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RPTR ALLDRIDGE

EDTR CRYSTAL

COMBATING THE OPIOID EPIDEMIC: EXAMINING CONCERNS ABOUT DISTRIBUTION AND DIVERSION

TUESDAY, MAY 8, 2018

House of Representatives,

Subcommittee on Oversight

and Investigations,

Committee on Energy and Commerce,

Washington, D.C.

The subcommittee met, pursuant to call, at 10:00 a.m., in Room 2123, Rayburn House Office Building, Hon. Gregg Harper [chairman of the subcommittee] presiding.

Present: Representatives Harper, Griffith, Burgess, Brooks, Collins, Barton, Walberg, Walters, Carter, Walden (ex officio),

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DeGette, Schakowsky, Castor, Tonko, Ruiz, Pallone (ex officio).

Also Present: Representatives Blackburn, McKinley, Johnson, Guthrie, Lance, and Welch.

Staff Present: Jennifer Barblan, Chief Counsel, Oversight and Investigations; Mike Bloomquist, Staff Director; Karen Christian, General Counsel; Jordan Davis, Senior Advisor; David DeMarco, IT Staff; Adam Fromm, Director of Outreach and Coalitions; Ali Fulling, Legislative Clerk, Oversight and Investigations, Digital Commerce and Consumer Protection; Theresa Gambo, Human Resources/Office Administrator; Brittany Havens, Professional Staff, Oversight and Investigations; Zach Hunter, Director of Communications; Christopher Santini, Counsel, Oversight and Investigations; Jennifer Sherman, Press Secretary; Alan Slobodin, Chief Investigative Counsel, Oversight and Investigations; Hamlin Wade, Special Advisor, External Affairs; Christina Calce, Minority Counsel; Jeff Carroll, Minority Staff Director; Tiffany Guarascio, Minority Deputy Staff Director and Chief Health Advisor; Chris Knauer, Minority Oversight Staff Director; Miles Lichtman, Minority Policy Analyst; Kevin McAloon, Minority Professional Staff Member; Andrew Souvall, Minority Director of Communications, Outreach and Member Services; C.J. Young, Minority Press Secretary; and Perry Lusk, Minority GAO Detailee.

Mr. Harper. I now call to order this hearing on "Combating the Opioid Epidemic: Examining Concerns About Distribution and Diversion."

One year ago today, on May the 8th, 2017, the committee opened a bipartisan investigation into the distribution of prescription opioids by wholesale drug distributors with a specific focus on unusually large opioid shipments to small pharmacies in West Virginia. The launch of this investigation was spurred by press reports of astonishing levels of opioid distribution to pharmacies in small, rural West Virginia towns.

Between 2007 and 2012, distributors sent more than 700 million hydrocodone and oxycodone pills to the State, or 433 pills for every man, woman, and child in the State. In that timeframe, 1,728 West Virginians fatally overdosed on these two drugs.

The numbers were eye-opening. The Sav-Rite pharmacy in Kermit, West Virginia, population around 400, received nearly 9 million opioids in a 2-year period. Another pharmacy, in nearby Oceana, West Virginia, received 600 times as many oxycodone pills as the Rite Aid drugstore just eight blocks away.

This led the committee, on a bipartisan basis, to request

information from the Drug Enforcement Administration and the so-called big three drug distributors, McKesson, Cardinal Health, and AmerisourceBergen. These distributors delivered more than 500 million opioids to West Virginia between 2007 and 2012, with Cardinal shipping 241 million opioids, AmerisourceBergen shipping about 119 million opioids, and McKesson shipping more than 150 million opioids.

Later in the investigation the committee also sent letters to two regional distributors with a major presence in West Virginia, Miami-Luken and H.D. Smith. We found that the stunning numbers that led us to start this investigation were much more common than we had hoped.

Among our discoveries are a single pharmacy in Mount Gay-Shamrock, West Virginia, population 1,779, that received more than 16.5 million hydrocodone and oxycodone pills between 2006 and 2016. In nearby Williamson, West Virginia, population 2,900, distributors sent almost 21 million opioids to two pharmacies during the same period. And this is just within the targeted areas that we reviewed.

We have learned much from the investigation but still have many questions. For example, why did the distributors repeatedly fail to report suspicious orders of opioids or exercise effective controls against diversion?

By 2005, internet pharmacies had transformed the DEA regulatory

paradigm with unprecedented large volumes of controlled substances being shipped to individual pharmacies. Pill mill doctors and pharmacies began to proliferate. The agency needed help, and given their position in the supply chain and their legal obligations to identify and report suspicious orders, identified the distributors as a main line of defense against diversion.

Through meetings and letters over a period of years, the DEA educated and coached the distributors on their responsibilities. The distributors have contended that the DEA provided insufficient communication and guidance. Distributors have also said that only the DEA can see the full picture with respect to pharmacy volume and that distributors are simply privy to their own data.

But were distributors' capabilities that limited? Distributors conduct due diligence, site visits, and can obtain market data. They can request and analyze a pharmacy's dispensing data, which provides the distributors with the ability to see all the controlled substances being dispensed by a pharmacy and the prescribers over a given period of time.

In some cases, such as what we have seen in West Virginia, the volume of controlled substances a distributor sends on its own should be cause for concern.

Distributors also contend that they do not set demand and simply

satisfy orders for prescriptions written by licensed doctors and filled by licensed pharmacists. But what about the distributor's legal responsibility to know their customer and perform due diligence?

And what does our work mean for the rest of the country? West Virginia is far from the only State heavily impacted by the opioid epidemic. It has hit every State, and everyone in this room has been affected in some way.

How many other communities across the country have received millions more opioids than their communities could reasonably sustain? How many other times did a distributor miss the red flags of their own distribution, let alone what could be found with due diligence? How many other Kermits and Williamsons are out there?

It is my hope that we will see some answers today as to how the drug distributors seemingly missed the red flags of diversion.

I want to welcome the witnesses and thank each of you for your participation to help us in this important investigation.

I also thank my colleagues from across the aisle for all of their hard work on this bipartisan investigation.

And I now recognize the ranking member of the subcommittee, Ms. DeGette.

[The prepared statement of Mr. Harper follows:]

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

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

This investigation has been bipartisan. And as you mentioned, it was a year ago today when we sent our first letters to three of the drug wholesale distributors before us today. Those letters described the devastation of the opioid crisis, and they referenced a report that, over 6 years, distributors showered the State with 780 million hydrocodone and oxycodone pills while 1,728 West Virginians fatally overdosed on those two painkillers.

Over the last year, we learned a lot more about the full scope of the epidemic in West Virginia. As the chairman said, we obtained data showing that pharmacies in tiny towns received millions of pills in just a few years.

But our work is not finished. We want to know what these companies knew about the rise of the opioid epidemic, when they knew it, and whether it informed their distribution practices.

In fact, over a decade ago the DEA sent letters to all registered distributors informing them that, quote, "The abuse of controlled prescription drugs is a serious and growing health problem in this country," end quote.

In 2007, CDC reported that drug overdose deaths nationwide increased by 276 percent between 1999 and 2014, and in West Virginia, drug overdose deaths were up by 550 percent.

A well-publicized 2008 JAMA study specifically implicated prescription opioids in the rise of overdose deaths.

In 2010, the New England Journal of Medicine article, "A Flood of Opioids, a Rising Tide of Deaths," showed that the prescription opioids death toll continued to rise, particularly in West Virginia.

In 2011, the Charleston Gazette published a major story describing how residents began calling the town of Williamson, quote, "Pilliamson," because so many opioids had flooded that town.

And this is just a small sampling of the articles that highlighted the rise of this epidemic.

So yet, even as this information was coming out, it appears that, over 3 years, distributors sent more than 11 million pills to one pharmacy in a town of 400 and more than 12 million total pills to two pharmacies in a town of 3,000. I mean, come on.

I know we are going to hear from the distributors that they had systems in place and that they only fill orders by pharmacies that hold valid DEA licenses. At the end the day, however, I think we can all agree, whatever systems were in place did not prevent damage to these communities caused by what appears to be the excessive supply of opioid pills.

Some of the counties that have been the focus of the investigation have the highest death and overdose rates in the Nation. The epidemic

has devastated families throughout that State, and it has placed huge burdens on the State's healthcare system, its child welfare program, and its economy as a whole.

Now, we need to understand the root causes of how we let this happen and why distributors apparently supplied so many opioids to certain small town pharmacies. For example, how did the tiny town of Kermit, with a population of 400, receive 9 million pills in just 2 years? Shouldn't the distributors' suspicious order systems have immediately flagged and halted shipment of this magnitude? And shouldn't the distributors have examined them more closely to determine the appropriateness for shipping them?

I also want to understand why major drug companies failed to have adequate suspicious order reporting programs in place and were forced to have to settle with the DOJ and the DEA not once, but twice during this epidemic. Do the distributors believe that any of their suspicious order reporting system failed? And if so, how?

I hope what we learn today will help us inform investigations all across the country, including in Colorado, which has had similar concerns raised about overdistribution.

Mr. Chairman, let me conclude by saying we agree it is critical that we understand what happened and how the Nation has found itself in the grip of this opioid crisis. But at the same time, I think that

the overall committee needs to make sure that we have adequate resources available to help those in need and to get people like those in the hard-hit places we will be talking about today the recovery that they need.

As we look back on what happened, we cannot turn our backs on those who were devastated by this crisis.

Thank you, and I yield back.

[The prepared statement of Ms. DeGette follows:]

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

Mr. Harper. The gentlewoman yields back.

The chair now recognizes the chairman of the full commitment, Mr. Walden, for the purposes of an opening statement.

The Chairman. Thank you, Mr. Chairman.

Over the last few years, the Energy and Commerce Committee has conducted multiple investigations, enacted major bipartisan legislation, and helped authorize historic levels of funding to help those battling this epidemic in our communities all across America. But clearly we have much more work to do, including two important hearings and a full committee markup this week on this issue.

Our efforts continue on two tracks. One is to provide new legislative solutions, new laws, new programs to combat the crisis. And the second track is to continue our year-long investigation into its causes.

As you have heard before, today's hearing marks a 1-year anniversary since we first asked the Drug Enforcement Administration and the Nation's largest distributors of opioids for information about the overwhelming amount of prescription opiates that flooded into countless communities all across the United States.

After hearing from the DEA in March, it is important that today we hear from the executives who lead the most influential pharmaceutical distribution companies in America. We have tough

questions for you today. You know that. But we ask you these questions in order for all of us to find solutions.

Today, a thousand people will go into emergency rooms overdosing on opioids. Today in America, 115 people will die from opioid addiction and overdose. This is why we are moving forward.

A decade ago, the DEA realized that its enforcement strategy had to change to fight the rising tide of internet pharmacies, internet pharmacies and pill mills. With more than a million DEA registrants, the DEA simply could not fight this only at an individual doctor and pharmacy level.

So to more effectively and efficiently combat this emerging law enforcement challenge, the DEA asked the drug distributors to play a more proactive role in identifying, analyzing, and reporting and blocking suspicious orders of controlled substances.

In 2005, the DEA started the Distributor Initiative Program. That program had a goal of educating registrants on maintaining effective controls against diversion and monitoring for and reporting suspicious orders. DEA held individual meetings in 2005 and 2006 with McKesson, with Cardinal Health, and AmerisourceBergen, and instructed companies on how to identify and submit reports of suspicious orders.

In 2006 and 2007, the DEA sent three letters to all DEA-registered distributors to put them on notice about their legal obligations.

However, soon after the start of this initiative, each of these three companies faced enforcement actions, in 2007 and 2008, for failures to maintain effective controls against the diversion of controlled substances. Cardinal Health and McKesson each paid civil penalties totaling millions of dollars.

Meanwhile, the opioid crisis worsened over the next decade, especially in ravaged communities like we have heard about this morning and in our investigations in small towns in West Virginia.

Even after the 2008 settlements, while concerns rose over the opioid epidemic, some distributors were still failing to exercise effective controls against diversion. This led to more enforcement actions and more settlements, including a record-setting $150 million civil penalty by McKesson in 2017. It remains an open question today whether the distributors have finally achieved effective DEA compliance programs.

Since the 1970s, distributors have had a statutory responsibility under the Controlled Substances Act to exercise due diligence to report and avoid filling suspicious orders. This responsibility is due to their unique position in the marketplace. They are the chokepoints in the U.S. prescription drug supply chain.

Three of those that are before us today, McKesson, Cardinal Health, and AmerisourceBergen, account for about 85 percent of the drug

supply. So it is not sufficient just to blame the DEA, although we have our own issues with the DEA's role in this. You have a unique set of resources and tools at your disposal and a shared responsibility in flagging suspicious activity and diversion. You are on the front lines of the defense in this crisis.

Instead, the information uncovered by the investigation over the last year is stunning. There is no logical explanation that we can find for why a town of approximately 400 people would receive 9 million opioid pills in 2 years or why a single pharmacy in a town of 1,800 people would receive nearly 17 million opioid pills in a decade. Then there are two pharmacies in a nearby town of 2,900 people which received nearly 21 million opioids in the same timeframe.

No matter how you cut these data, behind each of these numbers was a pill mill, and they proliferated for far too long.

So given what we know about the volume of opioid shipments to small towns in West Virginia and the associated pill mills and diversion schemes in those areas, it is difficult not to be troubled by the compliance efforts by our Nation's distributors.

So we look forward to getting a better understanding of the facts and to finally have this necessary and frank conversation. We owe it to the 115 Americans who will die today and every day from opioid overdoses and to their loved ones to understand what led to this crisis

and to identify solutions to stem the tide.

With that, Mr. Chairman, I yield back.

[The prepared statement of The Chairman follows:]

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

Mr. Harper. The chairman yields back.

The chair will now recognize the ranking member for the full committee, Mr. Pallone.

Mr. Pallone. Thank you, Mr. Chairman.

The opioid epidemic continues to devastate this country, and virtually no community in America has been left untouched. West Virginia in particular has been severely affected. For the last several years, West Virginia has had the highest overdose death rate in the country.

This committee's investigation has uncovered some very troubling information about seemingly large shipments of opioids from drug distributors to rural pharmacies in West Virginia over the course of several years.

And I think it is important for us to understand what went wrong and why, but we must also understand what needs to change so that we do not ever find ourselves in this situation again. For example, there is simply no excuse for distributors sending more than 13 million doses of opioids to a single pharmacy in a town of just over 400 people over a 6-year period.

Some of the distributors who supplied high amounts of pills to this pharmacy appear not to have submitted suspicious order reports to DEA even though the law requires them to do so. In addition, some

of the distributor's files are either sparse or unavailable, raising additional questions about whether they investigated the risk of diversion before shipping these pills.

In the end, Federal authorities raided and shut down this pharmacy, and its owner went to jail. And we must understand what went wrong here so that we can be sure that no town is ever again flooded with pills.

In another case, two doctors in the town of Williamson prescribed more opiates than entire hospitals did, according to a Justice Department press release, and these doctors were in fact the highest opioid prescribers in the entire State and were widely known to be running pill mills. One of these doctors ultimately went to jail; the other fled overseas.

It appears that certain distributor systems failed to detect the volume of prescriptions these pharmacies were filling for these doctors, which may have led to oversupply and diversion of pills.

It is the distributors' responsibility to know their customers, monitor orders, refuse suspicious orders, and report those orders to DEA. Distributors must perform these functions particularly when pharmacies order high volumes of opioids. But our investigation has shown that this did not always happen.

In fact, some of these distributors paid large fines to DOJ

because their systems failed and because they did not report suspicious orders to DEA as required. And these distributors promised to clean up their act, but just a few years later, they were again hit with multimillion-dollar fines for the very same shortcomings.

So I want to know how we can be confident that distributors have sufficiently improved their systems now so that going forward we will not miss key indicators that may help uncover diversion in other situations.

For example, one distributor told us that, with the benefit of hindsight, they wished they had asked different questions of at least two of the pharmacies we have examined. And I would like to know what kind of questions they believe will make the process more effective and reduce the possibility of diversion.

Mr. Chairman, this is a nationwide concern. The problems we found in West Virginia have broader lessons for the rest of the county.

I also want point out that this investigation focused on the role the distributors played in this crisis, but we know that there are many causes of this epidemic. This includes the role of some manufacturers in manufacturing these drugs, the role of some rogue physicians in overprescribing them, and the failure of regulators at the State and Federal level to adequately oversee the opioid supply chain.

But let me also highlight another important aspect of this

committee's work which I hope will not be lost as we look as how events unfolded in the past, because this crisis is far from over. Right now countless Americans, including those in the hard-hit areas of West Virginia, still need to access quality healthcare to help them recover from the opioid crisis.

In the past month, we have marked up a substantial number of opioid-related bills, and I am still concerned that we have made this push without taking the time to make sure we get it right without much of an emphasis on treatment. It is not enough to only look backwards at this crisis. We must take the necessary steps to actually help those who are suffering by providing comprehensive treatment to individuals and communities in need.

