



September 21, 2018

Dr. Scott Gottlieb
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Room 600E
Silver Spring, MD 20993

Submitted electronically to: www.regulations.gov

RE: ***Facilitating Competition and Innovation in the Biological Products Marketplace*** (Docket No. FDA-2018-N-2689-0001)

Dear Commissioner Gottlieb:

Kaiser Permanente appreciates the opportunity to respond to the U.S. Food and Drug Administration's (FDA) request for comments on *Facilitating Competition and Innovation in the Biological Products Marketplace*. We commend FDA's continued focus on increasing biosimilar competition, including through the recent release of the *Biosimilars Action Plan*.

Kaiser Permanente is committed to providing high-quality, affordable care and improving the health of our members and communities we serve. As the largest private integrated health care delivery system in the United States, the Kaiser Permanente Medical Care Program delivers health care to more than 12.2 million members in eight states and the District of Columbia. Within that footprint, we maintain an internalized pharmacy system, including 395 out-patient and 39 inpatient pharmacies, 90 clinic-administered drug sites, and 27 call center and central fill facilities, staffed by over 15,500 pharmacists and staff. In 2016, Kaiser Permanente administered 44 million inpatient doses of prescription drugs, and 10.6 million doses through our outpatient clinics. In 2017, our out-patient pharmacies dispensed 90 million prescriptions. Kaiser Permanente's current total drug spend is over \$8 billion annually.

Kaiser Permanente leads the market in biosimilar utilization, due to a strong commitment across our integrated system to providing both our members and employees with balanced, evidence-based information about the medications we prescribe. We are eager to share best practices from our efforts to facilitate clinically appropriate use of biosimilars in the few cases where they are available to patients. Major contributors to Kaiser Permanente's success include:

- Strong prescriber confidence in our physician-led and evidence-driven formulary;
- Permanente physician and care team commitment to open communication and partnership with our members in prescribing decisions;
- Our ability as an integrated system to leverage, generate, and disseminate robust clinical data demonstrating biosimilar safety, efficacy, and value;
- A culture of sharing biosimilar success stories within care teams and from physician-to-physician; and

- Internal policies that significantly restrict marketing and detailing by pharmaceutical companies in our facilities and to Permanente physicians.

Despite our success at encouraging biosimilar utilization where possible, we remain deeply concerned about the burden of unsustainably high biological product prices on our members. Biological products and specialty drugs are the fastest growing component of prescription drug spending. Treatment costs for some biologics can be hundreds of thousands of dollars per year, imposing crippling costs on patients, the health care system, and the government. Fostering a robust market for biosimilar competition is essential to reducing the burden of high drug prices. We applaud FDA for addressing this important issue and look forward to working with you as this initiative moves forward.

I. Facilitating the Development of Biosimilar & Interchangeable Products

Interchangeability

Kaiser Permanente supports FDA's efforts to facilitate the development of interchangeable products. Fostering a strong market for biosimilars holds promise for increasing competition and reducing the burden of high drug prices, especially where biosimilars are designated interchangeable. To be interchangeable, a biosimilar must demonstrate that it produces the same clinical result as the reference product in any given patient. When a biosimilar satisfies that high standard, the law should not create arbitrary barriers to substitution. Even in cases where a biosimilar is not interchangeable, laws and policies should not deter physicians from using their clinical expertise and discretion to prescribe a biosimilar. Indeed, the success of generic competition in the small molecule market is attributable in part to the efficient substitution and the unencumbered ability of physicians to prescribe effective, more affordable generics.

To date, there are no licensed¹ interchangeable biosimilars in the United States. Until there are clear standards on how biosimilar manufacturers can obtain interchangeability designations, cost savings to patients and the health care system from increased biosimilar development will not reach their full potential. FDA should do more to create certainty and predictability for biosimilar manufacturers seeking interchangeability designations, while still ensuring that such determinations are guided by high scientific standards. One way to give manufacturers the certainty necessary to invest in developing such products would be to finalize the draft guidance on the factors FDA will consider in making interchangeability determinations. Such certainty will promote increased competition and lower costs.

