July 16, 2018

The Honorable Alex M. Azar II,
Secretary
U.S Department of Health & Human Services
200 Independence Avenue, SW
Washington, DC 20201

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

Dear Secretary Azar,

Biocom is the largest, most experienced leader and advocate for California's life science sector, which includes biotechnology, pharmaceutical, medical device, genomics and diagnostics companies of all sizes, as well as research universities and institutes, clinical research organizations, investors and service providers. With more than 1000 members dedicated to improving health and quality of life, Biocom drives public policy initiatives to positively influence the state's life science community in the research, development, and delivery of innovative products.

In our mission of providing feedback and communication between regulators and industry, we are writing in response to the Department of Health and Human Services (HHS) Request for Information (RFI) on the Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs (Blueprint). With more than 12,000 establishments, California's life sciences industry generates nearly $317 billion in annual economic output, boosts the state's total gross product by $171.4 billion, supports more than 1.1 million jobs, and increases labor income by $92 billion per year[1].

Biocom appreciates the Administration's efforts to ensure that American patients have access to the prescription drugs they need and thanks you for the opportunity to engage to ensure that proposed changes to the current system meet the Administration's goals. We support many of the proposals outlined in the Blueprint and the RFI to improve competition, lower out-of-pocket costs, improve negotiations, and create incentives for lower list price. However, we have concerns with some proposals which may lead to unintended consequences that could potentially impact patient access and stifle the biopharmaceutical market. Our comments are detailed in the balance of this letter and focus on the following:

[1] *Biocom 2017 Economic Impact Report Databook*. 2017, issuu.com/biocom0/docs/biocom-2017-economic-impact-report-_9995632bde2e0c?e=30611789/53618285.

- Biocom urges the Department to reject the proposal to move drugs from coverage under the Medicare Part B program to the Part D program.
- Biocom urges against leveraging the authority created by the Competitive Acquisition Program CAP for Medicare Part B drugs.
- Biocom opposes the introduction of potential formulary flexibility and the elimination of protected classes.
- Biocom supports the implementation of an OOP maximum in Medicare Part D but opposes change to the treatment of manufacturers discounts provided in the coverage gap and their application towards TrOOP.
- Biocom supports the proposal requiring plans to share a portion of Medicare Part D rebates at the point-of-sale.
- Biocom supports the prohibition of pharmacy gag clauses.
- Biocom supports reforms to the 340B drug pricing program.

Oppose moving drugs from coverage under the Medicare Part B program to the Part D program

Biocom strongly urges the Department to reject the movement of drugs from coverage under the Medicare Part B program ("Part B") to the Medicare Part D program ("Part D"). The shift could result in (i) potential increases in beneficiary out-of-pocket expenses, (ii) limits on the physician's ability to provide adequate care and (iii) significant uncertainty for patient access. The impact of this shift can be determined based on the cost of the treatment, the combination of drugs the patient is using, the income level of the beneficiary, and whether the beneficiary has Medicare Part D or supplemental coverage[2].

Medicare Part B medicines are essential in providing treatment to some of the sickest and most vulnerable patients with conditions like cancer, rheumatoid arthritis, mental illness and autoimmune conditions. These often chronic conditions cannot be effectively treated by a one-size-fits-all approach. Medicines covered by Medicare Part B are typically administered by a physician and require complex acquisition, storage, and administration. Due to patient–drug interactions, the treatment regime typically requires modifications as the disease progresses. Medicare Part B covers all medicines that are medically necessary, while Medicare Part D plans are only required to cover two medicines per class and can select which medicines are made available to the patient. Shifting drugs from Medicare Part B to D could limit patient access to vital therapies. It is imperative that physicians maintain the flexibility to modify a patient's treatments to fit their conditions.

The proposed change could also result in patients paying more out-of-pocket cost. The 86 percent of beneficiaries who have supplemental coverage[3] for Part B medical services are not eligible for the low-income subsidy (LIS) in Medicare Part D. Shifting Medicare Part B medication to Part D, where cost sharing can reach 50 percent, could increase cost for Medicare Part B beneficiaries. An analysis conducted by Avalere revealed that the average out-of-pocket cost was 33 percent higher for Medicare Part D new cancer therapies ($3,200) than for those covered in Medicare Part B ($2,400)[4]. Higher out of pocket costs can also cause patients to abandon their medicines, causing their health status to worsen. In addition, the shift could cause higher Medicare Part D premiums.

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[2] Brow, Matt, and Richard Kane. "Avalere Analysis Highlights Complexities of Transitioning Medicare Part B Drugs into Part D." Avalere Health, 21 May 2018, avalere.com/expertise/life-sciences/insights/avalere-analysis-highlights-complexities-of-transitioning-medicare-part-b-d.

