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The Honorable Alex Azar
Secretary
US Department of Health & Human Services
200 Independence Avenue, SW
Washington, DC 20201

BY ELECTRONIC DELIVERY

Re: HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs

Dear Secretary Azar,

Celgene Corporation (Celgene) appreciates the opportunity to respond to the Department of Health & Human Services' (HHS') Request for Information (RFI) on policy actions that could improve affordability and access to prescription medicines.

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 HHS' 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, which is a guiding principle for our company. We believe all who can benefit from our

[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.

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.

The proposals outlined in the HHS Blueprint, "American Patients First" (the Blueprint) are bold, interrelated, and complex, and we appreciate the opportunity to share our perspective and recommendations as HHS develops policy in this critical area. We focus our detailed feedback in three areas where our experience provides insights that may be beneficial to the Administration's priorities identified in the Blueprint:

- **Patient out-of-pocket (OOP) costs**, and how all stakeholders can work together to ensure patients can access the medicines they need. We share HHS' overarching goal of making prescription medicines affordable to patients who need them. Medicare Part D enrollees, in particular, face escalating OOP costs, and we strongly support the President's proposal to introduce OOP protection for beneficiaries with the highest medical needs through an annual OOP cap. In addition, we encourage HHS to work with biopharmaceutical companies and Part D plans to explore novel approaches to make cost sharing more predictable and more affordable for patients.

- **Value-based payments**, and how HHS can foster payment innovation in the competitive market. We strongly support HHS' emphasis on value-based payment models, which, when properly designed, can and should facilitate patient access to high-value medicines and ensure that cost sharing is also value-based. These contracts can also provide predictability for payers and incentives for continued innovation for biopharmaceutical companies. We encourage HHS to remove current regulatory and operational barriers to payment innovation. Specifically, we urge HHS to update government pricing and anti-kickback rules to accommodate value-based contracts, and to increase flexibility in prescription drug coding as a foundation for indication-based payments. Finally, we encourage HHS to continue exploring long-term financing options for appropriate treatments.

- **Availability of generic competition after patents expire**, and how HHS, the Food and Drug Administration (FDA), and biopharmaceutical companies can support the virtuous cycle of innovation while holding ourselves to the highest standards in patient safety. We agree that safe and effective generics play an important role in the virtuous cycle of innovation, and we support the Administration's efforts to promote ongoing innovation and patient safety while ensuring generic competition. We recommend legislative and regulatory action that provides for innovators to sell samples to prospective generic applicants on commercially reasonable terms, while ensuring appropriate safety and liability protections.

Celgene reiterates our support for many of the Administration's proposals, and we look forward to working collaboratively with HHS and other stakeholders to ensure that all patients have access to the treatment and care they need. Our detailed feedback follows.

Reducing Patient Out-of-pocket Costs

Both the Blueprint and the RFI highlight current levels of patient OOP spending and the burden that such high cost sharing places on patients. We strongly support the Administration's focus on these costs and the search for means to reduce them. Patients across insurance markets face growing cost-sharing obligations, and many patients struggle to afford the medicines they need. As reflected in the Blueprint and the RFI, addressing the issue of high patient OOP costs will require cooperation and collaboration across the healthcare spectrum, and we are ready and willing to work with HHS and other stakeholders to develop innovative solutions that put patients first.

HHS has already taken positive steps to address beneficiary cost sharing. We applaud Administrator Verma's recent action to address so-called pharmacy "gag clauses" in Part D – clauses that prevent beneficiaries from receiving relevant, meaningful information to enable informed coverage decisions. We hope that the clear directive from the Centers for Medicare & Medicaid Services (CMS) will quickly and effectively eliminate this harmful practice. We further support the Administration's interest in improving beneficiary decision-making across all health insurance programs.

Below we offer additional recommendations in support of several HHS proposals.