Unless someone wants my minute, I will yield it back.

Thank you.

[The prepared statement of Mr. Pallone follows:]

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

Mr. Harper. The gentleman yields back.

I ask unanimous consent that the members' written opening statements be made a part of the record. Without objection, it will be entered into the record.

Additionally, I ask unanimous consent that Energy and Commerce members not on the Subcommittee on Oversight and Investigations be permitted to participate in today's hearing. Without objection, so ordered.

I would now like to introduce our witnesses for today's hearing.

First today we have Dr. Joseph Mastandrea, chairman of the board at Miami-Luken; John Hammergren, chairman, president, and CEO of McKesson Corporation; George Barrett, executive chairman of the board at Cardinal Health; Steven Collis, chairman, President, and CEO of AmerisourceBergen Corporation; and finally, J. Christopher Smith, former President and CEO, H.D. Smith Wholesale Drug Company.

You are aware that the committee is holding an investigative hearing. And when doing so, we have the practice of taking testimony under oath.

Do any of you have any objection to testifying under oath?

Seeing none, the chair then advises you that, under the rules of the House and the rules of the committee, you are entitled to be accompanied by counsel.

Do you wish to be accompanied by counsel during your testimony today?

Seeing none, in that case, if you would please rise. Raise your right hand, and I'll swear you in.

[Witnesses sworn.]

Mr. Harper. Each of you are now under oath and subject to the penalties set forth in Title 18, Section 1001 of the United States Code.

You may now give a 5-minute summary of your written statement. We will begin first hearing from Dr. Joseph Mastandrea.

You are recognized for 5 minutes.

I ask that everyone pull your microphone close to you, make sure it's on.

And you're recognized for 5 minutes, Dr. Mastandrea.

STATEMENTS OF DR. JOSEPH MASTANDREA, CHAIRMAN OF THE BOARD, MIAMI-LUKEN, INC.; MR. JOHN HAMMERGREN, CHAIRMAN, PRESIDENT, AND CEO, MCKESSON CORPORATION; MR. GEORGE BARRETT, EXECUTIVE CHAIRMAN OF THE BOARD, CARDINAL HEALTH, INC.; MR. STEVEN COLLIS, CHAIRMAN, PRESIDENT, AND CEO, AMERISOURCEBERGEN CORPORATION; AND MR. J. CHRISTOPHER SMITH, FORMER PRESIDENT AND CEO, H.D. SMITH WHOLESALE DRUG COMPANY

STATEMENT OF JOSEPH MASTANDREA

Dr. Mastandrea. Good morning, Committee Chairman Walden, Subcommittee Chairman Harper, Ranking Members Pallone and DeGette, and distinguished members of the subcommittee. Thank you for the invitation to testify before you today, and thank you for your tireless efforts to address our Nation's ongoing opioid epidemic.

I would like to share some background about Miami-Luken with you. The company was originally cofounded by my father, Robert E. Mastandrea, in 1962 as the Miami Valley Wholesale Drug Company in Dayton, Ohio. Nine years later, in 1971, the acquired the A.G. Luken Drug Company of Richmond, Indiana. It was then that the company Miami-Luken was born.

Since then, the company has made additional acquisitions in Ohio

and West Virginia, yet has always remained a relatively small regional distributors.

I first started working for the company at the age of 14 working in the warehouse. After graduating college, I worked a short time with my father learning the day-to-day operations of the business where I was involved in making sales calls, deliveries, and various warehouse duties.

It was a wonderful place to work, and I was proud of my father and what he had achieved. He was born in Italy and came to this country at the age of 13. He subsequently graduated from college and began a business career that would lead to the formation of Miami-Luken. Through my father's leadership, the company's culture was more like a family than just a place to work.

I entered medical school in 1979 and after my residency embarked on a full-time career as a physician in Dayton. Several years later I was asked to serve on the board of directors of Miami-Luken, which I accepted. Some years later, I became the chairman of the board and have held that position since that time.

Management of the company remained pretty much the same until 2007 when a new president was appointed by the board. This individual had extensive managerial experience in both the wholesale drug business and the wholesale grocery business and was more than qualified to lead

the company. He was knowledgeable, confident, and well-liked by the company's employees.

It was not until several years later, in 2013, after the board learned that the DEA had issued a number of subpoenas to the company, that we realized the government had concerns with the company's compliance efforts.

In response, we retained the services of a prominent attorney here in Washington who used to work for the DEA. This attorney worked with management to assist the company in fulfilling its DEA compliance obligations. We also instructed the company's president to purchase a computer program to better identify suspicious orders from customers, which he did.

When we subsequently learned that management was having difficulties with the computer system they purchased, it was apparent to us that we needed someone more capable in that position. The board immediately began looking for a replacement and after considering several individuals hired the company's current president and CEO, Michael Faul.

In addition to hiring Mr. Faul, the company hired a new director of compliance and security who worked with Mr. Faul to implement a number of significant changes in the company's compliance program.

These included more frequent and robust customer visits by

compliance staff, greater scrutiny of requests from customers to increase purchase quantities, increased facility and transportation security, implementation of compliance training, purchase of the NTIS database, enhancing the controlled substance profile that customers are required to complete during the on-boarding process, and the complete overhaul of Miami-Luken's standard operating procedures regarding DEA compliance.

The compliance director also worked with the software vendor to recalibrate the company's computerized suspicious orders notification system, improved its effectiveness in identifying suspicious orders on a daily basis, and started the process of uploading all relevant data on shared computer drives providing employees and DEA investigators easier access to information pertaining to individual customers.

He also hired additional staff to assist the company in its compliance efforts and created a new analytical tool on an Excel spreadsheet to assist in conducting due diligence on current and prospective customers. In fact, the compliance director last year was recognized by the National Association of Drug Diversion Investigators for his outstanding work in drug diversion prevention.

As a result of new management's enhanced compliance efforts, Miami-Luken terminated its relationship with multiple customers, many

of whom are still in business purchasing from other sources. Since 2014, we have reduced the sale of oxycodone by approximately two-thirds and the sale of hydrocodone by a similar margin.

It is our understanding that former management took what they believed to be sufficient steps at the time, believing that the State medical boards and State pharmacy boards were in a strong position to monitor the physicians and pharmacists they licensed.

Former management also believed that since Miami-Luken regularly provided the DEA with sales data for all its customers, the government would have advised us if they had any concerns with sales to specific parties.

Unfortunately, we know that is not enough. And as you know from the materials we have provided this committee last year, Miami-Luken has taken aggressive action going back several years to strengthen its compliance efforts and suspicious order monitoring system and reporting. And as I sit here now, I can assure you that our company employs a compliance program that is second to none.

In closing, I welcome any questions you have and will answer them to the best of my ability. Thank you again for this opportunity and for all your efforts.

[The prepared statement of Dr. Mastandrea follows:]

******** INSERT 1-1 ********

Mr. Harper. Thank you, Dr. Mastandrea.

The chair will now recognize John Hammergren, chairman, president, and CEO of McKesson Corporation, for 5 minutes.

STATEMENT OF JOHN HAMMERGREN

Mr. Hammergren. Mr. Chairman, Ranking Member DeGette, and members of the subcommittee, my name is John Hammergren, and for almost two decades I've had the privilege to serve as the chief executive officer of McKesson Corporation.

The impact the opioid epidemic has had on our Nation is devastating. Millions of Americans have been affected, including employees of McKesson and their families. We recognize the importance of this committee's investigation, and I appreciate the opportunity to appear before you today to help the committee address this crisis. I will also explain the steps that we ourselves are taking.

Our company has over 70,000 employees worldwide. Our distribution business receives 275,000 orders every day, serving 40,000 pharmacies and hospitals. Like all distributors, we have two critical priorities: to deliver medicines to pharmacies and hospitals when and where they need them and to help the protect the integrity of the supply chain.

As a distributor, we don't manufacture prescription drugs, we don't market them to doctors or patients, nor do we market any particular category of drugs, such as opioids, to pharmacists. Distributors respond to pharmacy orders, which are based on doctor's prescriptions.

For years we have reported every controlled substance transaction that we have made in West Virginia and across the country to the DEA. Other distributors provide similar information so that only the DEA has an overall view of opioids distributed in this country.

Distributing controlled substances represents a small share of McKesson's total business. The two schedules of controlled substances that include the most commonly abused prescription opioids constitute approximately 3 to 4 percent of our total revenue.

The committee has highlighted a large volume of opioids distributed to pharmacies in West Virginia by McKesson and other distributors. Over a 6-year period addressed by the committee, McKesson distributed approximately 151 million doses of oxycodone and hydrocodone there.

To put that into some perspective, if you look at all prescription drugs of any kind that McKesson distributed, the total number was nearly 2 billion doses in West Virginia during the same period.

There is no question that a key driver of the crisis, as the CDC

has said, is the overprescribing of opioids by doctors across the country. At the same time, there clearly were certain pharmacies in West Virginia that were bad actors that McKesson itself terminated. In hindsight, I would have liked to have seen us move much more quickly to identify the issues with these pharmacies.

We learned important lessons, so let me tell you how we're applying those lessons today.

Over the last 5 years, we have successfully used the latest technology and the best available expertise to strengthen controls. We have invested millions of dollars in enhancing our controlled substance monitoring program, or CSMP. A key part of that is sophisticated data analytics designed by outside experts which harness the power of advanced statistical models to set caps on sales to individual pharmacies. And then we block sales that exceed those caps, which are constantly monitored and fine-tuned.

Our CSMP team is independent of the business and has unilateral authority to deny a customer access to controlled substances. Our team includes former DEA agents with more than 240 years of collective DEA enforcement experience.

And the CSMP is working. In fact, over the last decade, we blocked and reported to the DEA over 1 million suspicious orders nationwide.

With a strong program in place today to monitor sales of opioids, we are extremely focused on advancing solutions to the country's opioid crisis more broadly.

First, we are moving forward with the development of a prescription safety alert system. This would be an electronic system to provide doctors and pharmacies with real-time red flags based on a patient's nationwide prescription history. Congress and the FDA can help make this a reality.

Second, we are requiring our customers to accept electronic prescriptions in 2019. Handwritten prescriptions are more prone to fraud.

Third, we're pushing for opioid manufacturers to use limited dose packaging, such as blister packs, to facilitate smaller prescription sizes.

And fourth, we've announced the formation of a foundation to fight the opioid epidemic and committed $100 million dollars to launch its mission.

McKesson and I personally fully understand the gravity of this crisis and our essential role in helping to address it.

Thank you again for the opportunity to testify today. I would be happy to address your questions.

[The prepared statement of Mr. Hammergren follows:]

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******** INSERT 1-2 ********

Mr. Harper. Thank you, Mr. Hammergren.

The chair will now recognize George Barrett, executive chairman of the board at Cardinal Health.

Thank you.

STATEMENT OF GEORGE BARRETT

Mr. Barrett. Chairman Harper, Ranking Member DeGette, and members of the subcommittee, Chairman Walden, Ranking Member Pallone, and other members of the full committee, thank you for the opportunity to be here today. I also want to extend my thanks to your staff for their professionalism and courtesy.

My name is George Barrett, and I have committed my professional career to healthcare in a wide range of roles for over three decades. Between 2009 and 2017, I was privileged to serve as CEO and chairman of Cardinal Health, which today is composed of more than 50,000 dedicated men and women.

We simply cannot look at the impact of opioid abuse on so many lives and not feel sorrow. I speak for the entire Cardinal Health team when I say that we care deeply about the devastation that opioid abuse is causing families and communities around our country. We are resolved to be a constructive part of the effort to alleviate this

complex national public health crisis.

Some of the issues we will discuss today involve the healthcare system in our neighboring State of West Virginia where hundreds of our employees live and work. The people of West Virginia are not just the recipients of the medicine and the medical products we distribute to hospitals and pharmacies, they are our coworkers, friends, neighbors, and family members.

I have visited the State to hear firsthand about the challenges of opioid abuse and how Cardinal Health can play a constructive role in addressing these challenges.

To the people of West Virginia, I want to express my personal regret for judgments that we'd make differently today with regard to two pharmacies that have been a particular focus of this subcommittee. With the benefit of hindsight, I wish we had moved faster and asked a different set of questions. I'm deeply sorry that we did not.

Today I'm confident that we would reach different conclusions about opioid orders from those two pharmacies. We've taken responsibility with our regulators. Cardinal Health has not distributed oxycodone or hydrocodone to either of these two pharmacies for years.

We understand that no antidiversion program is perfect, which is why we are so focused on continuous improvement. We are at the table

focused on alleviating this critical national health problem. We are committed to working with Congress, regulators, and others in the healthcare system to combat this crisis and address its effects.

There is no single root cause of the crisis, and addressing it requires that all healthcare participants work together, and we have to do it now.

We recognize the challenge posed by lawful yet high-volume prescribing of opioids. On the one hand, we know there are many individuals who rely on these medications to address suffering associated with terminal illnesses, painful neurological conditions, severe injuries, and other medical conditions.

On the other hand, we share the recent judgments of policymakers, including senior leadership at HHS, the FDA, the surgeon general, the CDC, and others, that there have been too many prescriptions for too many pills.

As a pharmaceutical wholesale distributor, we have a dual responsibility: to ensure that prescription medications are available for healthcare providers and their patients when needed while working to limit the potential for those prescription medicines to fall into the wrong hands.

Pharmaceutical wholesale distributors do not and should not have visibility into the medical judgment or the patients for whom

prescriptions are written. However, we can play a role by raising awareness of the dangers of overprescribing, which we are doing.

Our antidiversion tools are built around a core commitment to spot, stop, and report potential diversion. Our program is supported by a dedicated antidiversion team of investigators, auditors, analysts, former law enforcement officers, compliance officers, and pharmacists deployed nationwide and augmented by substantial external resources and technology.

From 2008 to the present, we have stopped suspicious orders for the shipment of hundreds of millions of opioids. We will not ship an order for hydrocodone or oxycodone to pharmacies that do not meet our standards. We have refused to onboard pharmacies that cannot pass our rigorous screening, and we have cut off existing customers that do not have effective controls.

But with a problem as large and complex as opioid addiction, we know there is always room to do better, and we will never stop working to continuously improve and refine our systems.

For over a decade, we have funded education and prevention programs that have been used in every State and more than 100 colleges and pharmacies. We have also launched an opioid action program including the free distribution of opioid reversal medication to law enforcement and first responders beginning in four of the Nation's

hardest-hit States across Appalachia.

As I indicated earlier, Cardinal Health is at the table and intends to be here for as long as the problem persists. Today I'll do my best to answer your specific questions and hope that our dialogue will continue.

Thank you.

[The prepared statement of Mr. Barrett follows:]

******** INSERT 1-3 ********

Mr. Harper. Thank you, Mr. Barrett.

The chair will now recognize Steven Collis, chairman, president, and CEO of AmerisourceBergen Corporation.

Mr. Collis.

STATEMENT OF STEVEN COLLIS

Mr. Collis. Thank you. Thank you, Chairman Walden, Subcommittee Chairman Harper, Ranking Member Pallone, Ranking Member DeGette, and distinguished members of the committee. On behalf of AmerisourceBergen's over 21,000 associates, thank you for the opportunity to be here today. We are committed to working with you and all stakeholders to help combat the tragic opioid abuse epidemic.

I will begin today by sharing three distinct perspectives that have shaped my thinking on this urgent issue.

First, like so many others, I have been touched and saddened by the excruciating stories that demonstrate the destruction wrought by the disease of addiction, many shared by your colleagues as they relayed the devastation that opioids have left in their States. Some time ago, a member shared a story of a mother who overdosed, leaving her two children starving and unattended for several days. Stories like this, and sadly so many that tell similar tragic tales, are always on my mind.

Second, I have seen friends, family, and those in my community fight through uncontrolled pain and have experienced firsthand the sad necessity of pain medications. This topic is frequently brought up in my conversations with doctors and healthcare professionals and was

the focus of a recent discussion I had with the CEO of a world-class cancer treatment center in which he articulated his concern that the reaction to the opioid crisis would prevent his team from providing necessary and appropriate end-of-life care.

Lastly, I have spent the majority of my 30-plus-year career in healthcare providing services surrounding the pharmaceutical industry with a focus on working to enable patient access to the medications they need.

As you all know, AmerisourceBergen's role in regard to prescription opioid medications is one of a logistics provider and distributor. We are responsible for getting FDA-approved drugs from pharmaceutical manufacturers to DEA-registered pharmacies that dispense them based on prescriptions by licensed healthcare providers.

We have no ability and no desire to encourage the prescribing or dispensing of pain medication. We do not manufacture or promote the prescribing of these medications. And we are not qualified to interfere with the very personal clinical decisions made between patients and their physicians.

Here are some things that AmerisourceBergen does do. For more than a decade, we've reported every opioid order we distribute on a daily basis to the DEA. So every order, every shipment, every day. We use statistical-based algorithms and data analytics tools to monitor

and assess every order we receive in an effort to identify, stop, and report suspicious orders.

