



Testimony of

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Mr. Chairman, Ranking Member DeGette, and members of the Subcommittee, my name is John Hammergren. For almost two decades, I have had the privilege to serve as Chief Executive Officer for McKesson Corporation. I appreciate the opportunity to appear before you today to describe our efforts to respond to the nationwide opioid crisis. In particular, I will address the ways in which we have significantly enhanced our monitoring systems and procedures, so that we can quickly identify and block suspicious orders, and cut off bad actors' access to controlled substances. I will also address other steps the company is taking to help proactively combat the crisis. We recognize the importance of, and understand the reasons for, the Committee's investigation, and we appreciate the opportunity to respond.

The impact the opioid epidemic has had on our nation is devastating. Millions of Americans have been affected, including employees of McKesson and their family members. This epidemic's human costs are felt by us directly, and all of us at McKesson are committed to doing what we can to respond to this complex public health challenge. We are actively engaged in a range of initiatives that address our responsibility to help protect the integrity of the pharmaceutical supply chain and that also contribute to finding solutions to the cycle of addiction that so many American families are struggling with. I have personally learned about those struggles in conversations with McKesson employees and others whose lives have been impacted by the opioid addiction epidemic.

Over the last five years in particular, McKesson has successfully used the latest technology and the best available internal and external expertise to strengthen controls and to help reduce the risk that opioids and other controlled substances could be diverted to abuse or other illegitimate uses. And since 2008, McKesson has blocked the shipment of over a million orders for controlled substances nationwide.

Before explaining the steps we have taken, let me first provide you with some background about McKesson. We are a company with a long history. In 1833, to help meet the growing demand for medicine, John McKesson and Charles Olcott opened a small drug and chemical shop in New York City's wholesale district. Throughout the company's 185 years in business, McKesson has contributed to building a safe, secure pharmaceutical supply chain, including with technological innovation recognized by the Smithsonian. Over more than a

century, McKesson expanded and improved the nation's infrastructure for distributing drugs and other medical products to a far-flung network of pharmacies and health care providers. Today, we have over 70,000 employees around the world, including nearly 23,000 employees in the United States, with distribution centers located in 26 states.

One of McKesson's primary missions is to help ensure that medicines prescribed by licensed doctors are delivered to licensed pharmacies so they are available for patients who need them, when they need them, where they need them. Our U.S. Pharmaceutical business does that by responding rapidly to 275,000 orders that we receive daily from pharmacies and hospitals across the country at our 28 distribution centers. In the case of controlled substances particularly, we have to balance our mission to deliver medicines to pharmacies and hospitals when and where they need them against our important efforts to prevent and detect illegal diversion of those drugs. This is a constant balancing act for all pharmaceutical distributors.

McKesson supplies branded, generic, and over-the-counter pharmaceuticals to more than 40,000 customers, including retail pharmacy chains, independent pharmacies, hospitals, health systems, integrated delivery networks, and long-term care providers. We enable the American health care system to deploy medicines very rapidly to patients who need them and to protect against dangerous shortages of critical drugs. In many cases, McKesson is able to accomplish delivery of prescription drugs to pharmacies across the country within a matter of hours, in both urban and rural areas.

Distributing controlled substances represents a small share of our overall business. The two schedules of controlled substances that include the most commonly abused prescription opioids constitute approximately three to four percent of McKesson's total revenue. The bulk of our business involves the distribution of *non*-controlled prescription drugs, along with over-the-counter products and other health care related lines of business. For example, we provide a range of medical-surgical supplies and equipment to physicians' offices, home care agencies, and surgery centers. In addition to distribution, McKesson has a robust technology and connectivity business, and we use Six Sigma to help health care organizations strengthen their businesses, control costs, work more efficiently, and improve quality.

Distribution of Controlled Substances to West Virginia Pharmacies

As a distributor, McKesson does not manufacture prescription drugs, and we do not market them to doctors or patients. Nor do we market any particular category of drugs, such as opioids, to pharmacies. Distributors respond to pharmacies' orders, which in turn are placed based on doctors' prescriptions. McKesson does not supply prescription drugs in amounts greater than pharmacies order, and we do not ship to a particular state or pharmacy without an order from a Drug Enforcement Administration ("DEA")-registered and state-licensed pharmacy.

