AMA
AMERICAN MEDICAL ASSOCIATION

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Maureen K. Ohlhausen
Acting Chairwoman
Federal Trade Commission
400 7th St., SW
Washington, DC 20024

Scott Gottlieb, MD
Commissioner
U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: Federal Trade Commission Workshop on "Understanding Competition in Prescription Drug Markets: Entry and Supply Chain Dynamics"

Dear Acting Chairwoman Ohlhausen and Commissioner Gottlieb:

On behalf of the physician and medical student members of the American Medical Association (AMA), I offer strong support for your commitment to address factors that impact competition (or the lack thereof) in the prescription drug market. The AMA applauds the decision of the Federal Trade Commission (FTC) to host a public workshop on "Understanding Competition in Prescription Drug Markets: Entry and Supply Chain Dynamics." In addition, the AMA is encouraged by your joint leadership and effort for the FTC and the Food and Drug Administration (FDA) to work together to advance thoughtful measures to increase competition and remove regulatory burdens that inhibit competition and that do not advance safety or efficacy. This is an essential model in advancing workable solutions and public policies that are crafted to the particular challenges faced by generic competitors that offer safe, efficacious, and affordable treatment alternatives to our patients.

Earlier this year, the AMA expressed strong support for the FDA's request for input on how best to preserve the balance Congress intended to strike in the Hatch-Waxman Amendments between encouraging innovation in drug development and accelerating the availability to the public of lower-cost alternatives to innovator drugs. Furthermore, many of the public responses submitted to the FDA docket and during the public meeting on this topic validate that some manufacturers have leveraged FDA regulations to prevent generic competition for purposes that do not appear legitimately related to patient safety and efficacy. Such actions should be considered anti-competitive. Thus, the AMA is very interested in the factors that may inhibit competition that the FTC has jurisdiction to address related to entry and supply chain dynamics and which the FDA may have jurisdiction to address as well. We do not expect that there will be simple solutions, but these fact-finding activities are focused on critical areas that are directly

related to innovation, commercialization, and manufacturing—all of which impact the ability of generic drug competitors to enter the market.

There are additional factors that impact demand, competition, and transparency, and thus pricing and affordability. We urge the FTC and the FDA to consider the impact of mergers and consolidations in decreasing competition and contributing to shortages. The AMA is very interested in learning more about the assessment, if any, that the FTC has made of the factors currently utilized to assess whether such consolidations and mergers will limit competition as applied in the context of the prescription drug market. We also urge consideration of the role of direct-to-consumer advertising for prescription drugs and whether it promotes essential consumer protections. Our policy supports mandating that direct-to-consumer advertising of prescription drugs should state the manufacturer's suggested retail price of the drugs to promote transparency throughout the supply chain. This is another area to consider broadly as you engage with other federal and state agencies as well as Congress to address various policies to advance transparency.

As the AMA shared with the Commissioner previously, policymakers are grappling with a number of policies that may drive increased value and improved pricing for prescription drugs, but these are complex and, often times, difficult to implement in practice. We commend both the FDA's and FTC's efforts to address the cost of prescription drugs by addressing the fundamentals−removing barriers to competition in order to lower costs. We look forward to working with this Administration to advance important goals, including promoting competition and patient access to safe and efficacious treatments and innovation.

Should you have questions, please contact Shannon Curtis, Assistant Director of Federal Affairs, at shannon.curtis@ama-assn.org or 202-789-8510.

Sincerely,

James L. Madara, MD