generic drugs, despite significant market differences. While the penalty was originally established to control price increases for branded medications when the market had exclusivity, it was improperly also applied to generics.

Dr. Gaugh, since the Medicaid generics penalty was passed in 2015, what impact have you seen in the generic market that has caused manufacturers to stop making certain generic drugs due to this policy?

*Mr. Gaugh. So we have seen quite a reduction in company continuing to produce products in their portfolio. So, as you have seen in the press of late, we talked about one company going bankrupt. Several other companies have talked about reducing their portfolio of products so that they can "right size their business,'' and that is what you are seeing happen because of that.

*Mr. Joyce. So because of legislation, per your words,

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companies have decreased their portfolios and, unfortunately, some others have ultimately become bankrupt.

*Mr. Gaugh. Correct. Other factors included, but yes, that is part of it.

*Mr. Joyce. Thank you. We have also heard some companies _ that over 90 percent of the drugs they are paying the penalty on did not receive a price increase, and they are even paying the penalty on drugs when the price was lowered. Can you walk us through how that would occur?

*Mr. Gaugh. It is a difficult thing to walk through in the 2 minutes and 13 seconds I have left. But yes, that can happen where you didn't increase your price, but the overall price of that particular product category came down, and yours appeared to go up, if that makes sense.

*Mr. Joyce. It doesn't make financial sense.

*Mr. Gaugh. Right.

*Mr. Joyce. And it certainly doesn't allow companies to continue to profit, or even maintain keeping the lights on.

Finally, Dr. Gaugh, can you please explain how the inflationary rebates included in the Inflation Reduction Act could further erode sterile injectable manufacturers' ability

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to invest in manufacturing improvements, or even simply in keeping the facilities up?

*Mr. Gaugh. Thank you for the question, yes. So those rebates are just added expenses, if you will, to a manufacturing company.

So with everything else that you are doing, the API, the finished dose production process, keeping the lights on, if you will, and then when you go to get your contract and the additional inflation reduction is another penalty added into that.

*Mr. Joyce. Do you feel that the Inflation Reduction Act harmed the ability for manufacturers to continue supplying the needed generic drugs?

*Mr. Gaugh. It can in the future because we are not quite there yet, as it is just being implemented. But yes.

*Mr. Joyce. I thank all of our witnesses for testifying here today.

And Mr. Chairman, I yield.

*Mr. Guthrie. Thank you. The gentleman yields back. The chair now recognizes Mr. Sarbanes for five minutes for questions.

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*Mr. Sarbanes. Thank you very much, Mr. Chairman. Thank you all.

Before this life I was a health care attorney and I represented, at different times, prescription drug manufacturers, generic drug manufacturers, pharmacy benefit managers, hospitals, physician groups, pharmacies. As a result of that, I gave up a long time ago thinking I would ever be able to understand drug pricing. And that situation gets worse by the day.

A number of you have commented on the lack of transparency, the need to get more data at our collective fingertips. But certainly, I think the agencies that are in this space need to have that data in order for us to get better results on a whole variety of things, including managing drug shortages.

Dr. Barber, who benefits from lack of transparency right now the most in this vast chain that is being described here today would you venture to say?

*Dr. Barber. Thank you for that interesting question.

I don't really want to ascribe intentions when we are talking about markets and how, you know, incentives are set.

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But if you, you know, look at it objectively, when government has to negotiate for drug prices, when patients have to access drugs and they can't afford them, and one party is blindfolded, they don't know how much drugs cost to manufacture, they don't know how much margins would be necessary in the supply chain to ensure quality manufacture, they don't know what profit margin is fair in terms of incentivizing market entry but not resulting in wastage or expenditure, one side knows those numbers, the other side doesn't.

So I would say that it benefits industry, the lack of transparency benefits industry.

*Mr. Sarbanes. Yes. Well, I think that the fact that we still have so _ that it is still so opaque, there is still so many black boxes in the system, even though the interest in this area is as high and as intense as it is, is evidence on its face that somebody is trying to hide the ball, which makes it difficult for government acting on behalf of the public and our constituencies to get the right solutions here.

You talked about the fact that raising prices alone

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certainly isn't going to solve the manufacturing shortage on the generic side, and without other strategies isn't going to solve the problem of quality and reliability. Can you talk about that a little bit more, and what _ how you would structure, let's call it investment, not just pricing, but investment to ensure that the dollars flow towards quality and reliability, and that the system can't be further gamed at that stage so that you still have manufacturers contributing to these shortages because of the quality and reliability deficit?

*Dr. Barber. Thank you very much. That is a very important point.

So prices, when we talk about the prices are too low, manufacturers can't compete, you raise a very important point that there is importance that we get value for money. We need to know what the price is going for, rather than just wholesale allowing, you know, higher prices and not necessarily getting that accountability.

So the things that I have proposed in my written testimony _ I am happy to follow up later _ are ideas.

I would recommend pilots. So, for example, with

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appropriate data FDA and CMS could rate generic manufacturers by the resilience of the supply chain, and then that rating could be incorporated by payers to adjust reimbursement for generic drugs appropriately, in a similar way as value-based modifiers adjust payments to providers based on the quality of medical services provided.