Modernizing Medicare Part D

The Blueprint highlights the President's proposal to update Medicare Part D. The Part D program has been incredibly successful, offering critical access to medicines through a robust, competitive prescription drug plan market. We strongly support the President's proposal to modernize the benefit and enhance its value for beneficiaries by creating a patient OOP cap on cost sharing. We also support changes to the structure of the catastrophic phase – particularly with respect to the federal government's responsibility. However, we caution HHS against making changes, such as excluding coverage gap discounts from beneficiaries' True Out-of-pocket (TrOOP) costs, that would reduce coverage and increase costs for patients. These changes are neither aligned with the overall goals of the Blueprint nor necessary to reduce Medicare spending.

First, we recommend that CMS exercise its authority to limit beneficiary cost sharing by establishing an annual OOP limit under the Part D program's non-discrimination provision.[2] While most Part D beneficiaries currently do not reach the catastrophic phase of the benefit, those who do typically have significant medical needs and face burdensome OOP costs that put them at risk for poor healthcare outcomes. Recent studies show that Part D beneficiaries abandon medicines that treat critical and complex illnesses as cost sharing grows. For example, patients in one study abandoned more than 60% of prescriptions for antipsychotics, multiple

[2] Social Security Act § 1860D-11(e)

sclerosis agents, and medicines to treat Alzheimer's Disease when cost sharing exceeded $250 per prescription.[3] In some cases, patients with life-threatening illnesses may forego their medicines at even lower levels of cost sharing. For example, in another study, patients abandoned 10% of oncology medications when cost sharing exceeded $100 per prescription.[4]

Additionally, as cost sharing for individual prescriptions adds up throughout the year, patients with significant healthcare needs face difficult choices about their care. Unfortunately, a majority will choose to delay or forgo needed treatment. For example, nearly two thirds of patients facing total cost sharing between $4,000 and $4,999 abandoned at least one prescription during the year.[5]

And, as patients forgo or self-alter their medication therapies, studies show outcomes decline. A review published in the *Annals of Internal Medicine* reports that medication nonadherence causes 125,000 deaths and 10% of hospitalizations.[6] In addition to these staggering human costs, the authors noted an annual financial impact of up to $289 billion in additional healthcare costs.[7]

Current projections indicate the risk of not addressing this issue now, as the number of Part D beneficiaries whose annual cost-sharing responsibilities reach the catastrophic threshold is rising each year. In 2015, more than one million Part D beneficiaries had total cost sharing above the catastrophic threshold – more than 300,000 more beneficiaries than two years prior.[8] These patients – among the highest-need in the Part D program – are at particular risk for cost-related nonadherence.

As a result, we strongly support the President's proposal to establish an annual OOP cap in the Part D program to protect beneficiaries against burdensome and unpredictable OOP costs. An annual OOP cap would provide consistent, clear, and targeted protection against high OOP costs for Part D beneficiaries, and would align Part D with other federal and commercial healthcare programs, including Medicare Advantage.

Importantly, the Congressional Budget Office's (CBO's) most recent analysis of the President's Budget estimates that creating an OOP cap in Part D would save the federal

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[3] Amundsen Consulting. "Medicare Part D Abandonment." November 2017.
[4] Streeter, S. et al. Patient and Plan Characteristics Affecting Abandonment of Oral Oncolytic Prescriptions. *Journal of Oncology Practice.* (2011). 7(3S).
[5] Amundsen Consulting. "Medicare Part D Abandonment." November 2017.
[6] Viswanathan M, et al. "Interventions to improve adherence to self-administered medications for chronic diseases in the United States: a systematic review." Ann Intern Med. 2012 Dec 4;157(11):785-95.
[7] Ibid.
[8] Kaiser Family Foundation. "No Limit: Medicare Part D Enrollees Exposed to High OOP Drug Costs Without a Hard Cap on Spending." November 2017. Available at: http://files.kff.org/attachment/Issue-Brief-No-Limit-Medicare-Part-D-Enrollees-Exposed-to-High-OOP-Drug-Costs-Without-a-Hard-Cap-on-Spending.

government $1.5 billion over 10 years.[9] While the assumptions underlying CBO's estimate are not specified, we believe that CBO's estimate also reflects reduced liability for the federal government in the catastrophic phase of the benefit. Celgene supports making these two changes together for the reasons described below.

