UNIVERSITIES ALLIED FOR ESSENTIAL MEDICINES

FROM:	Universities Allied for Essential Medicines (UAEM)
TO:	The Hon. Xavier Becerra, Secretary, the Department of Health and Human Services The Hon. Lawrence A. Tabak, Acting Director, the National Institutes of Health
RE:	Request to Recuse Mark Rohrbaugh from Xtandi March-in Proceedings
DATE:	February 23, 2022

Dear Secretary Becerra and Acting Director Tabak:

We, Universities Allied for Essential Medicines (UAEM), write to request that the Department of Health and Human Services (HHS) formally recuse Dr. Mark Rohrbaugh, the National Institutes of Health (NIH) Special Advisor for Technology Transfer, from having any decision-making role in the response to the 2022 petition to march-in and exercise other rights in the patents on the prostate cancer drug Xtandi (the "2022 petition" or the "2022 Xtandi petition"). UAEM is one of the petitioners.

Dr. Rohrbaugh has served as a decision maker for the NIH's responses to the 2016 petition asking the government to march-in and exercise other rights in the patents on Xtandi (the "2016 Xtandi petition" or "the 2016 petition"), as well as the subsequent administrative appeal and related advocacy. **His work emails and public statements demonstrate that he holds a bias against march-in rights to address unreasonable pricing**—a position that is inconsistent with the Bayh-Dole Act and implementing regulations and that has been rejected by the Biden administration. Unfortunately, Dr. Rohrbaugh has allowed his personal opinions to influence the NIH's operations, to the detriment of the American public.

Dr. Rohrbaugh also maintains close relationships with lobbyists who work to weaken public interest safeguards under the Bayh-Dole Act. His work emails[1] demonstrate that he frequently gives these individuals special assistance, insights, and inroads that he does not give other members of the public, and that he collaborates with and assists these lobbyists on placing negative messaging about reasonable pricing constraints.

Dr. Rohrbaugh is not capable of giving our petition impartial review, nor can he faithfully apply the law as it is written, as opposed to how he subjectively believes it should be. Since the United States is "a government of laws and not of men," Dr. Rohrbaugh is not free to subvert the will of the people by distorting the meaning of the Bayh-Dole Act. To ensure public confidence

[1] The emails referenced in this letter are enclosed.

in a fair outcome for the 2022 Xtandi petition, HHS must insist that Dr. Rohrbaugh be excluded from any role in responding to the petition.

About UAEM

As a global movement of committed students who passionately believe in social justice and health equity, we find it unacceptable that millions of people do not have access to medicines, especially those funded in *our* labs with *our* tax-payer dollars. At UAEM we believe that universities and publicly funded research institutions must be part of the solution to the access to medicines crisis by promoting medical innovation in the public interest and ensuring that all people regardless of income have access to medicines and other health-related technologies.

Discussion

1. **Dr. Rohrbaugh has drafted the NIH's responses to the 2016 Xtandi petition and related advocacy.**

Dr. Rohrbaugh has acted as a decisionmaker with respect to prior march-in petitions and is likely influencing or otherwise involved in the response to the 2022 petition.

NIH emails from March of 2016 show that Dr. Rohrbaugh was involved in drafting the response to the 2016 Xtandi petition. Other emails from the Spring of 2016 show that he drafted the NIH's responses to correspondence related to the petition. A March 25, 2016 email from the NIH Office of the Director (OD) assigns Dr. Rohrbaugh the task of preparing a "Dir Sig response" (Director Signature Response) to a letter supporting the 2016 petition. In other words, the OD assigned Dr. Rohrbaugh the task of drafting a response to the letter, for then-Director Dr. Francis Collins to sign. In an email dated March 30, 2016, Dr. Rohrbaugh states he was tasked with drafting a response to a March 28, 2016 letter from Senator Bernard Sanders and eleven U.S. representatives requesting a public hearing on the 2016 petition. Similarly, an April 26, 2016 email asks Dr. Rohrbaugh "to prepare a response for Dr. Collins' signature" for a letter from Ralph Nader requesting a hearing on the 2016 petition. Finally, an April 24, 2017 email chain reveals that the NIH assigned Dr. Rohrbaugh the task of drafting the response to the appeal of its decision rejecting the 2016 petition.