Another option is we could have CMS require manufacturers to provide data around supply chain quality and resiliency, and then adjust reimbursement through the CMMI. And the CMMI should be given flexibility to pilot varied approaches without restriction from Congress, and provide public evaluations of such approaches towards informing more long-term implementation to effectively address drug shortages.

*Mr. Sarbanes. Thank you.

Mr. Coukell, in two seconds, should there be more companies like yours?

*Mr. Coukell. We are not trying to replace the traditional industry, but I think there is a role for our model to help solve problems.

*Mr. Sarbanes. Thank you, and I yield back.

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*Mr. Guthrie. Thank you. The gentleman yields back. The chair recognizes Mr. Carter for five minutes for questions.

*Mr. Carter. Thank you, Mr. Chairman. This is an extremely important hearing.

Mr. Davis, I would certainly be remiss if I did not thank you for the opportunity to speak to your group earlier this week. Thank you for that, and thank you for being in our district. I appreciate that.

Folks, we all know what is going on: 240 drugs right now in shortage, 240, anything from cancer drugs to Tylenol. This is something that has got to be addressed.

I don't think it is any coincidence. It has been mentioned numerous times during this hearing, the coincidence that we have a sharp rise in consolidation in our health care industry with a shortage of essential medications. I think that that is more than just coincidence. In fact, I think it is one of the reasons why.

As you know _ and all of you know this _ 80 percent of the market right now is controlled by 3 PBMs, 3 pharmacy benefit managers control 80 percent of the market. And that

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is _ that, to me, is a big problem, and we need more competition in that area.

We have also seen an increase in hospital consolidation. We have had over 1,800 hospitals merge in _ since 1998 and _ between 1998 and 2021. As a result of that, we have got 2,000 fewer hospitals than we had at that time. So consolidation is a concern.

And when we look at the GPOs and the distributors, we see just 3 companies controlling almost 90 percent of the market.

Mr. Ebert, I will start with you. In markets like this, this consolidation has posed significant problems, especially when, according to some reports _ and you have seen them, just like I have _ that for every $100 spent on a generic drug, $44 goes to a middleman, goes to a PBM. Can you comment on the consolidation within your respective industry, and what impact it has had?

*Mr. Ebert. Thank you for the question. There has been consolidation in the industry. However, if you take a look at the definitive health care database that is out there, it does identify that there is a number of opportunities for

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pharmaceutical manufacturers to participate.

That database identifies over 150 entities in that _ in the GPO, if you will, market space, national GPOs as well as other regional cooperatives that participate in that arena. And those include a number of organizations that work with GPOs, but they do their own contracting. It is quite flexible for them to contract on their own, and at the same time there are opportunities within the GPO contracts for them to buy on their own.

I do believe, and I still believe _

*Mr. Carter. There may be opportunities, but I am not sure it is that easy to do.

*Mr. Ebert. Well, there are opportunities, and they are relatively _ you have to work at it. There is no doubt about it. But at the same time, there are other organizations such as the Department of Defense, large hospital systems that contract. There are other organizations such as pharmaceutical distributor source lines _

*Mr. Carter. Right.

*Mr. Ebert. _ and programs.

*Mr. Carter. Right.

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*Mr. Ebert. There are oncology GPOs. There is a number of opportunities to do so _

*Mr. Carter. Okay.

*Mr. Ebert. _ that they should be able to access.

*Mr. Carter. Okay. Mr. Davis, I am going to ask you the same thing in your industry and the distributors. What kind of impact has consolidation had on the availability of essential medicines?

*Mr. Davis. Yes, thank you for the question, Congressman.

So we are an industry that has experienced consolidation. But I would actually say in the last 15 years I am only aware of sort of one significant level of consolidation within our membership. We do, as you know, have 3 very large, national-scale members and then 32 what we would refer to as generally regional distributors.

I would like to just address one thing specifically. We have heard in both the policy debate and the business debate, there are some that said if you don't get a contract with one of the three largest distributors, it really compromises you. I can assure you on behalf of the 32 other members, many of

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whom either predominantly or exclusively focus on generic drug distribution, that there is a distributor market that is waiting for you. And if any generic manufacturer needs contact information, they can call me and I will put them in touch with the rest of them.

*Mr. Carter. Okay, thank you.

Dr. Gaugh, let me ask you. What about consolidation among purchasers of generic drugs? Has that led to any unsustainable low prices for manufacturers, which in turn leads for drug shortages?

*Mr. Gaugh. So from our viewpoint _ thanks for the question _ from our viewpoint, yes, absolutely. So as I mentioned earlier, 60 percent of the ANDAs approved by the FDA don't make it to the market _

*Mr. Carter. Right.

*Mr. Gaugh. _ because there isn't an outlet to go to.

*Mr. Carter. Right. I hope all of you saw the article that was in the Wall Street Journal earlier this week about generic drugs should be cheap, but insurers are charging thousands of dollars for them. It talks about Gleevec, which I dispensed a bunch of when I was a practicing pharmacy,

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about the price of it being almost $6,600, yet now you can buy it as cheap as $55. But still, the PBMs are charging $6,600. They are gangsters. This is robbery.

