Richard H. Bagger
EVP, Corporate Affairs &
Market Access

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

January 25, 2019

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

BY ELECTRONIC DELIVERY

Re: [CMS–4180–P] Modernizing Part D and Medicare Advantage To Lower Drug Prices and Reduce Out-of-Pocket Expenses

Dear Administrator Verma,

Celgene Corporation (Celgene) appreciates the opportunity to respond to the Centers for Medicare & Medicaid's (CMS) recent Proposed Rule, "Modernizing Part D and Medicare Advantage To Lower Drug Prices and Reduce Out-of-Pocket Expenses" (the "Proposed Rule").

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.

We applaud CMS' decision to codify the ban on "pharmacy gag clauses" that require pharmacists to withhold information from patients, potentially jeopardizing access and adherence to needed medications. Banning gag clauses is both consistent with CMS' overall focus on equipping beneficiaries with meaningful, actionable information to support decision-making and a direct benefit to patients enrolled in the Part D program.

We support the modernization and further improvement of the Part D program. For example, we support the Administration's proposal to include a patient out-of-pocket cap in Part D. We believe that a cap on beneficiaries' out-of-pocket expenses is both necessary and appropriate at this stage in the program's evolution; would have important benefits for patients and the program, through better adherence; and would improve clinical outcomes.[2] However, we also believe that certain core elements of the program, including the protected class policy, should remain in place.

Specifically, we are concerned that the proposed changes to Part D's protected class policy would undermine critical and long-standing protections for some of the program's highest-need beneficiaries. While we support the competition and choice that drive Part D's success, we believe that the proposed changes would risk upsetting the balance between plan flexibility and patient protection in a way that would likely adversely impact beneficiaries.

The reasons to maintain the protected class policy are many, and we both support and respectfully refer CMS to the comments submitted by the Pharmaceutical Research Manufacturers of America and the Biotechnology Innovation Organization.

The Protected Class Policy Remains Vital for Patients and the Part D Program

The need for additional patient protections in selected therapeutic areas is as important today as it was when the Part D program was launched, both from a clinical and a programmatic perspective. Patients who take protected class drugs have life-threatening and life-altering diagnoses, and restrictions on the medications that combat, stabilize, and manage their conditions can have serious consequences for patients. CMS recognized the importance of access to protected class drugs in its decision to terminate a contract because the sponsor was applying unapproved utilization management restrictions to protected class medicines.[3]

It is especially critical that patients who are stable on protected class therapies remain on the treatments that are working for them. Requiring patients with cancer, seizure disorders, or HIV/AIDS to switch medications could result in disease progression, uncontrolled symptoms, and higher non-pharmacy costs. CMS acknowledges this in the Proposed Rule, noting that "best practice utilization management practices would not require an enrollee who has been

[2] Celgene comments on HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs. Submitted June 27, 2018.
[3] Fox Ins. Co. v. CMS, 715 F.3d 1211, 1221 (9th Cir. 2013).

stabilized on an existing therapy of a protected class drug for a protected class indication to change to a different drug in order to progress through step therapy requirements."[4] However, the Proposed Rule would permit plans to apply the same type of utilization management protocols that CMS identifies as incompatible with clinical best practice.

The protected class policy also serves as an important programmatic safeguard against potential discrimination. Again, CMS noted the role of the protected class policy in promoting a level playing field in Part D, writing in 2005 that the protected class policy "was necessary to ensure that Medicare beneficiaries reliant upon these drugs would not be substantially discouraged from enrolling in certain Part D plans, as well as to mitigate the risks and complications associated with an interruption of therapy for these vulnerable populations."[5]

Part D Plans Have Many Tools to Manage Protected Class Medicines

We recognize that prescription drug formularies and utilization management protocols – when appropriately designed – can play a role in managing the use of prescription medications as part of a competitive, market-based healthcare system.

The Proposed Rule seeks to give Part D plans additional flexibility to manage prescription drug utilization; however,data show that Part D plans already have many tools to manage therapies in the protected classes and control program costs. For example:

- Part D plans require prior authorization or step therapy for more than half of branded medications in the protected classes;[6]
- Generic medications account for more than 90 percent of prescriptions in multiple protected classes, and a recent analysis found that the generic utilization rate is higher in the protected classes than in other therapeutic areas;[7]
- An analysis by the Medicare Payment Advisory Commission found that the collective net cost for protected class medicines decreased by 13 percent from 2006 to 2014;[8]
- The average Part D premium declined in 2018 and 2019;[9]
- Prescription drug spending grew by 0.4% in 2017, according to National Health Expenditure data.[10]

In addition, CMS has already established a process for excluding drugs from the protected classes based on "scientific evidence and medical standards of practice."[11] This process, combined with plan sponsors' ability to determine the tier placement, cost sharing, and utilization management protocols for medicines in the protected classes, allows CMS and plan

[4] 83 Fed. Reg. at 62163.
[5] Prescription Drug Benefit Manual, Ch. 6 § 30.2.5
[6] Partnership for Part D Access. "A Balanced Approach to Provide Patients Access to Medications While Allowing Powerful Tools to Control Costs." November 2018.
[7] The PEW Charitable Trusts. Policy Proposal: Revising Medicare's Protected Classes Policy. March 2018.
[8] MedPAC. Report to the Congress: Medicare Payment Policy. March 2017.
[9] Centers for Medicare & Medicaid Services. " Medicare Part D premiums continue to decline in 2019." July 2018. https://www.cms.gov/newsroom/press-releases/medicare-part-d-premiums-continue-decline-2019.
[10] Centers for Medicare & Medicaid Services. National Health Expenditure Fact Sheet. (2017). https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/nationalhealthexpenddata/nhe-fact-sheet.html.
[11] 42 C.F.R. § 423.120(b)(2)(vi)(C) (emphasis added).

sponsors to manage utilization of protected class drugs while ensuring that beneficiaries can access the therapies that will be most effective for them.

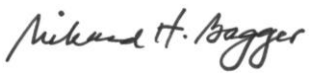
Conclusion

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 believe that the proposed changes to the protected class policy are unnecessary to promote a vibrant and competitive Part D program and are potentially detrimental to patient care. We urge the Administration to maintain the protected class policy in its current form and to pursue other changes that will enhance competition and negotiation. For example, we believe that targeted updates to current legal and regulatory safe harbors, combined with additional specificity and flexibility in prescription drug coding, would facilitate the development of value-based contracts for prescription drugs in Part D and elsewhere.[12]

We encourage CMS to preserve patient protections in Part D, and to pursue market-driven, pro-innovation policies that will also advance high-quality health care for Part D beneficiaries.

Thank you for your consideration of our comments.

Sincerely,



Richard H. Bagger
Executive Vice President, Corporate Affairs and Market Access

[12] Celgene comments on HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs. Submitted June 27, 2018.