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John Brooks
CMS Deputy Administrator and Director of the Center for Medicare

August 17, 2026

Public Citizen Comments Regarding Proposed Rule to Codify the Medicare Prescription Drug Price Negotiation Program (CMS-4215-P)

Dear Director Brooks,

Thank you for the opportunity to provide stakeholder feedback as CMS works to enact the Medicare drug price negotiation program.

Public Citizen is a nonprofit consumer advocacy organization with more than 1,000,000 members and supporters. The Access to Medicines program advocates for access to prescription drugs in the United States and internationally.

Public Citizen and health care access proponents across the nation invested tremendous energy into supporting Medicare drug price negotiation becoming law. We share CMS' goal of making this program a success to help prevent prescription drug manufacturer price gouging of seniors and people with disabilities with Medicare, and taxpayers who support the program.

Below, we outline several comments and recommendations in response to CMS' request for comment regarding codifying the policies of sections 1191 through 1198 of the Social Security Act.

In summary of our highest priority comments to this proposed rule:

1a) We strongly urge CMS against continuing to adopt a negotiation starting point using existing prices of therapeutic alternatives, all or some of which have not been negotiated by Medicare, as doing so will lead to inappropriately high maximum fair prices (MFPs) for Medicare beneficiaries and taxpayers.

1b) Instead, we urge CMS to adopt a holistic approach, with stronger consideration for section 1194(e)(1) MFP negotiation factors, through which drug corporations are paid a fair portion of the revenue necessary to recover risk-adjusted R&D costs, accounting for therapeutic advancement and the extent to which a selected drug addresses an unmet health need.

2) Retain CMS' proposed approach of considering all dosage forms and strengths of a drug with the same active moiety as a qualifying single source drug (QSSD) and including fixed combination products when one of the active moieties creates a new formulation and enables and alternative route of administration for the coadministered active moiety/ies. Doing so is vital to preserving program integrity and consistent with the intent of the legislation.

3) Ensure all Part B drugs sales – including sales reimbursed through Medicare Advantage (MA) – are considered when determining negotiation eligibility. Failing to consider MA Part B spending when determining negotiation eligibility and selection could inappropriately exclude costly medicines from negotiation that would otherwise be included.

4) Fully utilize the MFP renegotiation process to deliver savings to beneficiaries and taxpayers, including by considering percentage changes in MFP lower than 15 as potentially "significant" and considering a wide array of "material changes" that could impact MFP negotiations. CMS should also consider the magnitude of competing material changes when assessing the likely impact on MFP negotiations.

5) Provide greater transparency around R&D costs and other data to instill greater public confidence in the program. CMS' overly expansive interpretation of what information shall be held confidential would severely limit the impact of the legislation on industry drug pricing practices and the ability of the public to assess whether the Medicare drug price negotiation program is successfully negotiating "the lowest maximum fair price for each selected drug", as required under the Act.

6) Solicit information from patients, consumers, and other interested parties while promoting transparency around financial conflicts of interest with drug corporations.

7) Calculate negotiation eligibility for deemed biologics based on original approval dates, not the date of deeming.

Thank you again for this opportunity and for your consideration of these comments as CMS works towards implementing the Act.

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Recommendation 1a: Do not use the existing prices of therapeutic alternatives as the starting point for developing an initial price offer in drug price negotiations.

§ 429.510(d) outlines the proposed methodology from CMS for developing an initial price offer in drug price negotiations. CMS proposes in § 429.510(d) to take as a starting point for developing its initial negotiated price offer the average prices available for therapeutic alternatives for the selected drug. Below, we articulate two major concerns with this approach.

I. Starting with the prices of therapeutic alternatives will lead to ongoing inappropriately high prices.

Evidence shows that drug prices paid under Medicare Part D are significantly higher than those paid under other health programs in the United States, including Medicaid and the Department of Veterans Affairs, as well as those paid in other wealthy countries.[1,2,3]

Current inappropriately high prices, which burden Medicare beneficiaries and taxpayers, are the underlying reason that Congress passed a law to empower Medicare to negotiate in the first place.

These prices are set by drug corporations under monopoly conditions to maximize profits, while plans face broad coverage obligations under Medicare Part D. Taking prices of therapeutic alternatives set under these conditions as the starting point for developing negotiated price offers would bias the system towards inappropriately high, unfair prices. This would be inconsistent with the statutory requirement that CMS develops a methodology and process for drug price negotiation "that aims to achieve the lowest maximum fair price for each selected drug."[4]

II. Starting with the prices of therapeutic alternatives would be a missed opportunity for the law to provide virtuous systemic impact.

In support of its negotiated price offer starting point proposal, CMS states that "the cost of therapeutic alternatives in the current market [...] is an important factor when considering the overall benefit that the treatment brings to Medicare beneficiaries."

We agree that pricing of a medicine and its therapeutic alternatives impact Medicare beneficiaries, but it does not follow that prices of therapeutic alternatives should dictate the starting point of prices CMS negotiates. Moreover, while section 1194(e)(2)(A) of the Act requires CMS to consider the prices of therapeutic alternatives in developing a maximum fair price offer, there is a multitude of ways to

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[1] Government Accountability Office, *Prescription Drugs: Department of Veterans Affairs Paid About Half as Much as Medicare Part D for Selected Drugs in 2017*, GAO-21-111, January 14, 2021.
[2] Mulcahy AW, C.; Tebeka, M.; Schwam, D.; Edenfield, N.; Becerra-Ornelas, A. International Prescription Drug Price Comparisons. 2021; https://www.rand.org/content/dam/rand/pubs/research_reports/RR2900/RR2956/RAND_RR2956.pdf.
[3] Government Accountability Office, *Prescription Drugs: U.S. Prices for Selected Brand Drugs Were Higher on Average than Prices in Australia, Canada, and France*, GAO-21-282, April 28, 2021.
[4] 42 U.S.C § 1320f–3 (b)(2).

incorporate that information that do not inordinately prejudice the process toward entrenching current high prices, which are often multiples higher than those paid in other high-income countries. Indeed, analysts found that the Medicare-negotiated prices for the first 10 selected drugs, remain higher in all comparator countries in virtually all cases.[5] For many of these drugs, the Medicare-negotiated prices remain more than three times the prices in comparably large and wealthy countries.[6] At the end of recommendation 1b in these comments, we provide an alternative that will situate the maximum fair price in the context of the prices of therapeutic alternatives, but, crucially, without reinforcing the current regime of excessive prices.

Rather than provide virtuous systemic impact, the current process CMS is considering would reduce incentives for manufacturers of therapeutic alternatives to lower their prices. Using existing drug prices, especially those of branded drugs that have not been negotiated by CMS, as the basis for negotiations risks building inertia for higher prices into the system. By instead negotiating a maximum fair price through alternate methods, such as those we propose below, CMS' negotiation process could help reduce the prices of the alternative therapies, since the manufacturers of the alternatives may try to compete on price with that of the negotiated product.

Recommendation 1b: Instead, adopt a holistic approach, with stronger consideration for section 1194(e)(1) MFP negotiation factors, through which drug corporations are paid a fair portion of the revenue necessary to recover risk-adjusted R&D costs, accounting for therapeutic advancement and the extent to which a selected drug addresses an unmet health need and other section 1194(e)(2) factors.

When negotiating prices, CMS can deliver access and protect innovation by determining the maximum fair price using the baseline of risk-adjusted research and development (R&D) costs and the extent to which they have been recouped by the manufacturer.

Medicines are information goods. R&D costs—not other welfare metrics like "value"—should form the core basis for negotiating prices because R&D costs can help answer the inquiries central to information economics: how much does innovation cost, and how much compensation is necessary to induce innovation?

Exclusive rights allow prescription drug corporations to charge prices that are not linked to the cost of innovation. As one drug executive noted, "We all look at each other and keep pace with each other. Honestly, there is no science to it."[7] Pharmaceutical industry pricing practices reduce social welfare by limiting access and create massive inefficiencies in the form of deadweight loss. Governments tolerate

[5] Delaney Tevis, Matthew McGough, Juliette Cubanski, and Cynthia Cox. "How Medicare negotiated drug prices compare to other countries". KFF. Dec. 19, 2024. https://www.healthsystemtracker.org/brief/how-medicare-negotiated-drug-prices-compare-to-other-countries/

[6] Ibid.

