Richard H. Bagger
EVP, Corporate Affairs &
Market Access

Celgene Corporation
86 Morris Avenue
Summit, NJ 07901
Tel 908-673-9855
rbagger@celgene.com

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Seema Verma
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

BY ELECTRONIC DELIVERY

Re: Medicare Program; International Pricing Index Model for Medicare Part B Drugs (CMS-5528-ANPRM)

Dear Administrator Verma,

Celgene Corporation (Celgene) appreciates the opportunity to respond to the Centers for Medicare & Medicaid Services' (CMS) International Pricing Index (IPI) Model for Medicare Part B Drugs.

Celgene is a global biopharmaceutical company specializing in the discovery, development, and delivery of therapies designed to treat cancer and inflammatory and immunological conditions. Celgene strongly believes that medical innovation can lead to better health, longer life, reduced disability, and greater prosperity for patients and our nation. To this end, we seek to deliver truly innovative and life-changing therapies for the patients we serve. We are currently engaged in 160 clinical trials with 42 novel medicines across 60 indications. In 2017, we reinvested 45.5% of our revenue into research and development to discover and develop the therapies of tomorrow.[1]

Celgene strongly supports the Administration's efforts to ensure that all patients have affordable access to the care they need. As committed as Celgene is to discovering and developing new treatments, we are equally committed to patient support and access to those medical advances – a guiding principle for our company. We believe all who can benefit from

[1] Celgene 2017 Annual Report. Available at: http://files.shareholder.com/downloads/AMDA-262QUJ/6204845187x0x978672/138C3639-1839-499D-8191-34F9E08A0CBD/Celgene_AR_complete_PDF_041718.pdf.

our discoveries should have the opportunity to do so. Celgene focuses on putting patients first with programs that provide information, support and access to our innovative therapies.

However, we are deeply concerned that the IPI model, as proposed, would reduce patient access to Part B drugs. Rather than promote market-based negotiation, a goal that we and many other stakeholders support, the proposed demonstration would import price controls from countries that restrict patient access as a cost control mechanism. Ultimately, the IPI model would restrict patient access, increase complexity in the physician-administered drug distribution system and significantly disrupt Medicare providers.

Patients in the U.S. continue to struggle with burdensome out-of-pocket costs, including in the Part B program. We share HHS's frustration that other countries impose price controls and restrict access for patients. However, we respectfully encourage HHS to focus on policy solutions that will help American patients by leveraging market-based competition to reduce out-of-pocket costs, improve access and adherence and lower health system costs.

We strongly urge CMS to withdraw the IPI model in its entirety and continue working with a range of health system stakeholders to develop policy solutions that will enhance competition, strengthen market-based negotiations and promote patient access across insurance markets. Our detailed comments on the IPI model follow. In addition, we refer to the comments submitted by the Pharmaceutical Research and Manufacturers of America and Biotechnology Innovation Organization, which contain additional supporting evidence for many of the points raised in our letter.

Importing Foreign Price Controls and Access Restrictions Will Harm Medicare Patients

Underlying the IPI model design is an assumption that biopharmaceutical companies willingly sell prescription drugs at lower prices in international markets. In practice, many countries simply refuse either to cover approved therapies or set reimbursement at levels far below the value of innovative medicines. In these cases, companies must decide whether to sell a medication at the government-mandated price, or deny access to patients in those countries.

Foreign Price Controls Are Based on Patient Access Restrictions

Most other countries restrict patient access to new innovative medicines. The prices paid under international price control regimes reflect, and cannot be separated from, these significant access restrictions.

For example, nearly 90% of new medicines approved between 2011 and 2017 were available in the U.S., compared to 67% in the UK, and 48% in France and Canada.[2] These trends are well documented across therapeutic areas, including ones in which medications can be life-saving. For example, one analysis of 45 cancer drugs approved in the U.S. and covered by Medicare

[2] PhRMA Catalyst blog. New analysis shows that more medicines worldwide are available to US patients. https://catalyst.phrma.org/new-analysis-shows-that-more-medicines-worldwide-are-available-to-u.s.-patients. June 5, 2018.

from 2009 to 2013 found that only 26 were covered in the UK, 19 were covered in France, and just 13 were covered in Canada.[3]

Not all medicines approved in other countries are reimbursed, thereby limiting patient access. One analysis found that fewer than 40% of drugs that were approved by the European Medicines Agency between 2011 and 2018 received a positive payer recommendation.[4] When new treatments ultimately become available in other countries, patients may have to wait months or years to gain access. For example, patients in Germany, France, and the UK waited between 14 and 23 months for access to new medicines after U.S. approval.[5]

The price paid in any international market reflects the healthcare system in that country. We do not believe it would be possible to reimburse medicines at similar levels in the U.S. without enacting the access restrictions that are pervasive in other countries.