Just as importantly, we continuously focus on enhancing our diversion control efforts. And our best-in-class diversion-control team endeavors to track patterns and behaviors beyond just individual suspicious orders that have led us to refuse service or terminate service to pharmacies we've identified as problematic, including several of the pharmacies we have all heard about today in West Virginia.

And we collaborate with and support others who are also working hard to address the crisis, partnering with others across the country to provide drug deactivation and disposal resources, and with our customers, not-for-profits, and innovators to support take-back programs and advance ideas that could help combat the opioid abuse epidemic.

We believe we've taken meaningful action, but this epidemic cannot be solved unless we improve the ways we work together. Communication and technology between the DEA and pharmaceutical distributors should be enhanced. Specifically, the sharing of the DEA's comprehensive data of all opioid sales to all pharmacies on a de-identified basis would alert distributors if pharmacies are receiving controlled substances from other DEA registrants.

Beyond improved data sharing, additional DEA guidelines for distributors with uniform standards for suspicious ordering monitoring programs would create a more consistent approach across the more than 900 registered distributors in the industry and, in turn, more actionable input for law enforcement professionals.

We also support a number of solutions that are not specific to distributors, including revising prescriber guidelines, mandatory e-prescribing for controlled substances, enhanced prescription drug monitoring programs to enable physicians and regulators to determine if patients are obtaining prescriptions in more than one State, and a number of the proposals the subcommittee considered just last week.

Our work to play a role in combating abuse while supporting clinically appropriate access will never be complete. We always strive to be better. I join you today with an open mind and a sincere desire for additional guidance and ideas from this committee.

Thank you.

[The prepared statement of Mr. Collis follows:]

******** INSERT 1A-1 ********

Mr. Harper. Thank you, Mr. Collis.

The chair will now recognize J. Christopher Smith, former president and CEO of H.D. Smith Wholesale Drug Company.

Mr. Smith.

STATEMENT OF J. CHRISTOPHER SMITH

Mr. Smith. Good morning, Chairman Walden, Chairman Harper, Ranking Member DeGette, and members of the subcommittee. Thank you for inviting me here today.

I would like to start by telling you a little bit about H.D. Smith, how it began, and the vision that guided it from the very beginning.

My grandfather, who was a pharmacist, had the idea for it. And with that idea from his own father, my father founded H.D. Smith in Springfield, Illinois, in 1954, because he saw that there was a true need for a wholesale drug distributor that would commit to serving small town and rural independently owned mom-and-pop pharmacies and downstate hospitals as there was no other wholesale drug distributor like that in Springfield.

My father's vision in starting the company was to make certain that a wholesale drug distributor would not only commit to serving these underserved communities, but he did so with the mission that patient

care should never be disrupted because a rural small town pharmacy, hospital, or later, inner-city pharmacy, could not quickly and reliably supply the medicines that the patients in these communities needed right when they needed them.

This is the mission and vision he taught to me and my brother as we later joined the company and rose through its ranks over time. As a child, I sometimes accompanied my father when he, himself, would make emergency deliveries at night or over weekends. And as an employee of H.D. Smith, I did the same as well, along with many others. That is and always was our legacy.

I first began working for H.D. Smith full-time in 1980 as a buyer and gradually moved my way up through the ranks over the years. In September 2007, I was appointed president and COO. In March 2015, I became president and CEO.

In January 2018, H.D. Smith was acquired by AmerisourceBergen, and I no longer hold any office, position, or employment with H.D. Smith.

But it is important to remember that since its founding in 1954 until its acquisition in 2018, H.D. Smith always remained a family-owned business, which I am very proud to have served. I am certain, absolutely certain, that H.D. Smith's new management will observe my family's guiding principles just as loyally as I tried so

hard to do myself.

I share the committee's grave concern about the opioid crisis and am committed to doing all we can to address it. We always took seriously our responsibilities to distribute controlled substances appropriately. We had a DEA license. We sold only to DEA- and State-licensed pharmacies and hospitals. We followed DEA regulations in handling controlled substances. We reported all our purchases and sales of controlled substances to the DEA.

My company distributed all kinds of pharmaceutical products. Only a small percentage were controlled substances, including pain medication. We didn't advertise or promote the medication or do anything else to encourage doctors to prescribe them or pharmacies to dispense them. Our job as a distributor was to fill orders that pharmacies sent us.

In fact, as a distributor, we could only see part of the distribution chain -- the pharmacy that we supply. We didn't see the prescriptions the pharmacy filled or know the doctors who wrote them or have any contact with knowledge of the patients.

As a distributor, we had to manage to the twin imperatives of ensuring that we distributed pharmaceuticals appropriately, for legitimate purposes, and ensuring the pharmacies that they had the products they needed when the patient arrived with a prescription so

as to ensure undisrupted patient care.

To meet this challenge, we created strong diversion control systems and continually improved them overtime. We always did our very best to make sure that all orders we shipped went to pharmacies that dispensed medications only on legitimate prescriptions for legitimate medical reasons.

I am certain AmerisourceBergen will continue my company's proud tradition and do everything that can be done to help with the solutions to the opioid crisis in this country.

Thank you.

[The prepared statement of Mr. Smith follows:]

******** INSERT 1A-2 ********

Mr. Harper. Thank you, Mr. Smith.

I ask unanimous consent that the contents of the document binder be introduced into the record and to authorize staff to make any appropriate redactions. Without objections, the documents will be entered into the record with any redactions that staff determines are appropriate.

[The information follows:]

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

Mr. Harper. At this point, each member will have the opportunity to ask questions, and I will recognize myself first for 5 minutes.

I want to thank you all for participating in today's very important hearing. As the subcommittee closely examines this very serious opioid crisis, I think it would be helpful at the outset to help establish a baseline of understanding. And I would like for each of you to answer each question that I am going to ask now.

First, do you believe that the actions that you or your company took contributed to the opioid epidemic?

Mr. Barrett.

Mr. Barrett. Thank you, Mr. Chairman.

Mr. Harper. We're really looking here, because I've got a lot of questions, yes or no. And if it is not either one --

Mr. Barrett. No. No, sir, I do not believe that we contributed to the opioid crisis.

Mr. Harper. We'll come back to you then.

Dr. Mastandrea.

Dr. Mastandrea. Yes.

Mr. Harper. Mr. Hammergren.

Mr. Hammergren. No.

Mr. Harper. Mr. Smith.

Mr. Smith. I believe H.D. Smith conducted itself responsibly

and discharged its obligations.

Mr. Harper. Is that a no?

Mr. Smith. That is a no.

Mr. Harper. Okay.

Mr. Collis.

Mr. Collis. No. I believe we -- it's a no for AmerisourceBergen.

Mr. Harper. Do you acknowledge -- another question for each of you -- do you acknowledge that your company had past failings in maintaining effective controls to prevent the diversion of opioids?

Mr. Barrett.

Mr. Barrett. I believe that our organization understood the responsibilities and conducted them as best they could with the understanding at that time. I have no reason to challenge the good faith of the decisions made by people many years ago. But I can say that the decisions, as I mentioned in my commentary today, that we might have made on some of those pharmacies would look differently today.

Mr. Harper. Is that a no?

My question was, do you acknowledge that your company had past failings in maintaining effective controls to prevent the diversion of opioids?

Mr. Barrett. I think our organization understood its

obligations. We did resolve with regulators where we had areas where we thought we could have done better, and I think those resolutions satisfied the right balance of serving patients and satisfying those controls, sir.

Mr. Harper. So is that a yes, it's now a no? I'm trying -- I mean, I'm a little --

Mr. Barrett. I am looking back on history. And what I'm describing is an organization that I believe did its job at the time understanding its responsibilities to address the responsibilities of controlled drugs.

Mr. Harper. Dr. Mastandrea, the question is, do you acknowledge that your company had past failings in maintaining effective controls to prevent the diversion of opioids?

Dr. Mastandrea. Yes.

Mr. Harper. Mr. Hammergren.

Mr. Hammergren. Our organization has worked for decades to try to meet our obligations under the DEA regulations. And we continue to work today to evolve our processes to understand what they're asking us to do and make sure that we have state-of-the-art capabilities in place.

Mr. Harper. It seems like a pretty simple question. Do you acknowledge that your company had past failings in maintaining

effective controls to prevent the diversion of opioids?

Mr. Hammergren. In the past we've had challenges understanding the expectations that our regulator would like us to follow.

Mr. Harper. Mr. Smith.

Mr. Smith. Again, I believe H.D. Smith has acted responsibly. So the answer would be no.

Mr. Harper. Mr. Collis.

Mr. Collis. I believe we've always discharged our duties effectively and responsibly and have maintained an adequate diversion program.

Mr. Harper. The number of opioids shipped to pharmacies in small towns of West Virginia has been astonishing: nearly 800 million opioids in total distributed to West Virginia in just a 5-year period, 20.8 million opioids to Williamson, and nearly 17 million opioids to a single pharmacy in Mount Gay-Shamrock over a decade, 9 million opioids in just 2 years to Kermit.

Do the extraordinary volume of opioid shipments to pharmacies in small towns of West Virginia indicate a breakdown in the suspicious order monitoring system?

Mr. Barrett.

Mr. Barrett. Mr. Chairman, it is a very important question. I don't believe that the volume in relation to the size of the population

is a determining factor. We often know that there's a small population, a town, which serves a large service area that may have a medical center or a cancer institute in the nearby area.

I have said, and I said in my statements, and I repeat here, that I think some of the decisions on particular pharmacies in West Virginia, knowing what we know today, we would have made different decisions, sir.

Mr. Harper. Dr. Mastandrea.

Dr. Mastandrea. Yes.

Mr. Harper. Mr. Hammergren.

Mr. Hammergren. We had a pharmacy in Kermit, West Virginia, called Sav-Rite that we actually terminated in that period of time.

What I can say is that, knowing what we know today, in hindsight, we wish we would have terminated that relationship sooner.

Mr. Harper. Mr. Smith.

Mr. Smith. Can you repeat the question?

Mr. Harper. The question is, do the extraordinary volume of opioid shipments to pharmacies in small towns of West Virginia indicate a breakdown in the suspicious order monitoring system?

Mr. Smith. I don't believe we had a breakdown in our system.

Mr. Harper. Mr. Collis.

Mr. Collis. If you're talking specifically about

AmerisourceBergen, we didn't ship to any of those pharmacies. If you're talking about the industry, I believe it probably did.

Mr. Harper. My time has expired.

The chair will now recognize the ranking member of the subcommittee, Ms. DeGette, for 5 minutes.

Ms. DeGette. Thank you, Mr. Chairman.

Gentlemen, each of you in your own way spent time very carefully telling this committee what your companies do not do in terms of prescribing or things like that. But in fact each of your companies, under the Controlled Substances Act, has a duty to make sure that that controlled substances are distributed correctly.

Would you agree with that statement, Mr. Barrett, yes or no?

Mr. Barrett. Yes, we do.

Ms. DeGette. And, Dr. Mastandrea.

Dr. Mastandrea. Yes.

Ms. DeGette. Mr. Hammergren.

Mr. Hammergren. We have a duty to support --

Ms. DeGette. "Yes" or "no" will work.

Mr. Hammergren. We have a duty to support the --

Ms. DeGette. You have a duty to make sure that controlled substances are distributed appropriately, correct?

Mr. Hammergren. We have a responsibility to --

Ms. DeGette. Okay.

Mr. Smith.

Mr. Smith. Yes, we have a responsibility.

Ms. DeGette. Mr. Collis.

Mr. Collis. Yes, we have a responsibility.

Ms. DeGette. And in fact I would direct your gentlemen's attention to exhibit 59 in the binder, which was a letter dated September 27, 2006, which was sent to every commercial entity in the United States registered with the DEA to distribute controlled substances.

And on page 3 of that letter, it lists an entire panoply of things that your companies are supposed to do. The letter was then followed up on two times in 2007.

I want to start with you, Dr. Mastandrea, and I want to ask you, Federal regulations require you to design and operate a system to disclose Federal operators from pharmacies. Is that correct?

Dr. Mastandrea. I'm sorry. I really don't understand --

Ms. DeGette. Federal regulations require you to design and operate a system to disclose suspicious orders from pharmacies.

Dr. Mastandrea. Yes, I believe that to be correct.

Ms. DeGette. Yes, they do. Okay.

And according to -- and I want to focus a little bit on Kermit,

which is a town of 600 -- I'm sorry, 400.

According to data that Miami-Luken provided to the committee, in 2007 your company supplied Sav-Rite pharmacy in Kermit with nearly 1.5 doses of opioids. Is that correct?

Dr. Mastandrea. I believe so.

Ms. DeGette. In 2008 your company supplied Sav-Rite with nearly 2 million doses of opioids. Is that correct?

Dr. Mastandrea. It's my understanding that is correct.

Ms. DeGette. And then in 2009 you supplied Sav-Rite with another 800,000 pills. Is that correct?

Dr. Mastandrea. I believe so.

Ms. DeGette. Now, in fact you continued supplying Sav-Rite until 2011 even though the pharmacy was actually raided by Federal authorities in early 2009. Is that correct?

Dr. Mastandrea. I believe so.

Ms. DeGette. Now, Dr. Mastandrea, we asked Miami-Luken to provide us with its entire due diligence file on the Sav-Rite pharmacy, and this is what we got from you.

Do you recognize these documents?

Dr. Mastandrea. No.

Ms. DeGette. Okay. We can have somebody hand them to you, but I will assure you it's about 15 pages of purchase orders and sales

orders.

Do you think this is a sufficient due diligence file for all of the number of opioids that you were sending to this one Sav-Rite pharmacy in Kermit, West Virginia?

RPTR BRYANT

EDTR CRYSTAL

[11:00 a.m.]

Dr. Mastandrea. No.

Ms. DeGette. Okay. Thank you. And you know what, thank you for your honesty today. I appreciate it.

I want to ask you now, Mr. Hammergren, a question. Now, in 2006, McKesson supplied Sav-Rite pharmacy with nearly 2.3 opioid pills, which is more than 190,000 a month. Is that correct?

Mr. Hammergren. I believe so.

Ms. DeGette. And in 2007, McKesson again supplied Sav-Rite with over 2.6 million opioid pills, or more than 222,000 pills per month. Is that correct?

Mr. Hammergren. I believe so.

Ms. DeGette. Now, in your written testimony, Mr. Hammergren, you put a lot of thought into using population statistics and other arguments to justify your shipments to Sav-Rite and other pharmacies. We just heard Mr. Barrett talking about that, too. But when the committee asked you to provide McKesson's due diligence file for Sav-Rite, you gave us a single document from 2007.

Do you recognize this document, sir?

Mr. Hammergren. No, I don't.

Ms. DeGette. Okay. It's exhibit 3 in the binder.

Do you recognize that document now? You don't.

Mr. Hammergren. This is first time I've seen this document.

Ms. DeGette. Okay. Well, I will tell you for the record that this document, which says declaration of controlled substances purchases, which is a two-page document, is the only documentation that McKesson gave to this committee when we asked for the due diligence file for Sav-Rite.

Do you think that this fulfills the requirements of the DEA that your company do due diligence for distribution of opioids to this city?

Mr. Hammergren. I believe our relationship with Sav-Rite should have been terminated immediately.

Ms. DeGette. Yes or no, do you think this is sufficient documentation to show compliance with the rules of the DEA?

Mr. Hammergren. We continue to evolve our diligence --

Ms. DeGette. Yes or no will work, sir.

Mr. Hammergren. I've not reviewed the document. I can't provide an answer to that.

Ms. DeGette. Okay. Thank you very much.

Thank you, Mr. Chairman.

Mr. Harper. At this time, the chair will recognize Chairman

Walden, chair of the full committee for Energy and Commerce, for 5 minutes.

The Chairman. Thank you, Mr. Chairman.

And I appreciated the opportunity I had yesterday to meet with several of you and talk about how we work together going forward as a country to prevent this kind of disaster from continuing or ever happening again.

Mr. Hammergren, between 2006 and 2007 McKesson supplied Sav-Rite pharmacy in Kermit, as you've heard, a town of 400, 5.6 million opioids. Our research has indicated this pharmacy was fueled by prescriptions from a pill mill. This was widely known in the community.

In fact, our investigators have uncovered that the pill mill was widely known, and there were reports even in the media over years that indicated customers were selling pills in the parking lot and that the cash drawer was so full it could not be shut.

Now, McKesson started a program in 2007, I think you called it the Lifestyle Drug Monitoring Program, under which McKesson reviewed every single customer for high-volume orders for certain drugs. Is that correct?

Mr. Hammergren. That's correct.

The Chairman. Including hydrocodone and oxycodone. I think we referenced that in tab 1 in the binder.

So the initial threshold, as I understand it, set by McKesson was 8,000 pills a month. The document indicates that you picked that number as a reasonable monthly threshold, correct?

Mr. Hammergren. That's correct.