Thank you, Mr. Chairman. I will yield back.

*Mr. Guthrie. Thank you. The gentleman yields back. The chair recognizes Dr. Schrier for five minutes for questions.

*Ms. Schrier. Thank you, Mr. Chairman. Thank you to the witnesses. I have really enjoyed listening and learning from this conversation today.

Just for context, that "Dr.'' was a reference to the fact that I am a pediatrician. So I have gotten notifications about drug shortages for years. But I will tell you, this year is the first where I have been getting stopped at the supermarket, on the street, at the gym, with people telling me that they can't get their chemotherapy drugs, that it is _ you know, they are getting 80 percent of the dose, parents are telling me they can't get their child's ADHD medication. And that is pretty disastrous, both academically and if you have a young driver. So these are important medications.

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The Fred Hutchinson Cancer Center is in the greater Seattle area. They are having to delay stem cell transplants because they can't get some of the agents cheap. I mean, these are not expensive drugs, but they are a necessary precursor to a transplant.

And we have heard today from all of you about, really, the nuance and complexity of drug shortages and what is at the root of them. I think, though, that we can all agree in this room that it is really never going to pencil out economically for an American company to invest millions in manufacturing medicines like amoxicillin, Lidocaine, methylphenidate, saline, sterile water, and yet they are indispensable and used every single day in doctors' offices and hospitals.

I thought I might just float an idea. This is inspired by Operation Warp Speed, which I thought was a beautiful collaboration between the Federal Government and industry, it de-risked the procedure. It said if you are successful, we will contract to buy a certain amount of this medication. And I just wonder if there is a role in manufacturing medications.

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And what I am imagining _ and I am going to have some of you comment on this _ is could the Federal Government stand up a sort of generic manufacturing facility? It is open to any manufacturer who is willing to make whatever drug is in shortage at that time. The University of Washington has something like this for scientific innovations. The very expensive machinery is here. You can come and rent it, and reserve it, and do your research, and take it back to your private company.

And I am just thinking that this might be a way _ I mean, this is kind of like Civica, but Civica is funded by philanthropists, which makes me, like, on the broader scale, a little nervous to depend on charitable contributions. And I think the Federal Government could have a role here. We stand up the facilities, incentivize in some way the manufacture of these medications, and companies can turn a profit without having to make major investments.

And so I would love to hear this. I am just going to, for fun, start with Mr. Coukell, because you have had some experience here, go to Dr. Barber if possible, Mr. Gaugh, and Mr. Ganio for your comments. So pace yourselves. Two

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minutes left.

*Mr. Coukell. Thank you for that question, and just one point of clarification, that the capital to start Civica came from philanthropies and hospitals. The organization is self-sustaining. So I want to clarify that about the model.

But to your point, where could the capital come from to start an enterprise like that? And I think government can absolutely be a part of the solution.

In particular, we could look at categories of drugs that we don't make in the United States anymore. We could look at penicillin and cephalosporin antibiotics, for example, many of which are on shortage. At today's prices there is no commercial enterprise that could invest the capital to create a new manufacturing facility for those drugs in the U.S. So if we want them here for supply chain security or national security, it is going to take some kind of partnership.

*Ms. Schrier. And if we want to use low-level antibiotics to avoid antibiotic resistance, we have got to have amoxicillin and low-level cephalosporins.

Okay. Next, Dr. Barber.

*Dr. Barber. Thanks so much for this great question.

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The United States has manufacturing capacity, and we have immense resources and great researchers. There is 400 process scientists on staff at NIAID that could and that are working to improve manufacturing processes to make them more efficient. The U.S. has capacity to manufacture drugs which they use for the clinical trials. The capacity is there.

I think your question is important: How can we expand it? And I do support a robust public option, and it has a long history in the United States. A state-owned company, for example, from Congresswoman Dingell's great state of Michigan, manufactured anthrax and rabies vaccines for decades.

I believe there are no members from New York on this subcommittee, but the New York State Public Health Department manufactured diphtheria antitoxin.

The State of California, represented by Congresswomen Eshoo and Barragan and Congressmen Ruiz and Cardenas, is exploring public manufacture of insulin.

It is not a future dream that we can have public manufacturing. Public manufacturing has existed. It has worked, and it should be expanded. Thank you.

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*Ms. Schrier. Thank you. I have to yield back because of time, but I would love answers in writing.

[The information follows:]

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*Ms. Schrier. Thank you.

*Mr. Guthrie. Thank you. The _ Dr. Schrier yields back. The chair now recognizes Mrs. Harshbarger for five minutes for questions.

*Mrs. Harshbarger. Thank you, Mr. Chairman, and it is a pleasure to see four pharmacists on the panel today. I appreciate that.

By now you know I am a compounding pharmacist, and we have had drug shortages as long as I have I have been in practice, and that is over three decades. And it is critical that Congress work with stakeholders and Federal agencies to find solutions to the problems. That is where I have stepped in many times over my career as a compounder to deliver those drugs when we had shortages, whether it was to facilities or to physicians, patients, whatever.