Access Restrictions Have Both Direct and Indirect Consequences for Patients

Patients who do not have access to new innovative therapies, or whose access is delayed, experience numerous negative consequences including inadequate symptom management, disease progression and poorer health outcomes. Focusing on the most fundamental outcome – overall survival – demonstrates that access restrictions and delays have a severe and irreversible impact on patients. Specifically, mortality data show that cancer survival rates declined more in the U.S. from 1997 to 2012 than in other countries including Germany, the UK, France, and Canada.[6] For example, survival rates declined by 20% in the U.S. compared to 15% in the UK.[7] The 5-year survival rate for all cancers is 42% higher for men and 15% higher for women in the U.S. than in Europe.[8] A recent analysis put these survival gains into personal terms, noting that patients with various types of cancer live, on average, nearly 2 years longer from the time of diagnosis in the U.S. than in Europe.[9]

Patient access restrictions also have real and significant implications for innovation and drug discovery. The United States is responsible for the development of more biopharmaceuticals than all other countries combined. Economists have estimated that the adoption of European-style price controls in the U.S. from 1986-2004 would have resulted in a loss of 117 new medicines.[10] A separate analysis estimated that a 50% decrease in drug prices could reduce the

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[3] Zhang Y, Hueser HC, Hernandez I. Comparing the approval and coverage decisions of new oncology drugs in the United States and other selected countries. J Manag Care Spec Pharm. 2017;23(2):247-254. https://www.jmcp.org/doi/pdf/10.18553/jmcp.2017.23.2.247.
[4] IQVIA Market Access Conference 2018.
[5] IMS Consulting Group report for PhRMA. Patient access to innovative oncology medicines across developed markets. June 2016.
[6] PhRMA analysis of World Health Organization mortality database, using age-specific death rates.
[7] Ibid.
[8] Allemani C, et al. Global Surveillance of Cancer Survival 1995-2009. 2015. *Lancet* 85(9972): 997-1010.
[9] Philipson, T. et al. "An Analysis Of Whether Higher Health Care Spending In The United States Versus Europe Is 'Worth It' In The Case Of Cancer." *Health Affairs*. 31, NO. 4 (2012): 667–675.
[10] Golec J and Vernon J. "Financial effects of pharmaceutical price regulation on R&D spending by EU versus US firms." *PharmacoEconomics,* Jan 2010, 28(8):615-628.

number of drugs in development by up to 25%.[11] Finally, the U.S. Department of Commerce has noted that reference pricing and other price controls suppress global investment in research and development by more than 10 percent each year, and that addressing foreign price controls would benefit U.S. consumers through additional investment in research and development, increased competition and lower costs.[12]

HHS acknowledged these consequences in its "American Patients First" Blueprint, noting that "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 these policies."[13] We agree with HHS' prior assessment and believe it is still accurate, suggesting that the outcomes HHS warned against in the Blueprint could be realized if the IPI model proceeds.

For these reaons, we believe that the potential consequences of the IPI model for future innovation would be significant.

Price Controls Would Be Particularly Inappropriate for New Medicines

As HHS has acknowledged, the IPI model is a government price control for drugs within its scope. While the payment reductions in the model are ostensibly directed to the model vendors, the clear and primary purpose of the model is to set the prices for medicines. The fact that CMS is setting reimbursement and prices becomes particularly clear upon examination of the methodology for determining the "adjusted IPI" factor – a complex and multi-step process for reverse-engineering a pre-determined spending reduction.

We strongly oppose this anti-competitive approach and the application of foreign price controls to Part B medicines. We are especially concerned by CMS' references in the ANPRM to newly approved Part B drugs. It would be particularly inappropriate and ill-advised to include new drugs in the model.

In addition to the fundamental, negative consequences of referencing international prices, including newly approved drugs into the model would bring a host of methodological challenges. As CMS notes, international pricing data are not likely to be available for newly approved medicines at the time of U.S. launch; therefore, CMS would have to use a "standard factor" to establish reimbursement rates for new medicines in the demonstration. By applying a standard reimbursement reduction, HHS may penalize newly approved medicines for an assumed pricing differential that may or may not materialize in reality. Put simply, HHS could punish companies that demonstrate the very behavior that HHS is seeking to promote. It is exceedingly difficult to provide CMS with meaningful feedback about the potential inclusion of new drugs and use of a "standard factor" without a proposed reimbursement methodology.

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[11] Civan, Abdulkadir & Maloney, Michael. (2009). The Effect of Price on Pharmaceutical R&D. *The B.E. Journal of Economic Analysis & Policy*. 9. 15-15. 10.2202/1935-1682.1977.

[12] U.S. Department of Commerce. 2004. Pharmaceutical Price Controls in OECD Countries: Implications for U.S. Consumers, Pricing, Research & Development, & Innovation.

[13] American Patients First. The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs. https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf.

However, we can think of no standard factor that could be applied fairly and appropriately to new medicines before international pricing data are available.

Additionally, we believe that highly complex, personalized medications are not appropriate for any demonstration of this type. For example, manufacturing processes for chimeric antigen receptor (CAR) T cell therapies involve numerous interdependent steps that must completed on a prescribed schedule. In addition, these therapies must be transported according to a strict schedule and handling procedure. Given the complexity and specificity of the CAR T cell manufacturing process and the critical health status of CAR T cell patients, we are concerned that introducing vendors that do not have the sophisticated infrastructure necessary to support the safe distribution of these medicines would result in delays that neither patients nor the personalized manufacturing process can tolerate. We believe that it is critical that biopharmaceutical companies be permitted to work directly with providers to ensure the safe and timely delivery and administration of these therapies.

