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The Honorable Mehmet Oz, M.D.
Administrator, Centers for Medicare & Medicaid Services
Department of Health and Human Services
Baltimore, MD 21244-8013

RE: Comments on Proposed Rule, Medicare Drug Price Negotiation Program and Medicare Prescription Drug Benefit Program, CMS-4215-P, 91 Fed. Reg. 36236

Dear Administrator Oz:

On behalf of Americans for Tax Reform, we appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' proposed rule, "Medicare Drug Price Negotiation Program (DPNP) and Medicare Prescription Drug Benefit Program" (CMS-4215-P). This proposed rule would convert three years of program guidance into permanent, binding regulation, locking in a price control regime – created under the Biden administration – that will be far harder to revise once its devastating effects on drug development become clear.

ATR urges CMS to withdraw this rule, or, at minimum, substantially narrow the authority it claims for itself in several of the provisions discussed below.

The Inflation Reduction Act (IRA), passed without a single Republican vote and signed by President Biden, authorized the HHS Secretary to "negotiate" Medicare drug prices. In practice, the Secretary can simply set a price and tax any company that charges more up to 95 percent of their sales. The program covers 10 drugs in 2026, rising to 60 by 2029 and expanding by 20 drugs every year thereafter.

Codifying this program into permanent regulation lends legitimacy to a price control scheme that is a "negotiation" in name only. It will chill innovation, shift costs rather than reduce them, and foreclose the agency's ability to course-correct once those effects become clear. Further, our comments note four specific provisions of concern: the fixed combination drug proposal, the Bona Fide Marketing determination, the orphan drug exclusion period, and the absence of administrative or judicial review.

I. General Comments on Codification of the Negotiation Program

A. The rule does not address the program's chilling effect on innovation.

CMS asserts, throughout the preamble, that this rule is designed to continue to support innovation. Still, there are no meaningful provisions to mitigate the chilling effect this law has on drug development.

For example, CMS could have taken concrete steps to help safeguard drug development: publish standardized reasoning behind its pricing determinations so manufacturers can predict how R&D decisions affect future negotiated prices; set defined, public criteria for "therapeutic advance" and

"unmet medical need" in advance of selection rather than deciding after the fact; and commission an independent, ongoing assessment of the program's effects on approvals and R&D investment rather than relying on a one-time Regulatory Impact Analysis.

During an average drug development process, a manufacturer must invest an average of $2.6 billion and spend 11.5 to 15 years[1] in research and development. Approximately 0.05 percent of drugs make it from drug discovery to clinical trials. Of those few medicines that make it to clinical trials, only about 12 percent[2] are approved for introduction by the FDA. Even still, most approved drugs never recoup their development costs.

Companies cannot and will not invest billions of dollars and decades of manpower if they cannot expect to recoup these resources when they bring the medicine to market.

One study, conducted[3] by Tomas J. Philipson and Troy Durie of the University of Chicago, details how price control provisions, later included in the IRA, could lower R&D activity so drastically that it would result in 135 fewer new drugs, generating a loss of 331.5 million life years in the United States.

The law also treats drug types unequally. Under the IRA, HHS can impose price controls on small molecule drugs after 9 years (7 years post FDA approval + 2-year negotiation period). By contrast, biologics face price controls after 13 years (11 years post FDA approval + 2-year negotiation period). This has drastically disincentivized the creation and sale of small molecule drugs:

- Early-stage R&D investment in small molecule drugs has dropped by nearly 70 percent[4] since the IRA took effect.

- Since the IRA's passage, new small molecule clinical trial starts have declined 25 percent[5], while trials exploring new uses for already-approved small molecule drugs have fallen by 30 percent to 45 percent[6].

- For diseases most common among Medicare patients – Alzheimer's, heart failure, several cancers – small molecule research investment has fallen by a median of 74 percent[7].

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[1] Stephen Ezell, *The Bayh-Dole Act's Vital Importance to the U.S. Life-Sciences Innovation System*, Information Technology and Innovation Foundation (Mar. 4, 2019), https://itif.org/publications/2019/03/04/bayh-dole-acts-vital-importance-us-life-sciences-innovation-system/.

[2] Id.

[3] Tomas J. Philipson & Troy Durie, *The Impact of HR 5376 on Biopharmaceutical Innovation and Patient Health*, University of Chicago (Nov. 29, 2021), https://cpb-us-w2.wpmucdn.com/voices.uchicago.edu/dist/d/3128/files/2021/08/Issue-Brief-Drug-Pricing-in-HR-5376-11.30.pdf.

