April 14, 2023

Re: *Medicare Drug Price Negotiation Program Guidance*
Submitted via email to: IRARebateandNegotiation@cms.hhs.gov

Dear Sir or Madam,

Thank you for the opportunity to provide comments on the initial guidance memorandum regarding implementation of the Medicare Drug Price Negotiation Program.

The Alliance for Safe Biologic Medicines (ASBM) is a diverse group of stakeholders that includes physicians, pharmacists, patient advocates, researchers, and biopharmaceutical manufacturers. Since 2010, ASBM has worked closely with regulators worldwide as they develop and implement health policies, to ensure that these reflect the best interests of patients. To that end, we have surveyed thousands of physicians in 15 countries; and presented findings to regulators including the U.S. Food and Drug Administration (FDA), the World Health Organization (WHO), the Australian Therapeutic Goods Administration (TGA), Health Canada, the European Commission, the Italian and Spanish Ministries of Health, and others. We also regularly share with policymakers the perspectives of patient advocacy organizations which comprise the bulk of our membership.

ASBM supports policies which increase patient access to affordable, innovative medicines. We further believe that the perspectives of physicians and patients should be given particular weight during this process. Based on these principles, ASBM offers the following comments on CMS' initial guidance for the Inflation Reduction Act's Medicare Drug Price Negotiation Program.

A. Medicare Part D: A Highly Successful Program with a High Satisfaction Rate

Prior to my role as ASBM's Executive Director, I served for 6 years in the Department of Health and Human Services' Office of the Secretary, during which time Medicare Part D (prescription drug benefit) was developed and implemented. The idea of 'negotiation' was raised, evaluated, and rejected during the development of Part D due to numerous factors; among them were the negative impact on innovation and patient access to new drugs.

A recent survey of seniors enrolled in a Medicare Part D plan revealed a 90% satisfaction rate with the program—the highest rate since annual polling began 7 years ago. This high satisfaction rate is based on the program being user-friendly and affordable; over 85% of seniors surveyed claim affordable monthly premiums and co-pays.[1]

B. Historical Impact of Price Controls on Innovation and Patient Access

[*] *https://www.hlc.org/post/medicare-part-d-the-successes-and-the-challenges/*

In European countries and Canada, government-negotiated drug pricing (ie, price controls) have negatively impacted patients by undermining innovation and limiting patient access:

- In the 1970s, European companies developed most new drugs; however, since the implementation of price controls in Europe, 60% of new drugs are currently developed in the US, compared to 13% in Switzerland, 8% in the United Kingdom (UK), and 6% in Germany and France.[1]
- Of cancer medicines launched globally between 2011 and 2019, more than 96% are available to US patients while only 65% are available in other developed nations such as Australia, Japan and the UK.[2] Furthermore, cancer death rates per 100,000 are 1.6 to 1.8 times higher in Europe than those in the US.[3]
- Of new cancer medications, 90% are available to US patients within the first year of launch, whereas less than half of these are available to cancer patients in Germany, the UK, France, and Canada.[4]

Current US policy contributes to the availability of more life-saving medicines, earlier access to new drug launches, and fewer cancer-related deaths.

C. Negative Impact on Development and Adoption of Biosimilars

ASBM seeks to ensure that patients have access to safe biologic treatment options, including lower-cost biosimilar versions of innovator biologics. Market competition (between innovator products and multiple biosimilars to that product) has proven to be an effective means of reducing costs, both in the European Union and in the U.S.

For example, the cumulative savings in drug spend for classes with biosimilar competition is estimated to have been $21 billion over the past 6 years. Trends show an acceleration in savings per quarter, and in Q2 2022 alone, savings in drug spend due to biosimilar competition were estimated at $3.2 billion. As these products compete for market share, the average sales price (ASP) of biologics (both reference products and biosimilars) is declining. The prices of biosimilars have decreased at a negative compound annual growth rate (CAGR) of -9% to -24%; the prices of most reference products have decreased at a negative CAGR of -4% to -21%. 8 [5]

Despite these successes, the MFP statute threatens to undermine this market. Rather than providing clarity with its draft guidance, CMS has created more uncertainty. It is particularly concerning that CMS issued final policy for Sec. 30 without any opportunity for stakeholders to comment on the "pause" ("Special Rule") provisions which will have a major impact on the biosimilars sector. In addition, it imposes a new, subjective standard of "bona fide" marketing of a biosimilar before a reference product may be removed from the selected drug list in Sec. 70 of the guidance.

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[1] *"Europe negotiates a poor vaccine rollout"; Forbes, April 2021*
[2] *IQVIA Analytics, FDA, EMA, PMDA, and TGA data. New active substances approved by at least one of these regulatory agencies and first launched in any country from January 1, 2011 to December 31, 2019; June 2020.*
[3] "*Democrat plan on drug costs will stifle innovation", San Antonio Express-News, May 12, 2021*
[4] *IQVIA Analytics, FDA, EMA, PMDA, TGA, &w3 Health Canada data, April 2021.*
[5] *2022 Biosimilar Trends Report, Amgen*

D. Limitations on Stakeholder Input

Implementation of the Medicare Drug Price Negotiation Program will not follow typical timelines as in the case of other major health care legislation. Under the Inflation Reduction Act (IRA), CMS will implement policy changes via 'program instruction or other forms of program guidance' rather than traditional notice-and-comment rulemaking.