No single distributor knows the total volume of any drug distributed in a particular state or region, let alone to a particular pharmacy. That information is known to DEA, however. McKesson for years has reported every controlled substance transaction in West Virginia and across the country to DEA, and DEA gathers similar information from other distributors, in a proprietary DEA database called Automation of Reports and Consolidated Orders System

(“ARCOS”). Neither McKesson nor the other distributors have access to ARCOS. Only DEA has visibility over the entire landscape and can track and analyze aggregate data on the distribution of controlled substances in particular jurisdictions.

The Committee has highlighted the large volume of opioids distributed to certain pharmacies in West Virginia by McKesson and other distributors. For example, over a six year period addressed by the Committee, from 2007 through 2012, McKesson distributed approximately 151 million doses of oxycodone and hydrocodone in West Virginia. While that is a very large number, it’s important to put that data in context. During the same six-year period of time, McKesson distributed nearly *2 billion* doses of all prescription drugs in West Virginia. Put another way, West Virginia pharmacies overall were, and continue to be, very high volume customers for prescription drugs generally.

There is no question that beginning more than a dozen years ago, and continuing to this day, physicians have prescribed large numbers of opioids to millions of Americans for a wide range of conditions. In 2014 alone, according to the *New England Journal of Medicine*, doctors wrote 245 million prescriptions for opioids in the United States.¹ As the Director of the Centers for Disease Control and Prevention (“CDC”) noted in 2016, “[o]verprescribing opioids—largely for chronic pain—is a key driver of America’s drug-overdose epidemic.”²

The total volume of opioid shipments is sometimes compared to the population of a particular county in West Virginia, resulting in disturbingly large figures for the number of prescription opioid pills in a given county on a per-resident basis. These comparisons can be misleading, for several reasons.

First, these figures generally have been aggregated over a long period of time, often five or six years, or even longer. Over a sufficiently long time period, any per capita calculation of the number of opioid pills sold will appear high. This is all the more misleading if the figure for opioid orders is not considered in the context of total sales of prescription non-controlled substances during the same period of time.

Second, calculations based on population do not include any comparative baseline for the number of persons in the geographic area who have a legitimate need for opioids. Without such a baseline to compare against, it is not always clear whether shipments are “too high” relative to the legitimate need.

Third, these figures imply that town and county lines define the customer base for a particular pharmacy. That is often not the case. Pharmacies located in areas that are not densely populated, and especially in areas that border one or more other counties or states, may serve a much larger customer population than the population of the specific town or county in which the

¹ Nora D. Volkow and A. Thomas McLellan, *Opioid Abuse in Chronic Pain — Misconceptions and Mitigation Strategies*, 374 NEW ENG. J. MED. 1253, 1253 (2016).

² CDC Director Tom Frieden, Mar. 5, 2016 (quoted in “CDC Releases Guideline for Prescribing Opioids for Chronic Pain”) available at <https://www.cdc.gov/media/releases/2016/p0315-prescribing-opioids-guidelines.html> (visited on Apr. 29, 2018).

pharmacy is located. A small West Virginia town near the Kentucky border does not serve only the few hundred town residents any more than a pharmacy in Manhattan serves the millions of people who live and work in New York City. Comparing the number of units sold for a particular drug to the number of people in the town or county in which a pharmacy sits is not a meaningful way to assess whether drugs are being diverted to illegitimate uses.

A more refined calculation can account for some of these limitations. We can do this by calculating pills per capita on a monthly basis—instead of over a long period of time—for all counties in a particular area or on a statewide basis. And we can estimate the typical monthly number of pills for patients who receive opioid prescriptions from their physician by using public information and CDC surveys.

For example, if we look at data from January 2006 to November 2017, McKesson shipped a total of 342.8 million oxycodone and hydrocodone pills into West Virginia over that nearly 12-year period. The state had a population of 1.85 million (1.47 million adults) as of the 2010 census, so in per capita terms, McKesson could be said to have shipped approximately 185 pills of oxycodone or hydrocodone for each resident of West Virginia. Though this figure is significant, for meaningful analysis it should be compared to other data that reflect the prevalence of lawful opioid prescriptions and the volume of pills that physicians typically prescribe for a patient being treated with opioids.

If we take that same data and calculate per capita pills *per month*, the result is 1.6 pills per adult, per month. As an average, this figure is still subject to misinterpretation. It is certainly not the case that every adult in West Virginia received 1.6 pills each month. Studies suggest an average patient whose doctor prescribes oxycodone or hydrocodone is prescribed between two and three pills per day, or between 60 and 90 pills per month. Based on this range, a volume of 1.6 pills per adult per month works out to enough to fill legitimate prescriptions for roughly 1.8% to 2.7% of the adult population of West Virginia. While that is certainly not an insignificant share of the population by any means, to put it in context, CDC data from 2011-2012 reported that 6.9% of adults nationwide were prescribed opioids in any given month, and research suggests this means about 5% of adults were prescribed oxycodone or hydrocodone in any given month.