Now, there has been a lot of talk about the sourcing of APIs. The FDA is requesting from Congress new authorities to mandate that drug manufacturers and repackagers of APIs include information regarding the original manufacturer, the unique facility identifier on APIs, on finished drug products, and on the label of bulk drug substances.

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But it is also my understanding that the FDA already has access to this information as a result of various regulations and reporting requirements. And I recently sent a letter to FDA Commissioner Caleb posing a number of questions to better understand the FDA's legislative proposals so that we can work together on a potential workable solution.

And, Mr. Chairman, I ask unanimous consent to submit into the record a copy of this letter.

*Mr. Guthrie. I see no objection.

[The information follows:]

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*Mrs. Harshbarger. Okay, thanks.

And I think it is particularly important, the solutions to drug shortages put forward by Chair Rodgers's discussion draft, and especially Rep. Griffith's H.R. 167, which is the Patient Access to Urgent-Use Pharmacy Compounding Act.

And you know, many people don't know what compounders do. And per the FDA we have been divided into two different facilities, 503As for traditional compounders, 503Bs that are outsourcing facilities. And some two percent of prescriptions filled each year are compounding medications, and these are customized medications that meet a patient's specific need, and it is written by a prescriber. And we use all different modalities to fill that gap in health care.

The 503A compounding pharmacies, which are traditional, provide individual physician-prescribed drug products designated for a patient, and they are primarily regulated by state boards.

Now, 503B drug products are produced in outsourcing facilities, or CGMP facilities, and they are produced by bulk APIs, and are readily available for ambulatory care centers, hospitals, other health care systems. And they are regulated

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by the FDA. Our main discussion drafts today include flexibilities for 503B outsourcing facilities to help fill that gap, and also Rep. Griffith's bill will add flexibilities with guardrails for 503A facilities to provide urgent use of drug shortages to these patients.

You know, and you tell me if you agree, because lack of access is a patient safety issue. Do you agree? Just shake your head, yes or no.

Do you also agree that a delay in providing a medication can cause patient harm?

It does. It does. So that is why I support Rep. Griffith's bill and everything we are doing on this committee.

Mr. Coukell, is your facility _ you were talking about your facility in Petersburg. Is that a 503B facility?

*Mr. Coukell. No, ma'am. That is a facility that will approve _ manufacture FDA-approved drugs.

*Mrs. Harshbarger. Okay. So you have to go through the whole process, the IND and all that. Okay. In your view, what should be our national strategies for developing the ability to predict and prevent drug shortages?

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*Mr. Coukell. Thank you for that question. I think that we can look at a variety of data in terms of market consolidation, quality history, and so on. But the strongest predictor of a future shortage is a past shortage. And if we go down the list of essential drugs and look at which ones have been in shortage over the past decade or so, it gives us a pretty strong risk of _ indication of where the risk is, going forward.

*Mrs. Harshbarger. Yes.

*Mr. Coukell. To give you a sense, I said Civica is providing 80 drugs today. Half of them are on the ASHP drug shortage list right now, which tells you it is quite possible to predict the ones that are at risk.

*Mrs. Harshbarger. Well, ASHP has a more complete list of drug shortages than even the FDA does. And you know as well as I do, being a pharmacist, we have seen drugs on and off lists for 10 to 15 years, as somebody said earlier. Now, why is that?

Do you know approximately how many of the drugs currently in shortage and in shortage over the past five years are manufactured or sourced through APIs primarily from

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China and India?

*Mr. Coukell. I do not know that number, Congresswoman. We know, overall, that a substantial share of the world's supply of API comes from those two countries.

*Mrs. Harshbarger. Probably over 90 percent.

And I know my time is up, so I will yield back.

*Mr. Guthrie. The gentlelady yields back. The chair now recognizes Mrs. Trahan from Massachusetts for five minutes for questions.

*Mrs. Trahan. Well, thank you, Chair, and thanks to the ranking member, as well, for holding this timely hearing.

While I am pleased that there are some bipartisan bills to address drug shortages included, I am disappointed in the approach that my colleagues' discussion draft aims to take, and hope they work with Democrats to introduce a package that takes a more sustaining approach to addressing drug shortages.

You know, many of us have heard the pleas from our constituents back home for us to address this issue. As Dr. Schrier mentioned, we have heard from parents whose kids cannot take their Adderall prescriptions filled to help them

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focus. We have heard from constituents whose mothers and fathers cannot access the appropriate chemo drug for them, causing unnecessary side effects.

Drug shortages have disrupted the lives of too many Americans. And instead of passing legislation to help these families, my Republican colleagues included policies in their discussion draft that may end up incentivizing prolonged drug shortages.

It is no question that drug manufacturers are not fans of the 340B program, and there is no clear data that 340B is a driver of drug shortages. However, the provisions in today's discussion draft may incentivize manufacturers to prolong shortages if it means that they don't have to participate in the program. This is not the right approach, and we must take a more rigorous and thoughtful approach immediately.

You know, as a co-founder and co-chair of the Congressional Pandemic Preparedness Caucus, I am particularly interested in what we need to know to prepare for a future pandemic. So, Dr. Ebert, what are some of the main supply chain vulnerabilities that you discovered during the peak of

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the COVID pandemic?