[7] https://www.nytimes.com/2015/07/23/business/drug-companies-pushed-from-far-and-wide-to-explain-high-prices.html

this static (short-term) inefficiency in the name of protecting dynamic (long-term) incentives for innovation. HHS can help challenge this false dichotomy by negotiating lower prices that appropriately reward true R&D costs.

The IRA lists a series of negotiating factors to help determine the maximum fair price offers and counteroffers.[8] To develop a maximum fair price offer, CMS should adopt a holistic approach with stronger consideration for selection 1194(e)(1) MFP negotiation factors, through which drug corporations are paid a fair portion of the revenue necessary to recover risk-adjusted R&D costs, accounting for therapeutic advancement and the extent to which a selected drug addresses an unmet health need and other section 1194(e)(2) factors. We explain in further detail below.

I. Risk-Adjusted Research and Development Costs, Accounting for Federal Investment

The cost of innovation should be central in determining the maximum fair price assessment. Unfortunately, § 429.510(f) shows that CMS intends to deprioritize manufacturer-specific data, which represent more than half of the total number of factors provided under statute for CMS to consider in determining its maximum fair price offers and counteroffers.[9] § 429.510(f) of the rule goes so far to suggest that CMS may not even incorporate consideration for this information in its maximum fair price offer.

Under the Act, manufacturers are required to submit information "in a form and manner specified by the Secretary" that CMS requires to carry out the negotiation. To determine actual R&D costs, CMS can require granular information. Drawing on expert reviews[10] and prior legislative proposals[11], we recommend that total expenditures on R&D are itemized by direct and indirect costs, including for:

- Basic and preclinical research;
- Clinical research, reported separately for each clinical trial, per patient, per year, comprising
    - Personnel costs (including salary and benefits)
        - Administrative staff
        - Clinical staff
    - Materials and supplies
    - Clinical procedures
    - Site management
        - Site monitoring costs
        - Site retention
        - Other
    - Central laboratory
    - Equipment
    - Other direct costs
        - Publication Costs
        - Subawards/Consortium/Contractual Costs

[8] 42 USC § 1320f-3(e)(1) and 42 USC § 1320f-3(e)(2).
[9] 42 USC § 1320f-3(e)(1)
[10] NYU Law, Clinical Trial Cost Transparency at the NIH: Law and Policy Recommendations (2020), https://www.law.nyu.edu/centers/engelberg/pubs/2020-08-17-Clinical-Trial-Cost-Transparency-at-the-NIH
[11] S.909 - Prescription Drug Price Relief Act of 2021, https://www.congress.gov/bill/117th-congress/senate-bill/909/text

    - Other;
- Development of alternative delivery systems, dosage forms, strengths or combinations; and
- Other development activities, such as post-approval testing and record and report maintenance.

In the guidance for IPAY 2028, Appendix A, CMS appropriately delineated a wide array of information that would be required to be disclosed by manufacturers, pursuant to section 1194(e)(1) of the IRA,[12] but the proposed rule for IPAY 2029 does not seem to provide similarly detailed information on manufacturer disclosures. To the extent that any ambiguity remains, we recommend CMS clarify that this information, described under definitions relating to R&D costs in Appendix A of the IPAY 2028 guidance, should be applied for IPAY 2029 and be provided in an itemized and disaggregated fashion. This is particularly important with regard to reporting costs separately for each clinical trial, as there are significant differences in risk depending on trial phase, as described further below.

Obtaining disaggregated, detailed information offers two advantages over relying only on more generalized and potentially misleading research and development information disclosed pursuant to SEC requirements. First, CMS can risk-adjust R&D figures in a more sophisticated way, including by stage of clinical development, and better account for federal investment. For example, researchers have estimated success rates across clinical trials, including by drug class, disease and indication.[13] Together with the cost of trials and federal investment, CMS can use these figures to determine the cost of trial failures—and hence, risk-adjusted trial costs incurred by the manufacturer.

Table 1: Drug Development Success Rates (Hay et al., 2014)[14]

Stage	Phase Success	Likelihood of Approval
Phase 1 to Phase 2	64.5%	10.4%
Phase 2 to Phase 3	32.4%	16.2%
Phase 3 to NDA/BLA	60.1%	50.0%
NDA/BLA to Approval	83.2%	83.2%

Second, the granularity of R&D costs can increase the integrity of the data and help prevent gaming of R&D cost figures. Aggregate figures, like the ones reported by firms in financial filings, capture many kinds of expenses that inflate the real cost of R&D, making them less useful. For example, firms can include the costs of acquiring a candidate as an R&D expense, even if the acquisition cost was based on the expected revenue the candidate could generate—not necessarily the money that was spent in research and development.[15] (In the case of a drug that was acquired part way through its development, it should be incumbent on drug corporations to disclose disaggregated information on actual R&D expenditures on the drug candidate prior to its acquisition to the extent they want such costs considered by CMS.) In IPAY 2028, CMS excluded acquisition costs from its consideration of R&D costs. We encourage CMS to continue this practice. CMS was correct in its stated understanding that acquisition costs are generally driven by the estimated net of the present value that is assessed based on future revenue expectations for a drug, and that acquisition costs are not driven by R&D. In that context, if higher acquisition costs led to higher MFP offers, it would provide incentive for inflated acquisition costs in the future, which in turn would lead

[12] 42 USC § 1320f-3(e)(1)
[13] Michael Hay et al., Clinical development success rates for investigational drugs, 32 Nature Biotechnology (2014).
[14] Michael Hay et al., Clinical development success rates for investigational drugs, 32 Nature Biotechnology (2014).
[15] An analysis of 10-K filings by Knowledge Ecology International showed that pharmaceutical corporations sometimes include the costs of acquiring licenses and other assets as research costs. *See* https://www.keionline.org/wp-content/uploads/KEI-Written-Testimony-OR-SB793.pdf

to even higher MFPs for future selected drugs. Successful drug development organizations, like the Drug for Neglected Diseases Initiative, have shown that reporting real R&D costs is possible, and provide crucial insights on how that reporting might be structured.[16]

Furthermore, a three-year House Oversight Committee investigation into drug pricing found that drug corporations can also include in bulk R&D figures "non-innovative R&D expenditures." The Committee found that the corporations reviewed in their investigation "dedicated a significant portion of their R&D expenditures to research that was intended to extend market monopolies, support the companies' marketing strategies, and otherwise suppress competition."[17] A recent study from Department of Health and Human Services officials and coauthors indicates that R&D estimates touted by industry are significantly higher than what a transparent analysis of public data provides – an average of less than $900 million, including costs of capital and failed candidates, rather than more than $2.5 billion.[18]

Under a pure cost-plus payment model, sellers may have a perverse incentive to inflate costs incurred and reported, knowing that higher costs will result in increased payment. If pharmaceutical reimbursement is linked to actual costs reported, then drug corporations could inflate expenditures, especially to the extent they are risk adjusted for payment considerations. CMS is well positioned to overcome this obstacle and better incent efficient drug development by using data-driven proxies for R&D and production and distribution costs.

Importantly, the law requires manufacturers to submit information regarding "[p]rior Federal financial support for novel therapeutic discovery and development with respect to the drug." The extent to which R&D has been supported and subsidized by the Federal government and other public sources is a key factor in determining privately borne risk in developing a medicine. In addition to requiring companies to report and acknowledge all relevant public R&D contributions in all forms, HHS should work across government to gather such information and make it public.

