AMA
AMERICAN MEDICAL ASSOCIATION

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The Honorable Joseph J. Simons
Chairman
Federal Trade Commission
400 7th Street, SW
Washington, DC 20024

Dear Chairman Simons:

On behalf of the physician and medical student members of the American Medical Association (AMA), I encourage the Federal Trade Commission to monitor insulin pricing and market competition and recommend enforcement action against manufacturers that engage in anticompetitive actions to the U.S. Department of Justice. Over the past several years, physicians have become increasingly concerned that the rapid rise in the price of insulin for patients is unrelated to the actual costs of research, development, commercialization, or production. Instead, physicians are concerned that anticompetitive factors may be present in the market for insulin. The consequences of an anticompetitive market could include worse health outcomes for patients due to artificially high and unaffordable prices of a critical medication that has been and should continue to be widely available and affordable.

Approximately six million Americans use insulin, a drug that has experienced dramatic price increases over the past decade. High insulin prices impact stakeholders throughout the health care system, but the consequences fall most heavily on patients. Insulin is one of the many essential drugs across all categories of pharmaceuticals to recently experience remarkable price increases. While a variety of complicated factors contribute to increases in insulin prices, we remain concerned that anticompetitive behavior by manufacturers and pharmaceutical benefit managers (PBMs) could be one of them.

To date, at least five states and a federal prosecutor are demanding information from insulin manufacturers and PBMs. In addition, class-action lawsuits have been brought on behalf of patients. For example, a class action complaint filed in Massachusetts in January 2017 points to evidence that, "[i]n 13 instances since 2009, Sanofi and Novo Nordisk raised the benchmark prices of their long-acting analog insulins, Lantus and Levemir, in tandem, 'taking the same price increase down to the decimal point within a few days of each other'…Eli Lilly and Novo Nordisk have engaged in the same lock-step behavior with respect to their rapid-acting analog insulins, Humalog and Novolog." The complaint further alleges that these pharmaceutical companies artificially inflated their list prices to secure positions on PBMs' formularies, with PBMs demanding higher rebates in exchange for including drugs on their preferred-drug lists. Similarly, three insulin manufacturers—Sanofi-Aventis, Novo Nordisk and Lilly—along with three of the largest PBMs—CVS Health, Express Scripts and OptumRx—are subject to a class action lawsuit, alleging that they together caused "rapid and lockstep price increases of more than 150 percent in insulin treatments." On the state level, in 2017, Nevada passed an act that requires the state's Department of Health and Human Services to compile a list of prescription drugs that it determines to be essential for treating diabetes. The manufacturers and PBMs associated with essential diabetes drugs will have to submit annual reports to the state containing drug cost information, which will be analyzed by the state and

reported on its website. However, pharmaceutical companies have begun challenging the Nevada law in court.

The implementation of the 21st Century Cures Act has been hampered by rapidly rising costs of prescription medication. The disease burden to patients, their families, and the health system imposed by diabetes is substantial. Access to affordable insulin is essential to ensuring patient health outcomes are not simply stabilized, but improved.

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