AMA
AMERICAN MEDICAL ASSOCIATION

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

RE: Docket No. FDA-2017-N-3615 for "Administering the Hatch-Waxman Amendments: Ensuring a Balance between Innovation and Access; Public Meeting; Request for Comments."

Dear Commissioner Gottlieb:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to offer our comments to the U.S. Food & Drug Administration (FDA) in response to the 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. The AMA applauds your leadership and the immediate steps you have taken to address our long-standing concerns that certain FDA requirements and regulations are being misused to delay and deter generic competition in a manner not contemplated by Congress. The escalating cost of prescription drugs has not only increased overall costs to the health care system directly, but indirectly raises costs as patients are not able to receive appropriate treatment and their health status worsens, requiring more costly interventions in high-cost centers of care. Fundamentally, however, the human cost to our patients is not tenable and we urge swift action to implement reform measures that will correct manipulations of laws and regulations that Congress did not intend.

Misuse of Restricted Distribution and Risk Evaluation Mitigation Strategies

The AMA strongly supports recommendations made during the public meeting to deter the use of risk evaluation and mitigation strategies (REMS) in order to primarily (if not solely) create barriers to generic market competition. The AMA is concerned, for example, with the number of inquiries to the FDA from generic manufacturers unable to obtain brand-name samples for bioequivalence testing. We are also troubled by uses of elements to assure safe use (EASU) that circumstances strongly suggest are not initiated primarily to ensure safe use, but to instead chill competition. The AMA supports compelling samples sufficient for bioequivalence testing by three generic manufacturers as a condition of drug approval. We also strongly support allowing the FDA to require shared REMS or to approve separate REMS. We echo comments provided by other stakeholders that REMS patenting is contrary to public policy on its face and should not be allowable as a condition of FDA approval either. (While a manufacturer could patent a REMS—having an unpatented REMS should be a condition of FDA approval which would negate the financial incentive to seek such patents.)

Misuse of Citizen Petitions: Eleventh Hour Filings

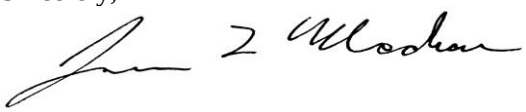
Equally troubling to the misuse of REMS are strong indicators that manufacturers are misusing citizen petitions to chill competition. Citizen petitions were designed to allow the public to directly petition the FDA when there was concern that the FDA action or inaction raised important product safety or efficacy concerns. Yet, is it clear that brand-name manufacturers are leading the way in filing such petitions as laid out during the FDA's stakeholder meeting and filing such petitions at the eleventh hour—a strategy that effectively slows the entry of generic competition. The AMA strongly urges that a rebuttable presumption be established that late-filed petitions are done so for anticompetitive reasons as opposed to advancing product safety and efficacy concerns when done so by a brand manufacturer. Also, the AMA strongly supports recommendations offered during the public meeting urging the FDA to establish a specific presumption that brand-name manufacturer petitions pertaining to generic applications filed within nine months of the expiration of the primary patent on the brand-name drug are a delaying tactic. Furthermore, the AMA supports requiring a preliminary finding that such petitions will likely be granted based on compelling evidence in order to proceed to a full review.

FDA and the Federal Trade Commission

The AMA strongly supports communication and information sharing between the FDA and the Federal Trade Commission (FTC) to identify instances when EASU and REMS more broadly are being used for anticompetitive reasons as opposed to safety. In addition, we urge the FDA and FTC to establish standing, regular meetings of experts from both agencies to address anticompetitive tactics as outlined above as well as others that emerge over time. We also urge that the FTC and FDA collaborate on needed additional authorities each agency needs to address practices that represent misuses of FDA laws and regulations for anticompetitive purposes, as well as FDA practices that may stifle competition without a congressionally intended benefit to advance safety and efficacy.

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 the FDA's approach to addressing high drug costs 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 patient access to safe and efficacious treatments and innovation. If you have questions, please contact Shannon Curtis, Assistant Director of Federal Affairs, at 202-789-8510 or shannon.curtis@ama-assn.org.

Sincerely,



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