In collaboration with U.S. Government entities that conduct and fund clinical trials, within HHS as well as elsewhere within the federal government, including the National Institutes of Health (NIH), the Biomedical Advanced Research and Development Authority (BARDA), the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration, the Department of Defense, and the Department of Veteran Affairs, CMS can supplement manufacturer-provided information to develop an R&D cost database and form proxies using average costs of R&D for different categories of therapies, using representative samples of R&D costs for different products. HHS can then use the appropriate category of proxy of demonstrated R&D costs to help determine the maximum fair price offer of a given drug. Optimally, HHS would also obtain as much data as possible on costs of failed clinical trials to best inform its calculation of risk-adjusted R&D costs. HHS and other agencies taking action to increase and systematize compliance with the Stevens Amendment, which requires disclosure of the total costs of programs or projects paid for with federal funds "[w]hen issuing statements, press releases, requests for proposals, bid solicitations

[16] DNDI, Transparency of R&D Costs, https://dndi.org/advocacy/transparency-rd-costs/

[17] U.S. House of Representatives Committee on Oversight and Reform, Majority Staff Report: Drug Pricing Investigation, December 2021, https://oversight.house.gov/sites/democrats.oversight.house.gov/files/DRUG%20PRICING%20REPORT%20WITH%20APPENDIX%20v3.pdf

[18] Aylin Sertkaya, PhD; Trinidad Beleche, PhD; Amber Jessup, PhD; Benjamin D. Sommers, MD, PhD. Costs of Drug Development and Research and Development Intensity in the US, 2000-2018. JAMA. June 28, 2024. https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2820562

and other documents describing projects or programs," can also provide greater insight into federal support for pharmaceutical R&D.[19]

Using the risk-adjusted, true R&D cost can help provide a fairer baseline from which to reward innovation. This can be adjusted to account for clinical benefit, as described in the following section.

II. Accounting for Therapeutic Value

To promote meaningful innovation, manufacturers that produce drugs with new, clinically meaningful benefit should receive robust rewards, including the ability to make a reasonable profit on risk-adjusted R&D investments that they incur. Manufacturers of products that do not show evidence of improving health outcomes, relative to other therapies at the time of approval, should not be excessively rewarded.

CMS should adjust its MFP offer higher when there is strong evidence showing a selected drug has a preferable safety and efficacy profile compared to therapeutic alternatives and when robust evidence shows it addresses an unmet health need. Conversely, when there is strong evidence that a therapy has a worse safety and efficacy profile or that it is a "me too" drug, which acts similarly to therapeutic alternatives, then the MFP offer should be lowered. Similarly, when there is a lack of strong evidence of benefit relative to other therapies, the MFP offer should be lowered.

The table below illustrates how CMS can incorporate therapeutic value information into its MFP offer determination, taking into account both the magnitude of relative benefit provided by the selected drug compared to other therapies, as well as the certainty of evidence of net clinical benefit[20] compared to other therapies available at the time of approval, taking into account the factors enumerated in the section 1194(e)(2) of the Act, including unmet medical needs.[21] A similar categorization of therapeutic benefit is used in Germany.[22]

Table 2: Adjusting MFP Offers Based on Therapeutic Advancement

Strength of Evidence	**Added Value**		
	Minor	**Significant**	**Major**
Low-to-Moderate	Little or no ↑ adjustment	Small ↑ adjustment	Small-to-modest ↑ adjustment
High or Proof	Small ↑ adjustment	Significant ↑ adjustment	Largest ↑ adjustment
No Data	↓ adjustment	↓ adjustment	↓ adjustment
High or Proof Against	Largest ↓ adjustment	↓ adjustment	↓ adjustment

Adjusting the MFP offer based on the magnitude and certainty of evidence about the therapeutic value of a selected drug can help to ensure pharmaceutical manufacturers are more greatly compensated when

[19] Government Accountability Office, Grants Management: Agency Action Required to Ensure Grantees Identify Federal Contribution Amounts, March 2019, https://www.gao.gov/assets/gao-19-282.pdf
[20] Taking into consideration both potential benefits and risks.
[21] 42 USC § 1320f-3(e)(2).
[22] Skipka et al., Methodological approach to determine minor, considerable, and major treatment effects in the early benefit assessment of new drugs, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5034755/

they generate more novel therapeutic advancements, while discouraging against developing "me too" drugs that are largely redundant with existing therapies. The table above provides general guidance for determining how to adjust MFP offers that will prevent inappropriately subsidizing corporations for medicines that lack evidence of improving health outcomes and allow for negotiated prices that reward genuine advancements. The appropriate adjustment in MFP offer for a medicine with strong evidence of providing major added health benefit may be large, but should conform to the principle stated at the beginning of this section: *how much does innovation cost, and how much compensation is necessary to induce innovation?*

By ensuring that drug manufacturers are well rewarded for true, novel therapeutic advancements and, importantly, avoiding inappropriately subsidizing corporations through excessive prices paid by patients and taxpayers for products that are required by statute to be included in formularies but that do not show increased benefit relative to other therapies, IRA drug price negotiations can promote an R&D ecosystem better aligned with serving unmet health needs.

While we take strong exception to CMS' proposed approach for reaching a starting point for a maximum fair price offer, discussed in recommendation 1a above, the approach CMS takes to analyzing comparative effectiveness between a selected drug and its therapeutic alternatives (described in § 429.510(e) of the proposed rule) could be consistent with this element of our proposal. We are grateful for CMS considering the source, rigor of study methodology, and risk of bias when reviewing literature from the public and manufacturer submissions to help ensure the integrity of the contributing data within the negotiation process, as indicated in § 429.510(e)(1) of the rule.

III. Net and Expected Net Revenues

As noted above, section 1194(e)(1) of the Act requires CMS to consider an array of manufacturer-submitted data, including the extent to which the manufacturer of a selected drug has recouped its research and development costs for the drug. However, Public Citizen is concerned that CMS is not appropriately considering this information, and that MFPs are higher as a result. Determining Medicare's fair share requires assessing how much additional reward the manufacturer needs to obtain the full appropriate reward during the remaining product life, taking into account the net and expected revenues from other payers. The more progress a manufacturer has made toward recouping risk-adjusted R&D costs through net revenues, the lower an MFP CMS should offer. When CMS finds that the manufacturer of a selected drug has accrued or is expected to accrue net revenues exceeding risk-adjusted R&D costs (including a reasonable profit) by the time the MFP takes effect, then the MFP offer should be lowered significantly.

CMS can obtain information about how much the manufacturer has already recouped and estimate how much the manufacturer expects to make from other payers over the remaining product life, and adjust its MFP offer based on the expected product volume sold to Medicare over the remaining product life to help determine a Medicare price. In IPAY 2028 CMS solicited comments in section 50.1 of draft guidance on whether to consider collection of forward-looking market data for selected drugs to help forecast revenue and volume data. We encourage collecting this data and considering it when assessing the extent to which manufacturers of selected drugs will have recouped risk adjusted R&D costs by the time MFPs take effect as well as future recoupment from other payers.

Because pharmaceutical corporations operate in a global marketplace and are not bound only to market products in the United States, global sales should be included in this calculation. The first factor for consideration for the purpose of negotiating the maximum fair price of a selected drug in the IRA includes "the extent to which the manufacturer has recouped research and development costs," which necessarily implicates the extent to which such costs have been recouped through U.S. *and* non-U.S. sales. We appreciate CMS incorporating global sales in its approach to considering net revenues and encourage it to continue to do so.

IV. Examining Patents for Potential Monopoly Abuses

Section 1194(e)(1)(D) of the Act requires CMS to consider data on pending and approved patent applications and other exclusivities when determining an appropriate MFP. In addition to using this data to help determine the remaining monopoly life of the drug before it faces generic competition, CMS can evaluate patent and patent application data to scrutinize whether they cover novel inventions that contribute to the therapeutic value of a selected drug or, rather, if they are more representative of legal maneuvering to lengthen monopolies without clinical benefit. If patent gamesmanship by a manufacturer unfairly extends exclusivity for a selected drug and improperly allows its manufacturer to collect exorbitant revenues without adequate competition, then CMS should lower its MFP offer, with consideration for the prices that might be available in the absence of such inappropriate monopoly extensions, and the continued inflated revenues a manufacturer will obtain from its patent abuses. To the extent negotiated prices exceed those that would be available in the absence of unfair monopoly extensions, companies will not be deterred from future misconduct.

