KEI Comments on:
KEN23378 1T draft of the 2023 Reauthorization of the Pandemic and All-Hazards Preparedness Act (PAHPA)

July 10, 2023

1. TITLE VI—ADDITIONAL POLI11 CIES OUTSIDE THE STAFF AGREEMENT FOR STAKEHOLDER FEEDBACK, Subtitle A—Chair Sanders Staff Proposal, (pages 72 to 77).

The proposed reasonable pricing language is fairly straightforward. The international reference pricing language is clear and easy to enforce, and the additional reasonable pricing language gives the funding agency considerable flexibility to fashion and revise additional criteria if needed. The initial text is fine as is, but KEI provides additional comments below that can be considered.

Agencies covered

The agencies covered in the reasonable pricing clause are limited to BARDA and the CDC. Left out are the National Institutes of Health (NIH) and other Department of Health and Human Services (HHS) agencies, the Department of Defense (DoD), and all other federal agencies. Given the significant role of the NIH and DoD in funding biomedical research, not to mention the Departments of Veterans Affairs and Energy, this is surprisingly narrow.

International reference pricing

The Sanders proposal for international reference pricing is similar to proposals that Pfizer, Lilly, Sanofi and other companies agreed to in contracts for COVID-19 countermeasures. The exact number of times COVID-19 contracts included international reference pricing clauses is unknown, because of the extensive redactions in some contracts. For example, in several contracts, the international reference pricing clause is found in clause H.7, titled Most Favored Nation Clause, or Sales to Covered Nations. In the DoD contact with Merck for the drug molnupiravir, clause H.7 is fully redacted including the title. There are also several contracts with different versions of a most favored customer clause.

In the Pfizer contract for the U.S. government's purchase of Paxlovid, Pfizer tried unsuccessfully to redact the international reference pricing clause, which is not mentioned in its SEC 10.K filing. It is worth noting that Pfizer sales for Paxlovid were $18.933 billion in 2022 and $4.069 billion in the first quarter of 2023. The 2022 sales of Paxlovid were the third best among all therapeutics, with only Humira and Keytruda reporting greater sales in that year.

The typical COVID-19 international reference pricing clause referred to the prices in "a nation that is a member of the Group of Seven (Canada, France, Germany, Italy, Japan, the United

Kingdom, and the United States) plus Switzerland". Senator Sanders has proposed in this bill Canada, France, Germany, Italy, Japan, and the United Kingdom, as the reference countries, which is identical except for Switzerland to the DoD COVID-19 contracts.

In the past, KEI has favored a somewhat different formulation for international reference pricing. Specifically, we have suggested a specific number of countries for the reference countries (7 or 9, for example) that have the highest GDP and at least 50 percent of US GDP per capita. KEI has also suggested using the median price for the group and not the lowest.

Some can argue about whether or not the international reference price is an appropriate standard for drugs or vaccines in general, but it has a particular appeal when applied to products that have benefited from U.S. government R&D subsidies.

Additional reasonable pricing criteria

The enumerated factors to consider in the more general reasonable pricing clause are correct and not overly prescriptive, and the addition of "Other factors, as the Secretary determines appropriate" gives the administration plenty of flexibility, all appropriate for a statute on this topic.

It is inevitable that companies will claim that any clause will have a negative impact on collaborations, and while this is true to some extent, this has to be compared to the benefits to the public. However, in the past, we have favored giving federal agencies the ability to waive the reasonable pricing language, when it is in the public interest to do so.