And could you share those lessons learned, particularly as we look to address drug shortages and reauthorize PAHPA?

*Mr. Ebert. Thank you for the question. During the pandemic there was a lot that was identified relative to some of the issues that were out there. And many times it is a function of what information you need, or what information is available, what is available. In fact, the group purchasing organizations work very closely with Federal Government and others relative to where supplies were throughout the country, and to distribute those products throughout the rest of the country, where needed, as the pandemic would shift as we go forward.

So information about where products are is extremely important. Also, information relative to the best treatments and best treatment protocols are important for us, as well. But we have been actively engaged in trying to work with the manufacturers relative to information regarding their products and where they are sourced at, so that we can better predict what is needed as we go forward.

*Mrs. Trahan. Thank you for that. You know, I am going

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to switch gears because a 2019 study by Vizient found that managing drug shortages cost hospitals and health care systems an estimated $359 million per year in labor, not including the impact on patients from delayed and canceled procedures caused by shortages of drugs and essential supplies.

In addition, on average, hospitals in the United States dedicate more than 8.6 million hours of additional labor time annually to manage drug shortages. And these figures are particularly concerning as we think about the workforce shortage that we have seen across the health care sector.

So, Dr. Ebert, in the event of a drug shortage, besides getting hospitals access to the product itself, what are some of the additional needs of hospitals that Congress should consider?

*Mr. Ebert. Well, the biggest issue is a quality and stable supply. That is what they are looking for, and that is what we hear on a routine basis. Hospitals recognize and depend upon GPOs to do the sourcing evaluations relative to quality and quality products that they serve.

The other key thing is open line of communications to

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where products may be and to manufacturers. GPOs are well versed, and have great partnerships with all manufacturers to identify where issues are and how they can potentially help us.

And then GPOs, many GPOs, also have buffer stocks, as we have heard about in the discussion today. So that for critical medications those buffer stocks are available, not just for one particular GPO that can be used for many organizations that may not belong to one GPO, but they are available for others that need that product for use.

*Mrs. Trahan. Thank you.

And Dr. Coukell, you discussed in your testimony the potential for the government to take action to assist domestic manufacturers to ensure that they meet the standards set by the FDA and are prepared to produce essential medications as soon as a shortage begins. Could you just describe the program, and why that would be a good investment for us to make?

*Mr. Coukell. Thank you for that question. Let me start by saying that once a drug shortage starts, it is really hard to stop. And if we are looking for a

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manufacturer to enter the market with a new FDA-approved drug, that has a timeline of several years. And so that is clearly not a quick solution for drug shortages.

But if we had been _ and we talked earlier about drugs that are so low in price that you can't competitively make them right now in the United States. So a manufacturer is unlikely to spend the money to have that drug ready to go if and when it goes into shortage.

But if the government were to fund some targeted ANDA development, so the manufacturer went through the FDA process and had that there in reserve so that when that drug goes into shortage _ and we could predict which drugs will go into shortage with reasonable accuracy _ we would be ready to start production right away. That would be a _ really, what that program would cost is less than what we would pay today to end, you know, just one high-profile drug shortage.

*Mr. Guthrie. Thank you.

*Mrs. Trahan. Thank you. Thank you.

*Mr. Guthrie. Thank you, the gentlelady yields back. The chair recognizes Dr. Dunn for five minutes.

*Mr. Dunn. Thank you very much, Chairman Guthrie.

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Now let me say I am very glad that our subcommittee is addressing the topic of generic shortages today. I appreciate the chair's discussion draft, and look forward to supporting efforts to address generic drug shortages on the supply side.

The Stop Drug Shortages Now Act takes important steps to unleash innovation and correct distorted markets. It seeks to examine how existing FDA authorities address shortages, and will also speed the inspections that the FDA engages in.

There are many players in the generic drug supply chain, and I appreciate all of our witnesses who represent those entities here today. Thank you.

Some of the proposals before us today seek to increase regulation, or give the FDA additional authorities related to reporting requirements and data collection. However, I think we have seen the failure of the FDA firsthand. Just look at the baby formula crisis. I think it is clear that empowering three-letter agencies is not going to solve our problem.

We need to examine policies that fix the supply side and embrace the free market in order to address these root causes. Policies that speed generic drugs' entry to the

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market and support generic manufacturing capacity, that is what we need.

We also need to empower compounders who can nimbly address shortages. And to do that we have to cut their red tape, as well, holding them back from answering the call to shortages when they occur.

And these shortages, by the way, are constant and they are chronic. The same drugs that are short right now were short when I was doing surgery 10 years ago. There is _ and more. And more, let's say. But there is no surprises there.

I am proud to be a cosponsor of Mr. Griffith's bill, H.R. 167, which enables 503A compounding facilities to produce drugs in urgent circumstances without jumping through all the FDA-required hoops. So we need to remove red tape to allow industry to quickly move ahead and not give more red tape to them.

I do have serious concerns with H.R. 3008, which would compel manufacturers to comply with additional FDA reporting requirements regarding disruptions to supply. This bill actually is highly prescriptive, and would bog down manufacturers with gathering and reporting data that may not

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even be useful or indicative of a shortage. For example, this bill requires reporting on increased demand that is sustained for six weeks or more. You know, there are increases and decreases in demand all the time that are caused, you know, by all kinds of reasons other than shortage.