Public Citizen analysis found that four out of 10 drugs subject to Medicare drug price negotiation for initial price applicability year 2026 would likely have faced competition before negotiated prices went into effect, were it not for patent evergreening tactics and other patent abuses.[23] As a result, Medicare will have lost between $4.9 and $5.4 billion in savings that should have accrued from access to competing, lower-cost treatments. These lost savings are nearly as much as what Medicare was expected to save when negotiated prices went into effect on all of the selected drugs in the first year of the program ($6 billion).[24] Evergreening practices were prevalent across the drugs selected for price negotiation for IPAY 2026. Nine out of 10 drugs subject to negotiation show evidence of manufacturers engaging in blatant anticompetitive uses of patents to fend off generic or biosimilar competitors or evergreening abuses representing minor modifications or tweaks that unfairly lengthen monopoly protection on the drugs. Patent protection on the branded drugs could extend well into the 2030s and possibly 2040.[25]

In the case of Enbrel, Public Citizen found that Amgen, Enbrel's manufacturer, reworked old patent applications from another company to cover Enbrel once Amgen's patent protection in the drug expired in 2019, so it could protect its monopoly power until 2029.[26] Medicare could have saved more than a billion dollars if biosimilars had been allowed to enter the market when the underlying patent protection

[23] https://www.citizen.org/article/using-the-inflation-reduction-act-to-rein-in-patenting-evergreening-abuses/
[24] Ctrs. Medicare & Medicaid Servs., Fact Sheet: Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2026 (Aug. 14, 2024), https://www.cms.gov/newsroom/fact-sheets/medicare-drug-price-negotiation-program-negotiated-prices-initial-price-applicability-year-2026.
[25] https://www.citizen.org/article/using-the-inflation-reduction-act-to-rein-in-patenting-evergreening-abuses/
[26] https://www.citizen.org/article/using-the-ira-to-rein-in-abuses/

was set to expire in 2019. Ignoring industry monopoly abuses that have resulted in inflated prices, as in Enbrel's case, would detract from CMS's mandate to deliver the lowest possible MFPs for Medicare's enrollees. Instead, where a manufacturer has gamed the patent system to unfairly extend exclusive control of a selected drug, CMS should consider (1) the prices that would be in place if proper competition existed, and (2) excessive revenues manufacturers have unfairly obtained from Medicare and its enrollees through this gamesmanship as it determines its MFP offer.

Similarly, analysis from patent experts at the Initiative for Medicines, Access, and Knowledge (I-MAK) found that follow-on patent protection extending the monopoly on Eliquis will generate $11.6 billion in U.S. sales for Bristol Myers Squibb and Pfizer, while Novo Nordisk follow-on patents creating a patent thicket covering formulations and delivery devices for semaglutide provide patent protections until 2042, despite the main compound patents having been filed in 2006.[27]

V. Marginal Production and Distribution Cost

Finally, beyond rewarding medical innovation, CMS should pay for the marginal cost of production and distribution for medicines used by Medicare beneficiaries. Using the marginal cost of production and distribution—rather than the average total—is the most precise way to determine minimum costs. It precludes the manufacturer from adding other costs into the figure.[28]

VI. Note on Negotiation Delay Periods

While our proposed method for CMS to determine maximum fair price offers is constructed to arrive at appropriate prices consistent with promoting medicines access and innovation regardless of how long a product has been on the market, currently negotiations are permitted only for older medicines. Specifically, CMS is allowed to negotiate prices only for drugs and biologics that will have been on the market for at least 9 or 13 years by the time such prices take effect, and longer for drugs first approved for an orphan indication and subsequently approved for a non-orphan indication.

Since CMS will only be negotiating prices of high spend drugs and biologics for which drug corporations have had many years to recoup risk-adjusted R&D costs, they will likely have done so many times over prior to the initial price applicability year. Indeed, experts found that by the time negotiated prices take effect for IPAY 2027 selected drugs, manufacturers will have already accrued net revenues from their sales exceeding risk adjusted R&D costs on each of those drugs[29], yet it is unclear whether that impacted MFPs CMS offered. In the case of semaglutide, Novo Nordisk is estimated to have achieved cumulative earnings of $43.1 billion in under 7 years on the market, compared to $1.6 billion, which is the amount authors estimate to provide an adequate return on risk-adjusted R&D costs when manufacturers are making R&D

[27] Initiative for Medicines, Access, and Knowledge. "Overpatented, Overpriced: A Data Brief on Medicare-Negotiated Drugs: Eliquis, Ozempic, Rybelsus and Wegovy." June 23, 2025. https://www.i-mak.org/wp-content/uploads/2025/06/Database-Brief-2025.pdf

[28] CMS could also consider forming proxies with consideration of pricing information of generic drugs in the same category of therapy, where available, to avoid perverse incentives to inflate marginal costs of production and distribution to obtain higher prices.

[29] https://www.brookings.edu/articles/cumulative-net-earnings-of-drugs-selected-or-likely-to-be-selected-for-negotiation/

investment decisions.[30] These findings suggest that for many drugs, Medicare-negotiated prices could approach the marginal cost of production and distribution without impeding R&D investment incentives. CMS should not shy away from approaching marginal cost pricing of medicines that have been super-blockbusters, such as those that have already generated tens-of-billions of dollars in revenues since entering the market, particularly when a selected drug only remains eligible due to patent gamesmanship, as detailed above.

By applying this methodology to determine maximum fair price offers and counteroffers, CMS can reward medical innovation and ensure reasonable prices. Indeed, to preserve the integrity of the system, CMS should only adjust its response to a manufacturer counteroffer if refinements to the input data are presented. Consistent use of this methodology can help realign incentives for pharmaceutical corporations and promote more meaningful medical innovation.

VII. Note on Consideration of Prices of Therapeutic Alternatives

While section 1194(e)(2)(A) of the Act requires CMS to consider the prices of therapeutic alternatives as one of several factors in developing a maximum fair price offer, it certainly does not require it to form the underlying basis for developing a starting point for such an offer. There is nothing in the Act that says or suggests that this or any other factor should be prioritized over or emphasized more than any of the others CMS is required to consider in developing a maximum fair price. As discussed above, it is our strong view that such an approach will inappropriately prejudice CMS toward inappropriately high offers, entrenching the existing regime of price gouging.

Rather than using prices of therapeutic alternatives to form the starting point for CMS' negotiated price offer, CMS should instead take the approach we have articulated above, and as a final step in the process, compare the maximum fair price reached to the prices of therapeutic alternatives. The maximum fair price CMS plans to offer should be reduced to a price that is no higher than the lowest price of a therapeutic alternative that has demonstrated safety and efficacy matching that of the selected drug, including generic and biosimilar versions of therapeutic alternatives marketed in the United States, if the planned offer is not already below this price. A similar approach to internal reference pricing was incorporated in Denmark's pharmaceutical reimbursement regime in 2005, wherein reimbursement is based on the lowest domestic price out of all products belonging to a substitution group.[31,32]

[30] Ibid.

[31] Ulrich Kaiser, Susan J. Méndez, Thomas RØnde, Hannes Ullrich. "Regulation of Pharmaceutical Prices: Evidence from a Reference Price Reform in Denmark." February 2013. https://docs.iza.org/dp7248.pdf

[32] It is difficult to estimate the impacts of this policy in isolation strictly by looking at the Danish experience, as there are other significant differences in their pharmaceutical system from that of the United States, including operating under a universal health care system and an obligation for pharmacists to first offer a patient the lowest-price product within a group of substitutes for a drug unless prohibited by the prescription.

Recommendation 2: Retain CMS' proposed approach of considering all dosage forms and strengths of a drug with the same active moiety, inclusive of products marketed pursuant to different New Drug Applications (NDAs) and Biologics License Applications (BLAs), as a qualifying single source drug.

§ 429.125(b) of the rule correctly cites section 1192(d)(3)(B) of the Act, which requires CMS to aggregate sales across dosage forms and strengths of a qualifying single source drug in determining whether such drug is negotiation eligible.[33] Additionally, section 1192(b) of the Act[34] requires CMS to select drugs for negotiation based on the rankings of total expenditures under Medicare Part D and Medicare Part B for negotiation-eligible drugs, as clarified under section 1192(d)(3)(B) to include spending "data that is aggregated across dosage forms and strengths of the drug, including new formulations of the drug, such as an extended release formulation, and not based on the specific formulation or package size or package type of the drug."

