Statement for the Record – McKesson Corporation

Good morning, Chairman Smith, Ranking Member Neal, and esteemed members of the committee. My name is Gene Cavacini. I serve as the Senior Vice President and Chief Operating Officer for McKesson's drug distribution business. In this role I oversee sales, distribution, and customer service operations in the United States.

McKesson applauds the Committee's focused efforts to mitigate drug shortages and shares your goal of bolstering the resiliency of our global pharmaceutical supply chain. I am grateful for the opportunity to be here today to share McKesson's perspective and to offer recommendations for your consideration.

McKesson is a diversified healthcare services company founded nearly two centuries ago. We play a critical role in healthcare delivery, making medications and supplies available to healthcare providers and patients across North America. About one third of all North American pharmaceutical products flow through our facilities every day. We're passionate about our mission to improve care in every setting, one product, one partner and one patient at a time. If you visit one of our more than 30 distribution centers you will probably walk under a banner that reads "It's not a package, it's a patient".

Understanding Drug Shortages

While the U.S. supply chain is part of a global system which is fragmented and complex, it has proven to be resilient in times of crisis. Today, distributors connect approximately 1,400 manufacturers to over 330,000 sites of care, and safely and securely deliver approximately 11 million products daily.

While drug shortages affect only 1% of all prescriptions, we know even that small percentage can have a significant impact on caregivers, healthcare providers, and most importantly, patients.

Drug shortages occur when commercially available supply of a drug does not meet demand. It is important to distinguish whether the occasional disconnect between supply and demand reflects true supply limitations, or temporary gaps in access.

Our view is that most drug shortages fall within three key categories: market-wide supply constraints, product-specific issues, and reimbursement and market access limitations.

Common causes within those categories include sourcing or manufacturing limitations, natural disasters, market economics, changes in prescribing or patient demand patterns, and product discontinuation. Key drugs and classes making headlines demonstrate the range of root causes, but also highlight the need for unique solutions.

While each drug shortage is unique, together, we can strengthen supply chain resiliency by understanding the root causes and deploying targeted solutions. McKesson's primary commitment is to get critical medications to our providers and the patients they serve. That commitment is foundational to our reliable and sustainable sourcing initiatives.

Predicting & Managing Drug Shortages

At McKesson, we are continually improving our processes, building redundancy and contingency-planning to proactively predict, identify, and mitigate drug shortages. A few examples include:

- Data Driven Solutions: Use real-time insights, predictive analytics, and AI capabilities to align our evolving supply and demand needs, anticipate shortages, and provide insights for channel participants about how to manage their inventories.

- Critical Care Drug Task Force: Multidisciplinary team of clinicians and supply chain experts that monitor, communicate, and respond to supply chain trends and needs; engage targeted customers as needed for feedback and assess cost sensitivity.
- Supply Optimization: Optimize inventory despite constraints, secure backup product and alternatives where available, and obtain supply from multiple manufacturers, when possible.
- Diversify Supplier / Manufacturer Partners: Open contracting and formulary model allows us to diversify partners and bring on new market entrants at all times.
- New Market Entrants: We support emerging and diversified suppliers with new product launches to bring greater supply to market.
- Equitable Allocation: When supply constraints occur, we work diligently to ensure equitable distribution of available supply across all our customers based on their ordering history.

As part of our proactive approach, we deploy a supply chain risk assessment. First, we examine risk across three key domains: clinical & patient need, supply vulnerability, and manufacturer resilience. Clinical and patient needs are paramount. We examine the drug's indication and impact on clinical regimen – meaning is it curative, is it foundational to common treatments, are there clinical alternatives? We also examine relevant operational differences between products, like refrigeration or special handling requirements. We evaluate supply vulnerability by determining the number of manufacturers in the market, the number of active pharmaceutical ingredient (API) sources, any history of disruptions, potential impactful regulatory actions, or geopolitical considerations.

Finally, we assess manufacturer/supplier resiliency. We examine their size, capacity, service lines, growth potential, regulatory actions, performance history and business health. We rely on our experience with them – past performance is often an indicator of future performance. We are limited, however, in utilizing data that is publicly available or willingly shared by the manufacturer or supplier.

For those drugs with the greatest clinical impact on patients, such as curative cancer treatments, we prioritize:

- Diversifying our suppliers
- Diversifying manufacturing sites and/or API sources
- Increasing monitoring or check-ins
- Long-term contracts
- Securing supply
- Supporting new market entrants
- Diversifying and bolstering access to GSI products

McKesson Public Policy Recommendations

A robust, competitive market is one that naturally buffers against drug shortages.[1] Government interventions should correct the market to its natural competitive state and be careful not to create misaligned incentives that could further exacerbate shortages. Policymakers should focus on products most at risk of shortage like generic sterile injectables, particularly those for cancer patients.