[4] Schulthess, D.G., O'Loughlin, G., Askeland, M. et al. The Inflation Reduction Act's Impact Upon Early-Stage Venture Capital Investments. Ther Innov Regul Sci 59, 769–780 (2025). https://doi.org/10.1007/s43441-025-00773-3

[5] Long, G. (2026). Trends in industry-sponsored clinical trial activity since passage of the Inflation Reduction Act. Journal of Medical Economics, 29(1), 957–971. https://doi.org/10.1080/13696998.2026.2646075

[6] Hanke Zheng, Julie A Patterson, Jonathan D Campbell, Early impact of the Inflation Reduction Act on small molecule vs biologic post-approval oncology trials, Health Affairs Scholar, Volume 3, Issue 8, August 2025, qxaf152, https://doi.org/10.1093/haschl/qxaf152

[7] Schulthess et al., supra note [4]

- A National Pharmaceutical Council investor survey found that 77 percent of investors said the pill penalty has created a disincentive to investing in small molecules, and roughly half reported the law has already affected deal value (45.5%), exit values (45.5%), and capital raises (56.5%).[8]

Had the IRA been law from 2000 to 2023, roughly one in three post-approval uses[9] for small molecule drugs may never have been developed.

Given these stakes – and the data already showing the program's toll on medical research – CMS cannot "support innovation" while finalizing a rule that locks in these incentives permanently without a single provision designed to counteract them.

B. Codification forecloses CMS's ability to course-correct.

To date, CMS has implemented this program through guidance, revising it along the way as the Agency gained experience through implementation. We have already seen evidence that the "negotiation" program is suppressing new drug approvals, redirecting R&D away from small-molecule therapies, and discouraging biosimilar and generic market entry.

The full effects of this law have not yet materialized. Unlike a codified regulation, guidance can be revised quickly in response to that evidence. Once codified, the program can only be amended through full notice-and-comment rulemaking, a process that takes years and invites litigation at every step. CMS is proposing to lock in a program still in the early years of implementation, before the record on its cumulative effects on drug development is anywhere near mature.

C. Price setting shifts costs rather than reducing them.

A "maximum fair price" lowers what the Medicare program pays for a selected drug, but it does not lower the cost of developing that drug. Manufacturers facing "negotiation" will adjust launch prices for new products, adjust list prices for other products in a portfolio, or deprioritize formulations most likely to trigger selection.

The budgetary "savings" CMS reports from the Negotiation Program reflect, in substantial part, cost-shifting within the health care system, primarily to commercially insured patients (the majority of Americans under 65) who do not benefit from the negotiated price.

CMS's Regulatory Impact Analysis should address this dynamic directly rather than treating the projected federal savings as a net benefit.

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[8] 77% of Investors Say IRA's "Pill Penalty" Disincentivizes Small Molecule Investments, National Pharmaceutical Council (Sept. 9, 2025), https://www.npcnow.org/resources/77-investors-say-iras-pill-penalty-disincentivizes-small-molecule-investments.

[9] IQVIA Institute, Proliferation of Innovation Over Time: Frequency, Timing and Clinical Value of Expansions Post-Initial Approval (Feb. 18, 2025), https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/proliferation-of-innovation-over-time.

II. Specific Provisions of Concern

A. Proposed § 429.125(b)(4)(i): The fixed combination drug policy penalizes manufacturers for improving drug formulations.

To be eligible for the DPNP, a drug must qualify as a Qualifying Single Source Drug (QSSD). Under existing policy, a fixed combination drug is treated as a QSSD tied to its shared active moieties. Proposed § 429.125(b)(4)(i) departs from that approach. If CMS decides a manufacturer added an ingredient that creates a new formulation with a different route of administration, CMS would treat all dosage forms and strengths of the shared ingredient sold by that manufacturer as one qualifying single source drug, not just the new formulation itself.

Under this proposal, CMS would sweep every dosage form and strength of the shared active ingredient into a single pricing determination, even when FDA has approved the new formulation separately and treated it as a distinct product.

This raises several concerns. First, CMS is not the agency with authority to determine what counts as a distinct drug. FDA already makes that determination through its own approval process, often requiring separate applications and dedicated clinical trials before a new formulation reaches patients. CMS should not substitute its own judgment for FDA's in order to expand its pricing authority.

Second, new formulations are not mere convenience upgrades. Manufacturers develop them to improve safety, reduce adverse reactions, ease administration, and improve patient adherence. This work requires years of additional research and its own clinical testing. Treating these kinds of investments as an attempt to evade selection discourages innovation that benefits patients.

Third, this provision provides no objective standard. CMS's own after-the-fact determination decides whether a formulation change triggers expanded pricing exposure, leaving manufacturers unable to know in advance whether an investment in a better version of an existing drug will be treated as ordinary innovation or as an evasion to be punished.

For example, Opdivo Qvantig, a subcutaneous version of the intravenous cancer therapy Opdivo, required roughly a decade of development, including its own large-scale randomized clinical trials. The FDA approved it as a distinct product with its own Biologics License Application.[10] The subcutaneous version, which combines nivolumab with hyaluronidase to enable subcutaneous administration, reduces infusion-related reactions compared to the IV formulation and is preferred by most patients who have a choice between the two.[11] Under the proposal, a product like this could instead be swept into the same QSSD determination as the original IV product. A manufacturer that spends a decade running large-scale trials to give cancer patients a faster, safer way to receive treatment should not find that investment rewarded with *more* exposure to price controls simply because CMS, after the fact,

[10] U.S. Food & Drug Administration, FDA Approves Nivolumab and Hyaluronidase-nvhy Subcutaneous Injection (Dec. 27, 2024), https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-nivolumab-and-hyaluronidase-nvhy-subcutaneous-injection.

