United States Senate
COMMITTEE ON FINANCE
WASHINGTON, DC 20510–6200

December 19, 2018

Dear Colleague:

I am writing to share my perspective on the important balance between biopharmaceutical innovation and cost—an issue that has been a touchstone of my career, and one that continues to be at the forefront of bipartisan policymaking. Throughout my 42 years in the Senate, I have focused on creating a competitive marketplace for prescription drugs as the best way to lower costs, ensure patient access, and create life-saving treatments and cures. Deviating from this approach and its underlying market-based principles will lead us down another, more dark path—one that involves more government intervention and less innovation.

More than three decades ago, I championed the Hatch-Waxman Act that established a system for regulating prescription drugs that rewards manufacturers for new products while encouraging generic competitors. Around that same time, I sponsored the Orphan Drug Act that provides incentives for the development of treatments for patients suffering from rare diseases. I also brokered the agreement that has allowed biologics to flourish, providing effective treatment for many types of cancer and other serious medical conditions. Most recently, I advocated policies that promote the development and use of biosimilars—essentially a generic, less costly version of a biologic.

These policies have contributed to a competitive system marked by a very high generic drug use rate, at approximately 90 percent, and frequent breakthrough improvements in treatment. That said, there is a problem. The high costs of some drugs—particularly specialty drugs—puts a financial strain on patients as well as the taxpayer-supported Medicare and Medicaid programs.

President Trump and Department of Health and Human Services' (HHS) Secretary Azar are right to focus on lowering the cost of prescription drugs. I share their view that the best way to lower costs is through market-based policy changes that increase competition and preserve the role of the U.S. as the worldwide leader in biopharmaceutical innovation.

There is tremendous opportunity to support the Trump Administration—and even work with Congressional Democrats—but it is imperative that any changes are consistent with market-based principles. These principles have guided my efforts and served us, as Republicans, well. They drove the development of the Medicare Part D Prescription Drug Program and are the reason that program is a great success. They should be the lens through which we assess the Administration's prescription drug proposals.

While the Administration is pursuing many positive proposals, I am compelled to speak out against policies that run counter to our principles. One recent proposal—to be implemented through the Center for Medicare and Medicaid Innovation (CMMI), known as the International

Pricing Index (IPI) Model—would import international price controls into the Medicare program on certain drugs and biologics, many of which are the first treatment option in a class of therapies and, thus, do not yet have a competitor. Specifically, the IPI Model would set the Medicare payment amount for these drugs and biologics when administered in a physician office as a percentage of the amount paid in select foreign countries. Lowering Medicare payments by using prices from countries with government-run health systems willing to forgo the latest treatments would fail to solve the problem that the U.S. subsidizes the rest of the world. It would also dampen research and development—depriving patients of future treatment breakthroughs and further eroding necessary competition.

Not only is this IPI Model policy worrisome, the mechanism used to propose it raises issues about the separate role of the legislative and executive branches. The IPI Model reinforces my long-standing concern that Congress ceded too much of its authority to the executive branch in establishing CMMI through the Affordable Care Act (ACA). Congress' intent in creating CMMI—to test different ways to pay providers to try to improve the care patients receive while also lowering overall costs—is laudable, but the ACA allows CMMI to waive any part of the Medicare statute and key pieces of the Medicaid statute while requiring little accountability to Congress. The specifics of the IPI are reminiscent of an Obama Administration-era CMMI proposal that also would have signified a broad override of the statute but was never implemented. The sweeping nature of these proposals highlight the danger of providing statutory authority in excess of what is needed for CMMI to achieve its intended purpose. Proper constitutional checks and balances are important no matter which party controls the White House.

As Chairman of the Finance Committee, I have called attention to CMMI's excessive authority. I had the Government Accountability Office (GAO) conduct an independent assessment of its work[1], and solicited feedback on ideas for requiring CMMI to be more accountable to the public[2]. I think of CMMI as analogous to the Independent Payment Advisory Board (IPAB) that was also established through the ACA. IPAB created a board of unelected bureaucrats that would have largely circumvented Congress to determine payment cuts to Medicare providers that could only serve to jeopardize beneficiary access. Congress recognized the abdication of its responsibility and wisely reclaimed it by repealing the IPAB in the Bipartisan Budget Act of 2018.

While I am not advocating that CMMI be repealed, I encourage you to explore how to right-size the CMMI statutory authority by placing protections on how it can be used, while still allowing it to execute its mission and achieve its goals through small demonstrations of payment changes.

I am not alone in opposing the idea of bringing international price controls to Medicare, or in expressing concerns about the mechanism the Administration would use to do so. Over 50 prominent conservatives and conservative organizations have urged HHS to withdraw the proposed IPI Model.[3] Nearly 350 patient and physician organizations share that same view.[4]

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[1] "CMS Innovation Center: Model Implementation and Center Performance," March 2018. Government Accountability Office.
[2] United States Senate Committee on Finance, "Bipartisan Chronic Care Working Group Policy Options Document," December 2015.
[3] Letter at https://www.atr.org/sites/default/files/assets/11-27-18%20Conservative%20Coalition%20Letter%20Opposed%20to%20HHS%20Part%20B%20IPI%20Rule.pdf, accessed on December 17, 2018.
[4] Letter at http://www.partbaccess.org/wp-content/uploads/2017/06/12.10.18-ASP-Coalition-letter.pdf, accessed on December 17, 2018.

Further, more than 150 economists have urged HHS to reject price controls, highlighting the harmful effects of the proposed IPI Model.[5] As you consider how to best to work with the Trump Administration and your colleagues across the aisle, I urge you to stand by Republican free-market principles as the best way to balance drug costs and innovation. Pursuing policies consistent with this path is vastly superior to importing international price controls into the Medicare program.

You can achieve meaningful changes that improve the lives of patients and put Medicare and Medicaid on more sustainable financial footing. These results are possible if we do not lose our way. I hold you all in high esteem. I will miss serving with you, but take comfort in my trust that you will continue to faithfully serve as caretakers of the important federal health programs on which so many Americans rely.

Sincerely,

Orrin Hatch
Chairman

[5] Letter at https://www.ntu.org/library/doclib/2018/12/Economists-Letter-to-HHS-1.pdf, accessed on December 17, 2018.