Biosimilar Development & FDA Review

FDA should take steps to facilitate efficient biosimilar development and licensing, through improved clarity on submissions and increased agency communications with biosimilar manufacturers throughout the review process. FDA plays an important role in promoting timely biosimilar competition, including regulatory review to ensure requirements are as efficient as

¹ "Licensed" is technically the appropriate term to use for biosimilars under a Biologic License Application (BLA) instead of "approved" (approved is the correct term for a New Drug Application (NDA) and an Abbreviated New Drug Application (ANDA). We use the terms interchangeably throughout because in some cases we refer to both NDAs and BLAs.

possible without compromising safety and efficacy standards. Submissions demonstrating biosimilarity should not require the same rigor as “safety, purity, and potency”² or “safety and efficacy”³ demonstrations for reference products. The use of expedited approval methods such as surrogate endpoints, biomarkers, or more efficient clinical trial designs may be appropriate tools to demonstrate biosimilarity, they may also facilitate investment in development.

Biosimilarity, however, is a more complex demonstration than bioequivalency, which is the required showing to approve generic drugs through Abbreviated New Drug Applications (ANDAs). Thus, more evidence demonstrating biosimilarity will be needed to successfully encourage prescribing and inform formulary development than what is sufficient for small molecule generics. Kaiser Permanente’s physician- and pharmacist-led formulary development process relies on access to robust data from FDA and other sources. Our physicians choose to prescribe from our formulary in an overwhelming majority of cases, because it is developed by their peers, based on ample evidence. Access to data is crucial to enable us to instill confidence in biosimilars among prescribers, which in turn increases patient confidence and utilization.

Due to the importance of clinical evidence in guiding biosimilar prescribing decisions, we encourage FDA to carefully balance efforts to streamline biosimilar review against the need for quality data in manufacturer submissions. We agree it is sometimes appropriate for FDA to allow flexibility and use of expedited methods in submissions, including in some cases when there are few alternatives to a high-price reference product. Biosimilars also should never be held to a higher standard of review than reference products. However, surrogate endpoints and biomarkers merely predict clinical outcomes – they do not provide a full risk-benefit profile for a drug. As a result, they leave gaps in information about how a drug will perform in real-world clinical settings that reduce physician confidence in prescribing decisions and sometimes lead to downstream complications in care.

A condition for approvals that are based on expedited methods should be the timely completion of Phase IV post-market studies, regardless of whether the drug at issue is a biosimilar, reference product, or small molecule drug. Phase IV studies are critical to understanding drug safety and effectiveness outside the narrow confines of clinical trials. Pharmaceutical companies often fail to conduct these studies even when they are required. A study in the *New England Journal of Medicine* found that among over 600 post-market studies mandated in 2009 and 2010, 20 percent were never started, while others were significantly delayed.⁴ These failures on the part of pharmaceutical companies deprive physicians and pharmacists of vital information that can help improve patient outcomes and avoid adverse medical events.

Kaiser Permanente also supports FDA’s interest in learning about best practices from the European Medicines Agency (EMA), which has greater experience with biosimilar approval and uptake. Europe has been more successful than the United States at fostering the right market conditions for biosimilar development, while still maintaining high scientific standards. Intellectual property laws in the United States create unique barriers to competition;

² BLA licensing standard

³ NDA approval standard

⁴ Woloshin, S. et al. (September 2017). The Fate of FDA Postapproval Studies. *New England Journal of Medicine*. Available at: <https://www.nejm.org/doi/full/10.1056/NEJMp1705800>

nevertheless, FDA may be able to learn valuable lessons from EMA's approach to biosimilars. EMA has approved over 40 biosimilars.⁵ By comparison, FDA has licensed 12 biosimilars, most of which are not yet available to patients due to patent disputes.⁶ As a result, patients in Europe have significantly more choices and affordable options than patients seeking the same care in the United States. We encourage FDA to reach out to EMA to start a dialogue, with the goal of identifying practices FDA could adopt to move our domestic biosimilar market forward.