[3] MedPac. *A Data Book: Health Care Spending and the Medicare Program*. www.medpac.gov/docs/default-source/data-book/jun17_databooksec3_sec.pdf?sfvrsn=0.

[4] Brow, Matt, and Richard Kane. "Avalere Analysis Highlights Complexities of Transitioning Medicare Part B Drugs into Part D." Avalere Health, 21 May 2018, avalere.com/expertise/life-sciences/insights/avalere-analysis-highlights-complexities-of-transitioning-medicare-part-b-d.

Oppose leveraging the Competitive Acquisition Program (CAP) Authority

Leveraging the authority created by CAP for Medicare Part B drugs and biologics could restrict patient access and create unnecessary burdens for physicians. Formularies and other utilization management tools used to drive better negotiation are not suited for Medicare Part B drugs. Because of the complexity of the treatments for most serious health conditions, it is critical that patients have the flexibility to work with their providers on finding the right regimen for their conditions. Further, leveraging the CAP authority would require additional care management and administrative work for physicians such as (i) management of medical documentation and reporting processes (ii) management of dual or segregated drug inventories for Medicare and non-Medicare populations (iii) and performing prior authorizations and exception requests.

Oppose introducing formulary flexibility and changing the Six Protected Class policy

Biocom opposes the Administration's proposal to allow Medicare Part D plans to add restrictions in the six protected classes or categories of drugs which could hinder a key Medicare Part D access protection for vital therapies for serious conditions in vulnerable populations.

Currently, Medicare Part D drug plans are required to include in their formularies access to all or substantially all drugs within six classes or categories of drugs, including Anticonvulsants, Antidepressants, Antineoplastic, Antipsychotics, Antiretrovirals, and Immunosuppressants.

Since its implementation, the six protected classes have ensured that beneficiaries have access to critical medicines and these protections remain necessary for reducing the adverse outcomes that may result from the disruption of therapies.

For the treatment of certain diseases covered within the protected classes, such as mental illness, cancer, and HIV/AIDS, it is critically important that patients and physicians have the continued flexibility to make treatment modifications based on changes to the patient's clinical needs. Furthermore, the proposal to eliminate the current requirement that Medicare Part D plans must cover at least two drugs within each therapeutic class or category would have a serious impact on patients' access to the appropriate treatment for their clinical needs.

Three of the six classes of drugs (Anticonvulsants, Antidepressants, and Antipsychotics) specifically treat psychiatric disorders, which fuel and are fueled by the nation's opioid crisis. From a mental health perspective, limiting drug choices within these three classes of drugs will reduce the nation's effectiveness in addressing our mental health crisis.

From a business perspective, reducing the choice of drugs from at least two within a class or category would, in essence, create a monopoly of one drug per class or category. Reducing choices and creating monopolies goes against American Patients First's intent to improve competition.

From a medical perspective, reducing the choice of drugs from at least two within a class or category appears to be premised on the outdated "monotherapy" model (one drug treats one disease). In contrast, the drugs used in current antiretroviral agents are administered as a combination and the drugs used in current antineoplastic treatments evolve as the disease progresses. Limiting a physician and patient's access will result in patients using a therapy that may not be best suited for their conditions.

Support establishing an Out-of-Pocket (OOP) Maximum but oppose changes to TrOOP

Biocom supports the Department's proposal to establish a maximum annual out-of-pocket spending limit in the Medicare Part D program. The cap on OOP would end beneficiary cost-sharing in the catastrophic phase of the benefit and increase the share of drug spending in the catastrophic phase paid for by Medicare Part D plans.

However, discounts provided by manufacturers in the coverage gap should be included in beneficiaries' true out-of-pocket costs (TrOOP). Exclusion of manufacturer discounts from TrOOP would increase beneficiary out-of-pocket costs by $4.1 billion between 2017 and 2020[5]. The proposal to exclude manufacturer discounts from a beneficiary TrOOP would increase costs for patients because some beneficiaries would stay in the coverage gap longer, reaching the catastrophic phase of coverage where their cost-sharing burden is reduced later.

Additionally, changes made to the reinsurance structure accompanied by the removal of manufacturer discounts counting toward TrOOP and the implementation of an OOP maximum would conflict if implemented together. With the lengthened time in the coverage gap, few beneficiaries would reach the OOP maximum, which results in minimal exposure for plans in the catastrophic phase. Changes to the reinsurance structure will create incentives for plans to inappropriately restrict beneficiary access to needed drugs, which may delay or impede access to needed care, and in turn increase overall health care costs.