Dr. Rohrbaugh's apparent influence over the NIH's official stance on march-in and reasonable pricing has also been evidenced by Dr. Collins' statements about march-in rights in congressional hearings. When asked by Congress why the NIH refuses to exercise march-in rights to address unreasonable pricing, Dr. Collins, who is not a lawyer, has stated that his "legal experts" told him

that the NIH is not legally authorized to march-in to address price gouging.[2] Dr. Rohrbaugh has a legal background, has worked in an advisory role to Dr. Collins, and as discussed below, has made it clear that he does not believe the NIH should use march-in to address unreasonable pricing. It is therefore likely that it was Dr. Rohrbaugh who provided Dr. Collins with the incorrect legal advice about the Bayh-Dole Act.

HHS has apparently delegated review of the 2022 Xtandi petition to NIH. Dr. Rohrbaugh remains an influential technology transfer advisor at the NIH. There is no question that Dr. Rohrbaugh wields influence over the NIH's march-in responses. It is thus highly probable that he has been assigned the role of preparing the NIH's response to the instant petition. His ability to give the petition impartial review–or not–is therefore a consideration that deserves careful scrutiny.

2. The Bayh-Dole Act and its implementing regulations authorize the NIH to march-in when a product arising from NIH-funded research is not "available to the public on reasonable terms."

Contrary to Dr. Rohrbaugh's personal beliefs, which are expressed in greater detail below, federal law empowers federal agencies that fund innovation to exercise rights that protect the public from unreasonable pricing on any inventions that were developed with taxpayer support.

More to the point, the Bayh-Dole Act authorizes federal agencies to march-in on a federally-funded invention when a rights holder fails to achieve "practical application" of the invention, meaning that the rights holder fails to make the benefits of the invention "available to the public on reasonable terms." 35 U.S.C. §§ 203(a)(1), 201(f); 37 C.F.R. § 401.2(e). Under legitimate methods of statutory interpretation, the term "reasonable terms" includes all terms on which the benefits of an invention–the resultant product–are made available to the public. An obvious term of a product's availability to the public is its price.[3] The NIH is thus authorized to take action when a rights holder charges an unreasonable price for a product embodying a federally-funded invention.

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[2] Implementing the 21st Century Cures Act: An Update from FDA and NIH Before the H. Comm. on Energy and Commerce, 115th Cong. 58-59 (2017).

[3] Under the canon against surplusage, the words "on reasonable terms" should not be interpreted to be rendered meaningless. Under the ordinary meaning rule, the words "available to the public on reasonable terms" should be given their ordinary meaning, and no reasonable person would understand "public" to mean "licensee." Under the general terms canon, "general words (like all words, general or not) are to be accorded their full and fair scope. They are not to be arbitrarily limited[.]" *See* Antonin Scalia & Bryan A. Garner, "Reading Law: The Interpretation of Legal Texts" (2012); *See also*, Comments of James Love and Knowledge Ecology International, Comment on FR Doc # 2020-27581, NIST-2021-0001-0023 (March 19, 2021).

The federal government also retains, for any federally-funded or "subject invention," "a nonexclusive, non-transferrable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world[.]" 35 U.S.C. § 202(c)(4).

These rights are part of the original compromise struck by Congress when passing the Bayh-Dole Act.[4] Grant recipients are authorized to retain monopolies over inventions developed with taxpayers' dollars in order to stimulate investment. The government is authorized to exercise reserved rights in the inventions, to protect the public against abuses of the granted monopolies.

This interpretation of the Bayh-Dole Act was recently affirmed by President Biden. In the last days of the Trump administration, the National Institute of Standards and Technology (NIST) issued a notice-and-comment rulemaking for a modification that would have prevented the exercise of march-in rights on the sole basis of the pricing of a product.[5] Even the proposal itself acknowledged the relevance of pricing; if it went into effect, pricing would have been a relevant consideration but could not serve as an exclusive basis for the authority. More than 80,000 members of the public submitted comments, the majority of which opposed the change. On at least two occasions, the Biden administration repudiated the proposal. First, President Biden issued an executive order directing NIST not to move forward with this specific regulation.[6] As of the date of this letter, the change has not been implemented. Second, in his report to the White House on drug pricing, HHS Secretary Xavier Becerra stated that HHS will give march-in petitions "due consideration" and rejected the proposed modification.[7]

Even if the regulation succeeded, pricing would still be relevant. During the comment period, some pro-patent rights lobbyists submitted comments stating that the modification did not go far enough because it did not forbid agencies from considering product pricing when deciding whether to