Real World Data & Evidence

Kaiser Permanente appreciates FDA's interest in use of real world data and evidence to support appropriate prescribing and post-market safety assessments of biosimilars. FDA defines real world evidence as "information on health care that is derived from multiple sources outside typical clinical research settings, including electronic health records, claims and billing data, product and disease registries, and data gathered through personal devices and health applications."⁷ Premarket use of real world evidence raises evidentiary concerns, since real world data is generally observational and non-randomized. Increased use of real world data in post-market contexts, however, could help uncover important information about product use by a larger, more diverse population in uncontrolled settings over a longer period than clinical trials.

Kaiser Permanente has successfully used real world data to build confidence in biosimilar prescribing among Permanente physicians. Our integrated structure enables us to harness the power of real world data to support conversions from reference products to biosimilars across our system. For example, our surveillance of patient switches from Remicade[®] to the biosimilar Inflectra[®] and from Neupogen[®] to the biosimilar Zarxio[®] provided concrete evidence of positive patient outcomes, demonstrating to prescribers that these conversions can be accomplished without changes in safety and efficacy. Our Drug Information Services (DIS) department (specifically, the Pharmacy Outcomes Research Group within DIS) frequently analyzes real world data related to drugs.

Based on our success using real world data within our system, we suggest FDA actively promote the value these data as another reliable and robust source of information to support biosimilar conversions.

We also support FDA's efforts to partner with private insurers to move toward a more unified and proactive system for drug safety monitoring, including for biological products and biosimilars. Kaiser Permanente already uses real world data to provide critical real-time safety and effectiveness information across our system. For example, our clinical databases were the first to detect serious risk of heart attack and cardiac death associated with Vioxx, a widely used arthritis and pain drug that was ultimately pulled from the market.⁸ We were proud to partner with FDA to uncover Vioxx safety concerns and reveal them to the public. Kaiser Permanente is

⁵ Biosimilars Approved in Europe (August 2018). Generics and Biosimilars Initiative. Available at: <http://www.gabionline.net/Biosimilars/General/Biosimilars-approved-in-Europe>

⁶ Biosimilar Product Information. FDA. Available at: <https://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/therapeuticbiologicapplications/biosimilars/ucm580432.htm>

⁷ Sherman, R. et al. (December 2016). Real-World Evidence—What Is It and What Can It Tell Us?. *New England Journal of Medicine*. Available at: <https://www.nejm.org/doi/full/10.1056/NEJMs1609216>

⁸ FDA Releases Memo on Vioxx. (November 2004). *New York Times*. Available at: <https://www.nytimes.com/2004/11/03/business/fda-releases-memo-on-vioxx.html>

also a collaborating institution in the Sentinel Initiative, FDA's national electronic system for proactively monitoring drug safety. We look forward to learning more about FDA's plans to enhance use of Sentinel and other data from private insurers in the context of biosimilars.

II. Increasing Provider & Patient Understanding of Biologics & Biosimilars

Provider & Patient Education

Kaiser Permanente appreciates FDA's interest in enhancing provider and patient education about biosimilars, which is a high priority for our Permanente Medical Groups and pharmacy business. Our success at encouraging clinically appropriate use of biosimilars within our system is in large part attributable to physician confidence in our formulary, which is developed by Permanente physicians alongside our pharmacy experts and relies heavily on access to clinical data. Educational efforts involving the whole care team and a culture of sharing patient stories are also critical components of Kaiser Permanente's success with biosimilars to date.