[11] Federico Cappuzzo, Zanete Zvirbule, Ernesto Korbenfeld, et al., Primary Results from IMscin002: A Study to Evaluate Patient Preferences and Perceptions of Health Care Professionals for Atezolizumab Subcutaneous Versus Intravenous for the Treatment of NSCLC, 6 JTO Clin. Res. Rep. 100815 (2025), https://doi.org/10.1016/j.jtocrr.2025.100815.

decides the new formulation looks too similar to the old one. If this rule is finalized as proposed, improving how a drug is delivered becomes a liability.

ATR urges CMS to withdraw the proposed fixed combination drug modification and, instead, defer to FDA on questions of drug product identity.

B. Proposed § 429.130: The Bona Fide Marketing determination gives CMS unchecked discretion over generic and biosimilar competition.

Proposed § 429.130 codifies the process and schedule by which CMS determines whether a manufacturer of an approved generic drug or licensed biosimilar is engaged in "Bona Fide Marketing." This determination governs whether a brand-name selected drug can be deselected from the program based on the presence of generic or biosimilar competition. As proposed, this determination rests entirely on CMS's own "holistic inquiry" process considering utilization, sales, availability, market share, and licensing arrangements, without a defined, objective standard for what constitutes bona fide (as opposed to token) marketing. An erroneous non-bona-fide finding keeps a brand drug under price controls despite having an actual competitor in the market.

Because this determination directly controls whether a manufacturer remains subject to negotiated pricing notwithstanding the presence of a competing product, ATR urges CMS to establish clear, objective, and public criteria for the Bona Fide Marketing determination in the final rule, rather than relying on an internal review process that leaves manufacturers unable to know in advance how CMS will apply it.

C. Proposed § 429.125(c)(3)(i): CMS can shorten the orphan drug exclusion period without justification.

Drugs that once qualified for the Orphan Drug Exclusion, but lost that status because they gained approval for a non-rare use, are given a statutory window before CMS can select them for negotiation: 7 years for small-molecule drugs and 11 years for biologics.[12] Proposed § 429.125(c)(3)(i) doesn't change the length of either window but changes the day the clock starts.

Under the proposal, that day is the first day after initial approval on which the drug no longer meets the orphan drug exclusion criteria. CMS also proposes that once the countdown starts this way, it keeps running even if that broader approval is later withdrawn. Thus, an orphan drug's path toward Medicare price "negotiation" could be locked in by an approval that no longer exists.

ATR urges CMS to explain why it chose this approach, and to confirm that a withdrawn approval will not be used to keep pushing a rare-disease drug toward negotiation eligibility it would not otherwise face.

D. Proposed § 429.30: The absence of administrative or judicial review heightens the stakes of every discretionary provision above.

ATR recognizes that the prohibition on administrative and judicial review of CMS's determinations under the Negotiation Program is statutory[13] and is not a departure created by this rulemaking.

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[12] Social Security Act § 1198, 42 U.S.C. § 1320f-7.
[13] Inflation Reduction Act of 2022, Pub. L. No. 117-169, 136 Stat. 1818 (2022).

ATR does urge CMS to recognize, however, that this limitation materially changes the stakes of the discretionary standards discussed above. Because manufacturers have no recourse, the precision of these standards at the drafting stage is the only protection available.

Where CMS retains an undefined, case-by-case determination – as with the fixed combination drug provision and the Bona Fide Marketing determination – and that determination cannot be challenged through any administrative or judicial process, the absence of a defined, objective standard is particularly concerning. In each case, CMS is both the author of the standard and its sole judge. A manufacturer has no path to contest an unreasonable or inconsistent application of these provisions, no matter how significant the financial consequences.

Given this reality, the objective, clear standards our comments have called for are necessary safeguards for manufacturers. Discretion this broad is rarely exercised with restraint. These provisions are only as narrow as the administration currently exercising it, and nothing in this rule prevents a future CMS from applying these same undefined standards far more aggressively than intended here.

ATR appreciates the opportunity to comment on this proposed rule. For the reasons set forth above, ATR urges CMS to withdraw the proposed rule, or, at minimum, to (1) withdraw proposed § 429.125(b)(4)(i) or replace its discretionary standard with an objective test; (2) establish defined, public criteria governing the Bona Fide Marketing determination under proposed § 429.130; and (3) clarify and justify its proposed methodology for measuring the orphan drug exclusion period under proposed § 429.125(c)(3)(i).

Thank you for your consideration of these comments.

Respectfully submitted,

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