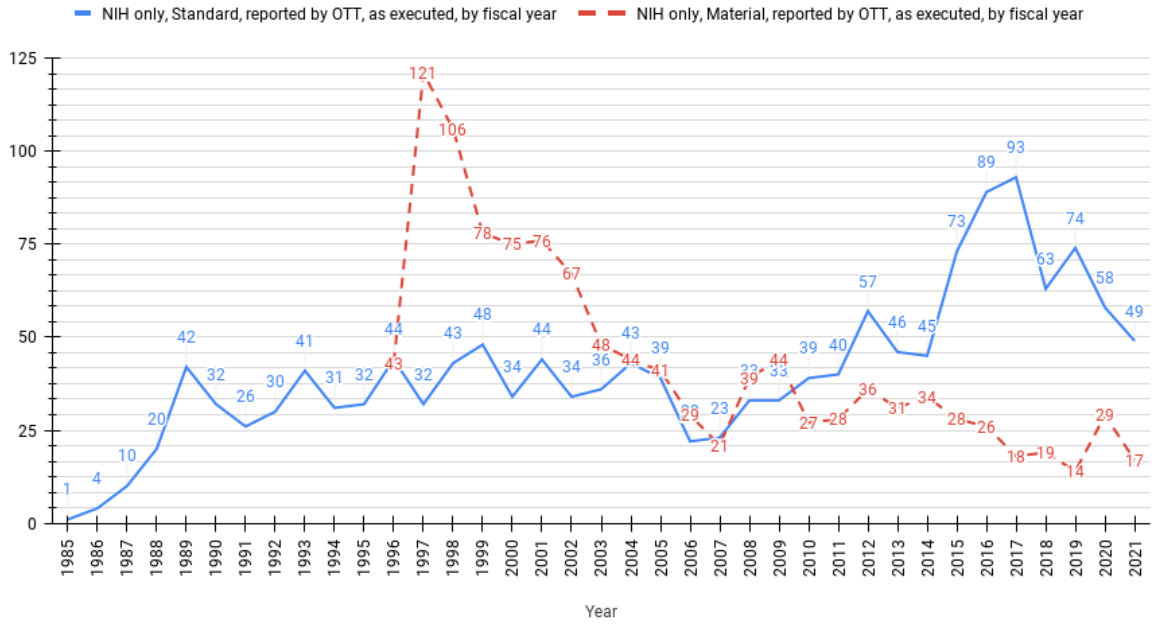
The 1995 NIH decision to eliminate the reasonable pricing clause

Before turning to the waiver issue, note that in the past, there has been considerable misinformation about the impact of the earlier NIH experience with the reasonable pricing clauses in CRADA and licensing agreements. The decision to eliminate the reasonable pricing clause took place in 1994/1995 during a collapse of the prices of biotechnology stocks, triggered by other factors, such as the failure of closely watched products, court decisions on patent law and President Clinton's proposals to control drug prices. The NIH eliminated the use of the reasonable pricing clause in April 1995.[1] While the clause had been used on both patent licenses and Cooperative Research and Development Agreements (CRADAs), most of the commentary about the decision focused on the CRADA experience. During the debate on the use in CRADAs, there was a concern that the NIH was not effectively enforcing the agreement, and this was in turn used by rights holders to argue that the benefits were non-existent, but that the clause discouraged collaborations. This is similar to the current attacks on the march-in rights clause in the Bayh-Dole Act, where the lack of enforcement becomes an argument against having the safeguard at all.

[1] Warren E. Leary, U.S. Gives Up Right to Control Drug Prices, New York Times. April 12, 1995. https://www.nytimes.com/1995/04/12/us/us-gives-up-right-to-control-drug-prices.html

In 1996, the NIH created a new type of agreement called materials CRADA. The new materials CRADA, which did not exist before 1996, was initially widely used by the NIH, spiking in 1997 at 121 times, vastly more than the “standard CRADAs” that had been subject to reasonable pricing clauses. When critics of the reasonable pricing clause combined the statistics from the standard and the materials CRADAs, they then claimed the elimination of the reasonable pricing clause led to a sharp increase in the collaborations. This was misleading however, as illustrated in Figure 1 below. In fact, the number of standard CRADAs were relatively flat and even declined through 2007, more than a decade after the reasonable pricing clause was eliminated. And today, the materials CRADAs are no longer used as frequently.

Figure 1: NIH Standard and Material CRADAs, reported by OTT as executed, by fiscal year



Waivers of reasonable pricing obligations

KEI has long advised legislators to give policy makers the possibility of a waiver of the reasonable pricing obligations, when the agency makes a written determination that such a waiver is in the public interest, explains why and provides notice to the public and accepts comments for finalizing the waiver.

Waivers exist in the Bayh-Dole Act on US manufacturing preferences, but are not very transparent, and decisions are only available to the public through FOIA requests, which take a long time to process.

ANNEX Pricing Clauses in U.S. Government Contracts for COVID-19 Products

In 2020 and 2021, several U.S. government contracts for the development of COVID-19 vaccines, therapeutics, diagnostic tests and other related products included provisions on pricing. Some contracts include a most favored nation pricing clause that specifically requires the company to provide the U.S. government with “a price lower” than the price offered to any centralized federal authority that is “a member of the Group of Seven plus Switzerland.” The non-US members of the G7 are Canada, France, Germany, Italy, Japan, and the United Kingdom.