So to that end, I have a few _ well, let's see, I actually wanted to start with Mr. Ebert, if I may.

I used GPO contractors back in the day when I was running my practice. In some cases I was able to negotiate directly with suppliers, but many cases, perhaps most cases, I leaned on your industry, and I did so for good reason. I could practice medicine, and you could get me a cheaper price. Tell me how GPOs have evolved from being just a price and a catalog, and sort of walk me through that value proposition, if you would, please.

*Mr. Ebert. Thank you for the question. GPOs over the years have evolved tremendously. They have invested a tremendous amount of time and expense into enhanced services, and those services could include anywhere from significant data analytics to help customers, providers understand where

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there are opportunities to save money just based upon their operations and procedures, as well. They have spent a lot of time relative to supply chain benchmarking, again, using the data that they do collect.

Also, one of the key things is they are able to work with their membership to share and identify best practices, not only from the standpoint of materials management or supply chain, but also we work very closely with clinicians and certain components of the health care supply chain.

So there is a number of things that we have done. And at the same time, as I have said before, we have great contacts and great opportunities to work with manufacturers so that we can understand what is going on in the industry relative to the shortages. We may not be able to solve them, but at least try to understand and help them to reduce shortages as much as we possibly can.

*Mr. Dunn. I think _ and I would note, without going too much into it, that I think the GPOs also have transparency requirements that actually set them apart from other members of the supply chain.

I am going to _ Mr. _ or Dr. Gaugh, I am sorry, the FDA

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already requires drug manufacturers to report when there is interruption in manufacturing. Additionally, the agency recommends that companies notify the FDA when there is a sudden, unexpected spike in demand, even when it is not due to a manufacturing issue. Is _ does this make sense?

*Mr. Gaugh. Thank you for the question. We believe that _ and especially under the Cares Act _ that the FDA has all the data that they need. So we are reporting data from our quarterly manufacturing on an annual basis. That gives them the API source, the API usage, the finished dose, source, and usage, and we think to have all the information they currently need.

*Mr. Dunn. Thank you very much. I see I am over on my time.

Thank you very much _

*Mr. Guthrie. Thank you. The gentleman _

*Mr. Dunn. _ for your indulgence, Mr. Chairman.

*Mr. Guthrie. The gentleman yields back. The chair now recognizes Dr. Miller-Meeks for five minutes.

*Mrs. Miller-Meeks. Thank you, Mr. Chairman, and I thank all of our witnesses for testifying before the

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committee today.

I am a physician, former nurse, and also the director of the Iowa Department of Public Health when we were not in a pandemic.

The impacts of drug shortages on patients can't be overstated. In a RAND study conducted after a shortage, there was an observed decline in drug volume between 28 percent and 35 percent, compared to the year before the drug entered the shortage. And I think that was alluded to earlier.

The reduction in volume of generic drugs _ drug fills was larger, with a median of 37.6 percent compared to brand-name drugs experiencing a shortage, which saw a median of 30.4 percent. Patients in rural Iowa, who already face significant challenges when it comes to accessing quality health care, have been hit hard by recent drug shortages, and this includes our rural critical access hospitals.

While the cause of the issue is multifaceted, there appears to be general agreement that economic challenges, especially in the generics market, are a major factor. Because generics manufacturers compete with one another on

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price, at some point it results in diminishing return on investment. If a price gets too low, multiple manufacturers might leave a particular market. Or if there is a single API, which was alluded earlier, it might leave the market. And if the one remaining supplier is hit with a disruption, such as a lack of API, water contamination, natural disasters, et cetera, there is a resulting shortage.

So I have a question. Is there a correlation of past drug shortages _ since this was brought up _ and reimbursement for that particular drug to the manufacturer, i.e. like we have done in the rest of health care, especially government-run health care, be Medicare or Medicaid? If we are setting the price for reimbursement too low we get shortages. Can you just go down the line? Is there any correlation? Yes, no, or you don't know.

Mr. Gaugh, I will start with you, and we will go that way.

*Mr. Gaugh. Thank you for the question. Yes, we do believe there is a correlation. And earlier in the hearing it came up, and we said there are many aspects to this as you go through the start to finish, so the manufacturer to the

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patient. And we are going to send back a document that _ a schematic document that maps all of that out.

*Mrs. Miller-Meeks. Mr. Coukell.

*Mr. Coukell. Numerous authoritative reports have examined the root causes of drug shortages, and they all conclude that price is part of the problem. That is not to say that government programs are creating drug shortages, but that erosion of margin is not helpful.

*Mrs. Miller-Meeks. Dr. Barber.

*Dr. Barber. I agree that there is no evidence that government programs are creating erosion, but price is always relevant. We have chosen a system where generic manufacturers can _

*Mrs. Miller-Meeks. Thank you very much.

*Dr. Barber. _ price, but there are other options.

*Mrs. Miller-Meeks. Mr. Davis.

*Mr. Davis. As we all see, it is a very complicated ecosystem, but we would agree with the assessment, Congressman.

