



**HEARING BEFORE THE UNITED STATES HOUSE OF REPRESENTATIVES
COMMITTEE ON ENERGY AND COMMERCE, SUBCOMMITTEE ON OVERSIGHT
AND INVESTIGATIONS**

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I. INTRODUCTION

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 for today's hearing on "Combating the Opioid Epidemic: Examining Concerns About Distribution and Diversion."

My name is George Barrett, and from 2009 to 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. I have devoted a career to healthcare in a wide range of roles for over three decades, and I appreciate the opportunity to share my perspective with you today.

The people of Cardinal Health are deeply committed to serving the American healthcare system. Although this hearing is focused on one aspect of our pharmaceutical wholesale distribution business, Cardinal Health is a global, integrated healthcare company, providing customized solutions for hospitals, healthcare systems, pharmacies, ambulatory surgery centers, clinical laboratories, and physician offices worldwide. Our pharmaceutical wholesale distribution business delivers thousands of products from hundreds of manufacturers and suppliers. Each year, we process in excess of 400 million orders. The overwhelming majority of

medications we distribute are non-opiate medicines such as antibiotics, or treatments for cancer, heart disease, diabetes, and other chronic conditions. With respect to all our distribution, our objective is simple: to enable the healthcare providers we serve to use these products to bring health and healing to their patients. We also recognize that in our role as a pharmaceutical wholesale distributor we have a dual responsibility—to ensure that prescription medications are available for prescribers and their patients when needed, while working to limit the potential for those prescription medications to fall into the wrong hands.

To meet our responsibilities, Cardinal Health has developed and implemented a constantly adaptive and rigorous system to combat controlled substance diversion. Despite the development of a quality system, we have not always gotten every decision right, and in the past we have entered into settlements with regulators to address aspects of our anti-diversion program. We have learned from our settlements and experience, and our anti-diversion program today is stronger and more effective as a result. While no program can ever be perfect given the evolving threats we face and the realities of human error and judgments, our goal is always to get it right, and we have stopped suspicious orders for the shipment of hundreds of millions of dosage units of controlled substances over the last decade.

At the end of last year, I passed on my duties as CEO to my successor, and I currently serve as the Executive Chairman of Cardinal Health's Board of Directors. All of us at Cardinal Health are acutely aware of the devastation that opioid abuse is causing families and communities around our country, including some within our own company. We simply cannot look at the impact of opioid abuse on so many lives and not feel sorrow. And on behalf of the entire Cardinal Health community, we are resolved to be a constructive part of the effort to alleviate this complex national public health crisis. We are engaged and at the table. There is no single root cause of the crisis and addressing it requires that everyone work together.

One of the key public policy issues we must address is 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 judgment of policymakers, including senior leadership at the Department of Health and Human Services, the Food and Drug Administration, the Surgeon General, the Centers for Disease Control and Prevention, and others, that there have been too many prescriptions for too many pills.

Pharmaceutical wholesale distributors do not and should not have visibility into clinical prescribing decisions or the patients for whom prescriptions are written. However, there are other steps we can take, and are taking, to raise awareness of the dangers of over-prescribing. We also have made available Narcan, an opioid overdose reversal medication, free-of-charge to first responders and law enforcement. Through these efforts and other elements of our Opioid Action Program, Cardinal Health is seeking to make a meaningful difference, focusing initially on some of the nation's hardest-hit states. We are also continuously focused on enhancing our own anti-diversion programs in collaboration with our regulators and others in our industry.

II. CARDINAL HEALTH – WHAT WE DO

As discussed above, Cardinal Health is a global, integrated healthcare services and products company. In our role as a pharmaceutical wholesale distributor, we serve more than 24,000 pharmacies and are in nearly 85% of U.S. hospitals. We make available nearly 400,000 unique products that ultimately support patients across the full continuum of care. We have been privileged to be able to assist in some of the most acute crises this country has faced. For example, in the aftermath of Hurricanes Harvey, Irma, and Maria, the men and women of Cardinal Health worked tirelessly to fulfill the needs of hospitals, pharmacies, critical care centers, and shelters so they could aid those in need. We did far more than simply move products from manufacturers to pharmacies. Our team went to extraordinary lengths to secure diesel fuel, high-water vehicles, planes, and helicopter support for the transport of products to critical locations, and on the ground worked under difficult conditions, putting the welfare of

patients ahead of their families' personal needs to ensure critical life-saving drugs and medical supplies were delivered to local hospitals. The level of commitment reflected in our team's actions during those crises is matched day in and day out as they perform their regular jobs, ranging from logistics management to anti-diversion monitoring and analysis. This is who we are.