Based on the data summarized in this letter, we believe that a Part D OOP limit is both feasible and necessary. Further, the Part D statutory language directs the Secretary not to approve Part D plans with designs that "are likely to substantially discourage enrollment by certain Part D eligible individuals under the plan."[10] CMS relied upon very similar language to establish an OOP limit for local plans in the Medicare Advantage program, and we believe that the Part D non-discrimination provision also supports OOP protection for beneficiaries with the highest healthcare needs.

Second, we support the President's recommendation to restructure the catastrophic phase of the benefit. Under the current Part D benefit structure, the federal government bears a disproportionate share of costs in the catastrophic phase of the benefit. The President and the Medicare Payment Advisory Commission have recommended that Part D plans assume most of the liability in catastrophic coverage; specifically, these recommendations would reduce the federal government's share from 80% of costs to 20%, and increase plans' share from 15% to 80%.[11]

Holding Part D plans responsible for more costs in the catastrophic phase is both consistent with the goal of private, competitive administration of the program and reasonable, given that the fundamental premise of insurance is that a health plan manages costs across the entire spectrum of patient populations and healthcare needs. Part D plans will likely assert that this change would require them to raise premiums. We disagree with this premise; the Part D market is designed to be competitive, and plans would have additional incentives to manage costs. Far from a shortcoming of this proposal, an increased focused on negotiation is one of the key outcomes the Blueprint seeks to achieve.

Finally, while we believe that the creation of a patient OOP cap would provide a clear and tangible benefit to Part D enrollees with high medical need and improve program flexibility, we discourage HHS from making changes that would reduce Part D benefits for many beneficiaries. Specifically, we are concerned that excluding coverage gap discounts from the calculation of beneficiaries' TrOOP costs would keep beneficiaries in the gap longer, reducing Part D program and plan expenditures at the direct expense of patients. As outlined above, increased costs for beneficiaries would likely result in medication abandonment and

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[9] Congressional Budget Office. "Proposals Affecting Medicare—CBO's Estimate of the President's Fiscal Year 2019 Budget." June 2018. Available at: https://www.cbo.gov/publication/53906.
[10] Social Security Act § 1860D-11(e)
[11] Medicare Payment Advisory Commission. June 2016 Report to the Congress. Available at: http://www.medpac.gov/docs/default-source/reports/chapter-6-improving-medicare-part-d-june-2016-report-.pdf.

nonadherence, putting them at risk for poor outcomes and higher costs elsewhere in the Medicare program.

Making Out-of-Pocket Costs More Predictable

Establishing a patient OOP cap in Part D would not only help decrease patient cost sharing at the pharmacy counter, but also enable HHS to take broader actions that could directly improve patients' clarity and understanding of their overall cost sharing for prescription drugs. Many patients, including those enrolled in Part D, face high OOP costs early in the year. For example, patients with certain diagnoses can move through the entire Part D benefit structure in a single month, requiring an upfront payment of thousands of dollars in cost sharing. Further, the growing – and now almost universal – use of percentage-based coinsurance makes it more difficult for patients to predict their cost-sharing responsibilities even on a monthly basis.

Some Part D beneficiaries could benefit from more predictable, "smoothed" cost sharing, wherein a beneficiary's total cost-sharing obligations would be divided into consistent, even payment amounts. An OOP cap would establish a patient's total possible cost sharing at a known amount, allowing Part D plans to "smooth" cost sharing over the course of the year. The Part D plan would continue to receive the same amount of cost sharing, but beneficiaries would be better positioned to plan for their prescription drug expenses because their monthly cost-sharing responsibilities would be consistent throughout the year. This policy is particularly well suited for older Americans who are often living on fixed incomes. Smoothing patient cost sharing could improve medication adherence and promote higher-quality care and better outcomes – potentially saving money elsewhere in the Medicare program due to avoided hospital, physician, or other costs.