Table A1, U.S. Government COVID-19 Contracts Containing Reference Price Constraints on Resultant Products

Contractor, Agency, and Contract Number	Subject	Page Located	Reference Price Term Excerpt
Pfizer The Army W58P0522C0001 November 17, 2021	Paxlovid Purchase Agreement	33	**H.7 Most Favored Nation Clause** (a) If, at any time prior to, or during, the base term and any exercised options of this contract, Contractor enters into any agreement with a Covered Nation under which the Covered Nation commits to purchase (i) the same or a lesser volume of Product than the U.S. Government commits to purchase (ii) at a price lower than the price the U.S. Government is obligated to pay for Product under this contract, Contractor shall provide notice of such lower price to the U.S. Government within 30 days of the execution of the Contractor-Covered Nation agreement and the U.S. Government may elect, at its discretion, to receive the benefit of this provision and purchase the Product at that lower price.
ANP Technologies, Inc. The Army W911QY20D0019 May 29, 2020	Development and Production of a Diagnostic	11	**H.1 Most Favored Customer** Awardee agrees that during the term of this contract and for a period of 5 years thereafter, that it shall not offer, sell or otherwise provide the production model of the CLIN 0001 end items (for the avoidance of doubt, CLIN 0001 end items in this clause shall mean a finished good of like material, like quality, to be used in a similar applications, and shall not include more general products to any entity at a price lower than that offered to the DoD. In the event that Awardee sells the production model at a lower unit price than that price sold to the DoD, Awardee shall immediately notify the Contracting Officer in writing of the lower price. For prior purchases, the Awardee shall reimburse the DoD, the difference between the lower price sold to the other customer(s) and the price sold to the DoD multiplied by the number of items sold. Such reimbursement shall occur within thirty days (30) of the Awardee discovering that the lower price was given to another customer. Notwithstanding the foregoing, the Parties may agree to apply the difference in price paid by the other customer(s) and DoD into additional quantities required by the DoD.”

Becton, Dickson & Company The Army W911SR2030001 July 1, 2020	Needle Production	17	**9. Government Preference** 9.1 Pricing. During the term of the Agreement, the Recipient agrees that, in the event that it enters into a Group Purchasing Organization (GPO) contract with a Qualifying Third Party (as defined below) with respect to a Qualifying Product (as defined below) with a per unit GPO price lower than that offered for the same Qualifying Product to the Government, the Recipient shall (i) promptly notify the Agreements Officer in writing of the lower price and (ii) extend the lower price to all future sales of the Qualifying Product to the Government. . . . "
Eli LIlly, The Army W911QY21D0012 P0002 April 7, 2021	Monoclonal Antibody Treatment Production	7-8	**H. 7 Sales to Covered Nations** (i) Due to the exceptional and unprecedented nature of the COVID-19 threat to global public health, as well as the investments made towards the development of a safe and effective therapeutic against COVID-19, Lilly agrees that it will not at any time prior to 30 September 2021 sell any COVID-19 bamlanivimab/etesevimab combination therapeutic supplied directly to the Government under this Agreement to any centralized federal authority (i.e., federal government or equivalent) of a nation that is a member of the Group of Seven plus Switzerland ('Covered Nation') at a lower price than the prices set forth in this contract. . . . "
Eli Lilly The Army W911QY21C0016 October 26, 2020	Monoclonal Antibody Treatment Production	18	**H.7 Sales to Covered Nations** (i) Due to the exceptional and unprecedented nature of the COVID-19 threat to global public health, as well as the investments made towards the development of a safe and effective therapeutic against COVID-19, Lilly agrees that it will not at any time prior to 30 June 2021 sell any COVID-19 therapeutic supplied directly to the Government under this Agreement to any centralized federal authority (i.e., federal government or equivalent) of a nation that is a member of the Group of Seven plus Switzerland ('Covered Nation') at a lower price than the prices set forth in this contract. . . ."
Emergent BioSolutions Canada Inc. The Army W911QY2090013 June 24, 2020	"the research and development of an advanced human immune globulin manufactured from human plasma with antibodies to SARS-CoV-2 (COVID-HIG) for post-exposure prophylaxis (PEP) of Coronavirus Disease (COVID-190"	16	**ARTICLE 9. Most Favored Customer** A. Awardee agrees that it shall not offer, sell, or otherwise provide the production model of the Prototype to any entity at a price lower than it offered to the DoD. In the event that Awardee sells the production model of the Prototype at a lower unit price than that price sold to the DoD, Awardee shall reimburse the DoD, the difference between the lower price sold to the other customer (S) and the price sold to the DoD multiplied by the number of items sold . . . ."