Cardinal Health, in its role as a pharmaceutical wholesale distributor, does not manufacture medications or market them to patients, nor does it diagnose medical conditions, write prescriptions, or otherwise practice medicine. Opioid prescriptions, like any other prescription medications, are written by healthcare providers for their patients, who take those prescriptions to licensed pharmacies to be filled. These licensed pharmacies in turn place inventory fulfillment requests with pharmaceutical wholesale distributors. As an intermediary in the pharmaceutical supply chain, Cardinal Health does not ultimately control either the supply of or the demand for opioids. Our role is to provide a secure channel to deliver medications of all kinds, from the hundreds of manufacturers who make them, to the thousands of hospitals and pharmacies that dispense them. We help ensure that pharmacies, hospitals, and the patients they treat receive medication—when and where they need them. At the same time, we also work diligently and with a sense of purpose to prevent the diversion of pain medications. We have developed and implemented robust suspicious-order monitoring and reporting systems, and we continuously strive to improve and adapt to address the ever-changing methods of drug diversion and abuse.

III. CARDINAL HEALTH'S ANTI-DIVERSION EFFORTS

Our anti-diversion program is rigorous, and over the last decade, we have invested tens of millions in continually upgrading our program to make sure it continues to be robust and effective in the face of evolving risks. Our goal is to spot, stop, and report the suspected diversion of medications out of the clinical setting for improper use. Our program has three key components, each of which is outlined in greater detail below. The program is supported by a

dedicated anti-diversion team that consists of nearly a hundred trained individuals, including investigators, statistical auditors and data analysts, former law enforcement officers, pharmacists, and compliance officers deployed on-site at our pharmaceutical distribution centers, in the field, and at our corporate headquarters, augmented by substantial external resources.

Over time, we have continued to enhance our anti-diversion program and have entered into settlements with the DEA and the state of West Virginia. We have learned and improved from each of them. From 2008 to the present, we have stopped suspicious orders for the shipment of hundreds of millions of dosage units of controlled substances. We also have terminated or refused to distribute controlled substances to over a thousand pharmacies. On our own initiative and in response to regulators, we have increased the size of our anti-diversion team, including bringing in personnel with additional regulatory, pharmaceutical, and law enforcement experience to further enhance the anti-diversion program. We have developed an analytical model to evaluate customers, assigned threshold ordering volumes, created a centralized database to store and track data on customers and orders, and designed new policies and procedures for anti-diversion personnel. Over the years, we have also trained thousands of our people on anti-diversion practices.

Know Your Customer. Know Your Customer is the ongoing process by which we learn about pharmacies to, among other things, better understand the range of legitimate requirements for controlled substances and establish distribution thresholds on a customer-specific basis using objective, statistical data and other criteria. Cardinal Health uses a multi-factor process to evaluate customers, even before they can be accepted as a Cardinal Health customer. These factors include verifying the customer is licensed by the Drug Enforcement Administration (DEA), and evaluating the product mix dispensed by the customer within certain drug families, as well as the location and business model of the pharmacy, the historic volume of controlled substances dispensed, and the ratio of controlled to non-controlled substances. Cardinal Health uses an escalation process through management to evaluate higher volume customers which

includes two-person approval for certain threshold levels and regular review of higher volume customers by a committee of anti-diversion management and specialists.

Electronic Monitoring. All Cardinal Health customers are subject to electronic monitoring, which occurs prior to order fulfillment. Threshold limits are established by the anti-diversion team for over 120 families of controlled substances, including oxycodone and hydrocodone, for each pharmacy or other healthcare provider. The thresholds are based on various factors specific to the customer and analysis of third-party data detailing dispensing volumes of customers nationwide. Through electronic monitoring, Cardinal Health monitors dosage units for each controlled substance drug family, as well as certain strengths of specific drugs known to be more frequently misused (e.g., oxycodone 15mg and 30mg products). When a customer's accrued orders hit the established threshold, the order is held and, outside of a rare occurrence, the order is cancelled. Cancelled orders are reported to the DEA and any required state regulators.

Site Visits. Cardinal Health conducts regular site visits to its customers across the country as part of its anti-diversion program. Site visits may be announced or unannounced. In 2017, Cardinal Health representatives conducted over 48,000 on-site inspections nationwide. These representatives look for any visible signs of diversion, such as long lines, a high volume of customers from out-of-state, lack of product diversity in non-prescription products offered for sale, or groups of people traveling together to fill prescriptions. As warranted by the circumstances, the teams also speak with the pharmacist-in-charge and/or other staff and review aggregate pharmacy dispensing data to identify any risk of diversion. The data reviewed includes aggregate prescription volume, percentage of cash business, ratio of controlled to non-controlled substance dispensing, and information about the pharmacy's customer base (e.g., hospice, orthopedics, oncology, pain clinics, etc.). However, it is important to note that privacy laws, such as HIPAA and other laws, prohibit Cardinal Health representatives from reviewing patient-specific prescriptions.