So while the large figures that are often highlighted in the media for the number of opioid pills prescribed and sold by pharmacies in West Virginia are significant, on a statewide basis, they reflect a volume of pharmacy opioid orders supplied by McKesson that is not inconsistent with the rate at which opioids were being prescribed by doctors and sold by pharmacies nationwide. Again, McKesson does not know at any given time how much is being shipped by other distributors, as we do not have access to DEA's ARCOS database that would shed light on the bigger picture. Finding a way to give all distributors access to that data, so that we can track how orders we receive relate to the total volume of controlled substances ordered by particular pharmacies or in particular geographic regions, is an important step that Congress and the states can take to help distributors conduct effective monitoring.

The data I summarized above is another way of saying that in recent years, doctors have been prescribing a tremendous volume of opioids to patients with a wide range of conditions,

both in West Virginia and across the country. As the Committee is well aware, and has investigated extensively, this is part of a major public health crisis in this country, a root cause of which is the over-prescribing of opioids. That trend recently has begun to recede, though opioid prescription volumes remain high nationwide, including in West Virginia.

We recognize that even if statewide volumes of orders for opioids seem consistent with national trends, particular counties or regions could have been outliers, with higher levels of orders relative to regional populations, though there are a variety of possible reasons for those variances across jurisdictional lines.

In its letters to McKesson, the Committee focused particularly on a pharmacy called “Sav-Rite No. 1.” Kermit, the small town in which Sav-Rite No. 1 was located, is in Mingo County, but it sits near the intersection of Mingo County, Wayne County, and Martin County, KY, which have a combined population of over 80,000 people. The Committee also referred to Family Discount Pharmacies, with locations in Mount Gay-Shamrock and Stollings, West Virginia. Logan County, where both Family Discount Pharmacies are located, has a population of about 35,000, putting it near the top quarter of West Virginia counties by population.

To be clear, while a simple comparison of the volume of opioid sales to the local town or county’s population is not by itself a reliable way of identifying suspicious orders, the volume of sales certainly is relevant to identifying suspicious orders. And in fact, in the specific case of Sav-Rite No. 1, McKesson did in November of 2007, more than a decade ago, *terminate* Sav-Rite No. 1’s access to controlled substances because of what we deemed to be a pattern of suspicious orders from that pharmacy.

Likewise, in 2014, McKesson terminated the Mount-Gay-Shamrock pharmacy’s controlled substance access after observing a suspicious volume of hydrocodone and alprazolam ordered by the pharmacy and because of concerns about some of the physicians whose prescriptions the pharmacy was continuing to fill. It also appears that several years before that, we had for a period of time cut off sales of controlled substances to that same pharmacy.

In hindsight, I would have liked to have seen us move more quickly to identify issues with those pharmacies and terminate their access to controlled substances, and we have learned lessons from that experience, which inform our approach today. As described below, with the benefit of sophisticated data analytics tools that are available today, over the last five years we have implemented a more robust and more heavily resourced system to survey and analyze large volumes of data, in order to quickly identify bad actors.

McKesson’s Controlled Substance Monitoring Program

Over the last five years, McKesson has invested millions of dollars in enhancing our Controlled Substance Monitoring Program (“CSMP”), which provides ongoing review and monitoring of the pharmacies and hospitals that purchase from us to help mitigate the risk that controlled substances, including opioids, are diverted to abuse and other inappropriate uses. In 2014, we began working with an outside consulting firm to design sophisticated data analytics for the CSMP. Among other enhancements, these analytics enable us to identify patterns in

pharmacy orders for controlled substances and to set thresholds for each pharmacy based on better statistical methods and computer-assisted analytics than we ever had available in the past. Our CSMP is a nationwide program and it applies to all independent pharmacies, including those that operate in West Virginia. We provided an overview of these enhancements to DEA in 2016.

Advanced analytics capabilities. McKesson has implemented a cutting-edge controlled substances threshold management program, using complex data analytics to set and manage individual customer thresholds for controlled substances. Our model analyzes each pharmacy's and hospital's order against established monthly thresholds to determine whether that order should be filled. If an order exceeds the monthly threshold, that order is blocked and not filled. McKesson reports each blocked order to DEA, and to state agencies when required. The thresholds are determined based on computer analysis of controlled substance orders by pharmacies of similar size in a broader geographic region (though not just the same town or county, for reasons explained above) and the pharmacy's own past pattern of controlled substance orders compared to non-controlled prescription orders.

