BEFORE THE

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Post Office Box 8013
Baltimore, Maryland 21244-8013

In the Matter of:	)	
Notice of Proposed Rulemaking	)	Docket ID: CMS-2018-0132
	)	File Code: CMS-5528-ANPRM
On Potential Options for Testing Changes to Payment for Certain Separately Payable Part D Drugs and Biologicals	)	

COMMENT OF CENTER FOR INDIVIDUAL FREEDOM

IN OPPOSITION TO PROPOSED RULEMAKING FOR TESTING CHANGES TO PAYMENT FOR CERTAIN SEPARATELY PAYABLE PART D DRUGS AND BIOLOGICALS

December 28, 2018

I. Introduction

The Center for Individual Freedom (hereinafter "CFIF") is a non-profit organization with over 300,000 grassroots supporters and activists across the United States. CFIF was established in 1998 for the purpose of safeguarding and advancing Constitutional rights and free market principles, as well as ensuring optimal American welfare, innovation, prosperity, leadership and worldwide preeminence.

As part of that mission, CFIF advocates for public policies that advance American healthcare and pharmaceutical development most effectively, freely and efficiently. On that basis, CFIF respectfully submits the following Comment, urging the Centers for Medicare and Medicaid Services (hereinafter

"CMS") to reject drug price controls as contemplated by its Proposed Rulemaking on Potential Options for Testing Changes to Payment of Certain Separately Payable Part D Drugs and Biologicals (hereinafter the "Proposal").

II. Discussion

Government-imposed price controls never work. Among the ironclad lessons of economic history, that remains one of the most inescapable and irrefutable.

Whether in the form of depressingly long automobile lines waiting to buy gasoline during the 1970s in the United States, or contemporary Venezuelan grocery store shelves emptied of even basic staples, the simple, inescapable fact is that price controls bring only shortages and dysfunction.

That reality applies just as surely to healthcare and pharmaceuticals, as demonstrated herein. Accordingly, it's imperative that the lives and well-being of American citizens not be placed at risk by introducing artificial price controls – effectively imported from foreign nations - to that sector.

America currently enjoys — by far — the most innovative and fruitful pharmaceutical industry in the world, accounting for approximately two-thirds of all new lifesaving and life-improving drugs brought to market across the globe.[1] That astonishing two-thirds proportion of new pharmaceuticals worldwide reflects the greater willingness of American pharmaceutical innovators to invest in promising new drugs and bring them to market. Nations that impose drug price controls simply don't cultivate the same degree of pharmaceutical research and innovation, effectively acting as free-riders on American development.

The price control regime contemplated by the CMS, however, would not only threaten our nation's leadership status, but also jeopardize all foundational research and development by vastly diminishing the incentive to undertake it.

Specifically, the CMS contemplates a foreign reference drug price regime known as "International Reference Pricing" for pharmaceuticals covered by the federal government's Medicare Part B program. By necessity, that means that Medicare would artificially impose a new pricing system based upon an international pricing index reflecting an average of what other nations pay for drugs developed in America. Consequently, foreign nations' price controls would be imported to America, rather than exporting our more effective free market policies to their shores.

That, in turn, would only encourage a regression to a foreign mean in terms of drug innovation.

According to the U.S. Commerce Department, those same foreign price controls reduce global R&D investment every year by between 11% and 16%, or $5 billion to $8 billion, with a cumulative $200 billion lost by the year 2025.[2]

The reason for that is obvious. The painstaking process of developing new drugs requires immense amounts of time, dollars and risk - approximately $2.6 billion and 10 years, on average, to see a new pharmaceutical through Food and Drug Administration (FDA) approval.[3] Earlier this year, the U.S. Council of Economic Advisors warned that slashing reimbursement for medicines in the U.S., "makes better health costlier in the future by curtailing innovation."[4]

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1 *Adis R&D Insight*, May 2018.

2 U.S. Department of Commerce, *Pharmaceutical Price Controls in OECD Countries: Implications for U.S. Consumers, Pricing, Research & Development, & Innovation*, (2004) https://www.trade.gov/td/health/drugpricingstudy.pdf.

3 Joseph A. DiMasi, Henry G. Grabowski and Ronald W. Hansen, Journal of Health Economics, *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, Journal of Health Economics, 47:20-33, May 2016.

4 Council of Economic Advisors, *Reforming Biopharmaceutical Pricing at Home and Abroad*, February 2018, https://www.whitehouse.gov/wp-content/uploads/2017/11/CEA-Rx-White-Paper-Final2.pdf.