This language clarifies the intent of policymakers of applying negotiated prices across dosage forms and strengths of a selected drug, which necessitates the approach CMS proposes in the rule to take for identifying potential qualifying single source drugs.

Further, the approach proposed by CMS will prevent gaming and abuse of the Medicare drug price negotiation program that may occur if prescription drug corporations were able to prevent a high-revenue product from qualifying for negotiation through product hopping and obtaining new NDAs and BLAs, effectively resetting the clock on the statutory 7- and 11-year delay periods before a drug or biologic may qualify for negotiation.[35] We appreciate that CMS plans to continue to take this approach.

Additionally, we urge CMS to move forward with grouping together fixed combination drug products containing at least one but not all of the active moiety(ies) / active ingredient(s) into the same potential qualifying single source drug when one of the active ingredients or active moieties "creates a new formulation and enables an alternative route of administration for the co-administered active moiety(ies)/active ingredient(s)." Experts have noted the example of hyaluronidase reformulations of cancer drugs, in which "the FDA considers hyaluronidase to be an active ingredient, [but] one of its primary purposes appears to be increasing the absorption/availability of other products, rather than treating certain forms of cancer on its own."[36] If drugs reformulated into combination products with hyaluronidase are considered distinct QSSDs, Medicare and its beneficiaries could be subjected to higher, unnegotiated prices for many years longer.

[33] 42 USC § 1320f-1(d)(3)(B)
[34] 42 USC § 1320f-1(b)
[35] 42 USC § 1320f-1(e)(1)(A)(ii) and 42 USC § 1320f-1(e)(1)(B)(ii)
[36] https://www.healthaffairs.org/content/forefront/administration-releases-medicare-drug-price-negotiation-program-draft-guidance-2028

Recommendation 3: Ensure all Part B drugs sales – including sales reimbursed through Medicare Advantage (MA) – are considered when determining negotiation eligibility.

In IPAY 2028 Medicare Part B was incorporated into the Medicare drug price program. Experts expressed concern that CMS' proposal to use "Part B claims data" to identify high-spend drugs and determine which Part B drugs are negotiation-eligible and ultimately selected for drug price negotiations will not encompass data from Medicare Advantage plans, which now enroll over half of the Medicare population.[37,38] We applaud CMS for taking this suggestion into account in § 429.120(b) of the proposed rule and including Medicare Advantage encounter data for Part B items and services to ensure these costs are included when identifying high-spend Part B drugs.

If spending on Part B drugs through Medicare Advantage is not considered, the program would be inappropriately prejudiced against selecting costly Part B drugs for negotiation. To ensure the program achieves the most savings for Medicare and its beneficiaries, it is essential that CMS considers all sales of Medicare Part B drugs, including through Medicare Advantage.

In addition, Public Citizen supports CMS' plans to use combined sales across Part B and Part D when ranking and selecting negotiation-eligible drugs as selected drugs, as indicated in § 429.105. Using sales combined across Part B and Part D when ranking and selecting negotiation-eligible drugs is consistent with section 1192(b)(1)(A) and (B) of the Act, which require CMS to rank negotiation-eligible drugs "according to total expenditures for such drugs under parts B and D" and "select from such ranked drugs […] the negotiation-eligible drugs with the highest such rankings." This approach is also consistent with the statutory definition of low spend Medicare drugs considering "total expenditures under parts B and D."

Lastly, due to a perverse incentive wherein physicians administering Part B drugs are reimbursed based on a percentage of the average sales prices of that medicine, negotiating lower prices on Medicare Part B selected drugs may pose unique access problems.[39] When CMS negotiates a price for a selected Part B drug that is lower than that of therapeutic alternatives, physicians would receive greater reimbursement from prescribing alternatives, costing Medicare and its enrollees more money. CMS should closely monitor beneficiary access to Part B negotiated drugs. Legislation is likely necessary to provide a lasting solution to the perverse incentives inherent in the Part B reimbursement system. However, CMS could consider a demonstration project under which physicians are reimbursed a flat amount, or a percentage of the ASP of all products within a therapeutic class, including biosimilars, or of the lowest-price drug within a therapeutic class. Using a blended payment rate based on prices of reference products and their biosimilars could help lower prices for Part B even beyond the negotiation program.[40]

[37] https://www.healthaffairs.org/content/forefront/administration-releases-medicare-drug-price-negotiation-program-draft-guidance-2028
[38] https://www.nejm.org/doi/full/10.1056/NEJMp2413686
[39] https://www.brookings.edu/articles/analyzing-the-expansion-of-the-medicare-drug-price-negotiation-program-to-part-b/
[40] https://www.nejm.org/doi/full/10.1056/NEJMp2413686

Recommendation 4: Fully utilize the MFP renegotiation process to deliver savings to beneficiaries and taxpayers, including by considering percentage changes in MFP lower than 15 as potentially "significant" and considering a wide array of "material changes" that could impact MFP negotiations.

IPAY 2029 is the second year in which CMS may renegotiate prices of selected drugs from previous initial payment applicability years. Section 1194(f) of the Act outlines a process through which CMS determines whether selected drugs from previous rounds of negotiation are renegotiation-eligible drugs and choosing from such drugs those to renegotiate. In addition to drugs for which there is a change in status to extended-monopoly or long-monopoly, the Act instructs CMS to determine that selected drugs with a new indication or for which the Secretary determines there has been a material change in a section 1194(e) factor are eligible for renegotiation. CMS is required to select for renegotiation all drugs for which there is a change in status to extended-monopoly or long-monopoly but has discretion to determine amongst other renegotiation-eligible drugs which are likely to result in a significant change in maximum fair price from that previously negotiated. The Act requires the Secretary to select for renegotiation drugs that meet that significant change threshold.

§ 429.605(d) of the rule outlines how CMS intends to consider whether there was a material change in a section 1194(e) factor, while § 429.610 describes plans for determining which renegotiation-eligible drugs to select based on the liklihood of a significant change in MFP.

Public Citizen urges CMS to consider the following non-exhaustive list of factors that should be considered "material changes", suggested by drug pricing experts at the Brookings Center on Health Policy:[41]

- *Section 1194(e)(1)(A): Assuming the manufacturer has not recouped its R&D costs at the time of its initial negotiation, recoupment of R&D costs should qualify as a "material change."*
- *Section 1194(e)(1)(B): A significant increase or decrease in the manufacturer's unit costs of production and distribution should qualify as a "material change."*
- *Section 1194(e)(1)(D): If primary patents or FDA-granted exclusivity periods expire or are invalidated and competition has not yet emerged in the form of an approved small-molecule generic or biosimilar, it should qualify as a "material change."*
- *Section 1194(e)(2)(A): It should qualify as a "material change" if other drugs are approved or existing drugs have new indications approved that render the selected drug no longer a therapeutic advance as compared to existing therapeutic alternatives; alternatively, it should qualify as a "material change" if the costs of those existing therapeutic alternatives change—for example, if a generic or biosimilar is approved and marketed for a therapeutic alternative, or if an existing therapeutic alternative is selected for negotiation and negotiates an MFP that is lower than its previous price.*

[41] https://www.brookings.edu/articles/articulating-policy-options-regarding-implementation-of-the-medicare-drug-price-negotiation-programs-renegotiation-provision/

- *Section 1194(e)(2)(B): It should qualify as a "material change" if the prescribing information for the drug changes meaningfully, such as if an accelerated approval indication is withdrawn or a safety warning, such as a newly identified side effect or contraindication, is added.*
- *Section 1194(e)(2)(C): It should qualify as a "material change" if additional evidence regarding comparative effectiveness becomes available, particularly one that adds significantly to the existing body of comparative effectiveness evidence. For example, if a new head-to-head study is released regarding the selected drug's efficacy relative to its most prominent therapeutic alternative.*
- *Section 1194(e)(2)(D): It should qualify as a "material change" if a selected drug no longer meets an unmet medical need, which may depend on whether other therapeutic alternatives become available for the conditions at issue.*

Additionally, Public Citizen encourages CMS to consider as relevant to the question of whether there has been a material change whether the manufacturer has secured longer monopoly protection due to patent thicketing or other abuse, which will delay Medicare and its beneficiaries from realizing savings from biosimilar or generic competition on a selected drugs for a year or longer (Section 1194(e)(1)(D)).