IV. LEARNING FROM OUR WEST VIRGINIA EXPERIENCE

Given the questions that have been raised by the Subcommittee and others, I would like to directly address our work in the state of West Virginia over the past decade and, in particular, the volume of opioid medications that Cardinal Health distributed in response to orders from DEA-licensed pharmacies.

As I noted previously, we share the judgment of policymakers that there have been too many prescriptions for too many pills across the country over the past decade. With regard to two of the pharmacies that have been a particular focus for the Subcommittee, Family Discount of Mt. Gay and Hurley Drug Company, we reached decisions at the time based in part on the demographics of the surrounding area, the characteristics of the individual pharmacy, and the views of our internal staff. Those decisions allowed the two pharmacies to continue to receive certain volumes of hydrocodone and oxycodone from Cardinal Health for longer than I think they should have based on what I have since learned about the circumstances surrounding those pharmacies. With the benefit of hindsight, I wish we had moved faster and asked a different set of questions. I am deeply sorry we did not. Today, I am confident we would reach different conclusions about those two pharmacies. Although both pharmacies continue to maintain active and valid DEA registrations and West Virginia Board of Pharmacy licenses, Cardinal Health has not distributed oxycodone or hydrocodone to Family Discount of Mt. Gay since 2012, or to Hurley Drug Company since 2014. We have also taken responsible actions by instituting improvements in our anti-diversion program and reaching settlements with our regulators, including the state of West Virginia. We understand no program is perfect, which is why we are so focused on continuous improvement. And we are at the table now, focused on alleviating this critical national health problem.

There are a variety of other factors that informed our historical decisions about our overall distribution volumes in West Virginia, including the fact that Cardinal Health's distributions of oxycodone and hydrocodone to West Virginia reflected only a small portion of

the company's total distributions of prescription medications in the state. For example, in 2008 oxycodone and hydrocodone constituted only around 7% of the prescription medications that Cardinal Health distributed to independent retail pharmacies in West Virginia. In addition, our distributions were made against the backdrop of what the Centers for Disease Control and Prevention has now chronicled as then widely accepted and publicized medical norms guiding physicians' prescribing practices. During that time period, those norms favored broader opioid treatments for longer periods of time with higher potency.

V. THE PATH FORWARD

Improving our anti-diversion program has been our primary focus. Yet, our commitment to alleviating the national problem of opioid abuse and misuse does not end there. For over a decade, we have funded education and prevention programs in communities across the country through Generation Rx, which the Cardinal Health Foundation developed in partnership with the Ohio State University School of Pharmacy. Generation Rx is a national prescription drug misuse prevention program that has been used in every state, at more than 100 colleges of pharmacy, and has provided more than a million people with tools and educational resources to prevent and address the issues that drive opioid abuse.

More recently, we launched our Opioid Action Program (OAP). We piloted OAP in four of the nation's hardest-hit states across Appalachia—Ohio, Kentucky, Tennessee, and West Virginia—to alleviate the opioid epidemic. It has four elements, each of which has been cited by leading experts as essential to the fight to reduce opioid abuse and casualties:

1. Narcan. We have distributed Narcan, an overdose reversal medication, free-of-charge to first responders and law enforcement. To date, we have distributed nearly 80,000 dosages.

2. Drug take-back events. We have sponsored drug take-back events in various communities, including sponsoring 39 drug take-back events across these four states during the DEA's National Prescription Drug Take Back Day in the past two weeks.
3. Student and prescriber education. We have successfully funded millions in expanded grants focused on youth prevention education, prescriber opioid awareness and reduction efforts, and community responses to the epidemic.
4. Medical school training. We have partnered with a leading school of medicine to refine and share medical school curricula that address opioid abuse and treatment through a collaboration with over 20 medical schools nationwide.

In addition, our employees have volunteered thousands of hours to community service to support drug take-back days and community awareness and education efforts at schools, senior centers, and elsewhere.

We also support practical reforms to alleviate the opioid crisis, including the creation of a national prescription drug monitoring program through collaboration with industry participants and state and federal regulators. And we support appropriate prescribing limits on opioids and legislation that would require prescriptions to be issued electronically. While none of these is a complete fix or a substitute for collaborative efforts by participants across the system, each would be an important step in the right direction.

VI. CONCLUSION

I believe the steps I have outlined above can make a genuine difference in our ability to combat the diversion of opioid medications. The men and women at Cardinal Health know there is much more to be done, and that we, as a country, have a long way to go. We at Cardinal

Health are committed to doing our part to alleviate this national challenge and welcome the opportunity to continue the search for solutions with the Subcommittee.

Thank you for the opportunity to be here. I look forward to your questions.