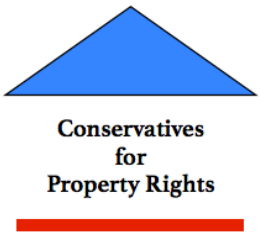

December 24, 2018

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-5528-ANPRM
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

To whom it may concern:

Conservatives for Property Rights (CPR), a coalition of policy organizations representing tens of thousands of Americans on a wide array of private property rights issues, welcomes the opportunity to comment in regard to the Advanced Notice of Proposed Rulemaking (ANPRM) concerning the International Price Index Model (IPI) for Part B Drugs (CMS-5528-ANPRM).

The IPI model proposed in this ANPRM raises a number of serious concerns, from a property rights perspective. The number one concern is that the model under consideration effectively imposes government price controls, which would cause deleterious effects and consequences for private individuals and entities.

The Center for Medicare & Medicaid Innovation (CMMI) proposes to design and test a model that uses reference pricing to arrive at the prices Medicare Part B sets for certain medicines purchased and administered under that program. The 14 foreign countries whose government-set price controls would comprise the index price for selected pharmaceuticals in the Part B pilot all have government-run health systems.

In addition, CMMI intends to require all Part B medical providers, as well as hospital outpatient facilities, Part B beneficiaries, and suppliers in up to half the country to participate in this model test. This is not CMMI's first time to exceed the limitations of pilot programs. Mandatory participation, wide application, broad geographic reach — these constitute effecting policy changes by other means. Such a far-reaching pilot design end-runs Congress and denies those who fall under the government mandate due process protections. Depriving due process and just compensation in such a manner may well be unconstitutional. At a minimum, this proposed model abridges the spirit of the Constitution and of the statutory parameters of the Affordable Care Act. Thoughtful people have questioned whether "innovation" can come from government. CMMI is again bolstering the case that government is not conducive to innovation.

The ANPRM-named foreign nations' health systems operate under a heavy government hand. The reference nations' health systems are not market-based and do not respect private property rights. They do not allow negotiations in a free-market environment that enables private parties to freely and independently arrive at terms, including price of product. Instead, those foreign countries' governments dictate prices to the private owners of the property — the medicines and other medical goods and services. Government-run and price-controlled health systems may "spend less" than the United States on health costs, but they also deprive the

sacred rights of private property and free enterprise and, thus, deny the many benefits derived from property rights and free enterprise.

Society benefits from private property rights in health care, which the IPI model would diminish. The White House Council of Economic Advisors has identified several benefits, along with the costs of price controls in socialized-medicine systems. The benefits of free enterprise and property rights include speedier patient access to innovations (e.g., new medicines), improved health outcomes from earlier access to medical innovation, a larger and more robust market, and the virtuous circle of innovation leading to further innovation. Consider:

> "Take the case of pharmaceutical innovation to improve patient health. Empirical research in this industry and others has shown that R&D investments are positively related to market size. For the case of medical innovation, evidence suggests that a 1 percent reduction in market size reduces innovation—defined as the number of new drugs launched—by as much as 4 percent (Acemoglu and Linn 2004).
>
> "Given that future profitability drives investment in this way, Lakdawalla and others (2009) examined the impact on medical innovation of the U.S. adopting European-style price controls. The study examined patients over the age of 55 and considered the reduction in R&D and new drugs approved that these price controls would cause. The paper examined increases in mortality for the heart disease, hypertension, diabetes, cancer, lung disease, stroke, and mental illness. . . . Given that innovations are financed by world returns mostly earned in the U.S., the mortality effects on health were substantial both in the U.S. and in Europe.
>
> "If M4A ["Medicare for All"] would entail the same experience with below-market prices as other countries with socialized medicine, it would reduce the world market size and thereby medical innovation, and ultimately mean that future patients would forgo the health gains that would have come from these forgone innovations."[1]

The costs of government price controls, imported or direct, are heavy. And the proposed IPI model runs the high risk of putting Medicare Part B in worse shape by the deprivation of private property rights in the pharmaceutical sector, among Part B providers, and of Part B beneficiaries.

First, importing foreign price controls on Part B pharmaceuticals, as proposed in the ANPRM, amounts to instituting government price controls in U.S. health care. This would set a terrible precedent, just as private-sector biopharmaceutical firms are breaking new ground through research and development in promising areas such as immunotherapy, genomics, and precision medicine. Private companies' R&D depends on reaping the rewards of a handful of market successes while they still have intellectual property protection. Imported foreign price controls deprives American innovators and providers of their property rights and the right to flourish from the fruits of their labor and investment.