We are grateful for the illustrative examples of material change scenarios presented in Table 2 of the rule. As it weighs competing material changes, CMS should not let multiple changes effectively cancel one another if, when considering the changes holistically, there would still likely be a significant impact on MFP. For example, if the manufacturer of a selected drug secures a new indication that may warrant a minor upward adjustment in MFP, while engaging in anticompetitive monopoly abuses to block competition that would warrant a significant downward adjustment in MFP, overall the change should still be considered material, as when both changes are considered holistically, a significant downward adjustment in MFP would be appropriate.

Regarding the question of what constitutes a likely "significant change" in MFP, we appreciate CMS taking consideration for whether a renegotiation-eligible drug will remain a selected drug by the time the renegotiated price would take effect. Since drugs selected for negotiation often represent billions of dollars in annual spending, even a single year of a lower MFP can have a substantial financial impact on Medicare and its enrollees, so we encourage CMS not to exclude drugs from renegotiation based on this criterion unless the renegotiated price is unlikely ever to apply. Similarly, while we understand the rationale for looking to mandated renegotiation thresholds while establishing that 15 percent constitutes a "significant change" in MFP, we urge CMS to consider more expansively what change in MFP may be significant for Medicare and its beneficiaries. When the underlying prices and costs of prescription drugs for Medicare and its beneficiaries are so large, even a relatively small percentage change in MFP can nonetheless be significant for the payers and patients who bear those costs.

Finally, as CMS undertakes renegotiation, just as with negotiation, we encourage it to adopt the methodology described in Recommendation 1 of these comments.

Recommendation 5: Provide greater transparency around R&D costs and other data to amplify the impact on industry pricing practices and instill public confidence in the Medicare drug price negotiation program.

§ 429.300 of the rule indicates that CMS will treat research and development costs as proprietary, unless the information that is provided to CMS is already publicly available, in which case it would be considered non-proprietary.

This overly expansive interpretation of what information collected by CMS through the drug price negotiation program shall be held confidential would severely limit the impact of the legislation on industry drug pricing practices and the ability of the public to assess whether the Medicare drug price negotiation program is successfully negotiating "the lowest maximum fair price for each selected drug", as required under the Act, which would instill greater public confidence in the program.[42]

CMS can achieve the lowest maximum fair price for drugs and amplify the impact of the Medicare drug price negotiation program on industry pricing practices by collecting detailed, disaggregated figures around R&D costs, and openly publishing the data. CMS has a unique opportunity to examine the assumptions of the industry business model. Sunshine on this business model would further aid the public discourse and policymakers beyond CMS working to advance measures supporting access to medicines and innovation. Greater disclosure would also be consistent with the U.S.-supported World Health Assembly resolution WHA72.8, "Improving the transparency of markets for medicines, vaccines, and other health products."[43]

As described above under recommendation 1b, CMS can collect an array of information about R&D costs through the negotiation program. Critically, the Act grants CMS authority to determine whether the submitted information is "proprietary" and hence subject to any disclosure limitations.[44] CMS is also required to publish "the explanation for the maximum fair price" with respect to the factors used to determine it, which include data about R&D costs, production costs, and patents and exclusivities.

The Medicare drug price negotiation statute provides no additional guidance on what information should be considered proprietary. CMS may be guided by trade secrets law. In federal statute, the Defend Trade Secrets Act defines the term "trade secret" as information that:

> *(A)the owner thereof has taken reasonable measures to keep such information secret; and*
>
> *(B)the information derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable through proper means by, another person who can obtain economic value from the disclosure or use of the information[.]*[45]

While detailed R&D costs may be kept "secret", they may not hold independent economic value to others, especially years after the costs have accrued.[46] Historically, NIH has disclosed some cost data in response to Freedom of Information Act requesters, further suggesting such information is not considered by NIH

[42] 42 USC § 1320f-3(b)(1)
[43] Seventy-Second World Health Assembly, WHA72.8, 28 May 2019, https://apps.who.int/gb/ebwha/pdf_files/WHA72/A72_R8-en.pdf
[44] 42 USC § 1320f–2 (c). ("Information submitted to the Secretary under this part by a manufacturer of a selected drug that is proprietary information of such manufacturer (as determined by the Secretary) shall be used only by the Secretary or disclosed to and used by the Comptroller General of the United States for purposes of carrying out this part.")
[45] 18 USC § 1839
[46] Curbing Unfair Drug Prices, A Primer for States (2017), Yale Global Health Justice Partnership Policy Paper, https://law.yale.edu/sites/default/files/area/center/ghjp/documents/curbing_unfair_drug_prices-policy_paper-080717.pdf

to be trade secret or confidential commercial information.[47] CMS can also aggregate information on a case-by-case basis. Moreover, CMS can share even information that is considered trade secret if it does so under a license for noncompetitive purposes, or limits disclosure to a subset of recipients who are not competitors.[48]

By more critically scrutinizing whether the information it receives is proprietary, CMS can publish much of the data it collects as part of its explanation for pricing determinations. This can help inform the public debate about the benefits and limitations of the current industry business model and have a transformative impact beyond the Medicare drug price negotiation program.[49]

Recommendation 6: Solicit information from patients, consumers and other interested parties while promoting transparency around financial conflicts of interest with drug corporations.

In § 429.515(b) of the rule, CMS indicates its plans once again to host public engagement events "to bring together patient-focused interested parties to share feedback with us on patient experiences with the conditions or diseases treated by the selected drug". In the sign-up form for patient-focused listening sessions for each of the selected drugs for initial price negotiation year 2026, applicants were asked to voluntarily disclose whether they had a conflict of interest, and the disclosure of a conflict was announced during the sessions. At those listening sessions for IPAY 2026 selected drugs, a CMS representative then stated whether or not a stakeholder indicated a financial conflict in the sign-up form. While limited, we were grateful for CMS taking that modest step towards promoting transparency. However, we are concerned that the absence of such a policy may make industry influence of groups receiving funding from drug corporations opaque, compromising the integrity of the stakeholder contribution process.

In IPAY 2028, section 60.4.1 of the guidance indicated that CMS planned to "omit identifying information for patient advocacy organization representatives". It is unclear if CMS intends to carry out this practice for IPAY 2029 public engagement events. While privacy rules may require CMS to omit names of patients, there is not a compelling privacy rationale for omitting the names of patient advocacy organizations who are participating in the stakeholder process. To the contrary, financial conflicts between patient advocacy organizations and drug corporations repeatedly have been shown to be common. That potential risk of bias in information presented by stakeholders should be transparent and understood by CMS and the public to promote the integrity of the negotiation program and its ability to reach the lowest possible MFPs, as required under law.

[47] See NYU Law, Clinical Trial Cost Transparency at the NIH: Law and Policy Recommendations (2020), https://www.law.nyu.edu/centers/engelberg/pubs/2020-08-17-Clinical-Trial-Cost-Transparency-at-the-NIH at footnote 178

[48] See Amy Kapczynski, The Public History of Trade Secrets, UC Davis Law Review, Vol. 55, at 1438-1440 https://lawreview.law.ucdavis.edu/issues/55/3/articles/files/55-3_Kapczynski.pdf; See also Christopher J. Morten, Amy Kapczynski, The Big Data Regulator, Rebooted: Why and How the FDA Can and Should Disclose Confidential Data on Prescription Drugs and Vaccines, Columbia Law Review, Vol. 109:493, at 552-555, https://scholarship.law.columbia.edu/cgi/viewcontent.cgi?article=3814&context=faculty_scholarship

[49] See e.g., the Senate Finance Committee report on hepatitis C medicines and its impact.

