AMA
AMERICAN MEDICAL ASSOCIATION

James L. Madara, MD
CEO, EXECUTIVE VICE PRESIDENT

james.madara@ama-assn.org

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The Honorable Lina Khan, JD
Chair
Federal Trade Commission
600 Pennsylvania Avenue, NW
Washington, DC 20580

Re: Solicitation for Public Comment to Understand Lack of Competition and Contracting Practices that May be Contributing to Drug Shortages

Dear Chair Khan:

On behalf of our physician and medical student members, the American Medical Association (AMA) appreciates the opportunity to provide comments on the Federal Trade Commission's (FTC) efforts to combat drug shortages. As you know, drug shortages have been a persistent problem plaguing patients and physicians for years. They show no signs of abating in the near future unless serious action is taken to identify root causes of the shortages, mandate transparency for the entirety of the supply chain, and bolster our domestic supply chain with a focus on building supply chain resiliency, among other interventions. The AMA supports more efficient regulatory review of prescription drugs and greater investment in production capacity. Also critical is a focus on anti-competitive or monopolistic actions that create market dynamics that ultimately result in drug shortages and increasing drug acquisition costs.

Physician practices have long struggled with persistent shortages of even the most essential drug products. Shortages of products such as sterile saline, which are critical in almost any practice setting, have persisted for years. Lidocaine shortages, another critical product for patient care, have also persisted, with no end in sight despite consistent promises by manufacturers that the drug supply will soon meet demand. More recently, two commonly used injectable chemotherapy drugs, carboplatin and cisplatin, were added to drug shortage lists resulting in changes to care plans for exceptionally vulnerable cancer patients across the country. While sterile injectable drug products have been the focus of much of the conversation around drug shortages, severe shortages have been seen outside of the sterile injectable market. For example, getting less attention are critical shortages of a range of antibiotics, which have impacted commonplace treatments such as pediatric formulations of amoxicillin. These shortages result in physicians and other health care professionals being forced to turn to alternatives, which in some cases are not considered standard or first line treatments, resulting in delays in care or worse patient outcomes.

The drug supply chain is complicated and can be opaque as to its practices, making it challenging to understand and to identify problems. Anti-competitive behaviors by prescription drug manufacturers, pharmacy benefit managers, health plans, group purchasing organizations (GPOs), wholesalers, and others have long been known to cause significant issues in prescription drug pricing. One mechanism is through market concentration where there are only a few competitors, allowing for practices that prioritize corporate profit at all costs while consumers see escalating out-of-pocket costs and lack of coverage for critical treatments. While the impacts of market concentration and other anti-competitive

actions by almost every market participant in the drug supply chain have clear and known impacts on costs, many of these actions potentially contribute to drug shortages as well.

While drug shortages can have numerous root causes, such as demand increases and manufacturing process issues, perhaps the biggest contributor to drug shortages in the generic product space are economic issues. Over time, the price of many generic drugs has been driven extremely low, resulting in few manufacturers of these products that operate on very thin financial margins with very little room for error. This has resulted in financial instability for manufacturers with little flexibility to expand to meet demand; to rectify manufacturing line problems; and limited advancement of their manufacturing technologies to create more resilient manufacturing lines–leading to many being driven out of the business altogether. Too few manufacturers in the space have resulted in a supply chain that is extremely vulnerable and lacks meaningful ability to provide consistent supplies of essential prescription drugs to all providers.

Contracting and purchasing practices by large volume purchasers, such as GPOs, wholesalers, and even large health systems and hospitals that engage in direct purchasing, has potentially contributed to creating the economic dynamics leading to these supply chain vulnerabilities. Given the volume some of these groups purchase in, purchasing patterns can play out in ways that result in the purchasing contracts being concentrated with very few manufacturers, or even just one manufacturer for a particular drug. That can potentially leave other manufacturers in a financial lurch, given that business will be concentrated elsewhere. The lack of business leads to a host of issues, including potentially driving manufacturers out of the market.

Another key issue is that the GPO/wholesaler market is dominated by very few extremely large players. With this highly concentrated purchasing power and a focus on negotiating the best possible prices for their clients, they can drive contracted prices very low across the market. Driving prices of a number of generics down to practically pennies per dose results in manufacturers operating on razor thin margins, which, as mentioned above, allows for practically no room for potential disruptions in manufacturing, no ability to upgrade manufacturing lines with new technology, and again, drives competitors out of the market entirely.

Having purchasing power so concentrated, with significant manufacturing volume committed to a limited number of purchasers, can also ultimately impact prices. If a drug should go into shortage, simple laws of supply and demand can result in skyrocketing prices for little available supply. This can especially impact smaller practices if they do not participate in a GPO. Small practices already have significantly higher drug acquisition costs, simply because they do not purchase in volumes significant enough to meaningfully negotiate on price. In times of shortage, this was felt acutely by smaller practices, as they do not have the volume or relationships with manufacturers to ensure they can purchase any of what limited supply may be available. In those cases, contracts with GPOs, wholesalers, and others will frequently take priority over the needs of smaller practices. This can create severe access issues for patients, particularly for those in rural and other underserved areas.

Given the issues outlined above, the AMA urges the FTC to investigate participants in the prescription drug supply chain to understand their potential role in contributing to drug shortage. This includes the newly announced investigation into the roles of market participants such as GPOs and drug wholesalers. Significant transparency around the entirety of the drug supply chain, including contracting, sales, pricing, and distribution practices and patterns are critical to successfully identifying root causes of drug shortages and determining appropriate legal or regulatory steps to mitigate them. The AMA also urges

additional investigation into the "grey market"[1] to determine whether pharmacies are engaging in anti-competitive behavior that significantly drives up the costs of drugs over the initial purchase price.

The AMA appreciates the FTC's attention towards this exceptionally serious matter. Should you have any questions or would like to discuss this issue further, please contact Shannon Curtis, AMA Assistant Director of Federal Affairs at Shannon.Curtis@ama-assn.org. We look forward to working with you as you continue this critical work.

Sincerely,

James L. Madara, MD

[1] https://oversightdemocrats.house.gov/gray-market-report