Additionally, as then-Deputy Health and Human Services (HHS) Secretary Alex Azar himself observed, the available evidence shows that every $1 billion to $2 billion in reduced R&D spending translates to one fewer new pharmaceutical per year.[5]

That increased uncertainty brought by artificial price controls will also jeopardize the amount of venture capital that outside investors remain willing to risk, which is particularly critical to the pharmaceutical industry because the overwhelming majority of enterprises do not realize profits for over 20 years and therefore stand unable to subsidize innovation themselves.[6]

Since many nations enforcing drug price controls impose single-payer socialized healthcare systems, and exploit American drug innovations, that also constitutes a backdoor method of bringing socialized medicine to the U.S.[7] Almost all of those foreign nations also suffer lower standards of living than the U.S., further rendering their price controls inappropriate for U.S. consumers.[8]

Foreign nations that impose drug price controls also jeopardize American intellectual property (IP) rights, which provide the foundation for our record of innovation and prosperity. Namely, the reason that many other nations pay less for pharmaceuticals is that their socialized healthcare systems threaten to ignore drug patents and simply sell generic copies if drug makers refuse to comply. That amounts to a form of government extortion, and a nation like the U.S. that protects intellectual property rights more than any other should find it particularly offensive.

Moreover, those nations' price controls prove dangerously penny-wise but pound-foolish in the form of diminished access to new drugs. American consumers benefitted from access to 70 of 74 new cancer drugs developed between 2011 and 2018, or 95%.[9] In contrast, only 74% of U.K. patients, 49% of Japanese patients and just 8% of Greek patients could access those new drugs. Whereas American patients can typically obtain new drugs immediately upon approval, other industrialized nations impose months or even years of delay as a consequence of their policies.

A very small percentage of potential new drugs ever make it to market after enormous R&D costs, exhausting safety trials, effectiveness tests, bureaucratic hurdles, foreshortened patent protections and a punitive product liability environment. So by imposing artificial price controls, governments make it more difficult to develop and commercialize new medicines, which in turn harms consumers in the form of fewer new drugs to extend and improve life.

Thus, other nations whose systems we're preparing to import simply delay the arrival of new drugs or deny them entirely. Better quality care in the U.S. is why America outpaces 10 European countries on cancer survival rates.

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[5] Remarks of HHS Deputy Secretary Alex Azar before the Policy Institute at Trinity College, Dublin, Ireland, *Eating Today and Eating Tomorrow: Competition, Innovation, and Pricing for Modern Medicine*, November 9, 2005.

[6] Fleming, J., *The Decline of Venture Capital Investment in Early-Stage Life Sciences Poses a Challenge to Continued Innovation*, Health Affairs, (2014), 34(2):271-6.

[7] United States Department of Commerce, *Pharmaceutical Price Controls in OECD Countries: Implications for U.S. Consumers, Pricing, Research and Development, and Innovation*, January 2004) https://www.trade.gov/td/health/drugpricingstudy.pdf.

[8] Office of the United States Trade Representative, *National Trade Estimate Report on Foreign Trade Barriers*, March 2017 https://U.S.tr.gov/sites/default/files/files/reports/2017/NTE/2017%20NTE.pdf; Office of the United States Trade Representative, *2017 Special 301 Report*, April 2017 https://U.S.tr.gov/sites/default/files/301/2017%20Special%20301%20Report%20FINAL.PDF.

[9] The Catalyst Blog, *New Analysis Shows that More Medicines Worldwide Are Available to U.S. Patients*, June 2018, https://catalyst.phrma.org/new-analysis-shows-that-more-medicines-worldwide-are-available-to-u.s.-patients; IMS Consulting Group, *Patient Access to Innovative Oncology Medicines Across Developed Markets*, June 2016.

Even the World Health Organization (WHO) acknowledged that unwelcome effect in its recent analysis of price controls' effect on pharmaceutical development:

> "Every time one country demands a lower price, it leads to a lower price reference used by other countries. Such price controls, combined with the threat of market lockout or intellectual property infringement, prevent drug companies from charging market rates for their products, while delaying the availability of new cures to patients living in countries implementing those policies."[10]

The impact of drug price controls on domestic employment must also be noted. The U.S. biopharmaceutical industry directly employs nearly 1 million Americans, and indirectly supports nearly 5 million other jobs nationwide.[11]

Thus, government-imposed drug price controls undermine intellectual property rights, stifle innovation, threaten American jobs and ultimately punish consumers in the form of fewer innovative pharmaceuticals.

III. Conclusion

For the reasons set forth herein, CFIF urges the CMS to reject the imposition of destructive drug price controls by way of the Proposal under consideration.

Respectfully submitted,

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[10] World Health Organization, *Priority Medicines for Europe and the World "A Public Health Approach to Innovation,* May 2013 https://www.who.int/medicines/areas/priority_medicines/BP8_3_pricing.pdf.

[11] TEConomy Partners LLC, *The Economic Impact of the US Biopharmaceutical Industry*, July 2017.