Support requiring Medicare Part D plans to apply a substantial portion of rebates at the point-of-sale

Biocom is supportive of the Blueprint's proposal requiring plans to share a portion of Medicare Part D rebates at the point-of-sale. We support efforts to ensure that beneficiaries benefit directly from significant price negotiations between health plans and pharmacy benefit managers (PBMs).

Privately negotiated rebates reduce list prices by as much as 30 percent but many Medicare Part D plans still required beneficiaries to pay cost sharing based on the full price of their medicine.

In recent years, negotiations between Medicare Part D plans and their PBMs have grown exponentially. Between 2010 and 2015, price concessions received by Medicare Part D sponsors and their PBMs increased nearly 24 percent per year, about twice as fast as total Medicare Part D drug costs[6]. Not sharing these rebates at the point of sale result in millions of patients paying higher cost sharing at pharmacies.

Support prohibiting Part D plan contracts from using pharmacy gag clauses

Commercial contracts between pharmacies and PBMs are usually invisible to patients and some purchasers. These arrangements can sometimes include restrictions that prohibit pharmacists from informing patients that their prescription drugs could be purchased at a lower price if paid out-of-pocket rather than purchased through their insurance plan. Also, prescription drug overpayments, also known as clawbacks, occur when copayments from commercially insured patients' exceed the total cost of the drug paid by their insurer or PBM. Biocom supports the Administration's proposal to prohibit Medicare Part D plan contracts from preventing pharmacists from telling patients when they could pay less out-of-pocket by not using their insurance.

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[5] Frieder, M. "Proposed Changes to Part D Would Increase Beneficiary Costs." Avalere Health, Mar. 2016, avalere.com/expertise/managed-care/insights/proposed-changes-to-part-d-would-increase-beneficiary-costs.

[6] Barlas, Stephen. "CMS Considering Pharmacy Counter Discounts for Part D Drugs in Future Other Pharmacy Changes Are Likely for 2019." *Pharmacy and Therapeutics* 43.2 (2018): 73–115. Print.

Support reforming the 340B Drug Discount Program

The 340B Drug Pricing program has seen significant growth in recent years, surpassing the scope and size that was originally intended by Congress. The lack of adequate oversight has led to increased spending across the healthcare system. The number of 340B hospitals grew from nearly 1,700 in 2011 to 2,479 in 2017[7]. In sales, the program has grown from $6.9 billion in sales at the 340B price in 2012 to $19.3 billion in 2017, a nearly 200 percent increase[8]. The program is forecast to exceed $20 billion by 2019 and $23 billion by 2021[9]. Although there has been a rise in 340B sales, data suggest that certain hospitals are not passing on the savings associated with sales from the program to patients in the form of financial or co-pay assistance.

Biocom supports the Administration's efforts towards lowering drug prices through the 340B reforms in the "American Patients First" Blueprint. Biocom recommends changing the definition of "patient" to help refocus the program towards its intended purpose. The lack of a clear definition of "patient" may be directly connected to the high number of covered entities who committed diversion. Biocom recommends that the definition be changed to clearly and explicitly define who is considered a patient under the 340B program.

Clinics that participate in 340B through the public service grant program are required, by virtue of their grant, to reinvest any profit derived from reselling 340B medicines into care for vulnerable and uninsured patients and report the value of the savings and charity care. However hospitals which operate under 340B are not required to report such data as the 340B statute does not require covered entities to track or report program savings and how they are used. It also does not require covered entities to report the level of charity care they provide to patients. The absence of these types of reporting requirements results in a lack of data and transparency on how hospitals use the savings they generate under the program and the overall value of the program. We urge the Department to implement report requirements to increase transparency and improve the integrity of the 340B program. Further, we recommend that the Administration conduct more audits of covered entities and make public the findings of such audits.

Biocom is dedicated to improving patient access to innovative therapies. Thank you again for the opportunity to provide these comments. We look forward to a continued dialog with HHS. If you have any questions about these comments, please contact Brittany Blocker, Manager of Regulatory Affairs at bblocker@biocom.org.

Sincerely,

Joe Panetta
President and CEO
Biocom

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[7] HHS. "American Patients First The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs." May 2018. www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf.
[8] Fein, Adam J. "The 340B Program Reached $19.3 Billion in 2017-As Hospitals' Charity Care Has Dropped." *Drug Channels,* 7 May 2018, www.drugchannels.net/2018/05/exclusive-340b-program-reached-193.html.
[9] BIO. 340B Drug Discount Program At-A-Glance
https://www.bio.org/sites/default/files/BIO_340B_Infographic_01252018.pdf