[4] Alfred B. Engelberg, J.D., et al. "A New Way to Contain Unaffordable Medication Costs – Exercising the Government's Existing Rights." *The New England Journal of Medicine* (Feb. 9, 2022).
[5] "Rights to Federally Funded Inventions and Licensing of Government Owned Inventions," 86 Fed. Reg. 35 (Jan. 4, 2021), *available at* https://www.federalregister.gov/documents/2021/01/04/2020-27581/rights-to-federally-funded-inventions-and-licensing-of-government-owned-inventions.
[6] The White House, "Executive Order on Promoting Competition in the American Economy," July 9, 2021, https://www.whitehouse.gov/briefing-room/presidential-actions/2021/07/09/executive-order-on-promoting-competition-in-the-american-economy/.
[7] U.S. Department of Health and Human Services, "Report to the White House Competition Council: Comprehensive Plan for Addressing High Drug Prices," September 9, 2021, https://aspe.hhs.gov/sites/default/files/2021-09/Competition%20EO%2045-Day%20Drug%20Pricing%20Report%209-8-2021.pdf.

march in on an invention. They urged NIST to promulgate a regulation stating that pricing is never relevant. They not only failed to accomplish their desired goal, but President Biden rejected the NIST proposal that the special interest lobbyists had said was too inclusive of reasonable pricing.

Pricing of the product remains a stand alone basis for the exercise of march-in rights.

3. **Acting on his personal biases, Dr. Rohrbaugh uses his official office to express views about march-in rights that are legally and factually erroneous.**

Dr. Rohrbaugh's official work emails and his public statements in his capacity as an officer of the NIH demonstrate that he holds strong, but incorrect beliefs that march-in authority should never be exercised to address unreasonable pricing, and that he allows those biases to influence his performance of his official duties as an employee of the NIH. The fact that Dr. Rohrbaugh's personal biases are impacting his decision making should disqualify him from serving as a decision maker for the 2022 petition.

a) Dr. Rohrbaugh's Work Emails

In his official capacity as an officer of the NIH, Dr. Rohrbaugh works closely with pro-patent rights lobbyists to place negative messaging in public fora about the use of march-in rights, reasonable pricing limitations, and other public interest safeguards under the Bayh-Dole Act.

On December 7, 2017, Joseph P. Allen, a prominent anti-march-in rights lobbyist, emailed Dr. Rohrbaugh about an op-ed asking HHS to use march-in rights to address unreasonable pricing on taxpayer funded inventions. Dr. Rohrbaugh replied by email the same day, asking the lobbyist to identify "legal academics who will publish their views . . . in an op ed" to offer their rebuttal.

In 2016, when the *New York Times* published an article critical of the National Cancer Institute for failing to protect patients from unreasonable pricing, Rohrbaugh helped Allen with drafting a letter to the editor titled, "The National Cancer Institute Didn't Deserve Its Treatment in the NY Times." On many occasions, Allen has requested information from Dr. Rohrbaugh, and Dr. Rohrbaugh provided the requested information to Allen, such as by answering a question about march-in procedures (the NIH has refused to answer any of petitioners' questions about the current march-in process).

In a January 2017 email exchange between Allen and Dr. Rohrbaugh, Allen mentions a phone call and draft letter to the editor in response to public criticism about an NIH patent license. He states:

"Was thinking about our call and got an idea how to frame a letter to the editor. One more data point: did any other company besides Kite respond to the NIH notice that the patents were available for licensing?" Rohrbaugh replied that no other company applied for the license. When other members of the public have asked about whether other companies applied for an NIH patent license, the NIH has refused to answer, stating that this information is business confidential.

Internal emails between Rohrbaugh and Allen illustrate that the two worked together to control the messaging about information they were privately concerned would support the idea that march-in rights should be exercised in cases of unreasonable pricing. In December of 2016, when Allen learned about the existence of reasonable pricing clauses in prior NIH licenses, he said he "hope[d]" he could show that the clauses had a "negative impact." Allen emailed Rohrbaugh the following:

> "The problem is that this is a precedent the other side will seize upon . . . . The only way to make lemonade out of this (as far as I can see) is to look at how such a clause impacted NIH licensing."

Instead of openly examining whether the clauses were helpful, harmful, or neutral to NIH licensing, Allen wanted only to find facts that would show that the clauses were *harmful*. He stated further:

> "If we can show a decline and subsequent rise after it was removed, that would certainly bolster the cause."