We encourage HHS to develop a demonstration to test "smoothing" in Part D. Beneficiaries would have the option to elect a smoothed benefit design within the demonstration, and Part D plans would agree to smooth beneficiary cost sharing for those who chose this option. HHS could offer several incentives for plans to participate in the demonstration, such as shared Part A and B savings, additional flexibility with respect to medical loss ratio reporting (e.g., clarification that costs associated with administering a smoothed plan design would be considered "activities that improve quality"), or consideration in the Star Ratings program.

HHS could seek stakeholder input on design elements of the demonstration through a Request for Comment or multi-stakeholder panel. Key design elements could include beneficiary eligibility, and whether the demonstration should be limited to individuals with certain diagnoses or expected prescription drug spending; Part D plan participation, and whether the demonstration should be limited to certain plan types; appropriate incentives for Part D plans; end-of-year reconciliation of beneficiary costs; technical and operational best practices; and desired outcomes and success metrics.

Financial Assistance from Biopharmaceutical Companies

Patient assistance, in whatever form it takes, plays a vital role in helping patients afford the treatments they need, and we are proud of the support that we provide to patients. Biopharmaceutical companies often provide financial assistance for medicines that have no generic or therapeutic alternatives. A 2018 study by the Leonard D. Schaeffer Center for Health Policy & Economics found that 51% of financial assistance programs – in this case, copayment coupons for top brand drugs – were for medicines with no generic alternatives.[12] We believe that patients should determine whether financial assistance programs are right for them, and that those who require financial assistance should not be penalized for accepting it. Patient assistance will likely become more critical, and not less, as insurance benefit designs continue to shift costs to patients.

We believe that no patient should have to go without treatment because of cost, and we supply millions of dollars in medicines every year to patients in need. We provide copayment support to eligible patients and educate patients on the availability of other organizations that may be able to lower their OOP costs. To date, more than 293,000 patients treated with Celgene's products have received support from us, including financial assistance, disease education, and support navigating the healthcare system.

We recognize the concern that financial assistance, especially for Part D enrollees who are likely to be especially sensitive to OOP costs, could impact plans' ability to manage costs by steering beneficiaries to lower-cost alternatives. However, we also know that patients and their physicians select treatment options based on their clinical circumstances and medical needs. We do not believe that patients who requires innovative therapies with no generic alternatives, for example, should be penalized by burdensome cost sharing. These patients need to remain on the therapies selected by their physicians – the question is at what cost to the patient.

We strongly believe that HHS, the Office of the Inspector General (OIG), patient advocates, and companies could work together to identify and implement solutions that would directly benefit patients and mitigate potential concerns about the use of financial assistance in public programs. We encourage HHS to work with the OIG and biopharmaceutical companies to explore how financial assistance could be beneficial and appropriate in Medicare Part D, particularly in addressing some of the cost-sharing challenges described earlier in this section.

Promoting Competition and Negotiation through Value-based Payments

The Blueprint and RFI request input on issues related to value-based payments, including current regulatory, legal, and operational barriers to their use and how the federal government can foster payment innovation. In addition, HHS seeks feedback on value-based

[12] Van Nuys, K. et al. "A Perspective on Prescription Drug Copayment Coupons." (2018). Available at: http://healthpolicy.usc.edu/documents/2018.02_Prescription%20Copay%20Coupons%20White%20Paper_Final.pdf.

payment concepts, specifically indication-based payments and long-term financing options for prescription medicines.

