KAISER PERMANENTE®

January 9, 2019

Walter G. Copan, Ph.D.
Director
National Institute of Standards and Technology
100 Bureau Drive, Stop 8930
Gaithersburg, MD 20899

Submitted electronically to: roi@nist.gov

Re: ***NIST Special Publication 1234 - Return on Investment Initiative for Unleashing American Innovation Draft Green Paper***

Dear Director Copan:

Kaiser Permanente[1] appreciates the opportunity to provide comments to the National Institute of Standards and Technology (NIST) on the Return on Investment Initiative Draft Green Paper. We commend NIST for its attention to promoting domestic innovation and facilitating returns on government investments in research and development. However, some proposals in the Green Paper would further empower pharmaceutical companies to reap exorbitant profits on products developed based on federally-funded research and overprotect existing inventions in a manner that actually discourages meaningful, new innovation. We strongly urge NIST to revisit Green Paper recommendations that would increase the pharmaceutical industry's ability to inappropriately prolong monopoly pricing through anticompetitive abuses of intellectual property incentives.

In addition to unleashing innovation, one of the goals of NIST's Return on Investment Initiative is to help maximize benefits realized by the American people from inventions developed using the billions of dollars spent every year on government-supported research. Unfortunately, drug prices have risen so high that they are threatening sustainable access to treatment, including for drugs financed in part by these investments. American patients do not receive a fair return on investment when they are forced to endure significant financial hardship to pay for drugs developed using their tax dollars.

Kaiser Permanente is concerned that some of the recommendations in the Green Paper—such as narrowing the government's rights related to inventions developed with federal funding and potential changes to *Inter Partes* Review—would further embolden the pharmaceutical industry to set outrageously high prices. In addition, by further empowering pharmaceutical companies to

[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 the Permanente Medical Groups, self-governed physician group practices that exclusively contract with Kaiser Foundation Health Plan to meet the health needs of Kaiser Permanente's members. As the largest private integrated health care delivery system in the United States, the Kaiser Permanente Medical Care Program delivers care to more than 12.2 million members in eight states and the District of Columbia. We are committed to providing high-quality, affordable care and improving the health of our members and the communities we serve.

over-patent and "evergreen" existing products, some of NIST's recommendations would heighten financial incentives to make incremental changes of limited clinical value to existing products in lieu of the more meaningful innovation the Return on Investment Initiative hopes to facilitate.

If implemented, the Green Paper's recommendations may also undercut the Trump Administration's laudable goals in the Department of Health and Human Services' (HHS') *Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs*.[2] President Trump and HHS Secretary Azar have repeatedly emphasized that lowering drug prices is one of the Administration's top priorities. Intellectual property incentives are key drivers of high drug prices because they provide pharmaceutical companies with monopolies that prevent competition from lower-cost generics. Thus, policies in the Green Paper that would prolong monopoly pricing for periods disproportionate to the value of patent-protected innovation would interfere with the Administration's broader drug pricing goals and should be re-evaluated.

Government Rights in Inventions Developed with Federal Funding

The federal government has a discrete and limited set of potential tools to lower drug prices. It has failed to apply some of those tools to date, which has contributed to the pharmaceutical industry's ability to increase prices to unsustainable levels, threatening patient access to drugs developed based on federally-funded research. Prescription drug spending is growing faster than any other part of the health care dollar.[3] Spending on ten breakthrough drugs alone is projected to cost the federal government $50 billion over a decade.[4] Between 2010 and 2015, prices for the 20 most commonly prescribed drugs under Medicare Part D increased at a rate ten times higher than inflation, with average increases of 12 percent each year. Twelve of the top 20 drugs experienced price increases of over 50 percent.[5] These startling statistics illustrate the need to give the government *more* tools to combat high drug prices, rather than removing or narrowing tools currently at their disposal.

With this context in mind, Kaiser Permanente cautions against policies that would further restrict potential mechanisms available to the government to lower prices, including by limiting the application of government use licenses and authorities to retain rights in patented inventions developed based on taxpayer-funded research. Given the magnitude of the public's investment in drug development, it is reasonable for the government to have remedies available to protect against private companies' efforts to exploit and restrict access to federally-funded inventions. Indeed, grants from the National Institutes of Health (NIH) led to the approval of 210 new drugs between

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[2] HHS. (May 2018). *American Patients First: Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs*. Available at: https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf.

[3] Altarum Institute. (September 2015). *Health Sector Economic Indicators: Insights from Monthly National Price Indices through July 2015*.