Allen also said, "this is one thing I hate to have learned."

What is "the cause" on which Allen believes he is collaborating with Dr. Rohrbaugh? **As an employee of the NIH, Dr. Rohrbaugh's "cause" should align with the public interest, and not privately work to undermine public interest safeguards.** The idea that those efforts to undermine reasonable price constraints is a "cause" suggests a deep ideological position.

In sum, Dr. Rohrbaugh's work emails demonstrate that rather than serving as an impartial decision maker, Dr. Rohrbaugh works behind closed doors with industry lobbyists, especially with regards to negative messaging about the use of march-in authority and other government rights to address unreasonable pricing. Instead of openly exploring where the facts about reasonable pricing constraints led, Allen and Dr. Rohrbaugh worked together to find only the facts that would portray reasonable pricing

limitations in a negative light. Dr. Rohrbaugh then reiterated those anti-march-in talking points at industry-sponsored events.

Allen has recently published a blog denouncing the current petition[8] and is widely quoted by the press as the primary lobbyists for rights holders who oppose the use of march in or government use rights. Considering Rohrbaugh's history of working with Allen to place negative messaging about march-in rights, it is likely that they worked together on the blog.

b) Dr. Rohrbaugh's Public Statements

In addition to his work emails, Dr. Rohrbaugh's public-facing comments also further corroborate his personal bias against march-in and other safeguards against unreasonable pricing.

On April 23, 2020, Dr. Rohrbaugh was a guest speaker on a webinar titled, "Bayh-Dole and the Coronavirus Crisis." The panel was organized by the patents rights lobbyists group Bayh-Dole Coalition, whose members include the Big Pharma lobbying organization Bio, and the group, "Conservatives for Property Rights." Allen hosted the event.

The webinar offered a one-sided discussion of the purported disadvantages of using march-in rights and other Bayh-Dole Act safeguards to expand access to Covid-19 technologies. Amid a growing groundswell of calls on the government to exercise march-in and other rights to help lower the price of the Covid-19 drug remdesivir, the panel's objective was clear: convince the public that this would be a bad idea. Working in his capacity as an NIH official, Dr. Rohrbaugh lent support and a perception of credibility to the industry-sponsored event.

At the outset of the webinar, Allen stated that "the Bayh–Dole Act does not give the government the authority to set the price of a successfully commercialized product. There seems to be some misunderstanding about that."

Rohrbaugh offered the following comments during the webinar:

> **Mark Rohrbaugh (00:08:49)**:
> Issues of drug pricing have been raised for years and are of concern to the American public. Because of concerns in the '80 about the price of AZT, the first drug for

8 https://www.ipwatchdog.com/2022/01/18/knowledge-ecology-internationals-new-march-petition-deja-vu/id=144562/.

> treating HIV/AIDS, NIH I added a reasonable pricing clause for products developed under its collaborations with companies, and in its licenses of exclusive patent rights. By 1994, five years later, industry partners had backed away from many agreements with the NIH. As a result, the NIH director at the time hosted public meetings to learn about the effect of the clause.
>
> **Mark Rohrbaugh (00:09:28)**:
> The consensus of patients, companies, researchers, was that the clause, the reasonable pricing clause had not provided benefits, but it formed a wedge to reduce the collaborative opportunities to develop new products. NIH then removed the clause in 1995 and collaborations rebounded after that.

What happened in the early to mid 1990s was a combination of factors, including a collapse of share prices for the biotech sector, which peaked in 1991, two years after the reasonable pricing clause was introduced, based upon factors unrelated to NIH policies.

This led to an intense lobbying campaign by drug corporations to eliminate the reasonable pricing clause, as one thing they could do. As is clear from the NIH's own published reports on the two CRADA forums in 1994, there was no consensus among patient groups that the reasonable pricing clause should be eliminated. There were a handful of drug-corporation-funded patient groups or advocates on one side, and patient advocates not funded by drug corporations on the other side.