Immunome Inc The Army W911QY2090019 July 3, 2020	"research and development of a standardizable and scalable [redacted] compromise of [redacted] antibodies . . . ."	16	**ARTICLE 9. Most Favored Customer** A. Awardee agrees that it shall not offer, sell or otherwise provide the production model of the Prototype to any entity at a lower price than that offered to the DoD. In the event that Awardee sells the production model of the Prototype at a lower unit price than that price sold to the DoD, Awardee shall immediately notify the OTAO in writing of the lower price. . . ."
Inovio Pharmaceuticals, Inc. The Army W911QY2090016 June 22, 2020	"the development of an FDA approved next generation electroporation device and array for DNA Vaccine delivery of INO-4800 against COVID-19, with demonstrated capability to be produced at a large scale, as well as full automation for production of the device arrays, (hereinafter referred to as the 'Prototype Project')."	17	**ARTICLE 9. Most Favored Customer** A. For a period of six (6) years from the Effective Date, Awardee agrees that it shall not offer, sell or otherwise provide the production model of the Prototype to any entity at a price lower than that offered to the DoD. In the event that Awardee sells the production model of the Prototype at a lower unit price than that price sold to the DoD, Awardee shall immediately notify the OTAO in writing of the lower price. . . ."
Maxim Biomedical, Inc. The Army W911QY20D0018 May 11, 2020	Diagnostic Production	10	**H.1 Most Favored Customer** A. Awardee agrees that during the term of this contract and for a period of 5 years thereafter, that it shall not offer, sell or otherwise provide the production model of the CLIN 0001 end items (for the avoidance of doubt, CLIN 0001 end items in this clause shall mean a finished good of like material, like quality, to be used in a similar applications, and shall not include more general products to any entity at a price lower than that offered to the DoD. In the event that Awardee sells the production model at a lower unit price than that price sold to the DoD, Awardee shall immediately notify the Contracting Officer in writing of the lower price. . . ."
Murtech, Inc. The Army W911QY20D0017 May 11, 2020	Diagnostic Production	15	**H.1 Most Favored Customer** A. Awardee agrees that during the term of this contract and for a period of 2 years thereafter, it shall not offer, sell or otherwise provide the production model of the CLIN 0001 end items (herein the 'Items') (for the avoidance of doubt, CLIN 0001 production model end items in this clause shall mean a finished good of like material, like quality, to be used in a similar applications, and shall not include more general products) to any entity at a price lower than that offered to the DoD."

Novavax The Army W911QY20C0077 P0002 June 4, 2020	"Vaccine Development and Production"	4	"The Contractor shall maintain a most favored customer provision for the product once authorized or licensed by the FDA, such that the Contractor shall not give any entity a better price than the DoD for a period of five (5) years from the award of this contract, limited to customers in the U.S. and purchases made in the U.S to include sale prices as compared to commercial clients with respect to quantity, location of delivery, fundamental differences in deliverable formulation, and material differences in terms and conditions for commercial contracts."
Sanofi The Army W15QKN1691002; MCDC2011-005 July 30, 2020	Vaccine Research and Development (including Clinical Trials) and Production	28	**5.1 Most Favored Nation Clause** (i) Due to the exceptional and unprecedented nature of the COVID-19 threat to global public health and in recognition of the long historical partnership between the U.S. Government and Sanofi Pasteur working on global pandemic solutions, as well as the investments made towards the development of a safe and effective vaccine against COVID-19, Sanofi Pasteur agrees that it will not sell any COVID-19 vaccine licensed under this Agreement to any nation that is a member of the Group of Seven plus Switzerland ('Covered Nation') at a price that is more favorable than those set forth in this Project Agreement."
SIO2 Medical Products, Inc. The Army W911NF2030003 June 5, 2020	Vaccine Delivery Device Research and Development	13	**9. Government Preference** 9.1 Pricing. During the period of performance and the exercised optional availability periods, the Recipient agrees that, in the event that it offers, sells or otherwise provides a Qualifying Product (as defined below) to any Qualifying Third Party (as defined below) at a per unit price lower than that offered for the same Qualifying Product to the Government or a third party purchasing Qualifying Product pursuant to a designation by the Government pursuant to Section 9.2 or 9.3 (an 'MCM Partner'), the Recipient shall (i) promptly notify the Agreements Officer in writing of the lower price and (ii) extend the lower price to all future sales of the Qualifying Product to the Government or an MCM Partner."
Merck Sharp & Dohme The Army W911QY21C0031 June 7, 2021	COVID-19 therapeutic	21	**H.7. fully redacted**