May 2, 2019

Dear Acting Commissioner Sharpless:

As organizations representing American consumers, taxpayers, and free-market advocates, we are writing to express concerns over the Food and Drug Administration's newly released guidelines on biosimilar naming, which could inhibit the utilization and availability of biosimilar drugs in the United States. Choice and competition are essential for American consumers to be able to realize the potential of lower-cost, clinically equivalent biosimilars. Our organizations have raised concerns over policies which deviate from the globally recognized International Nonproprietary Name (INN) system in the past, and we instead strongly favor guidelines based on the currently accepted system.

Essential to a functioning free market, robust competition simultaneously encourages innovation while driving costs downward for patients and taxpayers. One recent RAND Health study found that biosimilars are expected to save between $24 billion and $150 billion in the United States between 2017 and 2026. These savings will not only benefit consumers of biologics, but taxpayers who fund public payer systems such as Medicare and Medicaid which cover these prescription treatments, as well.

Congress has previously rejected, on a bipartisan basis, a unique naming system for biosimilars, as it "could lead to patient and prescriber confusion, increasing the possibility of medication errors," as well as interfere with existing state laws regarding generic substitution. We believe that the FDA should act in the spirit of this original legislation, rather than enacting new policy which will not benefit, but could in fact harm, patient safety and consumer savings opportunities.

Similar efforts were rejected by the FDA's European equivalent, the European Medicines Agency, during the biosimilar pathway creation process in the European Union (EU), where the

international World Health Organization (WHO) INN system is used, and where the INNs of the original product and the biosimilar version are the same. To date, there has been no evidence of safety and efficacy issues, and consumers in the European Union have seen double-digit price decreases for commonly used biosimilars.

Biologic drugs are the biggest driver of rising drug prices in the United States, and represent nearly all net spending growth on prescription drugs since 2014. Adding a unique naming system, which would impede interchangeability, could keep costs high due to lack of competition, even after the 12-year patent protection period has expired. We urge the FDA to set aside these new guidelines in favor of the internationally recognized, pro-consumer and pro-patient norm, and instead renew the agency's efforts to bring new biosimilar drugs deemed safe and effective to market as quickly as possible.

Sincerely,

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