March 27, 2019

The Honorable Anna Eshoo  
Chairwoman  
U.S. House of Representatives  
Subcommittee on Health  
House Committee on Energy & Commerce  
2125 Rayburn House Office Building  
Washington, DC 20515

The Honorable Michael C. Burgess, MD  
Ranking Member  
U.S. House of Representatives  
Subcommittee on Health  
House Committee on Energy & Commerce  
2322A Rayburn House Office Building  
Washington, DC 20515

Dear Chairwoman Eshoo and Ranking Member Burgess:

On behalf of the physician and medical student members of the American Medical Association (AMA), I write to offer our support for your efforts to address the escalating prices of prescription medication by removing barriers to market entry for affordable prescription medication and shining a light on anti-competitive practices in the pharmaceutical supply chain that can lead to price escalations. The AMA is pleased to support the bills that will be considered by the U.S. House of Representatives Committee on Energy and Commerce Subcommittee on Health and to offer recommendations that will further enhance the bills. In addition, the AMA continues to support the following bills related to the Affordable Care Act (ACA) that would help ensure that the ACA’s goals of increasing access to high quality insurance and guaranteeing key consumer protections are maintained, as well as reducing consumers’ health care costs: H.R. 1425, H.R. 1386, H.R. 1385, H.R. 986, H.R. 987, and H.R. 1010.

Consistent with the AMA’s long-standing efforts to increase transparency, we support H.R. 1781, the “Payment Commission Data Act of 2019,” introduced by Reps. Carter (R-GA), O’Halleran (D-AZ), Rice (R-SC), Panetta (D-CA), Gianforte (R-MT), and Welch (D-VT). H.R. 1781 would provide access to essential data that the Medicare Payment Advisory Commission (MedPAC) and the Medicaid and CHIP Payment and Access Commission (MACPAC) need to evaluate the practices of various entities within the pharmaceutical supply chain that are either not readily available or not available at all for independent analysis, including drug pricing and rebate data. It also includes important protections to ensure proprietary data remains confidential and is not subject to disclosures that would not prejudice or undermine the market position or business interests of entities subject to the disclosure requirements. The lack of independent, data driven, third-party analysis of drug pricing and rebate data continues to hamstring additional efforts needed to combat anti-competitive business practices that undermine affordability and harm patients. It is essential that MedPAC and MACPAC have this information to provide data driven recommendations to Congress in order to improve the affordability of prescription medication while still providing adequate incentives to support innovation.

The AMA supports H.R. 938, the “Bringing Low-cost Options and Competition while Keeping Incentives for New Generics (BLOCKING) Act of 2019,” introduced by Reps. Schrader (D-OR) and Carter (R-GA). H.R. 938 would remove any incentive that a first generic applicant would have to “park” the 180-day exclusivity conferred under the Food, Drug, and Cosmetic Act (FDCA). Currently, this exclusivity is
available to the first generic applicant only. H.R. 938 would create a strong incentive for other generic applicants to seek entry where the first generic applicant has been lax in securing final approval.

The AMA supports H.R. 1520, the “Purple Book Continuity Act of 2019,” introduced by Subcommittee Chairwoman Eshoo (D-CA) as an essential move in the right direction. We also support modifications to ensure innovator biological developers do not have an incentive to build up patent estates over time and game the listing process. H.R. 1520 would require that the Food and Drug Administration (FDA) publish the patents of approved biological products in the Purple Book and publish it electronically on the FDA’s website and update it routinely. FDA would be required to report back to Congress in three years with recommendations on the types of biological product patents that should be included in or removed from the mandated list. We urge the Subcommittee to specify that all applicable patents must be listed by the innovator biological manufacturer (referred to as the reference product sponsor) at the time of licensing. The enforceability of late-filed patent(s) by the innovator biological manufacturer when a follow-on biological application has already been filed with the FDA should not be afforded the same consideration as patents listed when the biological product is licensed.

The AMA supports H.R. 1503, the “Orange Book Transparency Act of 2019,” introduced by Representative Kelly (D-IL). H.R. 1503 would ensure that the Orange Book is accurate and up-to-date, by requiring manufacturers to submit complete and timely information with FDA, as well as ensuring that patents listed in the Orange Book are relevant to the approved drug product. Further, the bill provides that where patents are found to be invalid through a court decision or a decision by the Patent Trial and Appeal Board (PTAB), these must be removed promptly. The AMA urges several modifications of this bill to enhance the overall value of the information available to potential generic applicants. First, any court or PTAB decisions that are subject to an appeal should be noted under the applicable product to ensure the information is accurate. The AMA also urges that an explicit provision is added to specify that risk evaluation and mitigation strategy (REMS) patents should not be listed in the Orange Book to the extent this results in the proprietary REMS becoming a part of the drug label.

The AMA supports H.R. 1499, the “Protecting Consumer Access to Generic Drugs Act of 2019,” introduced by Representative Rush (D-IL). H.R. 1499 would strengthen the Federal Trade Commission’s (FTC) existing authority to combat anti-competitive pay-for-delay settlement agreements between a brand manufacturer and generic manufacturers. Settlement agreements that include provisions to delay the entry of a generic equivalent from the market are anticompetitive and the FTC currently bears the burden of establishing the anti-competitive nature of such agreements. H.R. 1499 would ensure that limited FTC resources are not expended establishing such agreements are anticompetitive while preserving the ability of generic and brand manufacturers to enter into legitimate settlement agreements.

The AMA supports H.R. 965, the “Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act of 2019,” introduced by Representatives Cicilline (D-RI), Sensenbrenner (R-WI), Nadler (D-NY), Collins (R-GA), Welch (D-VT), and McKinley (R-WV). H.R. 965 would establish a process by which generic manufacturers could obtain sufficient quantities of brand drug samples for testing required by the FDCA to establish the generic drug bioequivalence to the brand drug. This is urgently needed as brand manufacturers continue to erect barriers to accessing such samples and effectively delaying the entry of generic competitors. The bill would also establish a mechanism that permits the use of a different, comparable REMS and elements to assure safe use subject to the discretion
of the FDA. Brand manufacturers are increasingly using proprietary REMS as a mechanism to further delay generic entry. The FDA has been limited in its authority to provide an alternative REMS option. The AMA continues to strongly urge passage of what has been bipartisan legislation in the U.S. Senate and U.S. House of Representatives in prior Congresses and now reintroduced into the 116th Congress. We urge immediate passage of this bill.

The AMA applauds your leadership and efforts to advance legislation that will address anti-competitive behaviors and misuse of current laws, regulations, and policies that were established by Congress and regulators to spur innovation while safeguarding safety and efficacy. The bills under consideration by the Subcommittee on Health represent important and critically needed steps forward to increase competition and transparency. We look forward to supporting these efforts and offering our assistance to secure passage of this legislation.

Sincerely,

James L. Madara, MD