Further, we expect CAR T cell therapies to comply with U.S. Food and Drug Administration-approved Risk Evaluation and Mitigation Strategies (REMS). Including vendors in an approved REMS program inside of the demonstration would substantially increase complexity for all stakeholders.

In summary, we believe that there are market-based solutions to drive competition and enhance negotiation in Part B, and have offered specific recommendations to support the Administration's goals, including but not limited to updating legal and regulatory safe harbors and prescription drug coding standards to facilitate the development of value-based contracting arrangements.[14] Instead of addressing barriers to value-based negotiation in the US or promoting competition through a robust biosimilar market, the model bluntly adopts international reference pricing based on price controls and access restrictions that could compromise health care access for American patients.

<u>The Proposed Demonstration Is Inconsistent with CMMI's Focus on Innovation and Quality</u>

The IPI model is clearly inconsistent with the Center for Medicare and Medicaid Innovation's (CMMI) legislative charge to test models that address deficits in care or potentially avoidable spending for defined patient populations.

First, the IPI model would, by design, have national implications. CMS states that any price concessions provided to model vendors would impact a medicine's average sales price (ASP) outside of the demonstration. A reimbursement and delivery system change that is national in scope does not constitute a "demonstration" or "test."

[14] Celgene comments on Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Requests for Information on Promoting Interoperability and Electronic Health Care Information, Price Transparency, and Leveraging Authority for the Competitive Acquisition Program for Part B Drugs and Biologicals for a Potential CMS Innovation Center Model (CMS-1695-P). Submitted September 14, 2018.

Second, the model is not targeted to address identified deficits in care for a defined patient population. In fact, CMS proposes to randomly assign approximately half of Medicare providers and their patients to the demonstration group. This assignment would occur without regard for geographic location, specialty, patients served, or other meaningful differentiators that could target a defined patient population. It is unclear how thousands of patients who have been randomly auto-assigned to the demonstration group based on the providers that treat them could constitute a "defined patient population."

Third, the model takes a blunt approach to spending, arbitrarily reducing total Part B drug spending for included drugs by a pre-determined amount. "Potentially avoidable spending" is spending that is unecessary to achieve the desired outcome. Setting reimbursement rates at levels far below the value of Part B medicines will not maintain or preserve the desired outcome of beneficiary access to medically necessary Part B drugs. In fact, the proposed changes will compromise patient access and almost certainly lead to restrictive utilization controls. As outlined above, experience in many other countries demonstrates that such utilization controls have real and significant consequences for patient access.

Beyond its failure to conform to these important statutory directives, the IPI model is at odds with the spirit of CMMI's mission, which is to identify innovative payment and delivery models that can promote high-quality, high-value care. Instead of promoting innovation, the IPI model would both impose anti-innovation pricing practices in Part B and place patients' quality of care at risk by effectively forcing program vendors to adopt stringent and potentially harmful patient access restrictions.

<u>The IPI Model Would Be Highly Disruptive to Providers</u>

We do not believe that CMS should subject Part B providers, including many specialists who care for some of the Medicare program's most vulnerable beneficiaries, to major disruptions in their practices based on a randomized assignment to a demonstration. In its recent request for information on a competitive acquisition program, CMS acknowledged that introducing vendors into Part B and potentially modifying the buy-and-bill system could be disruptive to providers and requested feedback on how to mitigate the negative impact on clinicians.

In the span of several months, CMS has moved from seeking feedback about how to design a demonstration that relies on vendors in a thoughtful and stepwise manner to proposing a wholesale change to physician practice operations without apparent consideration for provider readiness, relative impact, practice size, geographic location, patient mix, specialty or other factors. We encourage CMS to reconsider both the mandatory nature and scope of the proposed demonstration.

At the crux of this element of the proposal is CMS's concern that current Part B drug reimbursement rates encourage providers to prescribe higher-cost medications. A recent analysis of prescribing behavior contradicts this assumption; the authors note that the report

"found no strong, positive correlation between drug payment and utilization and suggests that physician prescribing is not driven by payment-per-drug administration."[15]

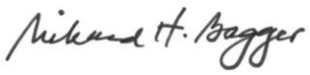
If the proposed changes to provider reimbursement would not meaningfully impact utilization of Part B drugs – as the study suggests would be the case – the model would disrupt practice operations with little benefit to the Part B program.

Conclusion

Celgene shares the Administration's goal of ensuring that all Americans, regardless of their source of coverage, have affordable access to the medicines they need. However, we do not support proposals to import anti-competitive, access restricting features of other countries' healthcare systems. We are proud of the innovation and value that prescription medicines bring to the U.S. healthcare system and American patients. We urge HHS to abandon the IPI model in favor of market-driven solutions that reflect the input and collaboration of stakeholders across the healthcare system.

Thank you for your consideration of our comments.

Sincerely,



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[15] XCenda. "Medicare Physician-Administered Drugs: Do Providers Choose Treatment Based on Payment Amount?" September 2018.