Timely access to data is crucial to Kaiser Permanente's formulary development process and helping providers evaluate when biosimilars are appropriate for their patients. We appreciate FDA's efforts to make more information about biosimilars, including review materials, available to the public through its website. The relatively robust data for both Inflectra (biosimilar for Remicade) and Zarxio (biosimilar for Neupogen) provided the information our physicians and pharmacists needed to evaluate whether switches were appropriate for individual patients. Unfortunately, review materials are not always made public, particularly when the product is not subject to Advisory Committee review or is not the first licensed biosimilar in its class. Even when such resources are public, posting is often delayed, sometimes by over a year. FDA should strive to make review materials for all licensed biosimilars available on its website within two months of approval.

Kaiser Permanente's success with biosimilar utilization also reflects a concerted effort across our system to provide reliable, evidence-based information about biosimilars to prescribers and care teams. We maintain a team of drug information pharmacists to answer physician questions and disseminate information about biosimilars and other drugs through bulletins, webinars, and presentations. These resources give our prescribers the tools and information necessary to appropriately switch patients onto biosimilars; they were used for conversions to Inflectra and Zarxio.

Our experience creating educational tools and resources for prescribing biosimilars suggests that prescribers would benefit from FDA-developed tools and resources on biosimilars, especially if these tools are made available in a flexible manner that accommodates busy schedules. Many physicians and health care professionals struggle to find time to participate in educational activities. Kaiser Permanente strongly supports FDA's proposal to make biosimilar webinars and other educational activities developed by the agency eligible for Continuing Education (CE) or Continuing Medical Education (CME) credit whenever possible to increase participation.

While clinical data is essential to biosimilar education across our system, a culture that promotes sharing meaningful prescriber experiences and patient stories is equally important for building prescriber confidence. Permanente physicians and our other health care professionals greatly

appreciate learning from the experiences of their colleagues, whom they know, trust, and respect. FDA should consider collecting and disseminating patient stories, in a manner that protects patient privacy and confidentially.

FDA should ensure that biosimilar education efforts include the entire care team—physicians, nurses, pharmacists, physician assistants, and other health care professionals. Many biological products and biosimilars are infusions or injections administered by nurses, who discuss these medications with patients and answer their questions on a regular basis. FDA should design educational materials and campaigns with a broad range of health care professionals in mind.

Most importantly, more must be done to increase patient confidence in biosimilars. No patient wants to feel like she is receiving an “inferior” medicine for her condition. Unfortunately, these misperceptions about biosimilar products are common (*See* “Reducing Misinformation about Biosimilars” section). Because providers are a trusted resource for patients, improving prescriber education about biosimilars should also enhance patient education and comfort. FDA can help by continuing to aggressively use its platform to assure the public that biosimilars are safe and effective alternatives to reference products, including through consumer-focused statements and public awareness campaigns.

Reducing Misinformation about Biosimilars

Kaiser Permanente is concerned that efforts to provide incomplete or misleading information about biosimilars reduce prescriber and patient confidence in safe and effective products. Because biosimilars are not identical to reference products, it is possible that a biosimilar may not always be the right choice for an individual patient. However, some reference product manufacturers have greatly exaggerated the risks and differences between products, ignoring legal requirements that biosimilars have “no clinically meaningful differences” from the reference product⁹ or suggesting that a switch is only safe if the biosimilar is interchangeable. These misinformation campaigns attempt to interfere with prescribing decisions that should be based on clinical evidence and the patient’s individual needs.

Reference product manufacturers use a variety of tactics to create doubt about biosimilars. For example, the manufacturer of the reference product Remicade has been disseminating a patient brochure cautioning against switching to the biosimilar Inflectra, because FDA has not deemed it interchangeable, despite evidence that switching does not reduce safety or efficacy. Online and social media campaigns undertaken by various manufacturers also characterize biosimilar use as risky (in one case, through an online video cautioning patients that switching is not a good idea if their medicines are working). These misleading claims have also been used by reference product manufacturers and third-party groups they fund to influence state and federal policies, including guidance on biosimilar naming conventions and state substitution laws.¹⁰