Expanded Compliance Team. In order to further enhance its compliance program, McKesson has added a number of subject matter experts to its CSMP team. In addition to hiring former DEA Special Agents and Diversion Investigators, McKesson has hired industry experts with experience in the retail pharmacy industry, experience as state and board of pharmacy investigators, experience with pharmaceutical manufacturers, and experience with data analytics. McKesson's team now includes individuals with more than 240 years of collective DEA enforcement experience. Moreover, the team leading our CSMP is independent of our sales function and has unilateral authority to terminate a pharmacy or hospital's access to controlled substances and to reject the onboarding of new pharmacies and hospitals.

Due diligence. McKesson performs comprehensive due diligence on prospective pharmacy customers before agreeing to supply controlled substances. We require all prospective customers to complete a detailed questionnaire, provide three months of dispensing data for analysis, undergo a site visit, and provide copies of all licenses. We also proactively monitor pharmacies' and hospitals' purchasing patterns and external events that might indicate a need to review that location more closely. For example, on many occasions, McKesson has performed a complete diligence review when a pharmacy or hospital requests an increase in its monthly threshold for a controlled substance. In addition, McKesson often performs a complete review when we receive a subpoena for information about a particular pharmacy or when we otherwise become aware of adverse information about a pharmacy. For example, in 2017, we terminated a West Virginia pharmacy's ability to purchase controlled substances after becoming aware that the West Virginia Attorney General had filed a lawsuit against the pharmacy related to its controlled substances dispensing practices.

Education. McKesson has been proactive with respect to educating the pharmacies and hospitals that purchase from us about the importance of compliance with DEA and state agency regulations. McKesson educates them and provides them with literature on how to identify the warning signs of prescription abuse and diversion. Similarly, McKesson has trained hundreds of our own employees on the company's regulatory obligations, including CSMP-specific training sessions at annual meetings.

As a result of these ongoing efforts, from 2008 through 2017, we blocked and reported to DEA over one million suspicious orders nationwide.

Additional Steps McKesson Is Taking To Address The Opioid Crisis

We are also looking ahead to find innovative ways to fight the opioid crisis more broadly, both through our company activities and through a foundation we recently formed to address opioid abuse.

We are working to develop an innovative solution contemplated by the leading not-for-profit standards setting organization in the healthcare solutions space, the National Council for Prescription Drug Programs (“NCPDP”), and now being advocated by the Health IT Now Opioid Safety Alliance. Such a prescription safety alert system, which other technology vendors could also develop, would help provide doctors and pharmacies with real-time red flags based on a patient’s nationwide prescription history, so that they can more easily identify prescriptions that may indicate potential abuse or misuse, such as doctor or pharmacy shopping. Today, when a patient fills an opioid prescription, the pharmacist may be unaware that the patient has recently filled other opioid prescriptions at other pharmacies, or that he or she has received multiple opioid prescriptions from multiple doctors. Our shared vision is that a pharmacy would receive a real-time clinical alert based on a patient’s prescription history. This information would allow the pharmacist to gather more information prior to dispensing the prescription, such as conducting a check with the prescribing clinician or reviewing the information from the state’s prescription drug monitoring program. Such a prescription safety alert system would work across state lines to encompass all prescriptions and all pharmacies, including failed attempts to fill prescriptions and transactions conducted in cash.

We are moving forward with the development of this innovative solution, which is in line with President Trump’s proposal for a nationwide prescription drug monitoring program. We understand from the pharmacy community that the system would meet a critical need. To maximize success, a truly effective solution must have access to data from all entities dispensing covered controlled substances. Thus, effective implementation would require support from the Food and Drug Administration (“FDA”) or Congress and require all pharmacies and providers to participate.

We believe that e-prescribing (electronically-delivered prescriptions) can also help prevent diversion. That is why, in 2019, McKesson will stop filling opioid prescriptions at pharmacies that are unable to accept e-prescriptions. Handwritten prescriptions can be forged, altered, or otherwise diverted to enable illegal access to opioids. All 50 states currently allow for e-prescribing, but only a handful of states require it. We aim to bring those pharmacists who are unable to accept e-prescriptions up to date with that ability, and move the industry toward an e-prescription-only opioids system. Congress and state legislatures could help by mandating e-prescribing by providers, in order to supplement industry efforts.