As all stakeholders focus on paying for value, biopharmaceutical companies and payers are increasingly negotiating contracts that attempt to tie payment to agreed-upon measures of clinical value. For example, a 2017 survey by Avalere Health revealed that 70 percent of health plans reported favorable attitudes toward outcomes-based contracts. A quarter of the plans that participated in the survey had at least one such contract in effect; most of these planned to pursue similar contracts in the future.[13]

These contracts are evidence of the private sector innovation that defines our healthcare system, and we believe that value-based payment approaches – when properly designed – can increase predictability for payers, and create incentives for continued innovation by biopharmaceutical companies. More importantly, these contracts can ensure that patient cost sharing reflects a treatment's value to the relevant patient population. However, value-based contracts tend to be highly complex and resource-intensive to implement for both biopharmaceutical companies and payers. We applaud HHS' interest in identifying regulatory solutions that could facilitate the evolution of these contracts and ensure that innovation in payment keeps pace with innovation in medicine.

We appreciate the steps that the Administration has already taken to support the development of innovative contracts. For example, we support FDA's recent clarification of permissible communications between biopharmaceutical companies and payers. As FDA notes, the final guidance "will inform market participants developing contracts that include value-based arrangements how to communicate information about how a drug might impact outcomes" and that FDA's goal is "to help facilitate contracting for new medical products that are based on the value that these products are delivering to health systems, providers and especially patients."[14] We fully embrace and share FDA's goal, and we appreciate FDA's thoughtful consideration of public comments in finalizing these documents.

Removing Regulatory and Legal Barriers to Value-based Payments

As a general principle, value-based payments should recognize the value of each product and the benefit it offers to specific patient populations. In addition, these payment arrangements should reward innovation, preserve patient access to novel therapies, and avoid high patient OOP costs.

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[13] Avalere Health. "Health Plans Are Actively Exploring Outcomes-Based Contracts." (2017). Available at: http://avalere.com/expertise/life-sciences/insights/health-plans-are-actively-exploring-outcomes-based-contracts.

[14] FDA Statement. "Statement from FDA Commissioner Scott Gottlieb, M.D., on new efforts to advance medical product communications to support drug competition and value-based health care." Available at: https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm610415.htm.

To encourage the development of new and bolder value-based payment approaches in the competitive market, HHS should update government pricing and anti-kickback rules to address and accommodate value-based arrangements. We recommend that HHS undertake rulemaking to update all government pricing calculations, and that the Department work with OIG to establish safe harbors for value-based arrangements under the anti-kickback statute. These regulatory actions will lay a critical foundation for further innovation and sophisticated negotiations between biopharmaceutical companies and payers.

Medicaid Best Price has been identified as a key barrier to value-based contracting; however, HHS should update all government price reporting (i.e., average manufacturer price, average sales price, non-federal average manufacturer price) to ensure a consistent and comprehensive approach across public programs.

New rulemaking should establish when companies may exclude payments made pursuant to value-based arrangements from government price reporting, in recognition of the fact that value-based payments reflect complex and population-based metrics. Value-based arrangements, when they are designed correctly, consider patient populations; while outcomes may be assigned at the patient level, these contracts tend to reflect a holistic and population-focused assessment of value. By definition, a population-based approach will incorporate variation at the patient level. Therefore, the price paid for any unit of medicine in a value-based arrangement may or may not represent the overall structure of the value-based arrangement. In fact, prices that could implicate Medicaid Best Price are particularly likely to be outliers.

Key issues for HHS to address in new rulemaking include: value-based arrangements generally, and which types of value-based contracting structures would be excluded from government price reporting; the role of financial risk, and whether a minimum level of risk would be necessary for a contract to be excluded; and any additional contract parameters that would protect against potential gaming (for example, that the arrangement's payment terms be determined in advance and remain fixed throughout the contract term).

Regulation should also clarify the treatment of value-based arrangements under the anti-kickback statute. Because "remuneration" is broadly defined in the statute, companies would benefit from additional clarity on how the existing safe harbors apply to value-based arrangements. We recommend that HHS work with OIG to clarify that the Department would not view value-based payments as "kickbacks" by updating regulatory safe harbors and corresponding guidance.