Kaiser Permanente is relatively insulated from these misinformation campaigns because our internal policies greatly restrict marketing and detailing by pharmaceutical companies in our facilities and to Permanente physicians. We generally limit detailing to formulary products and

⁹ 42 USC § 262(i)(2)(A)

¹⁰ Pfizer Inc. (August 2018). Citizen Petition to FDA. Available at: https://www.bigmoleculewatch.com/wp-content/uploads/2018/08/Citizen_Petition_from_Pfizer.pdf

audit detailing content when it is allowed within our system. Kaiser Permanente also goes to great lengths to ensure that our prescribers have access to other reliable sources of robust, unbiased information about drug products. As a result, our prescribers have less need to rely solely on information provided by the pharmaceutical industry.

While we have been able to mitigate their effect within our system, we remain concerned that these campaigns have polluted the overall information environment about biosimilars. We are particularly concerned about campaigns targeting patients. FDA should consider how it can encourage other health care system stakeholders to access reliable information about biosimilars from sources other than the pharmaceutical industry, including by adopting counter-detailing policies or similar detailing restrictions to Kaiser Permanente. FDA should also explore how current law could be used to prohibit false and misleading claims about biosimilars by reference product manufacturers.

III. Supporting Market Competition

Exclusivity

Kaiser Permanente believes FDA should avoid interpreting current law to expand exclusivity for reference biologics, causing further delay of more affordable, badly needed biosimilar options for patients. The 12-year exclusivity period under the *Biologics Price Competition and Innovation Act* (BPCIA) (Pub. L. 111-148) already delays biosimilar competition for too long, harming patients and resulting in billions of dollars in lost savings for taxpayers.¹¹ Even seemingly incremental expansions of exclusivity could be subject to abuse and gaming by pharmaceutical companies looking to block access to competing therapies.

Moving forward, we encourage FDA to take bold action to ensure that exclusivity incentives reward meaningful innovation, advancements in clinical care, and investments in therapeutic areas that would otherwise be neglected. Too often, these incentives are abused by the pharmaceutical industry to maintain high prices and monopolies without clinically meaningful improvements or innovation. Kaiser Permanente is encouraged that Commissioner Gottlieb acknowledges these problems and the need to ensure exclusivity provides “the right incentives.”¹² As prices for biological products continue to climb, FDA should work with Congress to reassess the costs and benefits of exclusivity incentives to ensure an appropriate balance between innovation and affordability.

Any review of exclusivity by FDA or Congress should also include the *Orphan Drug Act* (Pub. L. 97-414), which provides seven additional years of exclusivity for rare indications. Many biological products, which already enjoy 12 years of exclusivity, have orphan designations. The *Orphan Drug Act* intended to reward drug manufacturers for developing treatments for rare disease – an investment that otherwise would not be economically viable. Over the years, however, orphan drugs have become major revenue producers, which has led to abuse of the law’s original intent. Pharmaceutical companies sometimes seek orphan designations for drugs

¹¹ Policy Proposal: Reducing the Exclusivity Period for Biological Products, PEW Charitable Trusts, available at: <http://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2017/09/policy-proposal-reducing-the-exclusivity-period-for-biological-products>

¹² Tribble, S. (December 2017). FDA Commissioner: Are the Incentives Right for Orphan Drugs? NPR. Available at: <https://www.npr.org/sections/health-shots/2017/12/22/572673636/fda-commissioner-are-the-incentives-right-for-orphan-drugs>

already on the market, or tailor indications to overly narrow populations when the drug is typically used to treat common conditions. Due in part to these tactics, numerous drugs now benefit from orphan exclusivity. In 2016, 41 percent of new approvals included an orphan designation.¹³ The fact that Humira[®], the world's best-selling drug, was granted orphan status illustrates the perverse abuses of this well-intentioned law.

Post-Licensing Delays in Biosimilar Market Entry

Kaiser Permanente greatly appreciates FDA's interest in addressing the lag time between biosimilar licensing and marketing. FDA has licensed 12 biosimilars to date; only four are available to patients.¹⁴ Patent disputes appear to be the primary cause of delays.