The Chairman. And so do you know the average number of hydrocodone dosage units or pills McKesson distributed to that Sav-Rite pharmacy that you terminated a relationship with back in 2007?

Mr. Hammergren. I do not.

The Chairman. So we did some research. It appears it's 9,650 pills a day, which averages to 289,500 hydrocodone pills in a 30-day month, which is more than 36 times the initial monthly threshold set by the program.

The program required distribution centers to review any order in excess of the threshold and document why orders above the threshold were shipped.

Now, according to a document produced by McKesson, all customers had been reviewed by June 12, 2007. This clearly should have identified Sav-Rite, considering your own distribution was 36 times higher than the threshold you set. I think that document's in tab 2.

So did this program identify the Sav-Rite pharmacy?

Mr. Hammergren. It did not, sir. It should have been terminated sooner.

The Chairman. And if so, on what basis did McKesson decide to continue supplying hydrocodone far above your own threshold? This is what we're trying to figure out.

Mr. Hammergren. Our systems at the time were not automated enough, certainly, and we didn't flag it fast enough and get it fast enough.

The Chairman. So are there any documents justifying the continued distribution to Sav-Rite?

Mr. Hammergren. I don't know, sir. But, as I've testified, we terminated that relationship as soon as we became aware that the purchases were as you described.

The Chairman. In your testimony you note that the large distribution figures highlighted by the press in this investigation reflect a volume of opioid orders, quote, "not inconsistent," close quote, with the rate at which opioids were prescribed.

If this is the case and 9,600 pills a day distributed by McKesson to Sav-Rite in 2007 is reasonable, then why set the initial monthly limit at 8,000 per month? Or is this something you just -- the system did not catch?

Mr. Hammergren. We did not properly manage that Sav-Rite relationship and certainly didn't do it soon enough.

The Chairman. I see. So what we're trying to figure out is, are

there other Sav-Rites out there today? And this would apply to everybody on the panel. What is it in the systems you have or the DEA have that allowed this to happen then, and are they in place today to prevent this from happening? How do we shut down these pill mills?

Mr. Hammergren. We certainly learned, Mr. Chairman, from that experience at Sav-Rite, and we realized that we needed automated systems that don't allow any order to ship out of our facilities that are past those thresholds.

So today Sav-Rite pharmacy wouldn't get a single order from McKesson. Our systems block those orders as they're inbound. And if they want to have that order shipped we have to go out and do an investigation at that pharmacy to justify any increase.

So if they open -- if a pharmacy somewhere was going to open a new relationship with a hospice, our people would go out and view that and understand whether that is a legitimate business reason, exactly for your purpose.

The Chairman. And are your systems in place today that would identify an overprescribing physician or facility that is driving too many pills? How does that work?

Mr. Hammergren. That's one of the challenges, frankly, with the systems that McKesson has. We don't see the prescribing systems that are reported out of the pharmacy. So the way we have to manage it is

to determine a suspicious order based primarily on quantities compared to average pharmacies that are similar.

And clearly, the challenge in that is that suspicious is really an isolated individual customer-by-customer evaluation that isn't informed by the physician population, the prescribing habits, et cetera.

The Chairman. Unfortunately, my time has expired. I'm sure we'll have questions for the record. I'd appreciate the feedback from all of you on that topic, because we're trying to find solutions here.

Thank you, Mr. Chairman.

Mr. Harper. Thank you, Chairman Walden.

The chair will now recognize the ranking member of the full committee, Mr. Pallone, for 5 minutes.

Mr. Pallone. Thank you, Mr. Chairman.

I'm trying to run through this quickly, so I may have to try to have you summarize.

This committee's investigation has uncovered a number of shortcomings in the way that some distributors handled the distribution of opioids as this horrible epidemic unfolded. But what I really want to know is, moving forward, how do we ensure that adequate systems are in place to detect the kinds of problems that have clearly led to the oversupply and diversion problems we've seen in West Virginia?

For example, in Kermit, population 400, several distributors each sent millions of pills to a single pharmacy, and it's hard to understand why certain distributors didn't have systems to flag and prevent some of these shipments.

Another example, Miami-Luken alone sent almost 1.5 million pills to Sav-Rite in 2007 and almost 2 million pills in 2008, and on its face these levels seem ridiculous. At the end of the day, this pharmacy was raided and its owner was sentenced to prison.

So let me start with Dr. Mastandrea.

Have you made changes to your system to compare the number of pills you send a pharmacy against the population of that region to catch something like this before it gets out of control? Quickly, because I have more questions.

Dr. Mastandrea. Thank you, Congressman.

Yes, we have made changes. We've made significant changes. We have a full-time compliance officer that monitors all -- we're not that big, so it's not that hard to monitor our opioid distribution.

We have purchased a commercial algorithm-based system that stops the suspicious order in real time, is reported to the DEA in real time. We have site visits. We have an investigator that makes site visits. We review the accuracy and timeliness --

Mr. Pallone. I'm going to have to cut you off, only because I

want to ask Mr. Barrett a question.

Cardinal provided two pharmacies, Hurley Drug and Family Discount, which filled prescriptions for Dr. Katherine Hoover, and her clinic was widely known as the pill mill and Federal authorities closed it in 2010. Dr. Hoover was the number one prescriber in the entire State, yet she seemed to be able to write scripts for local pharmacies for years before her clinic was shut down.

One of your fellow distributors reported that Dr. Hoover alone was responsible at one time for 69 percent of the hydrocodone prescriptions at Hurley Drugstore in Williamson and more than half of the hydrocodone prescriptions at Family Discount.

So, Mr. Barrett, are there lessons that you believe can be taken from what happened with Dr. Hoover that will change how you conduct due diligence going forward?

Mr. Barrett. Ranking Member Pallone, thank you. And the answer is yes, I think we would do things very differently today. That kind of order volume would have been picked up and stopped just statistically by our algorithms.

I think the subjectivity of judgment of whether a pharmacy is legitimate or not legitimate today is really not the question. We look at data, and if the data tells us there is an aberrant pattern, we simply stop.

In this case, as it turned out, there was a bad actor in the area, a doctor, which we later found out, which is why we shopped shipment. But today's systems would simply stop that.

Mr. Pallone. All right. Let me go to McKesson.

McKesson has reached two settlements with DOJ about alleged failures to monitor for suspicious orders.

So, Mr. Hammergren, how will it be different this time? What serious changes have you made to your systems to flag suspicious orders?

Mr. Hammergren. We certainly have learned lessons from our experience in the past. And our systems today are automated and not subjective. As Mr. Barrett just said, we shut those orders off inbound in the door.

We also have hired very experienced, DEA experienced people to come out and help us investigate facilities before we bring them online and to make sure that we've not brought a bad actor on at any point in the process.

I think the thing that would continue to help us is if we can put physicians in a place where they have more information when they're prescribing, and certainly at the pharmacy level help the pharmacies understand red flags of patients that may be getting multiple doses in different directions.

So I think there's more that we can do as an industry. Blocking

the orders is certainly important, but you can imagine every time we block an order, there are legitimate patients in some of those pharmacies looking for their medications. So it's a little bit of a blunt force.

Mr. Pallone. Last question, going back to Mr. Barrett.

Cardinal also reached two settlements with DOJ over these same issues, and it's only fair I ask you the same question. How will this time be different? How can you assure us that you've addressed the issues raised in the settlement agreements? What specific enhancements have you made to your system?

Mr. Barrett. Thank you for the question.

The settlement in 2008 reflected the rising of what was internet pharmacy. Our organization I think was doing what it thought was right to adapt to that.

At the same time, we saw emergence over the next few years of pain clinics, many of which were legitimate, by the way, but as it turns out some were not.

And I think we had to learn during that process of the shift of this crisis. I think we've learned that and our systems today reflect that learning.

Mr. Pallone. Thank you.

Thank you, Mr. Chairman.

Mr. Harper. The chair will now recognize Mr. Barton for 5 minutes.

Mr. Barton. Thank you, Mr. Chairman.

And thank each of you for attending voluntarily. We didn't have to subpoena you. We appreciate that.

And, Mr. Collis, I understand that you forego back surgery to appear today, so we really appreciate you. I noticed you stood up a little bit ago and walked. Dr. Burgess will prescribe an opioid if you don't make it through the hearing.

This is an unusual hearing because each of you provides a much-needed list of products that are legal, and all of you represent corporations that have generally had a very positive record in your industry. And yet, we have a huge problem, 115 people a day are dying of opioid overdoses, and most of those are from legally prescribed opioids.

I'm an industrial engineer. I'm kind of a simplistic person. Our system that we're looking at starts with the patient and the doctor relationship. The doctor prescribes an opioid. It's sent to a pharmacy. The pharmacy accumulates orders and sends to a wholesale distributor, which is one of your companies in most cases. You get your drugs from a manufacturer.

The whole system is overseen by the DEA and is a part of a culture

which has evolved that pain is something that should be addressed in any way possible. And at the time the epidemic really took off, there wasn't a huge public outcry over opioid prescriptions. It's different today. The culture today is looking at the problem differently than it did 10 years ago or 15 years ago.

My first question, since you folks are part of the legal distribution system, is the overuse of legal opioids a solvable problem, yes or no? Legal opioids.

Let's start with the gentleman down at the end and work our way down.

Mr. Barrett. Yes, Congressman. Thank you for the question.

I think the practice of medicine is evolving, and I think that we know more than we did today. And I think, in fact, the prescribing of legal opioids, high-potency opioids, is declining.

Mr. Barton. I really just need --

Mr. Barrett. I think the answer is yes, it can be solved.

Mr. Barton. Yes or no?

Dr. Mastandrea. Yes, sir.

Mr. Hammergren. Yes, better informed physicians will solve the problem, I think.

Mr. Barton. Mr. Smith.

Mr. Smith. The use of drugs always come with a risk-return

tradeoff. So I think there will always be some risk-return tradeoff to this category of drugs and any other. So I'm not exactly sure what you mean by solve.

Mr. Barton. Well, I think "solve" is a pretty common term.

Mr. Smith. But I think we can greatly improve the situation.

Mr. Barton. You know, fixed.

Mr. Smith. I think that we can bring it back into much more acceptable levels.

Mr. Barton. I've got a minute and a half left.

Mr. Collis. There are already significant changes in prescription trends for legal opioids, but I think it can be vastly improved. I don't know if completely solved.

Mr. Barton. Generically, everybody said yes, with some modification. I think it can be, too.

Now, this is a little bit trickier question. What percent responsibility do you believe your part of the chain of the industry have in solving the problem, from zero percent, we have no responsibility, to 100 percent, it's all our responsibility?

You just all said that it is solvable. Now, what percent of responsibility do you think the distribution, wholesale distribution system has in solving the problem?

Again, we'll just start at one end and go to the other.

Mr. Barrett. Congressman, I don't feel qualified to give a percentage of responsibility. I think all of us in the healthcare system have to work together to address this, and I think we should.

Mr. Barton. Do you agree that you have some responsibility?

Mr. Barrett. I believe that we've got a role in an integrated healthcare system.

Mr. Barton. So you have some responsibility.

Dr. Mastandrea. Congressman, I believe that it's a shared responsibility among many different players, physicians, pharmacists, State medical boards, State pharmacy boards, DEA.

Mr. Barton. But you agree you have some responsibility?

Dr. Mastandrea. I have said that, yes.

Mr. Barton. Your company, your industry, not you personally.

Dr. Mastandrea. The percentage is shared.

Mr. Hammergren. We have a role to play, Congressman, certainly. And in your example, one of the most important roles we play is to make sure we find suspicious customers and suspicious orders and cut off the supply to those customers.

Mr. Barton. My time has expired, but I'll let each of you two.

Mr. Smith. Well, I would just say that H.D. Smith had its role as a distributor to play and did so.

Mr. Collis. I get the benefit of going last, so I just would say

it's very difficult to ascribe a percentage, given the shared responsibility.

Mr. Barton. Well, I think you do have a responsibility, I think it's a significant responsibility, but I don't think you have a majority of the responsibility. And hopefully, by the time we end these hearings, we'll get all the players in here.

Thank you, Mr. Chairman.

Mr. Harper. The chair now recognizes the gentlewoman from Florida, Ms. Castor, for 5 minutes.

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

This committee's investigation has made plain that drug wholesale distributors flooded areas of West Virginia and other parts of the country with massive amounts of opioids. This has fed into the public health epidemic that is costing us at least $8 billion per year nationwide and costing lives, 116 deaths every day. We focused on West Virginia because it has the highest opioid death rate in the country.

Mr. Barrett, your company Cardinal shipped 1.5 million opioid pills each year from 2009 to 2011 to a single pharmacy, Family Discount, in the small town of Mount Gay. That is an average of about 4,000 pills per day.

At the subcommittee's March 20 hearing, DEA testified that that amount shipped to that single pharmacy was, indeed, excessive. And

this was after Cardinal had been sanctioned by the DOJ through a settlement agreement for not following the law.

Mr. Barrett, you've said that the wholesalers don't control demand, but clearly you have a responsibility under the law to highlight and flag these suspicious orders. How did Cardinal estimate what was appropriate for a given pharmacy?

Mr. Barrett. Congresswoman, thank you for your question.

I think our organization recognizes it as a dual responsibility. One is to provide medicine to a system requiring it as prescribed, and the other is to do what we can to prevent those from falling in the wrong hands.

We've evolved over the years. We've become more attuned to the changes. I think today --

Ms. Castor. But this kept happening even after DOJ had warned you and you had accepted responsibility and said you would do a better job.

In more recent years, this pharmacy's total purchases of these drugs declined dramatically. In 2015 and 2016, it was down to about 500,000 pills. And that wasn't just from Cardinal, that was from everyone, from all distributors. That was but a fraction of what Cardinal alone had shipped them in earlier years.

So isn't this a clear reflection that that was not the medical

need in the community? The amount being shipped didn't reflect what could have been appropriately used in rural West Virginia, especially after DOJ had already warned you.

Mr. Barrett. Congresswoman, let me make two points about that, if I may.

One is I've acknowledged earlier that I had wished that we had moved earlier to stop shipping to that pharmacy, which we have many years ago.

Second, I think the evolution was of our looking at a system that was focused on the legitimacy of a pharmacy -- which, by the way, is still in business -- and the awareness of something happening in the system, which was a bad doctor. And we should have moved more quickly on that.

Ms. Castor. I'd now like to turn to McKesson.

Mr. Hammergren, your company McKesson distributed over 1.8 million opioid pills each year in 2006 and 2007 to Family Discount Pharmacy. That's an average of about 5,000 pills per day in this rural small town. Based upon a figure cited by DEA, McKesson shipped Family Discount roughly six times the amount of hydrocodone that an average pharmacy in rural West Virginia would have received during those years.

So a similar question to you. McKesson delivered millions of pills to the single pharmacy. Clearly, that's not reasonable and you

should have flagged that and stopped that right away. Why didn't you?

Mr. Hammergren. We did terminate the relationship with that pharmacy. And like Mr. Barrett, I would have liked us to have made a decision faster. That's the answer. We caught a bad pharmacy and shut it down.

Ms. Castor. And as I mentioned, this pharmacy's total purchases of oxycodone and hydrocodone dropped dramatically, but that wasn't until 2015, 2016. And that means the amount of opioids your company alone shipped back in 2006 was over three times as much as the pharmacy got from all distributors in 2016.

Now, you in your testimony, you pointed to, well, overprescribing by doctors, maybe the DEA should have done more, pharmacy bad actors. But you can't reasonably claim that this pharmacy's dispensing filled the medical need. I mean, it took you years to respond. Why was that?

Mr. Hammergren. I can't comment on the medical need, Congresswoman. What I can say is that today in our systems, any shipment that was outside those boundaries would never have happened. It would have been shut down and reported immediately.

Ms. Castor. Why didn't you address -- given that this community was ravaged by opioid deaths and addiction, and the town of Williamson was even nicknamed Pilliamson, don't you take responsibility for what was happening back then? Was it the profit motive simply overcame

the -- you saw that paying the penalties under settlement agreements was a cost worth paying because you were making so much money?

Mr. Hammergren. Congresswoman, we take all of these matters very seriously. Any settlement with a regulator we take very seriously. Our systems have evolved, and we continue to invest heavily to make sure that situations like that don't happen again.

Ms. Castor. I think this was the opposite of due diligence that was required under the law, and we're going to be looking for greater accountability.

Thank you, and I yield back.

Mr. Harper. The chair now recognizes the vice chairman of the subcommittee, Mr. Griffith, for 5 minutes.

Mr. Griffith. Thank you, Mr. Chairman.

Mr. Hammergren, in the limited time I have, I'm going to ask you a series of yes/no questions. But first, as background, my district borders southern West Virginia. McKesson was a major supplier of pharmacies there, as were some of the others, distributing millions of pills, most into West Virginia in towns that were between 30 and 60 miles from my district.

And last week, I was at an opioid conference and look at this map that they gave us. That dark brown area are the deaths per capita in the Commonwealth of Virginia, and you will note there's a correlation

with the dark brown areas most common to the border with West Virginia.