Indication-based Payments

Innovative medicines can bring different value to different patient populations based on a variety of factors, including improvement relative to other treatment options. In some cases, several indications may have similar value to patients; in others, one indication's value may be higher than another's. Indication-based payment models can ensure that a product's pricing reflects this dynamic by linking the price for each product indication to its value to the specific patient population it serves.

Sophisticated payers, providers, and biopharmaceutical companies have the data and expertise necessary to negotiate indication-based payments. We believe that indication-based payments could play a role in public and private insurance programs, including Medicare Parts B and D. However, current product coding rules make these contracts difficult to implement in an accurate and consistent manner. Therefore, we urge HHS to update standards for National Drug Codes (NDC) and J codes to accommodate indication-based payment arrangements.

Allowing biopharmaceutical companies to apply for unique NDC and J codes by indication would substantially improve our ability to implement indication-based payments, including in the Medicare program. Issuing separate drug codes would address many of the challenges associated with indication-based payments today, including:

- Aligning beneficiary cost sharing with each indication's value (i.e., connecting cost sharing to the appropriate list price);
- Accurately recording indication or diagnosis at the patient level;
- Reducing provider and payer confusion; and
- Enabling appropriate oversight of the contract.

The ability to align patient cost sharing to the appropriate list price is a critical benefit of separate drug codes. While differential discounting by indication can achieve lower prices for payers, patients do not necessarily benefit from these more complex negotiations. Creating a framework for different list prices by indication is the most straightforward way to ensure that patients pay the appropriate amount for medications based on their diagnoses. This approach is consistent with a recently announced indication-based pricing approach for a novel cancer therapy. In this case the two indications require different medication strengths, allowing for separate codes under current rules. CMS should extend this flexibility to other products to encourage additional indication-based list prices in Medicare Parts B and D, as described below.

<u>Indication-based Payments in Medicare Part D</u>

Allowing companies to apply for unique NDCs by indication would significantly encourage indication-based payments in Part D by removing some of the most significant barriers to their use today. Beyond changes to coding rules, we believe that any further requirements necessary to support indication-based payments in Part D would be limited. Specifically, Part D plans seeking to enter into indication-based payment contracts should commit to aligning beneficiary cost sharing to the negotiated price for the relevant indication. Updated, indication-based cost-sharing amounts should be reflected in Medicare Plan Finder to ensure that beneficiaries have precise and accurate information about their prescription drug costs.

Further, plans should monitor and audit prescription drug claims to ensure appropriate coding. As administrator of the Part D program and the contract holder with plans, CMS should confirm that plans have appropriate audits in place as part of its existing oversight and compliance programs.

CMS could issue technical guidance or convene a multi-stakeholder open door forum to share best practices and accelerate the adoption of indication-based payments in Part D. Celgene would welcome the opportunity to participate in any such stakeholder discussions.

Indication-based Payments in Medicare Part B

We encourage HHS to establish a voluntary indication-based payment demonstration in Part B. As in Part D, we believe that separate drug codes are a critical foundation of any indication-based payments in Part B, in large part because separate codes will again allow cost sharing to reflect the value of a prescription drug to the individual patient based on his or her condition. In the Part B context, we urge HHS to award unique J codes by indication, such that each unique NDC would correspond to a unique J code. Without separate J codes, a product's average sales price (ASP) would have to be set by NDC to enable accurate cost sharing. We believe that this approach is more complex, likely to cause provider confusion, and ultimately increase the risk of inaccurate payments.

Companies participating in the demonstration should be permitted to apply for new J codes at the time of each new indication's approval to allow for quicker adjustment of cost sharing and payments as new indications are approved.