For example, reference product manufacturers often hold numerous patents for the same biologic and can use that to their advantage in disputes with biosimilar manufacturers (e.g., the settlement agreement over 61 potential patent breaches associated with Amjevita[®], a biosimilar version of Humira. Humira is protected by over 100 patents, ranging from attributes of the product to manufacturing processes). This complex web of patents, often referred to as a "patent estate" or "patent thicket," gives the reference product manufacturer considerable leverage in settlement negotiations, because it is virtually impossible to manufacture the related biosimilar without breaching multiple patents. So even though FDA licensed Amjevita in 2016, its manufacturer agreed to delay market entry until 2023 and will even pay Humira's manufacturer royalties on Amjevita sales upon marketing.¹⁵ Other manufacturers developing Humira biosimilars are engaged in similar negotiations, also delaying entry of those products until 2023. Other brand-name companies are now trying to replicate the Humira strategy on their own biological products, which suggests an alarming trend.¹⁶

While patent settlements are outside FDA's direct purview, we strongly encourage the Agency to fully inform the Federal Trade Commission (FTC) and Congress to enable them to thoroughly review settlement agreements between reference product and biosimilar manufacturers for potential anticompetitive behavior. FDA should also explore how agency processes could be leveraged to help biosimilar manufacturers navigate potential disputes and challenges, such as by requiring more detailed disclosures of patents and manufacturing processes by reference product manufacturers. To the extent that such information could be shared with biosimilar manufacturers in the early stages of development, it may help companies anticipate and overcome obstacles to market entry.

REMS Abuses

Kaiser Permanente supports FDA's efforts to address abuses of Risk Evaluation and Mitigation Strategies (REMS). As part of REMS programs, FDA can require "elements to assure safe

¹³ Kesselheim, A. et al. (2017). Determinants of Market Exclusivity for Prescription Drugs in the United States. *JAMA*. at: <https://www.ncbi.nlm.nih.gov/pubmed/28892528>

¹⁴ Biosimilar Product Information. FDA. Available at:

<https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm580432.htm>

¹⁵ Berkrot, B. (September 2017). AbbVie, Amgen Settlement Sets Humira U.S. Biosimilar Launch for 2023. *Reuters*. Available at: <https://www.reuters.com/article/us-abbvie-amgen-humira/abbvie-amgen-settlement-sets-humira-u-s-biosimilar-launch-for-2023-idUSKCN1C32G5>

¹⁶ Koons, C. (September 2017). This Shield of Patents Protects the World's Best-Selling Drug. *Bloomberg Businessweek*. Available at: <https://www.bloomberg.com/news/articles/2017-09-07/this-shield-of-patents-protects-the-world-s-best-selling-drug>

usage” (ETASU), such as special certification for dispensing, prescriber training, and dispensing limited to certain health care settings. ETASU requirements are sometimes leveraged by pharmaceutical companies to restrict a drug’s distribution by erecting barriers to market entry that do not result in safety benefits for patients. While we strongly support the REMS program’s goal of improving safety, the program must be updated to ensure pharmaceutical companies cannot game the process to block biosimilar competition or artificially restrict distribution pathways to maintain unreasonably high prices.

Biosimilar manufacturers often seek access to samples of reference products to conduct studies to demonstrate biosimilarity and interchangeability to FDA. Some brand-name pharmaceutical companies use REMS to justify withholding samples, causing delays in competition. Recently, FDA posted a list of brand-name drugs where a request for access to a sample for generic development was blocked, revealing over 50 medicines for which generic alternatives have been delayed due to REMS abuses.¹⁷ To resolve this problem, Kaiser Permanente supports the *Creating and Restoring Equal Access To Equivalent Samples Act* (CREATES Act) (S. 974/H.R. 2212), which establishes a cause of action against companies that fail to provide samples on reasonable terms. The nonpartisan Congressional Budget Office (CBO) estimated that the CREATES Act would reduce federal health spending by \$3.8 billion over ten years. Private payers would also save significantly. In the absence of a legislative fix, we encourage FDA to exercise all authority it has over the REMS program to curb abuses.