[4] Avalere Health. (June 2015). *The Future Cost of Innovation: An Analysis of the Impact of Breakthrough Therapies on Government Spending*. Available at: https://avalere-health-production.s3.amazonaws.com/uploads/pdfs/1433526540_The_Future_Cost_of_Innovation_An_Analysis.pdf.

[5] *Manufactured Crisis: How Devastating Drug Price Increases are Harming America's Seniors*, Minority Office, U.S. Senate Homeland Security & Governmental Affairs Committee, available at: https://www.hsgac.senate.gov/imo/media/doc/Manufactured%20Crisis%20-%20How%20Devastating%20Drug%20Price%20Increases%20Are%20Harming%20America's%20Seniors%20-%20Report.pdf.

2010 and 2016, investing over $100 billion of taxpayer money in those medicines.[6] When drugs developed using federal funding are priced so egregiously high that reasonable access is threatened, it may be appropriate for the government to use tools available under the *Stevenson-Wydler Act* and *Bayh-Dole Act* to ensure taxpayers realize a fair return on their investments.

As the Green Paper correctly notes, the *Bayh-Dole Act* attempts to ensure inventions developed using federally-funded research benefit the American people. Under current law, the government can facilitate competition by allowing additional manufacturers to market drugs developed using taxpayer-funded research when "necessary to alleviate health and safety needs which are not being reasonably satisfied"[7] or when the "practical application" of the patented product is threatened because the product is not "available to the public on reasonable terms."[8] Whether the statute provides authority to intervene when high prices jeopardize access to drugs developed based on federally-funded research is the subject of considerable debate and remains unsettled law. As a result, NIH has never used this authority. Thus, clarification about how the *Bayh-Dole Act* can be used to increase access to extremely expensive drugs may be helpful.

Rather than interpreting the *Bayh-Dole Act* in a manner that would help increase access to drugs developed based on taxpayer investments, the Green Paper would restrict this authority to circumstances when there is "a compelling national issue or declared national emergency" after other remedies have failed. It would also specifically prohibit use of the *Bayh-Dole Act* as a mechanism to lower drug prices. These proposed limitations are unnecessary in light of the rigorous standards that already must be met to use march-in rights and repeated acknowledgement by the federal government that this remedy should only be used in extraordinary circumstances. Rather than unleashing new innovation, the Green Paper recommendations would only impede opportunities available to the Trump Administration to facilitate more affordable access to drugs that are prohibitively expensive.

***Inter Partes* Review**

While updating the *America Invents Act* (AIA) is not the central focus of the Return on Investment Initiative, Kaiser Permanente has concerns about the suggestions for modifying *Inter Partes* Review (IPR) that NIST plans to communicate to the U.S. Patent and Trademark Office (USPTO). The IPR process creates a more efficient alternative to challenging patents through the courts by allowing poor-quality patents to be invalidated administratively. In the context of the pharmaceutical market, IPR complements processes available under the *Hatch-Waxman Act* that help facilitate more generic and biosimilar competition against brand drugs that are a significant cost burden to patients, taxpayers, the government, and the health care system as a whole. Growing trends of over-patenting in a manner that adds minimal innovation and clinical value for patients has created a strong need for efficient mechanisms, such as IPR, to challenge potentially invalid patents in the pharmaceutical market.

While Kaiser Permanente acknowledges the important role that patents play in incentivizing innovation, we are deeply concerned about the pharmaceutical industry's pervasive abuse of the

[6] Cleary, E. et al. (2018). Contribution of NIH Funding to New Drug Approvals 2010-2016. National Academy of Sciences. Available at: http://www.pnas.org/content/early/2018/02/06/1715368115.
[7] 35 USC § 203(a)(2).
[8] 35 USC § 201(f).

patent system to protect high prices. The IPR recommendations NIST plans to share with USPTO must be evaluated within the larger context of how patent and other intellectual property incentives have actually been applied in the pharmaceutical market. Many companies have effectively extended monopoly power for their drugs far beyond the 20 years of protection intended under our patent laws, eroding the taxpayer's return on public investment. For example, top-selling drugs like Herceptin® and Rituxan® have potential monopoly spans of nearly 50 years[9], and Purdue Pharma protected its pricing power for OxyContin® by obtaining patent extensions 13 times before the original patent expired.[10] About 78 percent of drug-related patents are for drugs already on the market.[11] The fact that most patents filed by the pharmaceutical industry protect existing, rather than new, products raises questions about the extent to which these additional patents are unleashing the kind of meaningful innovation the Green Paper is hoping to foster.