We also note that supply-side shortages are often the result of upstream supply chain issues. Distributors have limited insight and even less control over these problems. We defer to manufacturers on what specific investments should be made to address those issues.

On other root causes, we offer the following recommendations:

Reimbursement and Market Access Incentives

The right incentives could make it financially appealing for new market entrants or existing manufacturers to invest in the necessary redundancies and quality programs to guard against supply disruptions. This will require significant investments to bolster the market and economic opportunity for historically competitive, low margin drug classes and those which rely on a limited number of global manufacturers (e.g., two or less). Determining drugs eligible for such programs and the duration of such efforts is imperative. Initiatives must not generate misaligned incentives to create or maintain a drug shortage.

Programs must have clear guardrails and metrics to ensure market correction and program exploitation are prioritized. Efforts must be led through public-private partnerships between federal agencies (e.g., FDA, CMS) and key stakeholders across the supply chain, including but not limited to manufacturers, distributors, patient advocacy organizations, and impacted physician specialty organizations. We outline key opportunities below:

- **Enhance Medicare Access and Reimbursement:** Mandatory equitable or favorable formulary placement under Medicare Part D could fuel greater competition, especially for biosimilars and competitive drugs classes. Formulary exclusivity contracts can make it difficult for new market entrants to secure enough patient volumes to make manufacturing investments. Mandatory coverage could level the playing field and address some access barriers. Additionally, enhanced reimbursement for drugs across therapeutic classes with a history of shortages or risk of shortage within Medicare programs can create economic favorability to support investment or reinvestment in manufacturing capabilities.
- **Limit Federal Program Rebate and Pricing Requirements:** We should consider modifying current policies and contemplate when it is best to allow manufacturers to 'reset' prices[2] to reflect the current cost of producing goods, or at minimum buffer against additional penalties that make necessary price increases disadvantageous.
    - *Inflation Reduction Act (IRA) Inflationary Rebate Penalties:* The IRA[3] does contain some level of safeguards to protect eligible inflationary rebatable Medicare Part D and B drugs that may be susceptible to shortage. However, this discretion is left to the Health & Human Services (HHS) Secretary and does not define the parameters for a drug becoming "eligible" for exemption, the market data/criteria needed to make such assessments, or the duration of a drug being excluded. We recommend codifying exclusions more clearly to create better economic safeguards for drugs in shortage and those at risk of shortage.
    - *Medicaid Drug Rebate Program (MDRP) Average Manufacturer Price (AMP) Cap Penalties:* Manufacturers of brand and generic covered outpatient drugs must pay each state Medicaid program a statutory rebate to participate in the program. The Medicaid Rebate is currently capped at AMP. Starting January 1, 2024, drugs facing Medicaid rebates higher than AMP will no longer by capped at 100% of the drug's AMP. This is likely to create considerable market constraints and may further drive manufacturers out of the market. We recommend suspending all MDRP rebate requirements for an established period of time to allow manufacturers to invest in the production of drugs in or at risk of shortage. We recognize the magnitude of impact will depend heavily on which drugs are eligible for such a safe harbor, and therefore recommend that at a minimum, penalties remain capped at 100%.

        - *Inclusion of inflationary penalties on generic drugs in the MDRP*: As a result of these penalties, when generic manufacturers pull their drugs from the marketplace due to pricing economics, the remaining manufacturers have no flexibility to raise prices when they are adversely impacted by the MDRP inflation rebates. We recommend suspending inflation penalties on generic drugs that are in shortage.
    - *Modify the 340B Program:* Federal pricing programs, such as a 340B ceiling price, can deter market entry of new generic manufacturers. We recommend temporarily excluding certain drugs (e.g., low-cost generics, critical drugs in or at risk of shortage) from the program or limiting the ceiling pricing to avoid "penny pricing" challenges (e.g., make ceiling price equal to AMP). This exclusion should accompany specific quality and production goals for manufacturers.
- **Quality-Based Incentives:** Ensuring quality of medicines, including manufacturer and supplier resiliency, is paramount to a safe and stable drug supply chain. In addition to product quality requirements, rewarding manufacturers that adopt quality best practices is a sensible and worthy pursuit. Integrating quality within drug manufacturing is not a new concept. For years, FDA has contemplated the need for a Quality Management Maturity (QMM) program for greater manufacturer transparency and is currently soliciting public comments on how to create a voluntary program[4]. Integrating business and manufacturing incentives is foundational to building global supply chain resiliency. As such, quality-based incentives such as accelerated approvals, vouchers, and enhanced payments for manufacturers demonstrating exceptional quality practices are appropriate. We support incentivizing a culture of quality, and whether done through FDA or industry-prescribed metrics, believe that improving global quality will favorably impact drug shortages. It is important to note that direct purchaser organizations conduct their own quality due diligence during sourcing. Such diligence may include a review of prior FDA inspections, product recalls, site inspections, and other quality assurance assessments.