And so, gentlemen, when you say that, you know, you're not sure that you have a role -- not all of you have said that -- it flies in the face of that map and the people of my district.

So, Mr. Hammergren, in May of 2008 McKesson Corporation and the Justice Department and DEA entered into a memorandum agreement, tab 4 in the binder there. You signed on behalf of McKesson Corporation on page 10 of the settlement and release agreement and page 7 of the settlement agreement.

Do you recall signing the document, yes or no?

Mr. Hammergren. Yes.

Mr. Griffith. The conduct at issue in this first settlement with the DEA was that the DEA believed certain McKesson distribution centers did not report suspicious orders and did not have effective controls against diversion. Because of the serious commitments that McKesson made to the U.S. Government and the $13.25 million civil penalty -- you recall that, don't you?

Mr. Hammergren. I do.

Mr. Griffith. Two months later, you presided over a July 23, 2008, board of directors meeting. And according to the board minutes at tab 12 in the binder, public policy issues were discussed affecting the corporation. In an accompanying slide at tab 13, DEA suspicious

orders, defined as orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency were categorized as high, in terms of the degree of political urgency, and impact to, and the level of engagement of the corporation.

The urgency of the DEA suspicious orders issue was tied to the May 2008 settlement, wasn't it, yes or no?

Mr. Hammergren. We certainly took the settlement, Congressman, very seriously.

Mr. Griffith. The corporation's high level of engagement meant McKesson management would put in a high level of effort to carry out the promises made in your 2008 memorandum of agreement. Isn't that correct?

Mr. Hammergren. It is correct that it was a top priority for us.

Mr. Griffith. In your experience as an executive at McKesson Corporation, when the company makes a legal commitment, especially one with a high level of engagement, the corporate leadership gives a directive and the appropriate personnel carry it out. Isn't that correct?

Mr. Hammergren. Congressman --

Mr. Griffith. Yes, correct?

Mr. Hammergren. Congressman, we took it very seriously.

Mr. Griffith. Yes. However, according to media reports, from

2008 to 2013, the McKesson Aurora, Colorado, warehouse filled 1.6 million orders, but only reported 16 suspicious orders. The Landover, Maryland, warehouse, which supplied West Virginia, routinely failed to report and fulfilled suspicious orders placed by numerous pharmacies in West Virginia.

While the Landover facility was closed in 2012, the serious lack of suspicious order reporting does not show a high level of engagement by McKesson, does it, yes or no?

Mr. Hammergren. We took our responsibilities very seriously.

Mr. Griffith. Yes or no? Failing to live up to the 2008 agreement does not show a high level of commitment, does it?

Mr. Hammergren. That's not true. We had a high level of commitment, Congressman.

Mr. Griffith. And you failed. The DEA alleged that McKesson distribution centers ignored thresholds and supplied pharmacies volumes of controlled substances that exceeded their assigned amount without a proper review. That also does not show a high level of engagement, does it, yes or no?

Mr. Hammergren. Congressman, we had a high level of engagement.

Mr. Griffith. Were any McKesson personnel fired in connection with any of the failures noted in the 2017 memorandum of agreement? That's at tab 5.

Mr. Hammergren. Congressman, the people involved today in the CSMP are vastly different than the people in 2008.

Mr. Griffith. Was anybody fired?

Mr. Hammergren. Congressman, the people are different today. Many of them have left the corporation.

Mr. Griffith. But they weren't fired.

Mr. Hammergren. We don't talk about specific --

Mr. Griffith. I'm not asking you to talk about specifics. I'm asking you to tell me if anybody got fired. Did you hold anybody personally responsible for what was happening in West Virginia and in Colorado and other parts of the country?

Mr. Hammergren. Congressman, everybody at the company is accountable to do what's right.

Mr. Griffith. But no one was fired. All right.

In January 2017, McKesson Corporation and the Justice Department and the DEA entered into another memorandum of agreement, because you didn't live up to 2008. As a result of this agreement, McKesson paid a record-setting $150 million fine.

In this memorandum of agreement, in section 2, acceptance of responsibility, McKesson acknowledged it failed to identify or report to DEA certain orders by certain pharmacies which should have been detected by McKesson as suspicious. This involved 12 out of 30

McKesson distribution centers. More than a third of your distribution centers were involved in these failures.

That is a widespread systemic failure. Wouldn't you agree?

Mr. Hammergren. Congressman, our organization in 2008 was working closely with the DEA.

Mr. Griffith. This is 2017.

Mr. Hammergren. I understand. And we have created a program that really we believe is meeting their needs, focused on suspicious customers and knowing our customers.

Mr. Griffith. And a third of them were out of compliance.

Mr. Chairman, I yield back.

Mr. Harper. The gentleman yields back.

Before I recognize the next person, Mr. Hammergren, it seems like a pretty easy question to answer if anyone was fired in response to Mr. Griffith's question. And the answer is yes, no, I don't know, or I refuse to answer. What is your answer?

Mr. Hammergren. Yes, people were fired as a result of this.

Mr. Harper. Thank you very much, Mr. Hammergren.

I'll now recognize the gentlewoman from Illinois, Ms. Schakowsky, for 5 minutes.

Ms. Schakowsky. I have to say that I'm pleased that you're all with us today to discuss the role your companies played in supplying

the opioid epidemic, but I have to also say that this reluctance even to answer that simple question, or reluctance, always qualifying your responsibility -- clearly, you had a responsibility.

And, Mr. Hammergren, you acknowledge that you wish you had terminated your relationship with Sav-Rite earlier and that you did end that relationship. But why did you then -- why did you ship 5 million pills before you shut it down?

Mr. Hammergren. Congresswoman, thank you for the question. Certainly, we've learned from our experience during the 2006, 2007, over a decade ago, and today's systems are much more robust than they were then. Our orders actually aren't even processed today if they're above thresholds. In those early phases of 12 years ago, our systems weren't as automated as they are today.

Ms. Schakowsky. You know, all of you, I hope, will acknowledge that since 1971, your companies are required by Federal law to halt and report suspicious orders of prescription opioids.

Did you, before all of this broke, have a process to do that, if I could just go down, to obey the 1971 law?

Mr. Barrett. Yes. Our organization, Congresswoman, has had a clear sense of the Controlled Substance Act and reported all orders to the DEA of narcotics.

Ms. Schakowsky. Okay.

Mr. Mastandrea?

Dr. Mastandrea. Yes, we did have a system in place, Congresswoman.

Mr. Hammergren. Congresswoman, we also reported all orders required.

Ms. Schakowsky. Mr. Smith.

Mr. Smith. At different points in time, the expectations of the DEA were different.

Ms. Schakowsky. Microphone, please.

Mr. Smith. At different points in time, the expectations of the DEA were different. Up till about 2007, the DEA expectation was for us to report suspicious orders after the fact with monthly reporting, and we did so.

It was in 2007 that the DEA expressed a very different expectation concerning controlled substance orders and that if it was suspicious they asked that we develop a system to hold those orders at the time they were received.

Ms. Schakowsky. Okay, I'm going to move on.

Mr. Smith. We implemented that system in 2008.

Ms. Schakowsky. Sir.

Mr. Collis. Congresswoman, AmerisourceBergen didn't exist. There were many predecessor companies. I'm not aware of any of them

that weren't committed to compliance with all Federal statutes.

Ms. Schakowsky. I just think it's really important to put on the record that this is not a new requirement, that yes, maybe there wasn't the kind of enforcement, but nonetheless, your companies had a responsibility.

I also want not only to look back and see what went wrong, but also to look forward to see how to do better. And it is apparent now that pharmaceutical corporations are taking advantage of the opioid epidemic by spiking the price of life-saving drugs like naloxone, and that that, in my view, is unacceptable. Pharmaceutical corporations can't start this epidemic with irresponsible and reckless on day -- recklessness one day -- and then turn around and profit the next.

So I wanted to again ask Mr. Hammergren, McKesson distributes Evzio, which has raised its price from $690 to $4,500. So what does McKesson earn net per unit for Evzio?

Mr. Hammergren. I can't answer that question, Ms. Congresswoman. I would say that we don't set the prices for branded drugs. Those are set by the manufacturers.

Ms. Schakowsky. And how much does McKesson net annually for the distribution of Evzio?

Mr. Hammergren. Congresswoman, I don't have that information. I'd be happy to get it for you.

Ms. Schakowsky. McKesson also distributes Narcan. What does McKesson earn net per unit for Narcan?

Mr. Hammergren. Congresswoman, I don't know the answer to that question.

Ms. Schakowsky. And how much does McKesson earn net annually for its distribution of Narcan?

Mr. Hammergren. I don't know that question.

Ms. Schakowsky. So I would expect that we'll put that in writing and that we'd get this information. Because, you know, you can't have it both ways, fellas. You know, the opioid epidemic is there, and now for life-saving drugs those prices are going through the roof.

And I yield back.

Mr. Griffith. [Presiding.] I thank the gentlelady, and now recognize the gentleman from Texas, Dr. Burgess.

Mr. Burgess. Thank you, and thanks for having the hearing.

Mr. Hammergren, let me just continue on that line for a moment, because I think this is an important point. You as a distributor do not set the list price of the compounds that you were being questioned about. Is that correct?

Mr. Hammergren. I don't believe so. If they're branded patented drugs, we don't set the price.

Mr. Burgess. So you receive an order and you fill an order.

You're agnostic as far as the price. That is set by the person selling the product. Is that correct?

Mr. Hammergren. Congressman, the manufacturer sets those prices, to the best of my understanding.

Mr. Burgess. Mr. Collis, you mentioned -- it was almost an offhanded mention, but it is important -- one of the first hearings that I sat through in this subcommittee in 2005 was a hearing on why don't doctors prescribe enough pain medicine. And you referenced that there are some people who are watching this debate who are concerned are they going to be able to get the medicines for the treatments for which they are being treated.

And I think that is a legitimate concern and we do need to be mindful. We cannot overlook the fact that there are serious, serious problems that need to be fixed. But I thank you for bringing that up, because that is an important reference point that we sometimes overlook.

Mr. Smith, let me just ask you, we've actually heard some back-and-forth, and I think there was a question on the other side dealing with a document or a letter from Mr. Rannazzisi at the DEA, Drug Enforcement Administration, that said, don't just report to us the total sales.

Mr. Collis, I think you said, we just report, we're not making

a judgment whether it's suspicious, this is what we deliver to place A, B, or C. Is that correct?

Mr. Collis. We do report every day, and we also report on a monthly basis all cost data, but we do make determinations of what is a suspicious order and we hold them.

Mr. Burgess. Sure, and I appreciate that. This is what is so frustrating to me for an all-hands-on-deck situation. The DEA says, don't just report your raw data. But you have algorithms. The DEA should have algorithms. I think the Center for Medicare and Medicaid Services probably should have algorithms in their database so that they can identify who are the outliers.

Not saying that someone is doing something wrong, it may be a pain clinic, it may be a cancer clinic, but let's afford some extra scrutiny if this is the amount of product that's going out so we don't end up with a situation such as in Kermit.

Now, Mr. Smith, let me ask you, your company, and I think you testified to this, your company reports suspicious orders. What does the DEA do with that information when you report it?

Mr. Smith. I don't really know.

Mr. Burgess. You've sold your company, I understand that.

Mr. Smith. But I don't really know. And the DEA, as we talk about the DEA, the DEA has not been the same in their outlook, attitude,

and interaction with the industry over my career. For most of my career, the interactions with the DEA were very collaborative and very purposeful, in terms of working with them to try to control controlled substance distribution.

Back about 10 years ago, with the advent of this expectation of holding orders, it became very, very difficult to interact with the DEA and to get feedback. They were, in fact, as evasive as possible in the midst of this crisis to us, in terms of giving us guidance. More recently, that attitude has been changing and improved.

Now, as you point out, as of 2018, I was pretty much out of the picture. I can only hope that the DEA will continue to work collaboratively with the industry going forward.

Mr. Burgess. And what you have just related is information that independently I and my staff have acquired, that the number of administrative actions against registrants by the DEA -- now I'm merely talking about doctors, because that was my focus when I began this -- but when you look at the numbers in the committee's memo, how things have just been going up through the roof, the number of administrative actions, I'm not talking about for West Virginia, I'm talking about for the whole country, 21 in 2014, at the same point that point in the graph was probably at its apex.

I've got to believe that the DEA -- I'm not saying that everything

that you've reported -- I want you to do your job, but I want the DEA to do their job, and it doesn't look like they have been. And I'll just share with you, they've been very, very difficult to get information out of the agency.

I hope you're right, Mr. Smith, I hope it is changing. But we cannot fix this problem if the agency required to be in charge simply is insensitive to our requests for information.

I thank all of you for being here today.

Mr. Chairman, I yield back.

Mr. Griffith. I thank the gentleman, and now recognize the gentleman from New York, Mr. Tonko, for 5 minutes.

I understand you have a UC request.

Mr. Tonko. I'll yield to Ms. Castor.

Ms. Castor. Thank you, Mr. Chairman.

I'd like to ask unanimous consent to submit for the record information relating to the salaries of the CEOs of the big three drug wholesalers, including the McKesson CEO, who made over $692 million in the 10 years leading up to 2017.

Mr. Harper. [Presiding.] Without objection, so ordered.

Ms. Castor. I yield back.

Mr. Tonko. Thank you, Mr. Chair.

Mr. Barrett, I asked about Cardinal's sales to pharmacies that

filled prescriptions written by two doctors, Katherine Hoover and Diane Shafer. Federal law enforcement put both of these doctors out of business around 2010.

Dr. Shafer was sentenced to 6 months in prison after she admitted to writing illegal opioid prescriptions. According to the United States Attorney's Office for the Southern District of West Virginia, she wrote more prescriptions than entire hospitals did between 2003 and 2010.

Dr. Hoover was the single largest prescriber of controlled substances in West Virginia between 2002 and 2010. When her clinic was raided, she fled to the Bahamas.

Cardinal served two pharmacies, Hurley Drug and Family Discount, which filled prescriptions from Dr. Hoover. In September 2008, a Cardinal employee raised an alarm about Hurley Drug in a memo, which noted that Hurley filled prescriptions from Dr. Katherine Hoover even though other pharmacies refused to fill her prescriptions.

According to this document, another pharmacist stated that he would not fill Hoover's prescriptions because, quote, "He had ridden by the office of Dr. Hoover and there are lines of people standing outside waiting to get into the office," close quote.

In fact, according to a 2011 news report in the late 2000s, quote, "Crowds of people filled the lot outside Dr. Hoover's clinic," and it

was, in quote, "an open secret that it was essentially a pill mill."

Is that accurate? And did your employee observe the lines of people outside that office as early as 2008, which could indicate a possible pill mill?

Mr. Barrett. Congressman, I've been briefed on those memos.

Mr. Tonko. Pardon me?

Mr. Barrett. Yes, I've been briefed on that report.

Mr. Tonko. Okay. So your employee's memo appears in Cardinal's due diligence file for Hurley, but it is unclear what actions Cardinal took based on it. For example, Cardinal continued to supply Hurley for another 6 years.

So why? Do you know whether Cardinal ever followed up on this memo?

Mr. Barrett. So we've not shipped that company high-potency opioids for many years. I mentioned earlier that based on what I've seen, I wish we had taken action earlier. I think we had a system that allowed for too much subjectivity about the legitimacy of a pharmacy.

Today's system simply would have taken the data, seen outlier data, and shut it off. And, as I said earlier, I've seen enough to know that I wish we would have acted earlier.

Mr. Tonko. Cardinal also supplied Family Discount Pharmacy, sending it more than 5.5 million pills from 2009 to 2012, after which

you ended your relationship with them.

According to a document in another distributor's files, in 2009, 51 percent of Family Discount's hydrocodone prescriptions came from Dr. Hoover. That distributor also reported to the committee that Dr. Hoover was responsible for 69 percent of Hurley Drug's hydrocodone orders, which the distributor considered a, quote, "cause of concern."

Mr. Barrett, in your written testimony, you say you wish you had asked a different set of questions before distributing to this pharmacy. It appears that Cardinal may have missed the red flags connecting Dr. Hoover to both Hurley Drug and Family Discount. So I'd like to know how this will be fixed going forward.

Mr. Barrett. Congressman, it is a great question. It is fixed going forward. As I mentioned earlier, I think both of the pharmacies to which you referred were influenced by this same doctor who, as it turns out, was a bad doc.

Today's systems would not allow subjectivity. Today's systems would simply say, we set thresholds or limits, based on certain criteria, primarily relationship between controlled drugs and on other drugs and the nature of the community. And if it crossed those thresholds, we simply would shut the order down, and that's what we do today.

Mr. Tonko. So is it your belief that these two situations would

have been caught much earlier?

Mr. Barrett. In today's system, absolutely.

Mr. Tonko. It's unbelievable that these numbers of pills were being sold and that this pill mill was getting away with activity.