Public Citizen research has found that drug manufacturers and their affiliated foundations and industry groups maintain vast networks of financial relationships with patient advocacy groups, universities, and professional associations, identifying more than $6 billion in grants dispersed by the trade group, the Pharmaceutical Research and Manufacturers of America (PhRMA), and its members from 2010 through 2022.[50]

In the context of a virtual ocean of drug corporation money flooding stakeholder groups that may speak at patient-focused listening sessions or other events, it is essential that disclosures of conflicts of interest resulting from financial relationships with drug corporations or other participants in the prescription drug supply chain are required to be disclosed and that such information is included in subsequent public readouts of the listening sessions. This includes financial relationships held by the individuals participating in stakeholder sessions as well as organizations they represent. Moreover, rather than only disclosing the existence of a conflict, the nature of the conflict should also be described. For example, CMS might announce that a participant in a stakeholder session represents an organization that has received funding from drug corporation A, drug corporation B, drug corporation C, and industry group Z.

We also encourage CMS to closely scrutinize public information available on conflicts of interest held by stakeholders that participate in patient-focused events in order to appropriately weigh the information provided, especially when it is consistent with positions espoused by manufacturers of selected drugs.

Any stakeholder session, regardless of format or scope, should be made as public and transparent as possible, including by livestreaming the event. Publication of event summaries or redacted transcripts should only be supplements to making the event available to the public through livestreaming, not as replacements for it.

We support CMS holding sessions which allow CMS to ask participants clarifying questions, to better elucidate understanding of stakeholder perspectives.

To the extent that CMS hosts events that invite discussion between stakeholders, it is essential that it is fully transparent whether participants have conflicts of interest with drug corporations or other participants in the prescription drug supply chain. It is essential that patients and other stakeholders without conflicts of interest have the opportunity to have their views heard without being undermined by participants with conflicts of interest.

As indicated above in these comments, we are grateful for CMS planning to consider the source, rigor of study methodology, and risk of bias when reviewing literature from the public and manufacturer submissions to help ensure the integrity of the contributing data within the negotiation process. It is essential that CMS extends this scrutiny to the stakeholder events it hosts, as well.

[50] Mike Tanglis. Mapping the PhRMA Grant Universe. Public Citizen. December 15, 2023 https://www.citizen.org/article/mapping-the-phrma-grant-universe/

Recommendation 7: Calculate negotiation eligibility for deemed biologics based on original approval dates, not the date of deeming.[51]

In § 429.125(c)(2)(ii) of the proposed rule, CMS indicates its plans not to begin the negotiation delay clock for deemed biologics until March 23, 2020, even for products that were first approved a decade or more before 2020. In IPAY 2027, CMS failed to select Creon under this misguided policy, despite it being on the market since 2009.

After a lengthy process of rulemaking and guidance and a transition period, the FDA issued a list of the products approved under NDAs that were deemed to be BLAs on March 23, 2020.[52] The list of drugs includes a range of products, some approved more than 50 or 60 years ago.

A prime motivation for converting these medicines from NDAs to BLAs was that their complexity made it difficult to get a substitutable generic approved.[53] Once classified as BLAs, the biosimilar pathway offered an opening to bring down costs.

This history makes CMS's IRA policy interpretation baffling, as CMS's policy does the opposite of what the BPCIA intended: allowing these drugs another way to maintain high prices for more years. The FDA, on the other hand, understood that the conversion of these NDAs to BLAs did not suddenly make old products new again. For example, FDA guidance made clear that the transition from NDA to BLA would not entitle a product to obtain the 12-year exclusivity period the BPCIA granted for newly licensed biologics. FDA specifically distinguishes a drug that was first licensed under the biological pathway to be different from a drug that was originally approved as an NDA and later "deemed licensed" under the pathway due to the BPCIA.

CMS's policy on deemed biologics will give a select group of drug companies extra time to rake in higher profits before the government can negotiate the cost of those drugs. This will cost the government more money and compromise patient access. The IRA requires that drugs selected for the Medicare price negotiation program be covered by all Medicare Part D plans, which has improved coverage of these drugs.[54] Medicare beneficiaries also may pay higher coinsurance due to a high-spend drug's escaping negotiation.

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[51] For more extensive analysis of CMS' proposed approach to deemed biologics, *see* Sarah Karlin-Smith. "Medicare Quietly Gifted AbbVie's Blockbuster Drug Seven Extra Years Before Price Negotiations", Public Citizen. August 6, 2026. https://www.citizen.org/article/medicare-quietly-gifted-abbvies-blockbuster-drug-seven-extra-years-before-price-negotiations/

[52] U.S. Food & Drug Administration. "'Deemed to be a License' Provision of the BPCI Act", Accessed August 16, 2026. https://www.fda.gov/drugs/guidance-compliance-regulatory-information/deemed-be-license-provision-bpci-act

[53] Eric Sagonowsky. "FDA Commissioner Scott Gottlieb blasts insulin pricing, unveils move to bolster biosimilar competition", Fierce Pharma. December 12, 2018. https://www.fiercepharma.com/pharma/fda-takes-insulin-pricing-move-to-bolster-biosimilar-competition

[54] Juliette Cubanski and Nolan Sroczynski. "The IRA Has Improved Coverage of Drugs Selected for Medicare Price Negotiation", KFF. February 11, 2026. https://www.kff.org/medicare/the-ira-has-improved-coverage-of-drugs-selected-for-medicare-price-negotiation/

Moreover, some experts have predicted that due to the exclusion of drugs with less than $200 million in annual Medicare spending and other exemptions, there may be a point at which there are fewer drugs eligible for negotiation than the 20 CMS is obligated to select for price negotiation each year. In that scenario, if Medicare defers negotiation on a drug like Creon due to the March 2020 start of the negotiation delay clock, then there will not be another drug negotiated in its place, further raising taxpayer costs.

Delaying a drug like Creon's eligibility for Medicare negotiation also could mean that some of these drugs never have a negotiated price because biosimilar competition comes on the market before or during the negotiated period. Only single-source drugs without generic or biosimilar competitors are eligible for negotiation. If Creon faces biosimilar competition before IPAY 2034, then it will evade price negotiations entirely.

Public Citizen identified two other drugs that would stand a good chance of being picked for Medicare drug price negotiations in the next few years if it weren't for the deeming policy. Those drugs include Novo Nordisk's Tresiba (insulin degludec) which was first approved in September 2015.

There is a real possibility that CMS's deeming policy could impact other products not on the FDA's 2020 list of drugs that were converted from NDAs to BLAs due to the BPCIA, as there is reason to believe that in the future the agency could have to reclassify other drugs. The FDA is currently tasked with better defining biologics due to an ongoing legal battle with Eli Lilly.[55] The BPCIA updated the definition of biological product to include "protein" or "analogous product." In 2020, the FDA finalized its definition of protein in rulemaking. Since that decision, the FDA has faced legal challenges related to its interpretation of "analogous to a protein."

Eli Lilly believes the FDA misclassified its experimental GLP-1 retatrutide as a small molecule, not a biologic. In Sept. 2025, an Indiana district court judge ruled that the FDA's classification of Lilly's drug wasn't arbitrary, but it also set aside a secondary FDA determination that the product is not "at least analogous to a protein" and asked the agency to better define this classification.[56] FDA's eventual definition of products that are analogous to proteins could impact what products are regulated as drugs or biologics. If any drugs are converted to biologics post-approval, under CMS's current interpretation, they'd likely get to restart their clock under the Medicare drug price negotiation program and delay or escape price negotiation.

The implications of a potential reclassification of a drug like retatrutide post-approval would be huge, as the drug, which is currently being studied for obesity and a range of related conditions, including diabetes,

[55] Brian Burgess, Sierra Perez-Sparks, Cassie Snyder. "District Court Sets Aside FDA's Interpretation of "Analogous" to a Protein for Purposes of the "Biological Product" Category", Goodwin Law, October 3, 2025. https://www.goodwinlaw.com/en/insights/publications/2025/10/alerts-lifesciences-district-court-sets-aside-fda-interpretation

[56] Alexis Kramer. "Lilly appeals ruling over retatrutide classification in case that could impact compounders", Endpoints News. February 13, 2026. https://endpoints.news/lilly-appeals-retatrutide-classification-ruling-in-case-that-could-impact-compounders/

heart and kidney problems, and liver disease, is expected to be a multi-billion-dollar blockbuster.[57] Every year that CMS is prevented from negotiating the price of this drug could cost the U.S. government vast sums of money.

