AMA
AMERICAN MEDICAL ASSOCIATION

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

Re: Facilitating Competition and Innovation in the Biological Products Marketplace; Public Hearing; Request for Comments; Docket No. FDA-2018-N-2689-0001

Dear Commissioner Gottlieb:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to provide comments in response to *Facilitating Competition and Innovation in the Biological Products Marketplace; Public Hearing; Request for Comments*. We applaud your efforts to remove regulatory burdens that are not related to safety and efficacy and that hinder market competition for prescription medications. We welcome working with you and other federal agencies, such as the Federal Trade Commission (FTC), in order to develop and implement well-crafted and effective public policy solutions that would alleviate the financial burdens the high cost of prescription medications impose on patients, physicians, other health care providers, and the health care system.

Physicians experience and see first-hand the difficulty and burden high pharmaceutical costs have imposed on our patients, on physician practices, and the broader health care system. The AMA supports policy solutions that:

- result in lower cost prescription drugs, with assured, affordable access for those who need them;
- increase transparency along the pharmaceutical supply chain;
- increase competition and production capacity in all segments of the pharmaceutical and biological markets; and
- decrease the administrative and red tape burdens to obtain medically necessary treatments faced by patients, physicians, pharmacists, and other members of the health care team.

The AMA strongly supports accelerating and expanding regulatory action to increase pharmaceutical market competition and combat anti-competitive practices. Strong competition by generic drug products is essential to ensuring that patients have access to affordable treatments. The AMA applauds your efforts to address long-standing concerns that certain U.S. Food and Drug Administration (FDA) requirements and regulations, particularly those surrounding Risk Evaluation and Mitigation Strategies, have been misused by certain manufacturers to delay and deter generic competition from entering the market. In order to ensure a thriving market for generic drugs, that market must be free from

anticompetitive actions by manufacturers that are intended to keep generic competition at bay. As agencies with a mutual interest in curbing anti-competitive actions by pharmaceutical manufacturers, the AMA supports collaboration and coordination between the FDA and the FTC to ensure that brand manufacturers are not engaging in anticompetitive behaviors, as opposed to those driven by legitimate safety concerns.

The AMA is strongly supportive of FDA efforts to ensure a robust biosimilar market and is pleased to see biosimilar products finally becoming available for patients. With biologic products frequently coming with steep price tags, the development of biosimilars represents one of the few tools currently available to provide patients with lower cost treatment options. However, to ensure uptake of biosimilar products by physicians and patients is successful, we support your efforts to ensure that there are no artificial barriers in place that may hinder integration of these products into treatment regimes. In general, the AMA is concerned with any regulatory actions that draw unnecessary distinctions between biosimilars and their reference products. With new products such as these, actions that seek to make strong distinctions between the reference product and the biosimilar that are not evidence-based and not clinically relevant may have the unintended consequence of giving that product an appearance of being less safe or less efficacious.[1] As neither of those is necessarily true for licensed biosimilar products, we urge the FDA to consider the impacts that these distinctions may have on uptake of the products. Given the significant financial implications of these products, it is in the best interest of patients and the health care system to ensure these products find their way into treatment plans without barriers and bias.

The AMA urges the FDA to monitor and address misinformation concerning biosimilars, including inaccurate information concerning safety and efficacy of biosimilars. We applaud the FDA's efforts to provide educational materials for physicians and consumers on these new products and welcome opportunities to work with the FDA to inform these communities about these products and their approval process.

We look forward to working closely with you and other federal agencies to take rapid, direct action where authority exists to lower the costs of the appropriate prescription medication that patients need as determined by their physician, while also reducing the barriers patients and the health care team face in so doing. If you have questions, please contact Shannon Curtis, Assistant Director, Division of Federal Affairs, at shannon.curtis@ama-assn.org, or 202- 789-8510.

Sincerely,

James L. Madara, MD

[1] However, the AMA does not support substitution back and forth between the prescribed reference product and the biosimilar unless interchangeability has been established by the FDA or expressly prescribed by the treating physician.