Participation in the demonstration should be voluntary for companies and providers; however, providers who opt into the demonstration should commit to recording utilization by indication for all products included in the demonstration. We recognize that accurate recording of beneficiary diagnosis and indication may require additional training and oversight, and we recommend that HHS consider reimbursing participating providers at fair market value for administrative costs associated with the demonstration. Current Part B reimbursement rules should continue to apply outside of the demonstration.

Any indication-based payment framework has the potential to encourage mis-coding, because provider reimbursement will also vary by indication. While we expect that the vast majority of providers who elect to participate in a demonstration would record utilization accurately and consistently, HHS should establish an appropriate program integrity framework to guard against accidental or intentional mis-recording of patient diagnoses.

Long-term Financing for Prescription Medicines

HHS seeks input on the potential benefits of long-term financing options for prescription medicines. We agree that long-term payment structures could be especially helpful to some payers, such as state Medicaid programs or smaller health plans. These arrangements are well-suited for products with certain characteristics, including those that are used infrequently but provide a high value to patients and innovative therapies for which there is pent-up demand due to treatment breakthroughs.

Implementing long-term financing arrangements could require additional regulation and guidance, particularly in the Medicaid and Part D programs. Long-term financing arrangements

would need to accommodate scenarios in which the payment terms for a therapy extended beyond the patient's coverage term with the health plan. For example, a Part D plan could negotiate a long-term contract under which the plan pays a portion of the therapy cost upon achievement of a clinical outcome. If the beneficiary switches to another Part D plan before that clinical milestone occurs, the "negotiating" Part D plan would need certain beneficiary-level information from the "receiving" plan. HHS may therefore want to establish common practices or expectations with respect to information-sharing for health plans participating in public programs. HHS may also wish to work with payers and biopharmaceutical companies to update and refine accounting rules, and to agree upon how stakeholders should administer long-term arrangements from a financial perspective.

Finally, HHS will need to determine whether federal reimbursement – either to states, payers, or providers – should be modified when a long-term financing contract is in place. We encourage HHS to issue a dedicated Request for Information or convene a multi-stakeholder working group to collect feedback on long-term contracts and develop operational solutions for public programs.

Promoting Generic Competition After Innovator Patents Expire

Celgene supports the robust balance between incentives for innovation and generic competition. The Hatch-Waxman Act has created a sustainable system where nearly 90 percent of prescriptions every year are generics, representing massive price reductions compared to the original innovator brand. Last year, the FDA approved a record-high 1,027 new generic medications.[15] Between 2018 and 2022, based on anticipated loss of exclusivity, an estimated $105 billion in price decreases will be realized by the healthcare system. Policies that enhance competition after innovators' patents expire drive the virtuous cycle of incentives for innovation and the continuing value from generic competition.

Celgene has demonstrated a nearly-two-decade commitment to managing the risks associated with our therapies, including teratogenic risk, and operational excellence in risk management to minimize risk to patients and burdens to the health care system. We are resolutely dedicated to ensuring patient safety and are proud of our record of no congenital malformations associated with these drugs in over one million prescription cycles. We firmly believe that our commitment to developing the most effective risk mitigation systems and our unwavering efforts to operate these systems have allowed hundreds of thousands of patients to benefit from our life-saving medications without putting them, their families, their health care providers, or the public at undue risk. Our commitment to patients extends to ensuring that other companies that utilize Celgene products subject to Risk Evaluation and Mitigation Strategies (REMS) with Elements to Assure Safe Use (ETASU) in clinical testing share our

[15] Uhl, K. "2017 Was Another Record-Setting Year for Generic Drugs." Available at: https://blogs.fda.gov/fdavoice/index.php/2018/02/2017-was-another-record-setting-year-for-generic-drugs/

commitment to safety and implement necessary safeguards. Celgene offers to sell its products that are subject to REMS with ETASU in response to requests from generic manufactures for use in clinical testing, subject to necessary safety-related requirements.