Treatments' initial FDA approval dates should start the negotiation eligibility clock, not the date the application was converted from a drug to a biologic. Doing the latter unfairly gives preferential treatment to certain products and harms patients at the expense of big pharma. CMS should immediately rectify this policy in final rulemaking for IPAY 2029.

Additional Recommendations:

- ***We recommend CMS clarify that the information on R&D costs should be provided in an itemized and disaggregated fashion.[58]***
  As indicated above, in the guidance for IPAY 2028, Appendix A, CMS appropriately delineated a wide array of information that would be required to be disclosed by manufacturers, pursuant to section 1194(e)(1) of the IRA,[59] but the proposed rule for IPAY 2029 does not seem to provide similarly detailed information on manufacturer disclosures. To the extent that any ambiguity remains, we recommend CMS clarify that this information, described under definitions relating to R&D costs in Appendix A of the IPAY 2028 guidance, should be applied for IPAY 2029 and be provided in an itemized and disaggregated fashion. This is particularly important with regard to reporting costs separately for each clinical trial, as there are significant differences in risk depending on trial phase, as described further in recommendation 1b.

- ***As CMS considers manufacturer-specific data provided under section 1194(e)(1) of the Act, it must critically scrutinize the assumptions and calculations provided in manufacturers' narrative texts.***
  § 429.510(f) of the rule indicates that CMS may use "the assumptions and calculations in the accompanying narrative text" submitted by the manufacturer in its consideration of this data. Manufacturers may make unrealistic assumptions about cost of capital and risk and otherwise seek to use this narrative to inflate the price implicated by the data it provides under section 1194(e)(1) of the Act. CMS must remain vigilant to prevent such mischaracterizations from leading to inappropriately high maximum fair prices. In that context, we were grateful that CMS indicated in IPAY 2028 guidance Appendix A that when calculating monetary values, there would no longer be adjustments for cost of capital due to observations in previous initial price applicability years. We encourage CMS to continue that policy.

- ***Take a more holistic approach to considering federal financial contributions to drug development, including with consideration for other forms of support, such as critical scientific contributions to underlying inventions, upstream research and funding thereof, and other support from public sector research institutions and publicly supported research programs.***

[57] Annika Kim Constantino. "Eli Lilly says next-generation weight loss drug clears crucial obesity trial", CNBC. May 21, 2026. https://www.cnbc.com/2026/05/21/eli-lilly-weight-loss-drug-retatrutide-clears-obesity-trial.html
[58] This a reiteration of a point included in recommendation 1b, to avoid it being lost in the wider-ranging recommendation above.
[59] 42 USC § 1320f-3(e)(1)

The FY2026 NIH budget is approaching $50 billion dollars, the vast majority of which funds extramural research through competitive grants to researchers at universities, medical schools, and other research institutions in every state.[60] For decades, the NIH and the public have played an integral role in drug development and the NIH role in basic research is understood by many. Researchers recently found that "[o]verall, NIH funding contributed to research associated with every new drug approved from 2010-2019, totaling $187 billion."[61]

While traditionally the NIH is understood to provide support for foundational basic research, increasingly, the public sector is providing more contributions later in drug discovery. A recent review of patents associated with all drugs having a new molecular entity approved by FDA over a 10-year period found that 19% of the drugs had origins in publicly supported research and development and 6% originated in companies spun off from a publicly supported research program.[62] An earlier study showed that over 40 years, 153 new FDA-approved drugs, vaccines, or new indications were discovered by public sector research institutions, more than half of which were used in the treatment or prevention of cancer or infectious diseases.[63] CMS should account for these vital public contributions as it develops maximum fair price offers.

Additionally, when pending and approved patent applications disclose U.S. government scientists as inventors, or it is the position of an agency of the U.S. Government that its scientists should be listed as coinventors,[64] this should be considered in-kind financial support and the maximum fair price offer from CMS should be adjusted downward to take account for this public support, which de-risks drug development.

- ***Do not use inflated value metrics for coupons, goods donated, or other forms of voluntary access concessions when calculating the global, total lifetime manufacturer net revenue for the selected drug.***

  In IPAY 2028, Appendix A of the negotiation guidance indicated that CMS intended to consider coupons and donated goods in its "Global, including U.S., Total Lifetime Manufacturer Net Revenue for the Selected Drug" definition. It is unclear how CMS intends to approach coupons, goods donated and other voluntary concessions in IPAY 2029. If it retains the IPAY 2028 approach, manufacturers may seek to argue for aggressively high offsets to their revenues from such coupons and donations, such as the full list price that would have been paid for a donated product, or the difference between such price and a coupon price and the amount paid by an insurer. It would be more appropriate to

[60] Approximately 80% of the FY2026 NIH budget goes towards these purposes.
[61] Ekaterina Cleary, et. al. Government as the First Investor in Biopharmaceutical Innovation: Evidence From New Drug Approvals 2010–2019. Institute for New Economic Thinking Working Paper Series No. 133. https://doi.org/10.36687/inetwp133
[62] Rahul K Nayak, Jerry Avorn, Aaron S Kesselheim. "Public sector financial support for late stage discovery of new drugs in the United States: cohort study." BMJ 2019; 367 doi: https://doi.org/10.1136/bmj.l5766 (Published 23 October 2019)
[63] Ashley J. Stevens, et. al., "The Public Role of Public-Sector Research in the Discovery of Drugs and Vaccines." N Engl J Med 2011; 364:535-541. DOI: 10.1056/NEJMsa1008268 https://www.nejm.org/doi/full/10.1056/nejmsa1008268
[64] In a recent dispute with the biopharmaceutical corporation Moderna, the NIH correctly argued that as part of its four-year partnership with Moderna, NIH scientists coinvented the NIH-Moderna vaccine sequence. Moderna refused to name NIH scientists as coinventors and instead quietly abandoned these patents earlier this year. See *Sheryl Gay Stolberg and Rebecca Robbins. "Moderna and U.S. at Odds Over Vaccine Patent Rights" New York Times.* *https://www.nytimes.com/2021/11/09/us/moderna-vaccine-patent.html* and Public Citizen's Letter on the Moderna Vaccine Patent Dispute https://www.nytimes.com/interactive/2021/11/09/us/public-citizen-nih-moderna-vaccine.html

understand such price concessions, including any provided through patient assistance programs, as voluntary. They should not be considered in the net revenue calculation.

If CMS declines to take this position, it should use the cost of goods donated and should not use a hypothetical price a party may have paid for the product absent such voluntary concession(s).

- ***Move forward with plans to publish a list of negotiation eligible drugs, but instead of only 30, publish all negotiation eligible drugs.***
  We are grateful for CMS plans to continue to disclose publicly a list of negotiation eligible drugs, rather than only announcing the list of selected drugs. CMS can provide even greater transparency by releasing a list of all the negotiation-eligible drugs, which may include up to 50 drugs from Medicare Part B and 50 drugs from Medicare Part D.

- ***Do not weigh the utilization when considering the prices of therapeutic alternatives in determining an appropriate MFP.***
  As detailed above in these comments, we strongly discourage CMS from utilizing the prices of therapeutic alternatives when determining the starting point for a potential MFP offer. Additionally, CMS indicates its intention in § 429.510(d)(3)(ii) to weigh utilization of therapeutic alternatives when assessing how their prices should contribute to an MFP starting point. We strongly discourage CMS from taking this approach due to concern that it could inappropriately underweight considering lower prices of biosimilar therapeutic alternatives which may not yet have captured a significant share of the market. In analysis of this provision in IPAY 2027 guidance, experts noted that "[p]lacing significant emphasis on the price of a reference biologic therapeutic alternative when lower-priced biosimilars of that reference product are approved and marketed would bake in the existing challenges of our system in encouraging biosimilar competition, and benefits (with a higher starting point) biologics manufacturers for their ability to discourage use of biosimilars."