Brand-name companies also use REMS to enter into restrictive contracting arrangements that make it impossible for providers and pharmacies to acquire drugs at a reasonable price. Many of the drugs subject to these arrangements are biological products. Some companies have used ETASU requirements to contract exclusively with a limited number of specialty pharmacies, protecting high prices by controlling access to their products. Even though Kaiser Permanente’s National Specialty Pharmacy has extensive experience complying with REMS and ETASU requirements, many pharmaceutical companies do not allow us to acquire and dispense restricted drugs within our system. Not only do these restrictions allow companies to burden patients with higher prices, they also inhibit the ability of integrated health systems to implement safety checks, monitor quality, and coordinate care when information related to the REMS drug will not be automatically included in the patient’s electronic health records and our pharmacy systems because valuable prescribing information is held outside our system.

Kaiser Permanente recommends that REMS explicitly permit health systems or pharmacies that can demonstrate they meet or exceed REMS requirements to access and dispense REMS drugs. Therefore, we support new FDA guidance or regulations clarifying that REMS programs cannot arbitrarily restrict distribution. These modifications would help facilitate lower drug costs through competitive pricing and national purchasing negotiations. It would also leverage existing systems and tools designed to enhance patient safety and continuity of care.

FDA-FTC Collaboration Against Anticompetitive Behavior

¹⁷ Reference Listed Drug (RLD) Access Inquiries. FDA. Available at: <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/ucm607738.htm>

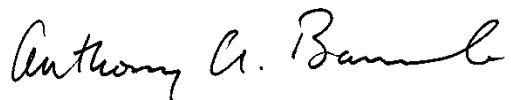
Kaiser Permanente supports FDA's interest in working with the Federal Trade Commission (FTC) to increase competition in biological product markets. Further coordination between FDA and FTC would foster greater understanding about how FDA processes are abused for anticompetitive purposes. At the recent public meeting on biosimilars, FDA recognized FTC as a "vital partner" in the Agency's work on competition.¹⁸ FTC has also made clear it is willing to partner with HHS to make pharmaceutical markets more competitive, identifying biosimilar naming, REMS abuses, and interchangeability as areas of interest.¹⁹

In addition to the topics FTC already identified, we encourage FDA and FTC to jointly review exclusivity, settlements between reference product and biosimilar manufacturers, product hopping and evergreening through "biobetter" reformulations, abuse of citizen petitions, and misleading communications about biosimilars by reference product manufacturers. The agencies should also issue public reports to share their findings with outside stakeholders and experts.

* * *

Kaiser Permanente appreciates the opportunity to provide feedback in response to FDA's request for comments. We would be pleased to discuss these comments and our experience with biosimilar and biological products in our integrated delivery system. If you have questions, please contact me (510.271.6835; anthony.barrueta@kp.org), Laird Burnett (202.216.1900; laird.burnett@kp.org), or Polly Webster (202.216.1900; polly.f.webster@kp.org).

Sincerely,



Anthony A. Barrueta
Senior Vice President, Government Relations

¹⁸ Remarks by Scott Gottlieb, M.D. (September 2018). Public Meeting on Facilitating Competition and Innovation in the Biological Products Marketplace. FDA. Available at: <https://www.fda.gov/NewsEvents/Speeches/ucm619277.htm>

¹⁹ Statement of the Federal Trade Commission to the Department of Health and Human Services Regarding the HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs. (July 2018). FTC. Available at: https://www.ftc.gov/system/files/documents/advocacy_documents/statement-federal-trade-commission-department-health-human-services-regarding-hhs-blueprint-lower/v180008_commission_comment_to_hhs_re_blueprint_for_lower_drug_prices_and_costs.pdf