Supply Preservation Programs

Improving access and preservation of API bolsters global supply chain resiliency. This requires creating and aligning incentives across the supply chain that go beyond on- or near-shoring manufacturing capabilities. For maximum benefit, all efforts must be contemplated in coordination with federal and state Strategic National Stockpile (SNS) efforts.

- **Incentives for Buffer Stock Programs:** If implemented with the appropriate safeguards, creating incentives for manufacturers to maintain a 3 to 6-month reserve capacity of critical medicines could be another solution for drug shortages in certain therapeutic categories. Manufacturers should further be encouraged to maintain reserve capacity of APIs and other necessary ingredients for emergency production, if needed.

In order to prevent against inadvertently aggravating a drug shortage, these programs should be made available to both hospital and community providers. While we support CMS's overall goal of creating a buffer stock incentivization program for hospitals as early as CY 2024, we believe that the current proposal could further exacerbate access gaps if additional sites of care are not included. As the recent cancer drug shortage has demonstrated, creating safeguards in only one part of the care delivery ecosystem disproportionally disrupted access for patients unable to seek care in hospitals or Cancer Centers of Excellence. Buffer stock programs should include core capabilities to support the safe and efficient storage, management (e.g., staffing, record keeping), and rotation of supply (e.g., virtual vendor managed inventory). Additionally, since demand can fluctuate regionally and by individual customers, the

ability to seamlessly pass product both regionally and nationally should be a key attribute for entities facilitating buffer stock programs.

Most providers and manufacturers may not have the infrastructure and core capabilities necessary to operationalize buffer stock programs. Distributors are ideally positioned to serve in this role and should be recognized as preferred partners to entities working on behalf of providers or manufacturers. Should CMS elect to move forward with permitting a buffer stock program(s), it is important that the agency has methods for evaluating impact to the supply chain, and tactics ready to deploy should unintended consequences be observed.

Supply Chain Visibility

Enhancing the integrity of our global supply chain necessitates greater visibility and insight into the original source of excipients (inactive substances that serve as the vehicle or medium for a drug or other active substance), APIs, and finished dosage products. We continue to support efforts to improve data collection from manufacturers to improve our understanding of potential supply chain vulnerabilities. The ongoing collaboration between distributors and FDA and Administration for Strategic Preparedness and Response (ASPR) continues to provide valuable insights.

Where FDA and ASPR may see market softness across distributors, early warning signals should be shared with distributors to optimize our ability to respond. For example, while distributors continue to diversify our supply sources, lack of "origin" insights prohibit us from ensuring our efforts are truly creating safeguards or simply new sourcing routes to the same "origin" source. Additionally, while distributors conduct their own partner evaluations to ensure suppliers meet core quality metrics, these may not uncover the same vulnerabilities as identified in FDA evaluations.

We recommend the private sector and federal agencies maintain an open dialogue - one that encourages sharing data and insights while protecting commercial interests. The focus should be on the exchange of required information, rather than onerous reporting requirements. We must continue to build trust across public-private partnerships in order to effectively identify early warning signs that a shortage may be on the horizon.

To avoid unnecessary burdens, there should be clarity on the criteria for inclusion of APIs or finished product(s) on the critical medication shortage list. Similarly, when that drug is no longer on the shortage list and there is evidence that market supply has stabilized, then reporting requirements should be rescinded.

McKesson believes solving drug shortages requires the collaboration of all the stakeholders in the supply chain, and we are committed to doing our part. By addressing the highly variable root causes, bolstering supply preservation efforts, and improving communication between stakeholders, we can make meaningful progress in protecting the health of our nation.

For more information on McKesson's pragmatic, solutions-oriented approach to mitigating drug shortages, please visit www.mckesson.com/drugshortages.

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[1] Experience with the Generating Antibiotic Incentives Now (GAIN), passed in 2012, demonstrates that without the appropriate reimbursement and market access incentives, manufacturers are reticent to invest in the development and marketing of drugs when presented with incentives focused on expedited FDA reviews and extended exclusivity

alone. Source: https://www.fda.gov/news-events/fda-brief/fda-brief-fda-reports-its-progress-advancing-policies-developing-next-generation-antibiotics

[2] “Resetting” price in this context means allowing a manufacturer to establish a once in a lifetime “new” price for a drug for the purposes of Federal drug reporting programs, such as 340B and the MDRP. As such, 340B ceiling price and MDRP Average Manufacturer Price (AMP) calculations would start anew and not be subject to the restrictions of predecessor market dynamics.

[3] U.S. Congress. HR 5376 Inflation Reduction Act of 2022.

[4] Food and Drug Administration. Quality Management Maturity Program for Drug Manufacturing Establishments; Request for Comment. Sept 15, 2023.