Efficiently weeding out weak patents is especially important when pharmaceutical companies use "evergreening" strategies to prolong monopoly pricing by making minor changes, often of negligible clinical value, that enable additional patents on existing drugs. For example, Revlimid®—a multiple myeloma drug that is Celgene's biggest revenue producer—has a potential patent lifespan of at least 40 years. Before the patent expired on Celgene's predecessor drug (Thalomid®), Celgene modified and patented changes to the product to turn it into Revlimid, which effectively restarted the clock on generic competition.[12] Revlimid's numerous patents now cover everything from methods of use, to various formulations, to the product distribution system needed to comply with Risk Evaluation and Mitigation Strategies (REMS) requirements, and more.[13] Humira® is another well-known example of extreme use of evergreening. AbbVie has applied for at least 247 patents on Humira®, over 100 of which the USPTO granted.[14] This web of overlapping patents, known as a "patent thicket" or "patent estate," makes it incredibly difficult for generic manufacturers to launch lower-cost versions of drugs. Other brand-name companies are now trying to replicate AbbVie's strategy, which is an alarming trend.[15]

IPR facilitates thoughtful and efficient review of evergreening patents, making it more difficult for pharmaceutical companies to use invalid patents to block generic competition for years. While a pharmaceutical patent case often exceeds 30 months in court, IPR takes 12 to 18 months and still

[9] I-MAK. (2018). *Overpatented; Overpriced: How Excessive Pharmaceutical Patenting is Extending Monopolies and Driving Up Drug Prices*. Available at: http://www.i-mak.org/wp-content/uploads/2018/08/I-MAK-Overpatented-Overpriced-Report.pdf.
[10] Feldman, R. and Wang, C. (2018) *May Your Price be Evergreen*, University of California Hastings College of Law. Available at: file:///C:/Users/D727253/Downloads/SSRN-id3061567.pdf.
[11] *Id*.
[12] Kodjak, A. (May 2018). How a Drugmaker Gamed the System to Keep Generic Competition Away. *NPR*. Available at: https://www.npr.org/sections/health-shots/2018/05/17/571986468/how-a-drugmaker-gamed-the-system-to-keep-generic-competition-away.
[13] I-MAK. (October 2017). America's Overspend: How the Pharmaceutical Patent Problem is Fueling High Drug Prices. Available at: http://www.i-mak.org/wp-content/uploads/2017/11/Excess-Costs-Briefing-Paper-FINAL_-2017-10-24.pdf.
[14] I-MAK. (2018). *Overpatented; Overpriced: How Excessive Pharmaceutical Patenting is Extending Monopolies and Driving Up Drug Prices*. Available at: http://www.i-mak.org/wp-content/uploads/2018/08/I-MAK-Overpatented-Overpriced-Report.pdf.
[15] 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.

allows review by a panel of expert patent law judges. Only a small percentage of enforceable patents are challenged under IPR, and the USPTO must first determine that there is a "reasonable likelihood" that at least one patent claim is invalid before IPR can commence.[16] Importantly, the U.S. Supreme Court recently upheld the IPR process, ruling that it does not violate Article III of the U.S. Constitution.[17] Thus, claims that IPR allows frivolous challenges or denies patent holders due process are without merit.

Forcing IPR to adopt the more burdensome processes and standards used in federal court would delay access to more affordable generics for American patients, embolden the pharmaceutical industry to continue abusing the patent process, and violate congressional intent under the AIA to establish a more efficient alternative mechanism for patent review. Kaiser Permanente therefore strongly discourages NIST from recommending that USPTO make unnecessary changes to IPR that would increase the burden for challenging weak and potentially invalid patents, which would undermine both efforts to reduce high drug prices and unleash meaningful innovation.

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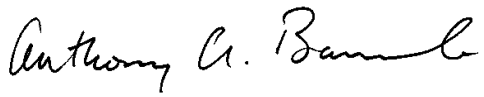
Kaiser Permanente appreciates the opportunity to provide feedback in response to NIST's draft Green Paper. We would be pleased to discuss our experience with high drug prices further. If you have questions, please contact me (510.271.6835; anthony.barrueta@kp.org) or Polly Webster (202.216.1900; polly.f.webster@kp.org).

Sincerely,



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[16] Waxman, H. et al. (July 2018). Proposed CREATES Amendment could Impede the Availability of Affordable Generic Drugs. Commonwealth Fund. Available at: https://www.commonwealthfund.org/blog/2018/proposed-creates-amendment-could-impede-availability-affordable-generic-drugs.
[17] *Oil States Energy Services, LLC v. Greene's Energy Group, LLC*, 584 U.S. __ , (2018); *SAS Institute Inc. v. Iancu*, 584 U.S. __ , (2018).