To the extent that "the reasonable pricing clause had not provided benefits," this was due entirely to the reluctance of NIH to enforce the clause, as a result of industry lobbying efforts. However, for two products, Taxol and ddI (didanosine), the NIH did enforce Bayh-Dole Act safeguards, and this produced benefits for the public. There was a moderation of the pricing for Taxol, using a reference pricing model. For ddI, there was a sharp decrease in the price of the drug compared to other HIV drugs and a shorter term of exclusivity, that not only provided benefits to the public, but that was also the subject of a separate case study by the NIH that Rohrbaugh decline to cite in their public statements.[9]

Moreover, on the issue of a purported decline in industry collaborations, the primary data relied upon in those forums concerned CRADAs, and this data has been presented in a misleading manner. Prior to 1996, when the reasonable pricing clause was in effect, there existed only one type

[9] *See* National Institutes of Health Office of Technology Transfer, "Videx® Expanding Possibilities: A Case Study," September 2003, *available at* https://www.ott.nih.gov/sites/default/files/documents/pdfs/VidexCS.pdf.

of CRADA, now known as a standard CRADA. After the clause was removed, the NIH created a new type of CRADA—material CRADAs—which, of course, increased the CRADA counts overall. From fiscal year 1989 to 1994, the average number of NIH standard CRADAs executed was 34. From fiscal year 1996 to 2009, the average number of NIH standard CRADAs executed was 36, only a small difference, and for a period when the NIH budget increased dramatically, from $7 billion in 1989 to $30.5 billion in 2009.

Dr. Rohrbaugh stated further, at the same event:

> **Mark Rohrbaugh (00:09:51)**:
> Similarly, NIH has declined to exercise its march-in authority under Bayh–Dole, in response to several requests over the last 20 years to address the prices of drugs utilizing patented technology funded by the NIH. In each of those determinations, NIH directors have said that the march-in provision of Bayh–Dole does not authorize the control of drug prices by NIH. No other federal agency has disagreed with this interpretation since the beginning of Bayh–Dole 40 years ago.

This statement, too, is misleading. The NIH's directors are not lawyers. To the extent that NIH leadership has declined to exercise Bayh-Dole Act safeguards, they have based their decision on policy reasons. And when Director Collins has offered opinions on legal issues, they were provided by Dr. Rohrbaugh, who has been his advisor and collaborator on efforts to block march-in requests. Only the Department of Commerce can implement regulations for march-in rights and the government-use license,[10] however, and its sub-agency NIST tried, but failed, to issue a regulation that would eliminate pricing considerations.

Before the Covid-19 pandemic, Dr. Rohrbaugh participated in media discussions about march-in rights, always speaking against the use of the authority to address unreasonable pricing. In 2017, for example, he told the *New York Times* that "[c]ompanies will not take technologies from us if we say the government will decide in the future what the price will be," adding that, ""N.I.H. has made it clear that its job is not to decide prices of drugs, period[.]" Similarly, in 2016, Dr. Rorhbaugh told *BuzzFeed News*, "it is not [the NIH's] mission to control drug prices."[11]

The idea that companies will not partner with the government when they are subject to price constraints has been disproven by contracts executed during the current pandemic. The Department

[10] 35 U.S.C § 206.
[11] Dan Vergano, "If Taxpayers Invent A Drug, Should The Government Just Give It Away?" BuzzFeed News (Dec. 31, 2016), https://www.buzzfeednews.com/article/danvergano/nih-drug-giveaway.

of Defense (DoD) has entered into a number of contracts for the research and development and/or purchase of Covid-19 health products that include reference price constraints. Apparently, DoD does not hold the same biases against price limitations as does the NIH.

Conclusion

We have outlined several examples of Dr. Rohrbaugh's views about march-in rights and explained how those beliefs are contradicted by the Bayh-Dole Act and its implementing regulations. We have demonstrated that he has served as a decisionmaker in past march-in requests and provided evidence indicating that he is incapable of giving the 2022 Xtandi petition impartial consideration.

We are also concerned that Dr. Rohrbaugh has directed NIH officials involved in the 2022 petition to stonewall petitioners. Petitioner Eric Sawyer's correspondence inviting a dialogue with the NIH aboot the petition and asking direct questions about the process has been met with the same canned response that the recipient will share the information with its colleagues, even though the correspondence requests timely answers to straightforward questions. NIH emails reveal that in the past, Dr. Rohrbaugh has directed that correspondence from public interest organizations advocating for the exercise of march-in rights be fielded through him.

We request a teleconference with someone other than Dr. Rohrbaugh to address these concerns.

Sincerely,

Merith Basey MSc
Executive Director, UAEM North America

On behalf of Universities Allied for Essential Medicines (UAEM)
cc: Mark Rohrbaugh