*Mrs. Miller-Meeks. Mr. Ebert.

*Mr. Ebert. As Mr. Davis said, it is complicated.

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However, our concern many times is payments don't always make it down to the source of where they _ where you want them to go. For example, to the generic manufacturers.

*Dr. Ganio. And I agree. I think we have already established the root causes involve market incentives. But I think we have to be careful not to just throw money at the problem, and make sure those investments are going toward quality.

*Mrs. Miller-Meeks. Yes, my point is not to throw money at the problem. My point is to make that correlation, which we know exists.

We have the same _ you know, we just put forth in Congress a bill last year in order to subsidize chip manufacturing, to bring it back to the United States. Are we doing the same thing to other industries? And my concern with the public option is that because we are underpaying what it costs to make a generic drug, what it costs to stay in business _ having been a small business owner _ and pay property taxes, which private businesses pay, that we will then subsidize another type of industry, and will end up paying more than we would pay if we were fairly reimbursing.

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That is the point that I am making.

Mr. Gaugh, in your written testimony you highlight how prevalent generic medications are, stating that over 90 percent of prescriptions filled today are done so using generics. Can you highlight how drug shortages impact the generic markets differently?

And part of this will be some correlation or some effect of the IRA, as well, and whether there are specific factors that lead to generic shortages.

*Mr. Gaugh. Thank you for the question. And yes, we are going to go right back to reimbursement as being the factors that lead to the drug shortages.

So you can look today at cisplatin, which was _ we understand this week that it has been resolved, but it is still an ongoing issue. In that particular case there were seven companies that make cisplatin. It was down to only three when the drug shortage occurred, and so the other four weren't able to come back. Hence, the drug shortage. When one company has 50 percent of the market and goes out of the market, you just can't catch up fast enough.

*Mrs. Miller-Meeks. Thank you, sir.

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With that I yield back.

*Mr. Guthrie. Thank you. The gentlelady yields back. The chair recognizes Mr. Obernolte for five minutes.

*Mr. Obernolte. Thank you very much, Mr. Chairman, and thank you to all of our witnesses for this hearing on what is an extremely important topic.

Over the August break I met with my health care advisory board, which includes representatives from all of the hospitals in my district, and the shortage of certain drugs was the number-one issue for most of them. I heard about shortages of sedatives, of anesthetics, chemotherapy drugs, which I know we have in common with a lot of hospitals, but also about epinephrine, which surprised me. And they let me know in no uncertain terms just how important solving this problem is to them.

Dr. Ganio, I read something really interesting in your testimony that I wanted to follow up on. One of the recommendations that you made is that the FDA finalize metrics for quality management maturity, and then require suppliers to report those metrics. And in doing so, that would create information that is publicly available that

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would allow purchasers to prioritize purchases from manufacturers that were less likely to experience shortages in drugs in the future.

And that piqued my curiosity because, you know, as a _ someone who is a fan of limited government and, you know, of of requirements from government only being a last case solution when the mechanisms of the free market can be employed, you know, I think that that would be great, this idea that just some more transparency and freer exchange of information could solve the problem.

But I mean, I also have to admit being a little skeptical, because that ignores the complications of drugs where there is only a sole source, that ignores situations where unpredictable demand has caused a shortage, rather than any error in forecasting on the side of the manufacturer.

So could you talk a little bit more about that, and give us some hope that maybe that could be a possible solution to this problem?

*Dr. Ganio. Sure. And I will refer back to the FDA's root causes report that established a lack of market incentive for quality manufacturing as a root cause of

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shortages.

And Mr. Gaugh had just previously cited cisplatin had 50 percent of the market. But when you read the inspection report from that plant inspection, if that doesn't terrify you then I don't know what would.

So if the purchasers who built up 50 percent of the market share for that company knew what they were investing their money in, would they have then continued to buy from that company, or would they perhaps have bought from another company?

So that is where we feel like the transparency into quality _ the QMM program is a pilot that the FDA has been working on. It looks at a culture of quality, not just a particular manufacturer's specific supply line. And we think that gives purchasers that additional information to know, okay, this is the cheapest product, but maybe it is not the best investment for me to buy at this time.

*Mr. Obernolte. So just playing devil's advocate, isn't there already a market mechanism for that? Because if you are a manufacturer who is willing to have invested in a more robust supply chain that is less susceptible to disruption,

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couldn't you evangelize that fact to potential buyers, and use that to justify a higher price for your product, and use that as a competitive advantage without the intervention of the FDA?

*Dr. Ganio. Well, that is where we hope that the market forces continue to encourage competition. And if everyone is rising up to the standards that we would expect to see in a QMM program, then hopefully we are leveling the playing field and price competition comes back to where it should be.

But without that transparency and equality, it is not a level playing field, and purchasers are just simply buying the cheapest product available.

*Mr. Obernolte. Right, yes. Well, I mean, I would think that, if there was a competitive advantage to be had there, there is an incentive for a manufacturer to go seize it.

But we will continue to explore it because, as I said, the _ this idea that greater transparency would solve part of this problem, I think, is a very attractive one. But whatever we do, we absolutely must fix this problem because it is affecting the health care of the constituents of

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everyone on this dais, and we have heard that message loud and clear from the health care providers in our district. So I want to thank you very much for being here, and for your service in trying to accomplish that really important goal.