I just hope that all of the distributors before us have much more rigorous due diligence standards in place today that can help them spot these red flags.

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

Mr. Harper. The gentleman yields back.

The chair will now recognize Mrs. Brooks for 5 minutes.

Mrs. Brooks. Thank you, Mr. Chairman.

Mr. Smith, I'd like to talk about Family Discount Pharmacy that has been mentioned here already. Your company terminated Family Discount Pharmacy's ability to purchase controlled substances in 2011. Is that correct?

Mr. Smith. I believe that we discontinued selling them anything at that -- around that time.

Mrs. Brooks. Correct, in 2011. But prior to that, was H.D. Smith aware of the prescriber we've heard about, Dr. Katherine Hoover, who was responsible for providing over 262,000 hydrocodone prescriptions to Family Discount Pharmacy as well as other nearby pharmacies in February of 2008? Was H.D. Smith aware of the Dr. Hoover

problem?

Mr. Smith. I am not aware of the specific timing of when our due diligence team became aware of that issue. I do know that with Family Discount that when we implemented our controlled substance ordering monitoring program, we began to limit the controlled substances that we sent and --

Mrs. Brooks. Excuse me. Did Dominic Grant work for you.

Mr. Smith. I beg your pardon?

Mrs. Brooks. Did Dominic Grant for you? Did George Euson work for you?

Mr. Smith. George Euson worked for me.

Mrs. Brooks. In 2008?

Mr. Smith. Uh-huh.

Mrs. Brooks. Where I have an email indicating that Dr. Hoover had prescribed, had filled over 262,000.

Mr. Smith. Okay.

Mrs. Brooks. So I do believe that your director of corporate security was aware of that.

Mr. Smith. Thank you.

Mrs. Brooks. If you turn to tab 16 you'll see that over a year later H.D. Smith noted in a November 12, 2009, report -- 2009 -- that Dr. Katherine Hoover was responsible for 51 percent of the hydrocodone

scripts being filled by Family Discount.

Now, knowing that, was Family Discount Pharmacy -- had that become a concern for your company in November of 2009?

Mr. Smith. It appears that it was at that time.

Mrs. Brooks. And did H.D. Smith report this to the DEA?

Mr. Smith. I'm not sure what the timing of what we would have reported to the DEA was.

Mrs. Brooks. Well, in fact, we know that Family Discount did make some reports to the DEA between May of 2008 and May of 2009, but not at this time, in November of 2009.

In April of 2015 then, interestingly, did H.D. Smith -- so you then terminated with Family Discount in 2011, but then, going to April of 2015, did H.D. Smith make the decision to resume its business relationship with Family Discount Pharmacy?

Mr. Smith. That's possible. We have a robust program, and that includes reviewing new data that comes along. It is possible that we could reopen an account if we saw that there were indications that the situation was different.

On the other hand, that doesn't end our robust due diligence. We can continue to do that and can decide to close it again.

Mrs. Brooks. Let's talk about the due diligence. Were you aware that Family Discount had been dropped by some of the other distributors

here at the table when you renewed your relationship? Were you aware of that?

Mr. Smith. No, I was not aware.

Mrs. Brooks. So please turn to tab 19, speaking of due diligence. An email was sent by an H.D. Smith employee in January of 2016 expressing concern that the company was providing controlled substances to Family Discount's other location, located just 3 miles away, despite the fact the company, your company, had never performed any new customer due diligence on that pharmacy. Were you aware of that?

Mr. Smith. No.

Mrs. Brooks. The employee's email also noted that this pharmacy had reached its hydrocodone threshold only 12 days into a month. Were you aware of that?

Mr. Smith. No.

Mrs. Brooks. And did you report the suspicious activity to DEA?

Mr. Smith. I do not know.

Mrs. Brooks. I would assume you did not.

Following the January 2016 correspondence, did either Family Discount location continue to place controlled substance orders that exceeded the monthly thresholds established by H.D. Smith, this new amazing system you put in place?

Mr. Smith. I do not know.

Mrs. Brooks. Well, you might want to take a look at emails in June and October of 2016 showing that Family Discount had placed orders in excess of established thresholds, that, in fact, one of your employees indicated that the justification was to meet our guideline to obtain our monthly discount. What monthly discount?

Mr. Smith. I'm not sure what that refers to.

Mrs. Brooks. A monthly discount with the manufacturer?

Mr. Smith. No.

Mrs. Brooks. Monthly discount -- no idea what monthly -- what deals were being cut?

Mr. Smith. I'm not sure what that refers to.

Mrs. Brooks. H.D. Smith then blocked Family -- H.D. Smith block Family Discount's ability to purchase controlled substances on February 16 of 2018. Were you in charge at that time of the company?

Mr. Smith. No. My managerial responsibilities ended at the acquisition of H.D. Smith in January of 2018.

Mrs. Brooks. In January of 2018. Well, I will say that according to a document we received, the committee, the company cited its reason for taking this action and finally terminating the relationship with Family Discount was due to reference negative news articles.

With that, I yield back.

Mr. Harper. The chair will now recognize Mr. Ruiz for 5 minutes.

Mr. Ruiz. Thank you, Mr. Chairman.

This crisis continues to overwhelm our healthcare system, and as an emergency physician I have been involved in the front lines taking care of opioid-addicted and overdosed patients way before it made national headlines. Doctors struggle with treating pain adequately and identifying drug seekers.

Hospitals in my district are seeing an increase in uncompensated care, because they are seeing more and more patients with chronic opioid-related kidney, heart, and lung complications, not to mention overdoses.

It is good that more funds are going to fight the opioid epidemic. I agree with that. I encourage that. But if you eliminate mental health coverage, emergency care coverage as an essential health benefit, or if you repeal Medicaid expansion, then you actually are taking 1 step forward and 10 steps back and are actually hurting patients and making the problem worse.

Moving forward, I think it is critical that the various players -- DEA, hospitals, physicians, pharmacists, manufacturers, and distributors -- work together to identify and implement systems and processes that move us forward to identify and implement solutions.

I understand that as this crisis has continued to escalate, many

of you have put internal systems in place to increase accountability, but we have been told that before and it turned out to be untrue. And there's a difference between what you have on paper and what you are actually implementing.

At our March 20 hearing, members of this committee described the quantity of opioid pills sent to particular pharmacies in this region and asked DEA Administrator Patterson whether those amounts were excessive and whether the distributors failed to adequately exercise due diligence. The DEA agreed on both counts.

So I'd like to quickly go down the line and find out whether the problems that led to this overdistribution have been fixed.

Dr. Mastandrea, Miami-Luken distributed substantial quantities of pills to certain places in West Virginia. For example, your company sent Sav-Rite pharmacy in Kermit, a population of only 400, nearly 2 million pills in just 1 year.

Would Miami-Luken's current system discover these large shipments and more closely examine them to determine if such a large volume was appropriate and not going to a rogue operation, such as a pill mill?

Dr. Mastandrea. Yes, sir.

Mr. Ruiz. And how can you guarantee us that that system will be implemented?

Dr. Mastandrea. It's already implemented.

Mr. Ruiz. So you're saying that there's no mistakes currently being done that you know of? There's no way of -- what is your system to find and review in case you do make a mistake?

Dr. Mastandrea. Each order is reviewed by our -- we purchased a Buzzeo system. It's a computer algorithm that tells us whether or not the order deviates from frequency, pattern, size. And we stop it in real time if it does. We pend the order. If the order is adjudicated to be an appropriate order, then we release it. If it's not, then we report it.

Mr. Ruiz. The DEA data indicate that McKesson also supplied the Sav-Rite in Kermit, population of 400, with almost 5 million opioids over a 2-year period.

So, Mr. Hammergren, if a pharmacy serving a comparable population placed those large orders today, particularly in an area hard hit by opioid diversion, would McKesson's monitoring systems be capable of flagging these orders for further review to make sure that they are not affiliated with a pill mill?

Mr. Hammergren. Congressman, that's a good question. We would not ship to Sav-Rite today.

Mr. Ruiz. Okay. So, in terms of your system, if this happened to another comparable city, do you have a system in place to flag? The

first question.

Mr. Hammergren. We have a system in place that would block the order if it was a pharmacy that was outside of a boundary, a threshold being set.

Mr. Ruiz. So why hasn't that happened? Why did you have another settlement in 2017, when you told us this exact same thing in 2008?

Mr. Hammergren. We had a system in place from 2008 to block suspicious orders. Our settlement in 2017 was really related to our reporting of suspicious orders.

Mr. Ruiz. And so the implementation of those reporting and also the shipping of orders.

So I think it's very important that we also identify, which we see on multiple scenarios where corporations and agencies will hold up their policy on paper, but then the actual implementation of those are either not enforced or they're not transparent to determine what's working and what's not working.

Mr. Collis, since you are now responsible for H.D. Smith's customers as well as your own, this question is for you. Without debating the merits of the West Virginia litigation that's currently undergoing, do you now have a way to assess orders for high volumes of pills against the populations receiving them?

Mr. Collis. I believe we do. I believe we have a robust system

and we've always had one.

Mr. Ruiz. Okay. I yield back my time.

RPTR ALLDRIDGE

EDTR CRYSTAL

[11:57 a.m.]

Mr. Harper. The chair will now recognize the gentleman from Michigan, Mr. Walberg, for 5 minutes.

Mr. Walberg. Thank you, Mr. Chairman. And thank you for having these hearings.

As we look at the various players -- and today, of course, we have distributors -- we had the opportunity to have DEA in front of us, and that was an amazing time of testimony as well with amazing failings that went on in DEA also.

But this epidemic knows no boundaries. When we talk of losing 115 Americans every day to the opioid epidemic, these are people that are our neighbors, our friends, our fathers, our family members, our sons, our daughters, our mothers. It knows no bounds. But the sheer number of opioids dumped into small town America is simply baffling and incomprehensible to me.

Many of us have tragic stories of pill mills in our district. And my district in Michigan is, unfortunately, no different. In Monroe County, one doctor alone was able to get his hands and prescribe over 2 million pain killers in just two short years.

I, for one, am interested to have the distributors here today to tell us exactly how and why this type of thing happens and to hear the steps that they have or will take.

Mr. Collis, you wrote in an editorial last year that AmerisourceBergen has, and I quote, "reported and stopped tens of thousands of suspicious orders since 2007," end quote. If a specific pharmacy is reported for suspicious orders multiple times during a short period, would that trigger a heightened investigation of that customer?

Mr. Collis. I believe it absolutely would. I wouldn't say we don't make mistakes, but I will tell you one of pharmacies that's been mentioned several times, we had them on service for 38 days, and we reported them 36 of the 38 days. And on the 38th day we stopped servicing them.

Mr. Walberg. In the editorial, you also noted that AmerisourceBergen uses, and I quote, "complex algorithms to identify and stop orders that are deemed to be suspicious." From 2012 to 2015, AmerisourceBergen reported 394 suspicious orders for a single West Virginia pharmacy, Beckley Pharmacy.

If the company opens an investigation of a pharmacy like Beckley, the investigators would want to know the percent of controlled substance prescriptions the pharmacy filled, correct?

Mr. Collis. That's correct.

Mr. Walberg. Whether there are signs of drug activity around the pharmacy. Is that correct?

Mr. Collis. We would review the type of business that they are servicing. Some of my colleagues on the panel here have talked about the type of business. If they service a hospice account or pain management clinic, we would investigate that.

Mr. Walberg. If there are any known pill mill doctors writing prescriptions, you would want to note that, correct?

Mr. Collis. If we knew that they were servicing a pill mill doctor, by your description, we would not service that pharmacy. If their business was designed around that, we would not service that.

Mr. Walberg. AmerisourceBergen reported 199 of its suspicious orders for Beckley Pharmacy between 2013 and March of 2014. But documents your company provided to the committee indicate that Amerisource didn't investigate the pharmacy until February 2015.

Please, if you would, turn to tab 46 to see the investigator's February 2015 report, which found, and I'll read that:

The pharmacist said that 50 percent of prescriptions he filled were for controlled substances and that customers told him other pharmacies wouldn't fill their prescriptions. Some of the pharmacies top 10 prescribers were among the top hydrocodone prescribers in the

State, and the pharmacy security guard referred to customers as drug addicts and drug dealers and said he witnessed numerous drug deals in the parking lot after customers filled oxycodone prescriptions.

Amerisource didn't stop doing business with that pharmacy until November 2015, 10 months after the investigator's report, which itself came only after your company filled hundreds of suspicious orders. The company is supposed to use, and I quote, "complex algorithms" to identify problems pharmacies have.

So why did it take so long?

Mr. Collis. I have a team, some them are behind me. We trust them. I think that we -- I have never heard of this pharmacy before. But we're committed to continuous learning. And if we made mistakes, hopefully we'll rectify them and they won't happen in the future.

Mr. Walberg. Well, if we could get the response to that question, since you're not aware of it. It comes from your reports and the reports that we have in front of us.

Mr. Collis. We ship 100,000 orders a day. It's not feasible that I would know about all the orders.

Mr. Walberg. Well, we'll appreciate the response to that.

Mr. Chairman, I have other questions I'll have included in the record.

Mr. Harper. Certainly. Each of the witnesses will be aware, you

may be getting written questions following this. We'd ask for your response to those as quickly as possible, including an answer to that question, Mr. Collis, at your earliest convenience.

At this time, the chair will recognize the gentlewoman from California, Mrs. Walters, for 5 minutes.

Mrs. Walters. Thank you, Mr. Chairman.

And, Mr. Barrett, these questions will be asked of you.

When Cardinal began setting threshold limits for pharmacies in 2008, the company set Family Discount's hydrocodone threshold at 27,000 doses a month. In a little over a year, Cardinal adjusted the pharmacy's threshold 14 times. And by August 2009, it was cleared to receive 110,000 hydrocodone pills a month.

The pharmacy's threshold for hydrocodone reached a peak of 150,000 dosages a month in January 2010, a level it remained at for a year and a half before Cardinal officials reviewed and reduced it.

Mr. Barrett, when a pharmacy goes over its monthly drug threshold, does Cardinal inquire about the reason for the higher drug order?

Mr. Barrett. Thank you, Congresswoman.

Today, if an order reaches its threshold, it simply stops. So the process is the threshold is set, and the threshold is set based on a number of factors, the size of the community it serves, not just the population but the community it serves. Other factors. Does it

serve a hospice center, a surgical center, et cetera. If an order reaches that threshold, that limit, it simply stops.

Mrs. Walters. But in the past, did it question it, before today?

Mr. Barrett. So as I look back at some of the historical documents, I think the thresholds probably should have been set with a different set of eyes. I've mentioned this notion of asking different questions. And I think today we'd probably set those quite differently.

But I think at the time of those pharmacies you referred to, thresholds probably should have been adjusted down more quickly.

Mrs. Walters. Did they -- did Cardinal make an assessment as to whether the explanation for increasing its threshold made sense and verified it in any way?

Mr. Barrett. It's hard for me to answer that fully. Again, this is part of the history. I have no reason to question the good intent of those doing that kind of assessment. They were professionals. I think they were looking at the incoming order of prescribing.

I think now we know some of that prescribing was driven by some behavior that we would have liked to have caught in the physician world. And today that simply could not happen.

Mrs. Walters. Okay. In Family Discount's case, the pharmacy gave several explanations as to why it needed higher drug threshold.

But in April 2009, the pharmacy said its hydrocodone volumes increased because of the closure of a nearby pharmacy called Sav-Rite pharmacy.

Mr. Barrett, do you know why Sav-Rite closed in 2009?

Mr. Barrett. I'm sorry, Congresswoman, I don't.

Mrs. Walters. Okay. Well, it closed because it was raided by the DEA as part of a crackdown on prescription drug diversion.

Sav-Rite, which is located about 30 miles away from Family Discount, closed after it was raided by the DEA, as I just mentioned. And the raid was covered in the local media at the time, but due diligence files Cardinal provided the committee do not indicate that the company knew about this event. Is that something Cardinal should have investigated or known?

Mr. Barrett. I think today under our procedures in our, essentially, know your customer model, we try to take into account what factors that we can that are fact. Those weigh into the judgment along with various analytical tools that relate to the nature of the community of practices that a pharmacy serves. So very likely today that would have been a factor that would have been -- it would have been caught in the system.

Mrs. Walters. Okay. Cardinal's policies indicate that, as of 2016, two people must now sign off on the decision to raise certain drug threshold levels above 20,000 and above 40,000 a month. Before

that policy was adopted, was Cardinal failing to properly vet threshold level adjustments?

Mr. Barrett. I'm not sure, Congresswoman, that I could say that we were failing to reflect that. I think we were using the tools of the moment. And it was probably much more subjective judgment than what would happen today. Today it is a much more rigorous, evidence-based, data-based decision, and it doesn't have the same kind of subjectively I think that was present at that moment.