Because over-prescribing of opioids has played such a large role in the crisis, we also support providing opioids in limited-dose packaging. FDA could help by requiring that opioids be distributed in limited-dose packaging, usually “blister packs” and specially designed bottles. We plan to proactively engage with opioid manufacturers to develop plans to use limited-dose

packaging, with the goal of providing only what is needed and making it easier to do so for everyone involved. FDA Commissioner Dr. Scott Gottlieb has indicated his support for a move toward limited-dose packaging.

Additionally, as a distributor, McKesson plays a key role in getting those drugs manufactured by others into pharmacies and to patients quickly. We will work with manufacturing partners to put new *non-opioid* pain relievers into the hands of pharmacists and hospitals as soon as possible. We are often able to get new drugs to pharmacists within less than twelve hours of their availability—a tool we used, for example, to help the CDC distribute the H1N1 flu vaccine during that crisis. We understand that some new non-opioid pain relievers are under FDA review.

Pharmacist training is another key tool in preventing opioid abuse and overdose deaths. McKesson is committed to providing pharmacists with free training on how to identify patients who may be at risk of overdose and may potentially benefit from the use of naloxone or other overdose reversal medications. These trainings have been independently developed by the Accreditation Council for Pharmacy Education, an accredited continuing education program from the *Pharmacist's Letter*. Members of our HealthMart network, which services 5,000 independently owned pharmacies, all now have access to the HealthMart Operations Toolkit, which offers: (1) opioid education and training courses; (2) drug abuse prevention solutions; (3) best practices to prevent drug abuse when filling prescriptions; and (4) community outreach resources with strategies to promote drug abuse prevention at the local level.

McKesson also provides funding and support to the Healthcare Distribution Alliance's Allied Against Opioid Abuse initiative, which is a national education and awareness initiative to help prevent the abuse and misuse of opioids. And we are working with the Community Anti-Drug Coalitions of America (CADCA) to launch a substance abuse prevention pilot program tailored specifically to veterans.

Among our other efforts, we have partnered with the Pennsylvania Attorney General to help combat opioid abuse by delivering 300,000 drug deactivation pouches to local communities in 12 counties, in order to reduce diversion.

Finally, McKesson has set up a new foundation dedicated to fighting the opioid epidemic and committed \$100 million to support the foundation's mission. The standalone foundation will have independent subject matter experts on its Board of Directors. We expect foundation funds to support, among other things, educating providers on evidence-based clinical best practices in the treatment of pain, prevention and intervention initiatives and education on the dangers of opioid use, and increasing access to opioid treatments, including medication-assisted therapy and life-saving overdose reversal drugs.

Policy Solutions

In addition to the steps McKesson itself is taking, we support public policy changes to discourage opioid abuse and to help those battling opioid use disorder. We appreciate the Committee's efforts to date and pledge our continued collaboration in the development of

effective legislation. We are particularly supportive of legislative efforts the Health Subcommittee recently passed that would promote greater use of electronic prescribing; standardize electronic prior authorization; encourage prescriber, dispenser, and patient education around the risks of opioid use; and establish programs for the return and destruction of unneeded opioids. We also support the President’s declaration of the opioid crisis as a national emergency, and we provided the President’s Commission on Combating Drug Addiction and the Opioid Crisis with our recommendations to consider for its final report, some of which were included.

Since 2015, our McKesson Opioid Task Force—composed of clinical, operations, regulatory, and policy experts—has been working on identifying and developing real world policy solutions to the crisis, issuing two white papers on the topic. The most recent, “[Call to Action: Execute Solutions Today to Combat the Opioid Crisis](#),” recommends incentivizing implementation of opioid stewardship or similar clinical excellence programs; ensuring proper patient education on opioids and their alternatives; requiring e-prescribing of controlled substances; requiring electronic prior authorization by payers to ensure that prescriptions are medically necessary; piloting pharmacist-led opioid care management programs; and implementing a prescription safety alert system, a concept initially conceived by NCPDP.

We encourage Congress to prioritize a prescription safety alert system to ensure that all stakeholders who have been impacted by opioid abuse, especially patients and their loved ones, can benefit from this promising solution. Further, we urge Congress to require use of electronic prior authorization to better align prescribing with best clinical practices, prevent misuse, and ensure access to patients with legitimate need.

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McKesson, like DEA and the other key players in the pharmaceutical supply chain, has learned important lessons as we have responded to the opioid crisis. We are acting on those lessons, and I believe we have significantly enhanced our capability to identify problematic pharmacies and quickly cut off their access to opioids and other controlled substances. We 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 answer your questions.