Lowering the Cost of Prescription Drugs: Reducing Barriers to Market Competition

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for the

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Chairwoman Eshoo, Ranking Member Burgess and distinguished Members of the Committee, thank you for the opportunity to testify today. I am Tony Barrueta, Senior Vice President of Government Relations at Kaiser Permanente. As the largest private, integrated health care system in the United States, we provide pharmacy benefits to over 12 million people, dispensing 90 million prescriptions and administering 54 million inpatient and clinic doses annually. Our non-profit model combines coverage and care delivery. We also operate pharmacies that dispense drugs prescribed by the Permanente Medical Group physicians. Kaiser Permanente therefore has a unique perspective on drug prices. Our mission for pharmacy, and all services we provide, is to deliver high-quality, affordable care and to improve the health of our members and communities we serve.

Kaiser Permanente greatly appreciates the Committee's attention to drug prices. High drug prices impose a crippling burden on our members and our ability to carry out our mission. Drug companies have virtually unfettered discretion to raise prices, which imposes considerable—and often devastating—financial hardship on patients and families. We are very concerned by over-patenting, exclusivity gaming and pernicious lifecycle management trends. Too often, the primary goal of these tactics is to leverage the law to stifle competition, rather than to protect meaningful clinical advancements. It is past time for a new policy framework that fosters competition and prices patients can actually afford, while still rewarding innovation.

Congress has a critical role to play in mitigating this behavior by evaluating the extent to which current laws—including the *Federal Food, Drug, and Cosmetic Act* (FDC Act)—are

¹ Kaiser Permanente comprises Kaiser Foundation Health Plan, Inc., the nation's largest not-for-profit health plan, and its health plan subsidiaries outside California and Hawaii; the not-for-profit Kaiser Foundation Hospitals, which operates 39 hospitals and over 650 other clinical facilities; and Permanente the Medical Groups, self-governed physician group practices that exclusively contract with Kaiser Foundation Health Plan and its health plan subsidiaries to meet the health needs of Kaiser Permanente's members. As the largest private integrated health care delivery system in the United States, Kaiser Permanente delivers care to more than 12.2 million members in eight states and the District of Columbia.

subject to gaming that empowers the drug companies to extend monopoly pricing well beyond congressional intent. We applaud the Committee for working to make the patent landscape more transparent and stopping tactics such as pay-for-delay settlements and exclusivity "parking." We are especially grateful the Committee is considering the *CREATES Act*, which would curb abuses of the REMS program that arbitrarily block generic manufacturers from accessing samples they need to conduct the tests required for FDA approval. These anticompetitive practices significantly delay generic and biosimilar availability, hampering our ability to provide more affordable options to our members. They also create uncertainty that disrupts our ability to design optimal pharmacy benefits. Our research pharmacists actively monitor pipelines to forecast when competition may enter the market. When competition does not occur at the expected time, it undermines our efforts to negotiate better prices from drug companies that would allow more affordable premium pricing and cost-sharing.

Our approach to pharmacy benefits shows what is possible when competition exists.

Kaiser Permanente has long led the market in generic utilization. The rest of the market has nearly caught up with us, due in large part to greater generic availability across more therapeutic classes. More than 91 percent of drugs prescribed in our system are generic, which exceeds market averages of 89 percent. Every 0.1 percent increase in generic utilization saves our system \$28 million. While others have been slow to transition to biosimilars, Kaiser Permanente embraces them. For example, within our system, Inflectra (biosimilar) is used over 75 percent of the time instead of Remicade (the reference biologic). Inflectra utilization in the rest of the market is 2.3 percent. Major contributors to our success include our: (1) evidence-driven formularies; (2) ability as an integrated system to generate and disseminate unbiased information about drugs; and (3) restrictive approach to marketing by pharmaceutical sales representatives.

- Evidence-Driven Formularies: Our approach to designing pharmacy benefits focuses on a drug's clinical value. Permanente Medical Group physicians and Kaiser Permanente research pharmacists collaborate closely to develop our formularies. On an ongoing basis, our pharmacists develop an objective analysis for each drug. Then our physician experts review the evidence and make recommendations. This rigorous approach instills confidence in our formularies, leading our clinicians to prescribe consistently with them in the vast majority of cases. As a result, when generics and biosimilars perform just as well or better than a more expensive brand drug, they prevail within Kaiser Permanente.
- <u>Dissemination of Unbiased Information</u>: Kaiser Permanente generates and disseminates robust clinical information for use at the point of prescribing. "Drug Education Coordinator" pharmacists answer questions and provide information proactively to clinicians. Our integrated structure and use of a common electronic health record (EHR) also enables us to harness real-world data generated within our system to compare effectiveness between drugs and demonstrate that biosimilars are safe and effective. These data provide our clinicians with concrete evidence of positive outcomes, bolstering biosimilar prescribing confidence.
- Restrictions on Pharmaceutical Industry Marketing: The Permanente Medical Groups have policies that significantly restrict marketing or "detailing" by pharmaceutical sales representatives. In general, sales representatives who are allowed in our facilities must register and may not market nonformulary drugs unless specifically asked by a physician. These policies help prevent potentially biased marketing information from deterring prescribers from biosimilars, generics and other high-value therapeutic alternatives.

These best practices enable Kaiser Permanente to deliver pharmacy benefits in a way that thrives on competition and empowers us to negotiate lower prices while delivering positive

outcomes for patients. Breaking down barriers to generic entry is therefore of critical importance to our model of care. We cannot fully leverage our process to spark competition if generics and biosimilars are not available in the first place.

That's why the work the Committee is doing is so important. Today's proposals represent positive first steps toward a more functional and competitive market for drugs, which we know from experience will lead to better, more affordable care. But there is more work to be done. We hope the Committee builds on today's hearing by exploring additional ways to curb pervasive anticompetitive abuses by brand companies. Specifically, we encourage you to consider:

- Whether exclusivities under the *Biologics Price Competition and Innovation Act*, the *Orphan Drug Act* and the *Best Pharmaceuticals for Children Act* could be narrowed to more appropriately balance rewarding innovation with access to affordable medicines;
- Whether the Federal Trade Commission (FTC) should have more expansive authority to review drug companies' anticompetitive practices, including to help Congress understand and address patent abuses, such as patent thickets, evergreening and product hopping; and
- Whether agencies such as Food and Drug Administration (FDA), the National Institutes for Health (NIH), the Patient-Centered Outcomes Research Institute (PCORI), the Agency for Healthcare Research and Quality (AHRQ) and others could play a role in providing academic detailing and unbiased sources of information to counter drug company marketing tactics such as direct-to-consumer (DTC) advertisements, industry detailing and free samples.

Thank you for considering our perspectives on these important issues. Kaiser Permanente shares your commitment to lowering drug prices and reducing barriers to biosimilar and generic market entry. We look forward to working with you to advance meaningful solutions.