Mrs. Walters. Okay. Cardinal Health has advised the committee staff that, starting in 2012, your corporation implemented stronger compliance systems. However, I would note that, in March 2017, the California State Board of Pharmacy filed a complaint against Cardinal's Valencia, California, facility for shipping suspicious orders, including hydrocodone, during 2012 to 2015, to Pacific Plaza Pharmacy.

I would further note that the conduct of the Cardinal Valencia facility figured in the 2008 $34 million settlement with the Justice Department and DEA. The shipments to Pacific Plaza involved sharp increases in the volume of controlled substances over a period of time. There were also orders of significant amounts of the highest available strength of drug compared to lower strengths, a red flag for illegitimate pharmacy dispensing.

I understand Cardinal is contesting the complaint. But,

Mr. Barrett, shouldn't Cardinal Health's stronger compliance system have been able to detect and to prevent these transactions?

Mr. Barrett. Congresswoman, if I'm responding, I think, to the case that you referred to, and, again, this is important, we ship to a pharmacy that had an employee that stole a product. We were then criticized for shipping to the pharmacy and not being able to detect that internal theft.

Again, I think this in some ways highlights part of the challenge. We ship to hospitals and pharmacies all over this country. There are things that may happen inside their watch.

If the volumes are not things that would normally hit our thresholds that are happening at a much lower level, and this can happen, that is something we probably would not somebody detect.

And so, again, this may or may not be the situation you're referring to. If it is, and I think it may be, that's essentially what the issue is.

But for us today, we are driven by strict thresholds, and those are limits on the amount of certain products, 120 categories of drugs that can go to certain pharmacies.

Mrs. Walters. Okay. Thank you.

I'm out of time.

Mr. Harper. The chair now recognizes the gentleman from Georgia,

Mr. Carter, for 5 minutes.

Mr. Carter. Thank you, Mr. Chairman.

And thank all of you for being here today. We appreciate this very much.

I have to say that I'm pleased thus far that my colleagues have not made this a witch hunt. But instead, I think they've asked some great questions and very fair questions.

What I've heard, and I've been kind of in and out, but what I've heard is that you've acknowledged that you have a responsibility here and that you understand that. What I think I've also heard is that if you knew back then what you know now, you'd do things differently. And I think that's true for all of us in this profession. And I say that having practiced pharmacy for over 30 years.

I'm going to ask you all to be very, very honest with me right now, because I'm concerned, as Dr. Burgess mentioned, about the role of the DEA.

Now, we've already had the DEA before this committee, and I think we had -- I think we kind of had it backwards. I wish I could have another shot at them, to be quite honest with you, to ask them some questions.

But let me -- I just ask any of you. I assume all of you are compliant to ARCOS, that you're reporting. What does DEA do with that

information? Do you know? And if you can be brief, because I've got a bunch of questions.

I ask you, Mr. Hammergren. Do you have any idea what DEA does with that information?

Mr. Hammergren. No, I don't, sir.

I would also say, Congressman, some of this testimony, you see these pharmacies switch wholesalers back and forth.

Mr. Carter. Absolutely.

Mr. Hammergren. We don't see it before that happens.

Mr. Carter. Okay.

Mr. Collis, do you have any idea what the DEA does with this?

Mr. Collis. No. No. We would like more feedback. We'd also like [off mic] the rules, for example, on what constitutes a suspicious order.

Mr. Carter. Okay.

Mr. Collis. Very, very helpful. I know one of the gentlemen and I think we would be very interested in complying with the rules.

Mr. Carter. Let me ask any of you. Has the DEA ever come to you and said do not send opioids to that pharmacy or to that clinic or to that hospital? Has anybody ever been told that by the DEA?

Mr. Collis. Not to my knowledge.

Mr. Carter. Have they ever given you any kind of directions or

guidelines? You know, I get it if they're outside of the rim, you know, and obviously there's something going on. But, I mean, aside from that.

Mr. Collis.

Mr. Collis. Well in 2007, we had a lot of discussion with them, and we developed our current controlled substance order monitoring program and with the understanding that this was where they wanted the industry to go to.

So I would say we do have regular consultation with them. We have worked with them on training programs.

I wouldn't say it's -- I would say, like all relationships, it can be improved and worked upon.

Mr. Carter. Right. Right.

Mr. Collis. But it's not totally without communication and collaboration.

Mr. Carter. Let me ask you this. Obviously, you know the difference in a schedule two drug and a schedule three drug. The DEA schedules those depending on the tendency for addiction.

When did hydrocodone become a C two drug?

Mr. Collis. I do not know.

Mr. Carter. I will tell you. It became a C two drug in 2014.

Why did it take so long, do you think, for the DEA to reclassify

hydrocodone from a C three to a C two drug? Do you treat C two drugs differently from C three drugs?

I know you do, because when I get them from you, or when I used to get them from you, I had to sign different documents that came in a different box. They came sealed.

Now, we're talking about all these pills that came here, and they weren't sealed, they weren't on a different invoice or anything else.

I'm just wondering, and, again, I wish I could ask the DEA this, why did it take so long to reschedule hydrocodone?

The last thing I will say is this. Mr. Smith, you were involved in the situation in West Virginia. And I'm not taking up for you guys. You guys have a responsibility, and I believe you take that responsibility very seriously. And what I said earlier, I believe. I believe that if you had it to do to over again, you'd do some things differently.

Mr. Smith, there was a doctor, a Dr. Katherine Hoover, who accounted for 69 percent of all the prescriptions that were written during that timeframe in this town in West Virginia. Do you know whatever came about with Dr. Hoover? Do you know where she is today?

Mr. Smith. I believe they referred to her earlier, and that she's either -- oh, I'm sorry.

Thanks, Steve.

I believe she was referred to earlier and that there's either been disciplinary action taken with her or she's left --

Mr. Carter. She fled to the Bahamas. She bought an island. Twenty-one doctors, Dr. Burgess pointed out, 21 doctors in the whole Nation.

Now, when you're sending drugs to a pharmacy, and it's out of control, there's one of two things happening. Either that pharmacy is out of control and they're selling drugs out the back door, or there's a doctor who's out of control in that area.

Has the DEA ever come to you asking you about a particular doctor?

Mr. Collis. Not to the best of my knowledge.

Mr. Carter. Nobody has.

Dr. Mastandrea. We have received subpoenas regarding physicians.

Mr. Carter. Good. Thank you. I'm glad to hear that. And I hope that we will hear that.

I'm sorry. I'm out of time. But, again, we all have responsibility in this. All of us. There is no one solution to the opioid epidemic. All of us. Pharmacists, distributors, manufacturers, physicians, all of us have a responsibility.

And I appreciate your role in that responsibility and you accepting that role in that responsibility. This is very important.

You can help, and I hope that you are committed to helping. I believe that you are.

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

Mr. Harper. The gentleman yields back.

The chair will now recognize the gentleman from Pennsylvania, Mr. Costello, for 5 minutes.

Mr. Costello. Thank you, Mr. Chairman.

Mr. Barrett, the committee asked Cardinal Health how it assessed whether the 6.5 million opioid pills distributed to Family Discount Pharmacy over a 5-year period was an appropriate number to send to a town of less than 2,000 people. The company's response was that Family Discount in Mount Gay-Shamrock was a large pharmacy that served the broader Logan County, which has a population of 35,000 people.

When Cardinal investigators reviewed several high-volume purchases of controlled substances in 2008, they did not cite the county population in their investigation. They instead cited the population within a 35-mile radius of the pharmacy as 2,600 people. I know which figure looks better for the company, but why is the company now relying on the county population data when it cited a more limited area in its investigation of this pharmacy?

Mr. Barrett. Mr. Congressman, let me start by saying, and I have mentioned earlier, if we looked at that pharmacy today and those

patterns, we would have come to different conclusions. So I can only observe what I see in the documents back then.

I think the pharmacy is -- its volumes are not necessarily dictated by the size of the community. It's dictated by the nature of the customers that it serves: hospitals, clinics, surgery centers, regional centers.

So in some cases, rural centers -- excuse me -- rural pharmacies, which have small populations, search a large area. So I think that may have been part of the judgment.

What is important for me today is looking at it with today's eyes. And with today's eyes, I still think we would have made a different decision.

Mr. Costello. Thank you.

Cardinal also told the committee that when assessing pharmacy drug orders it doesn't have the full picture of how many pills are being sent to a pharmacy or the surrounding area by other distributors. That's because the company does not have the ARCOS data collected by the DEA. But this argument that the distributor has to see the full picture to recognize issues with its own distribution is nevertheless problematic, I think.

Using ARCOS data, the committee was able to determine how many opioids Cardinal alone dispensed to pharmacies in ZIP Codes surrounding

Family Discount. The company sent over 16 million hydrocodone and oxycodone pills to that West Virginia region between 2006 and 2016. Family Discount received 6.7 million of those pills and its Stollings location received another 1 million.

Mr. McKinley, I apologize if I pronounced Stollings wrong. I think I got it right, but if I did.

Cardinal could see that 46 percent of its own distribution of opiates to the region was going to two related pharmacies.

Mr. Barrett, can you really tell me that Cardinal needed to know what other companies were distributing in order to raise a red flag? I understand what you just said about hospitals in the region, but I'm trying to dig a little bit deeper here.

Mr. Barrett. So again, I can only repeat what I've said about this. I've seen enough in reviewing this file to say that we should have seen patterns earlier. But I think the comment that was in our document is generally true about how we do assessment of pharmacies, that there are many factors that go beyond simply the size of the community.

Mr. Costello. Right. But you did cut off Family Discount in 2012. Why is that?

Mr. Barrett. Again, I think our team had enough data at that point in that moment at that time to say we are not comfortable with

these levels of hydrocodone and oxycodone and at that point made a decision to cut off those pharmacies.

Mr. Costello. But that data did not yield conclusions as to other pharmacies at that moment in time? Presumably not if you didn't stop.

Mr. Barrett. I really can't answer that. I'm sorry. I just don't know the answer to that, sir.

Mr. Costello. In addition to knowing what Cardinal itself distributes to a pharmacy, the company can also ask a pharmacy to produce a drug dispensing report. Is that correct?

Mr. Barrett. I'm sorry. Could you repeat one more time

Mr. Costello. In addition to knowing what Cardinal itself distributes to a pharmacy, the company can also ask a pharmacy to produce a drug dispensing report. Is that correct?

Mr. Barrett. I think that may occur from time to time, yes.

Mr. Costello. In the case of Family Discount, Cardinal asked for and received drug dispensing reports, an example of which can be found on tab 55, tab 55 in the document binder. Dispensing reports contain information about all the prescriptions and drugs a pharmacy sends out the door, not just the drugs that Cardinal supplied. Is that correct?

Mr. Barrett. I think that's correct, sir.

Mr. Costello. And for Family Discount, investigators requested drug dispensing reports multiple times as they reviewed high orders

for controlled substances. Isn't that right?

Mr. Barrett. Sir, I believe all this is in the documents. But I believe that's correct.

Mr. Costello. Very good.

I will yield back the balance of my time.

Mr. Harper. The chair will now recognize the gentlewoman from Tennessee, Mrs. Blackburn, for 5 minutes.

Mrs. Blackburn. Thank you, Mr. Chairman.

Thank you all for being here today. We appreciate this.

And I think probably what you're hearing from us on each side of this dais is enough is enough. And you all have faced penalties. You have had settlements. You have had memorandums. We have covered every bit of that.

And just as we are doing more at this committee to get our arms around this issue, legislation that we are moving forward with, we expect you all to do more also.

And I have spent a lot of my time since I was in the senate in Tennessee, the Tennessee State Senate, doing roundtables, visiting treatment centers, sitting down with families, law enforcement, hearing their stories. And what we know is that the opioid crisis is different. The detox, the treatment, the recovery is different. And this is going to have to be a concerted effort to end this crisis.

And Senator Portman has CARA 2.0 in the Senate. I have it along with Congressman Ryan here in the House. It's totally bipartisan. Another billion dollars to go toward addressing this crisis. So we do expect you all to work with us on this.

And I have got kind of a different set of questions I want to run through fairly quickly, and this will be a yes or no. And I'm going to start with you, Mr. Barrett, straight down the list.

Have any of you personally met with families who have lost loved ones or survivors, individuals who are in recovery? Just yes or no right down the line.

Mr. Barrett. Yes, ma'am.

Dr. Mastandrea. Yes.

Mr. Hammergren. Yes.

Mr. Smith. I have not.

Mrs. Blackburn. You have not?

Mr. Collis. Yes.

Mrs. Blackburn. Okay. So four of you have.

Now, let me ask you this. Do you have employees who are in treatment or recovery for opioid addiction, and does your insurance cover that treatment for these employees? Because what I understand is it takes about a year to a year and a half for someone to rewire their brain. Yes or no, straight down the line.

Mr. Barrett. I believe our coverage does cover behavioral health issues.

Dr. Mastandrea. Yes, we do have employees who have had substance abuse problems, and we do cover substance abuse treatment.

Mr. Hammergren. Sadly, Congresswoman, I've had employees as well that are in treatment. And in addition to the insurance, we've also got a fund that helps them anytime it's outside of the treatment from insurance to cover those costs.

Mr. Smith. I was generally not told about any health conditions of any employees, so I can't speak to that. But I do believe that during my tenure that would have been covered.

Mrs. Blackburn. Yes or no is fine.

Mr. Collis.

Mr. Collis. I'm not aware. I do not know.

Mrs. Blackburn. You do not know.

Well, let me ask you this. When you started distributing the opioids, were you aware of the addictive nature of this drug? Yes or no, straight down the line.

Mr. Barrett. Our company's been distributing opioids --

Mrs. Blackburn. Yes or no.

Mr. Barrett. -- for as long as it's been in business. I would assume that we know that all drugs have side effects.

Mrs. Blackburn. Okay.

Yes or no.

Dr. Mastandrea. Yes.

Mrs. Blackburn. You were.

Dr. Mastandrea. We know the requirements of the DEA schedules.

Mrs. Blackburn. Okay.

Mr. Smith.

Mr. Smith. We know there's a tradeoff with every drug.

Mrs. Blackburn. Okay. All right.

Mr. Collis. It's done in a pure clinical decision.

Mrs. Blackburn. All right.

Okay. We've talked a little bit about your algorithms and the way you've changed your protocols, moving to more of an evidence-based database, a platform less subjective. And we hope that that helps with the distribution.

I want to know from each of you, how many pharmacies have you removed from your distribution list?

Straight down the line. You can say -- give me the number or "I don't know." And then you'll submit it for the record.

Mr. Collis. We have 800.

Mrs. Blackburn. I'll get to you in a minute.

Mr. Barrett.

Mr. Barrett. We have cut off or refused to do business with a thousand or more.

Mrs. Blackburn. A thousand.

You don't know? Please submit for the record.

Mr. Hammergren. Hundreds.

Mrs. Blackburn. Hundreds? I'd like an exact, please.

Mr. Smith. What time period are you asking for?

Mrs. Blackburn. Well, through the history of your company. How many of --

Mr. Smith. I wouldn't be able to give an exact number, but hundreds.

Mrs. Blackburn. Okay, find a number and let us know.

Mr. Collis. We have a robust list that we have 800 pharmacies.

Mrs. Blackburn. I would to know -- 800. That you've cut off or that you distribute to?

Mr. Collis. That we do not ship to.

Mrs. Blackburn. Eight hundred. Okay. That is wonderful.

And how often does your algorithm flag a -- and you all can submit this, because I'm out of time, and there are others who want questions.

I want to know, how often does your system flag a bad pharmacy? And then what is your threshold? You have mentioned thresholds several times, but you have not given a specific as to what that threshold is

that kicks a pharmacy out. And if each of you will submit that in writing, I'd appreciate it.

Thank you. I yield back.

Mr. Harper. The chair will now recognize the gentleman from New Jersey, Mr. Lance, for 5 minutes.

Mr. Lance. Thank you very much, Mr. Chairman.

Dr. Mastandrea, Miami-Luken noted that in June of 2015, following a review of Westside Pharmacy's dispensing data, the company identified concerns with two of the pharmacy's top prescribing physicians of oxycodone, Dr. David Morgan and Dr. Sanjay Mehta. The company has said that you expressed your concerns to the pharmacy's owner who assured you the pharmacy would no longer fill their prescriptions effective June 30 of 2015.

However, as I understand it, in October of that year, Miami-Luken learned that Drs. Morgan and Mehta continued to be among the pharmacy's top prescribing physicians.

When Miami-Luken learned that Westside pharmacy had not been truthful by continuing to fill prescriptions written by these doctors, did you drop the pharmacy as a customer?

Dr. Mastandrea. We probably dropped that customer within 30 days of finding out that she was not cooperating with us.

Mr. Lance. On November 4, 2015, your director of compliance

performed a site evaluation at Westside Pharmacy. You will find this evaluation in the binder at tab 33. Shouldn't your site investigators have investigated the pharmacy's falsehoods instead of ignoring them?

Dr. Mastandrea. I'm sorry. The question was shouldn't the investigators have done what?

Mr. Lance. Shouldn't your site investigators have investigated the pharmacy's falsehoods instead of apparently ignoring them?