Mr. Chairman, I yield back.

*Mr. Guthrie. Thank you. The gentleman yields back. Seeing all members of the subcommittee being present and having asked questions, the chair now recognizes _ we are going to waive on, and we have our good friend from Florida.

Ms. Castor, you are recognized for five minutes.

*Ms. Castor. Well, thank you, Mr. Chairman, for allowing me to waive on, because this is such an important matter.

And I want to thank you all. You are almost done. You are almost done.

But Mr. Ganio, at the very outset you really got my attention: 309 drugs in shortage that you are identifying now. You said most in a decade, and that folks are really struggling. You called it a crisis untenable.

Mr. Ebert, you said it is a pressing problem. That tracks exactly with what I am hearing from neighbors at home.

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They are just scrambling to find workarounds and get people the access to the medications that they need.

I did a roundtable at Saint Joseph's Children's Hospital in Tampa with patients and doctors and pharmacists and providers, and here is some of what they said. Parents, they said, they have children who can't get their chemotherapy drugs or the IV medical nutrition that they need to survive. There was one ER doc who said he scrambles every day. He contacts pharmacists to see what drugs are in stock so that he knows that day what prescriptions for patients will be available. A cancer researcher who almost had to halt a clinical trial for a CAR T, and a pediatrician who has hired an employee just to handle pharmacy callbacks.

So everyone is struggling to keep up with the cascading impacts of the shortage. It is a colossal waste of money and a colossal waste of time. We have got to fix this. I am not certain that the bills that are being proposed here by the GOP majority get that job done.

One of the folks who is really focused on brainstorming solutions is Laura Bray with Angels for Change. She has appeared before the committee. She is from the Tampa Bay

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area. That is a volunteer-supported non-profit that works to connect providers with the drugs they need. So I want to ask you about that model.

They have a pilot called Project Protect, where they give a small grant to a 503B compounding pharmacy to manufacture a drug that they take _ they model what _ and predict what is going to go into shortage. And then, with very modest funding, they get purchasing commitments from hospitals, a pharmacy who can produce this essential drug before the shortage begins, typically for about 10,000 to $50,000.

So Mr. Ganio, for a _ do you know about this Project Protect and predictive modeling, where you select some of the most vulnerable drugs for some of the sickest patients?

Are there ways that we can better align the supply chain to allow more accurate predictive modeling and give us early warning, early warnings for drugs and shortages _ in shortage?

*Dr. Ganio. Thank you for the question. And yes, Laura is obviously very passionate, and she has done some good work that has been a little outside of the box, and I think that

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program is one that could be scaled.

We heard my colleague here from Civica talk about ANDAs at the Ready, which would be a similar model for commercial manufacturers. But the predictive modeling is the important part of that. It is identifying which drugs are most at risk using multiple data points.

And we talk about transparency and improving _ understanding where we rely on single sources or single nodes in the supply chain. Those only help inform those predictive models even further, and give us more decision _ more tools for decision-making in identifying things like Project Protect. Or even as we talk about buffers or stockpiles of certain medications, we don't need to buffer every single medication in the supply chain. We just need to find the ones that are most vulnerable, most essential, and choose those.

So I think the increased predictive modeling actually opens the opportunity for public-private partnerships like the Angels for Change, and gives us an idea of where those vulnerabilities are to start shoring up.

*Ms. Castor. And Dr. Barber, this seems to track with

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some of your recommendations, these type of public-private partnerships and more predictive modeling. What do you think?

*Dr. Barber. Thank you very much for that question. Modeling only works when you _ the data is good, right? Trash data in, trash models out is the adage we learned in my Ph.D. So I echo the comments made that we need to improve prioritization, right? We need to know where the problem is.

So what are the most essential drugs? Not all drugs are equal. What are the most brutal supply chains? Single source?

And yes, modeling will get us only so far. But we need investment, systemic investments like the ANDA program and not just charity, to address this.

*Ms. Castor. Well, thank you all very much. I hope that the majority will take this to heart, and work these kind of public-private partnerships into their proposals. Thank you.

*Mr. Guthrie. Thank you. The gentlelady yields back, and that concludes everybody who has been present for questions. And I think almost all of us said what I think is

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important for all of us to say, particularly being the first hearing after a _ after being home working, is this is what I am hearing back home. And so that is _ that should shape policy that we do here in Washington, D.C.

So there is actually a _ so we have concluded questions. We are almost finished. But there are documents for the record. We have gotten the list to the _ both sides for the majority and minority. I submit the requests for the record.

Without objection?

*Ms. Eshoo. Without objection.

*Mr. Guthrie. Without objection, so ordered.

[The information follows:]

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

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*Mr. Guthrie. And I will remind members they have 10 business days to submit questions, and I ask that the witnesses promptly reply. I know there were some who said they will reply in writing, and then there could be other questions coming forward, and members should submit their questions by the close of business on September the 27th.

So without objection, the subcommittee is adjourned.

[Whereupon, at 12:57 p.m., the subcommittee was adjourned.]