We support the Administration's efforts to promote ongoing innovation and patient safety while ensuring generic competition. Further, we applaud FDA's continued implementation of its authority over REMS with ETASU in a manner that builds upon Agency and stakeholder learnings and puts patient safety at the forefront, while minimizing burdens to the health care system.

REMS with ETASU play a critical role in ensuring that beneficial drugs can be made available safely to patients. Indeed, FDA may only require a REMS with ETASU if FDA finds that the drug can only be approved with the ETASU to mitigate a specific serious risk of the therapy. REMS with ETASU are carefully designed and reviewed by FDA to ensure the elements are commensurate with the specific risk of the drug, are not unduly burdensome on patient access, and minimize the burden on the health care delivery system.

Access to Reference Product Samples for Bioequivalence Testing

To address the issues raised in the Blueprint regarding access to samples for bioequivalence testing, we recommend legislative and regulatory action that provides for innovators to sell samples to prospective generic applicants on commercially reasonable terms while ensuring appropriate safety and liability protections. Such policies must include a robust process for FDA review and authorization of the safety protections that will be implemented by generic manufacturers.

First, we recommend that FDA finalize the draft guidance "How to Obtain a Letter from the Food and Drug Administration Stating That Bioequivalence Study Protocols Contain Safety Protections Comparable to Applicable Risk and Evaluation Mitigation Studies for Reference Listed Drugs."

Celgene appreciates the FDA's efforts to date to develop a process for it to review a prospective generic applicants' protocols for testing where the innovative drug is subject to a REMS with ETASU, as reflected in the agency's 2014 draft guidance document entitled "How to Obtain a Letter from FDA Stating that Bioequivalence Study Protocols Contain Safety Protections Comparable to Applicable REMS for RLD." In particular, we applaud FDA's commitment to ensuring that all manufacturers, including generic applicants, implement critical safety protections for these drugs. However, the draft guidance has not yet been finalized and leaves many significant questions unresolved.

Therefore, we encourage the FDA to finalize this draft guidance to provide additional clarity on certain questions. First, the guidance should call for bioequivalence protocols or related documents that FDA reviews to include adequate information on adverse event monitoring and reporting, quality assurance, quality control, compliance systems, programs to address patient injury, and the storage, handling, and disposal of the product. Second, the

guidance should also include a process for FDA to modify or revoke a letter issued to a prospective generic applicant if FDA later determines that its testing presents a public health risk (e.g., if the generic applicant does not adhere to the protocol). Finally, because the Food, Drug, and Cosmetic Act provides for an array of civil and criminal penalties for violation of a REMS, the guidance should clarify the Agency's basis for asserting that providing samples does not violate the statute.

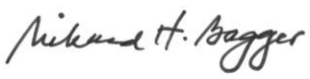
Furthermore, to further clarify unresolved issues about sale of samples, Celgene supports appropriate federal legislation that provides for innovators to sell samples to prospective generic applicants (often termed eligible product developers) on commercially reasonable terms while ensuring appropriate safety and liability protections. Any such legislation must include a robust process for FDA review and authorization of the safety protections that will be implemented by eligible product developers in testing samples of drugs that are subject to REMS with ETASU. If legislation requires innovators to provide samples to eligible product developers, the legislation should also protect innovators from liability that may arise as a result of the developer's actions and provide for indemnification and insurance requirements that ensure this liability protection is meaningful. Finally, Congress should provide that the sale of samples to an eligible product developer pursuant to the legislation does not violate the innovator's REMS with ETASU.

Conclusion

Celgene shares the Administration's goal of ensuring that all Americans, irrespective of their source of coverage, have affordable access to the medicines they need. We are proud of the innovation and value that prescription medicines bring to our healthcare system, but we recognize that scientific innovation can only realize its full potential if patients can access care. We offer our specific recommendations with the goal of helping to advance the Administration's work in this important area, and we would welcome the opportunity to discuss our comments and any of these issues in further detail.

Thank you for your consideration of our comments.

Sincerely,



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