Dr. Mastandrea. I think that they should have investigated the pharmacy in totality.

Mr. Lance. After you knew the pharmacy wasn't telling you the truth by continuing to fill prescriptions written by Drs. Morgan and Mehta, did Miami-Luken agree to increase Westside Pharmacy's oxycodone threshold in November 2015?

Dr. Mastandrea. I am not aware of that.

Mr. Lance. I request that you review the situation and give the committee an answer, yes or no. Not being aware of that is not sufficient, and please report back to the committee with the answer.

Dr. Mastandrea. My counsel will do so.

Mr. Lance. Thank you.

Given that the DEA cited Miami-Luken's relationship with Westside Pharmacy in its order to show cause, doesn't that raise a question in your mind about your company's due diligent efforts with respect to

this pharmacy?

Dr. Mastandrea. Congressman, we were in the process of vetting that particular customer at the time we received the order to show cause. We had already terminated -- I believe there were 13 different customers that were on the order to show cause and we terminated, prior to receiving the order to show cause, all of them with the exception of Westside Pharmacy, which we were in the process of vetting at the time. When we found that they were on the order to show cause, enough was enough, and we terminated the relationship.

Mr. Lance. It's my belief that the relationship was terminated at a point well beyond when it should have been terminated.

I realize that monitoring for and reporting suspicious records is often complicated. Therefore, I take this opportunity to discuss a proposal that may enable distributors and the DEA to use the data that is available to them in a more effective way. And this is for the entire panel.

Technology today that didn't exist when ARCOS was put into place is able to deliver information that would allow the DEA to stop a suspicious order before it is filled. I, along with colleagues in the Senate, I am working on a proposal that would create a new data platform for the DEA to utilize moving forward so that this situation is ameliorated to the greatest extent possible.

To the entire panel, will you commit to working with me and other Members of Congress -- and this will be completely bipartisan, I assure you -- to create a system that can effectively ensure that we are ready to police suspicious orders in a way that is truly effective? And as Congresswoman Blackburn suggested, going down the line.

Gentlemen.

Mr. Barrett. I would support any technology that would help us do this job better, yes.

Dr. Mastandrea. Yes.

Mr. Hammergren. I look forward to working with you.

Mr. Smith. I am no longer employed in the industry, but I wish you the best of luck.

Mr. Lance. Yes, we will need more than luck.

Mr. Collis. Yes. Absolutely.

Mr. Lance. Thank you.

I yield back the balance of my time, Mr. Chairman.

Mr. Harper. The gentleman yields back.

And I would like to clarify for the record that Miami-Luken did increase the threshold, as Mr. Lance described. The chair will now -- and also would like to put into the record a letter so signifying.

Without objection.

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

[The information follows:]

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

Mr. Harper. Now the chair will recognize the gentleman from West Virginia, Mr. McKinley, for 5 minutes.

Mr. McKinley. Thank you, Mr. Chairman. And thank you, because I'm not a member of this committee, for the opportunity to address the panel and carry on.

I'm from West Virginia we've been hearing about all day today. The fury inside me right now is bubbling over with how we're going to address this problem. And for several of you to say you had no role whatsoever in this, I find it particularly offensive when we've had over 900 people a year dying in West Virginia because of lack of attention on your algorithm and your operation. And deflecting responsibility saying, "I just had to fill the order," no, you had a role. You had a role.

So let me just -- Mr. Hammergren, if I could focus on you. You said you have notified the DEA of suspicious activity -- suspicious orders. But between years 2001 and 2014, did any of those suspicious orders involve West Virginia?

Mr. Hammergren. I can't be certain, Congressman. We've reported between 2000 -- in that period of time, around a million orders to the DEA as suspicious.

Mr. McKinley. Well, I just want to, for all of you, between 2001 and 2014, none of you were complying with State law. State law says

if there is a suspicious order that you file with the DEA, you're supposed to send a copy of that order to the West Virginia Board of Pharmacy, and none of you have done it between those time periods. Not only a suspicious order, but at the end of every month, you're supposed to file a report that says, during the past month, they give you 15 to the end of -- after 15 days, you're supposed to file a report with the Board of West Virginia Pharmacy saying no suspicious orders took place in West Virginia.

But you didn't do it. And that was some of the heart. That was the genesis. That's when this disease really took hold in West Virginia. And you weren't complying. But yet you said the same thing. You said: We're not responsible.

I think you very much were responsible.

So, Mr. Hammergren, again, do you agree that a person like Dr. Hoover should be held accountable for her actions and perhaps pay more than a fine for her actions?

Mr. Hammergren. Congressman, I don't know Dr. Hoover, and I don't know the situation of her case.

Mr. McKinley. Do you just think in general doctors that spread this poison, writing 40,000, 50,000, 100,000 of prescriptions on opioids, should pay a penalty?

Mr. Hammergren. Absolutely, Congressman.

Mr. McKinley. Okay. What about pharmacies, pharmacies that are following that order? The one that we have in particular, Sav-Rite pharmacy. Should that pharmacy, should that pharmacist be held accountable for what he's done?

Mr. Hammergren. In fact, I think that pharmacy was closed, per some earlier --

Mr. McKinley. What about -- no, no. It may have been closed. He may have lost his job. But what about him or her who filled the order? Should she have been held accountable?

Mr. Hammergren. I don't know the specifics. I can't comment on it.

Mr. McKinley. Okay. I'm coming back. I'm setting this up. I want to know whether you all should be held accountable. Because if the doctors and the pharmacies are being held accountable, I sure as the dickens would think you all have a role in this thing, too.

So if I could, I want to go back again, Mr. Hammergren, to you. Let me try again with another. Do you regret any role that your company has played in this crisis?

Mr. Hammergren. Congressman, I don't know how you could look at this crisis and not feel terrible about what's going on in this country. And I certainly believe in situations like the Sav-Rite pharmacy and --

Mr. McKinley. So you do regret --

Mr. Hammergren. I feel terrible about this --

Mr. McKinley. -- that what McKesson did in participating in this scourge that's ravaged this country, you regret it?

Mr. Hammergren. I feel terrible about this crisis.

Mr. McKinley. So what's the proper accountability? What's the punishment? It's just a slap on the wrist of maybe 100th of 1 percent of the revenue? What's the accountability, what's the punishment that fits this crime when 900 people in West Virginia lose their life or 115 people lose their lives across this country? Just a slap on the wrist? A financial penalty? Or should there be time spent for participating in this?

So I just want you to feel shame about your roles, respectively, in all of this, how we're going to get through this.

So apparently I have run out of time, but -- let me just leave it at that. I am so frustrated for the people in West Virginia and across this country that you all have not played and stepped up, took more responsibility for this.

I yield back my time.

Mr. Harper. The chair now recognizes the gentleman from Ohio, Mr. Johnson, for 5 minutes.

Mr. Johnson. Thank you, Mr. Chairman.

And, gentlemen, thank you for being here today.

I have listened with interest to today's testimony and the questions that you have responded to. It's a very tough subject. Eastern and southeastern Ohio sits at the epicenter of the opioid epidemic. I hear about it every day that I'm out and about in my district.

And I don't know if you've heard this yet today, but I'm glad you folks are at the table. And part of my questioning is going to be, where do we go from here? What are the solutions to this problem that you folks have been looking at and maybe some things that you're looking at down the road?

Let me start out with Dr. Mastandrea. Do I have that pronounced right? And I apologize

Dr. Mastandrea. Yes, sir.

Mr. Johnson. Okay.

As I mentioned, I represent eastern and southeastern Ohio. It includes the town of Wheelersburg in Scioto County. In 2008 Scioto County had an overdose death rate of more than 27 times the national average.

For several years, 2005 through 2011, Dr. Margy Temponeras owned and operated the Unique Pain Management Clinic there in Wheelersburg. This clinic was a pill mill. Temponeras saw more than 20 patients per day who paid cash, starting at $200 for each appointment, and received

monthly prescriptions for similar combinations of medications such as 120 to 150 pills of oxycodone and 90 pills of Xanax.

In April of 2017, Dr. Temponeras pleaded guilty in U.S. District Court to conspiracy to distribute a controlled substance, which she did through a pain clinic and dispensary.

Between November 2008 and August 2010, Miami-Luken supplied the Unique Pain Management Clinic with controlled substances, including oxycodone.

So my first question. According to the DEA, December of 2008 was the first full month that Miami-Luken began shipping to Dr. Temponeras. In that month's shipment, 97 percent of the total dosage units were controlled substances and 84 percent of the controlled substances ordered, totaling 71,100 dosage units, were oxycodone.

Do those numbers seem unusually high to you?

Dr. Mastandrea. Congressman, I find it to be unusual that we would sell directly to a physician. I find it unusual that she would be a dispensing physician. By doing that, she bypassed all of the checks and balances that were in place.

Mr. Johnson. Okay. But I'm not talking about what she did. I'm talking about what you guys did. Did those numbers --

Dr. Mastandrea. That's right. And what we should not have done, we never should have supplied to a dispensing physician.

Mr. Johnson. All right. Given that, should those orders be investigated, do you think?

Dr. Mastandrea. Those orders should have never been shipped.

Mr. Johnson. But should they be investigated?

Dr. Mastandrea. How so?

Mr. Johnson. Well, I think, if my facts are correct, Miami-Luken claims to have investigated Dr. Temponeras and the clinic. You, yourself, stated that in November 2008 one of the company's salesmen conducted an inspection. However, according to the DEA, that inspection was cursory at best and it failed to take into account the area's prescription drug problem.

Then, in 2009, Miami-Luken CEO Tony Rattini and compliance manager Jim Barclay showed up to investigate on a day when the facility was closed and never returned to visit when it was open.

So I guess my question to you is, looking back in retrospect, are those instances, in your opinion, adequate due diligence? I mean, you express outrage now that it never should have happened. But was due diligence supplied, do you think, when the opportunity presented itself?

Dr. Mastandrea. Due diligence was attempted in that particular situation.

Mr. Johnson. When they showed up and didn't show back up, the

alarm bells didn't go off?

Dr. Mastandrea. I said it was attempted.

Mr. Johnson. Okay. All right.

My time has expired. But I do appreciate you folks being here. And I know that -- I know there's a lot of emotion around this issue. There certainly is in my district. And I want to thank you for any work that you are doing and continue to do to help us get a handle on this, 115 people dying per day. We need your engagement at your level to get this problem resolved.

Mr. Chair, I yield back.

Mr. Harper. The chair now recognizes the gentleman from Florida, Mr. Bilirakis, for 5 minutes.

Mr. Bilirakis. Thank you, Mr. Chairman.

And I appreciate you all being here. This is something we need to focus on. It's an epidemic, and we need your engagement, as my colleagues said.

So I'm glad to hear that the drug distributors acted in recent years to reform the policies and tighten controls on the distribution of opioid pain pains. But I'm surprised to hear, why did it take so long?

And Florida was awash in pain-- I represent the State of Florida, the Tampa Bay area, as you know, and the Tampa Bay area, in particular,

but the whole State of Florida was awash in pain pills back in 2010. And it's taken significant efforts by law enforcement and Florida lawmakers, the local lawmakers, to battle the prescription drug epidemic in recent years.

On the part of the distributors, I'm concerned that you may not be on the same page. For instance, Mr. Barrett, Cardinal was the subject of a DEA administration action in Florida several times over the years. The DEA took enforcement action against Cardinal's Lakeland, Florida, distribution center in 2007 for failure to maintain effective controls against the diversion of hydrocodone and again for similar allegations involving oxycodone in 2012.

In court documents involving the 2012 action, the company made an interesting point. Cardinal said between 2009 and 2012 it stopped distributing controlled substances to 149 Florida pharmacies. But the company noted that 113 of those Florida pharmacies still had DEA registrations as of 2012. That means even though Cardinal had cut off pharmacies it suspected of drug diversion, other drug distributors were still doing business with them.

I understand the committee's investigation turned up numerous examples in West Virginia of one distributor dropping a pharmacy due to diversion concerns only for another distributor to immediately start doing business with the pharmacy. I mean, that's very concerning

again.

So for all the witnesses, starting over here, I'd like all your companies to address two questions, please.

First, when your company is considering bringing on a new pharmacy as a customer, do you verify whether that particular pharmacy was cut off from another distributor for suspected diversion?

Please begin.

Mr. Barrett. Congressman, I don't think we can know for sure. Actually, we don't have access to that information that another company has necessarily cut off a pharmacy. We may, but there's nothing in the mechanics of the regulatory process that makes that happen.

Mr. Bilirakis. All right. Next, please.

Dr. Mastandrea. We ask them whether or not -- why they are coming to us and whether or not they were with another distributor and why they left that distributor.

Mr. Bilirakis. And you take their word for it?

Dr. Mastandrea. We do as much due diligence investigation as we possibly can, but it's, unfortunately, a trade.

Mr. Bilirakis. Next, please.

Mr. Hammergren. It's difficult for us to get accurate information on that.

Mr. Bilirakis. Next, please.

Mr. Smith. In my experience at H.D. Smith, that was something that we sought from the customer, an explanation, if they were leaving another wholesaler. But, no, we didn't talk to the other wholesaler about it.

Mr. Bilirakis. Next.

Mr. Collis. I agree with the previous comments. That information would be very helpful, Congressman.

Mr. Bilirakis. Okay. Next question. And second, what safeguards do you have in place to ensure your company is not bringing on a bad actor as a customer after they were dropped by one of your competitors?

Let's start again from you.

Mr. Barrett. So, Congressman, given the observation I made earlier, which is you don't know for certain, we try to take, in this know-your-customer program of ours, any information that will help us dictate the nature of that pharmacy, who it serves, what its customers are, and whether or not there are any red flags.

Mr. Bilirakis. So what safeguards do you have?

Mr. Barrett. I'm sorry?

Mr. Bilirakis. What safeguards do you have in place, any particular safeguards? Name a few safeguards.

Mr. Barrett. Well, as I mentioned today, we have either not taken

on or shut off a thousand pharmacies over these last 7 or 8 years. So we literally put in place --

Mr. Bilirakis. What kind of process?

Mr. Barrett. If they won't qualify, they don't get products from us.

Mr. Bilirakis. Do you have any kind of a process that you go through?

Mr. Barrett. Yes, a very rigorous process, sir.

Mr. Bilirakis. All right. Go next, because I don't have a lot of time. Next, sir, please.

Dr. Mastandrea. We ask for drug utilization reviews from every new customer.

Mr. Bilirakis. All right. Next, please.

Mr. Hammergren. We certainly -- first, we'll check with the regulatory agencies, the DEA and the State boards of pharmacy, make sure the licensing is all done. That would be a baseline check.

So certainly if there was a problem that was reported to the DEA and the DEA reported it to us, or a State pharmacy board, that would be the end of the decision relative to that pharmacy.

Mr. Bilirakis. Do you do that as well, sir?

Mr. Smith. We had a due diligence process that included all the elements I think that you've heard from the other wholesalers.

Mr. Bilirakis. Okay. Yes, please.

Mr. Collis. If we did bring on a new customer, we would have extensive monitoring requirements and look at -- in our suspicious order program, we'd be looking at what is the content of the orders that we receive from that pharmacy.

Mr. Bilirakis. Would you also -- for the first two -- would you also check with the regulatory agencies as well.

Mr. Barrett. Yes. We can't onboard a pharmacy without the proper authorization from the regulatory agencies.

Mr. Bilirakis. That's a common practice for you as well?

Mr. Barrett. It's a standard practice.

Mr. Bilirakis. Okay. Standard practice.

Okay. Thank you very much. I appreciate it.

I yield back, Mr. Chairman.

Mr. Harper. The gentleman yields back.

Certainly, I think each of you recognize and would agree that the distributors are the first line of defense against diversion of opioids.

And I know we've spent a lot of time on West Virginia. Is it been on the front line of the opioid epidemic. That's why we use apportions of the State as a case study in this investigation. But it leads us to wonder are there other hot spots across the country that there are

problems that maybe we haven't really seen enough of that information yet.

So given what you've heard today, will each of you commit to look for communities across the country where the volume of opioids that your company distributed appear far in excess of what the community can sustain?

Mr. Barrett. Sir, we will and we do.

Dr. Mastandrea. Absolutely.

Mr. Hammergren. Absolutely.

Mr. Smith. I'm not in a position to do that.

Mr. Collis. We will. And, unfortunately, you know, opioids seem to thrive in communities where there often is, you know, hardship. And so we feel particularly concerned about that.

Mr. Harper. I want to thank each of you for taking your valuable time to help us on this very important matter. I know everyone recognizes the seriousness of this. We're going to have to look at every aspect of what goes on. But we do appreciate the time.

I want to remind members that they have 10 business days to submit questions for the record. And I ask that the witnesses agree to respond promptly to those questions.

[The information follows:]

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

Mr. Harper. With that, the subcommittee is adjourned.

[Whereupon, at 12:50 p.m., the subcommittee was adjourned.]