It takes an average of $2.6 billion and 10 years to develop a new medicine approved by the Food and Drug Administration. To impose foreign price controls, as proposed, on pharmaceutical innovators is to diminish the ability to pursue R&D at the same levels. Further,

---

[1] Council of Economic Advisors, "The Opportunity Costs of Socialism," Oct. 2018, p. 47.

the IPI model runs counter to the goals of the National Institute of Standards and Technology's (NIST) new Green Paper in its Return on Investment Initiative. NIST cites medical innovation as a U.S. R&D priority for both economic and security interests.[2] NIST notes that private property rights in one's innovation is critically important toward protecting these national interests. IPI would diminish drug innovators' property rights in their inventions and thus set back achieving the U.S. economic competitiveness and national security interests NIST discusses.

Second, doctors, particularly those in small, rural practices, would be hurt by the IPI pilot. Physicians' practices face many demands and constraints, in the pursuit of providing their expertise to people in need. Reducing their income from administering sophisticated medicines to patients with complicated situations directly deprives these learned intermediaries a portion of the fruits of their labor. Further, doctors practicing in Part B would have fewer new therapies with which to treat their patients, as IPI will contribute to a decline in drug R&D and new medications entering the market. This represents government disrupting market-based exercise of private property rights. In at least a portion of cases, the IPI model would force doctors either to forego taking new Medicare patients or to stop seeing Medicare beneficiaries altogether. Thus, by infringing on the property rights of medical providers, this proposal would reduce the number of Medicare practitioners.

Third, this proposal comes just as the Medicare population is swelling with the retirement of Baby Boomers over the next two decades. The price controls-import idea could not have worse timing. Moreover, beneficiaries for whom medication is administered in a doctor's office or outpatient facility tend to have more complex medical cases while the mode of drug delivery is not oral. The growing number of affected patients coupled with the medical expertise required in administering these medications cast the IPI proposal as shortsightedness.

In a sense, the Medicare program represents a part of seniors' deferred enjoyment of a portion of the fruits of their labor. Medicare is not welfare. Rather, Medicare is a social contract with those who worked the requisite number of years to qualify for the program's benefits upon reaching age 65. Had they not been required to pay taxes toward Medicare, beneficiaries would have received those tax dollars as earnings at the time they were in the workforce. At this stage in seniors' lives, they do not have as many options or out-years to make up for the income and earnings lost to Medicare taxes those years ago. They now rely on the government to keep its pledge for their health care at this stage. The IPI model reneges on part of that promise.

This may be merely budgetary slicing and dicing to CMS. But the IPI proposal is tantamount to changing the rules of the game for beneficiaries who have few alternatives to the government health program. IPI effectively deprives affected seniors of their property rights — it is government denying their access to medication options that may be best for their case, that they would otherwise choose, but that Medicare's use of foreign price controls will render unavailable or nonexistent. This would risk the current earliest availability of new medicines much earlier here than in countries with government-run health systems and price controls. Also, in government-run health systems, price controls lead to rationed care. The IPI model would thereby assault beneficiaries' property rights in a terribly offensive manner.

* * * * *

[2] National Institute of Standards and Technology Special Publication 1234, Dec. 2018.

Therefore, the idea of importing socialized health systems' drug price controls for Medicare Part B is misguided. It would do harm to Medicare beneficiaries, medical providers, pharmaceutical innovators, and the U.S. innovation ecosystem. Thus, it would harm important, significant segments of American health care. Importantly, it would do little to curb foreign free riders and forcing them to start paying their fair share for the medical innovation in which America's private sector invests.

Better alternatives for combatting foreign freeloading would be to demand, in trade negotiations, the World Trade Organization, and international encounters, that foreign countries open their health systems to free negotiations among private parties, start using market-based pricing, and enact deregulatory changes where U.S companies are concerned. Compel foreign countries to end their discriminatory pricing and anti-intellectual property practices and policies, and to adopt value-based payments where medical innovations are concerned. This approach, by which the administration has achieved success, would respect private property rights while valuing the intellectual property and the huge risk and investment not only in the product that reached the market but also the extensive trial and error of sophisticated R&D.

Respectfully,

James Edwards
Executive Director
Conservatives for Property Rights

Ed Martin
President
Phyllis Schlafly Eagles

George Landrith
President
Frontiers of Freedom

Tom DeWeese
President
American Policy Center

Kevin L. Kearns
President
U.S. Business & Industry Council

Daniel Schneider
Executive Director
American Conservative Union

C. Preston Noell III
President
Tradition, Family, Property, Inc.

Seton Motley
President
Less Government

Matthew Kandrach
President
Consumer Action for a Strong Economy