CMS has required stakeholders to submit comments on the guidance within 30 days of the March 15, 2023 memorandum (by April 14, 2023); the notice-and-comment period of the Administrative Procedure Act or the Medicare Act is typically longer for complex legislation. ASBM believes that the shortened comment period limits the ability of patients and other stakeholders to provide meaningful input on the guidance. Furthermore, CMS is only seeking input on select portions of the guidance and is not soliciting comments on provisions that are considered 'final.' ASBM believes that some of these 'final' provisions, such as those related to selection of drugs for price setting and biosimilars are key issues upon which stakeholders deserve an opportunity to comment. For example, Congress has specified that drugs must reach a certain age (9 or 13 years post-launch) before they are subject to maximum fair price (MFP) setting. CMS has finalized (without accepting comments) a policy that will include innovative drugs that have not yet reached the requirements for time on market that are outlined in the IRA.

E. Process Pitfalls

Stakeholders will have limited visibility on how CMS negotiates the MFPs for selected medicines. As outlined in the guidance, the only point of engagement for patients and physicians is via an information collection request (ICR)—a process typically used for technical data collection under the Paperwork Reduction Act.

MFP price setting will be based on therapeutic reference pricing. This standard often fails to consider patient subgroups and preferences, as many alternative therapies do not fit within broad judgments of clinical similarity. In addition, referencing price reporting metrics used by other government agencies (eg, the US Department of Veterans Affairs) are inappropriate benchmarks for care delivered in a community setting, as these procurement prices are intended for special populations receiving care in closed health care delivery systems.

Furthermore, CMS proposes a narrow definition of 'unmet' need when setting prices, including only diseases for which there are limited or no treatment options. ASBM believes that defining unmet need in this way will devalue medicines that address important patient needs and will reinforce, rather than reduce, expected harm to progress against unmet need.

F. Impact of CMS Guidance on Innovation

ASBM believes that CMS' guidance negatively impacts continued innovation by setting rules that will devalue existing patents or exclusivities for selected drugs. Specifically, the Agency intends to consider the length of the available patents and exclusivities and may consider adjusting the preliminary price downward if the patents and exclusivities will last for a number of years. This policy could penalize companies for having secured

patent rights prior to FDA approval (particularly for small molecules) but would be especially damaging for post-approval research and development (R&D).

The R&D that happens after initial FDA approval, including costly and labor-intensive clinical trials, results in innovations that improve patients' lives. Post-approval research is vital, particularly for disease areas like cancer. More than 60% of oncology medicines approved a decade ago went on to receive additional approvals—70% of which occurred seven or more years after initial approval and required significant investment in research and development on the part of the manufacturer. These new uses can provide treatment options for different diseases or patient populations (e.g., pediatric populations). With the policies defined in the IRA guidance, manufacturers will have to reconsider whether post-approval research is feasible in terms of time and resources. They must also consider the impact of a lower MFP if they have obtained patents or exclusivities for these post-approval indications.

ASBM believes that the CMS guidance increases uncertainty for the future of the emerging biosimilars market. Biosimilars play an important role in bringing lower-cost therapies to patients and have provided $21 billion in savings over the last six years. While Congress enacted a 'Special Rule' enabling certain biosimilar manufacturers to request a delay in the selection and price setting for certain reference biological products, the timelines and criteria imposed to obtain this 'pause' may offer insufficient predictability for biologic and biosimilar manufacturers in the marketplace.

CMS' guidance states that the biosimilar delay will not be available when patent litigation between the biosimilar and reference product manufacturers is ongoing, even if there is a high likelihood that a biosimilar will be approved and marketed under the required timeframes. For example, there may be a settlement for certain dosage forms or strengths, or a biosimilar may elect to market at risk. Nevertheless, CMS would find active litigation 'determinative' that a delay should not be granted.

The MFP initial guidance also does not adequately describe how CMS will protect continued R&D of medicines that help reduce barriers to care for medically underserved communities or meaningfully engage those communities in its decision-making.

ASBM believes that CMS' determination of price for selected drugs may disincentivize innovation in areas that help improve equitable access to care, including for small molecule medicines. A 30-day window to submit data on a selected drug (including whether it meets an unmet need) may not be sufficient to obtain the perspectives of underserved communities with fewer resources. Consequently, this would lead to the inclusion of skewed evidence that does not reflect inputs from diverse and underrepresented groups, such as value assessments conducted by the Institute for Clinical and Economic Review.

G. Implications for Patient Access

While the Part D redesign will help patients by establishing a cap on out-of-pocket spending, government price setting under the IRA could significantly impact patients' access to medicines in Medicare Part D. Specifically, price setting for one selected drug could impact other therapeutic competitors in the same class of medicines. In some cases, Part D plans could force patients to switch from medicines that they have been stable on for months or years. Numerous studies have found that switching stable

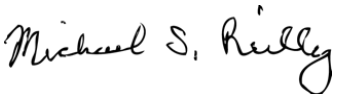
patients to a new medicine for non-clinical reasons leads to increased side effects and non-adherence and is often associated with negative health outcomes.

ASBM fears that the downstream effects of broad government price setting will ultimately reduce consumers' choice of plans and formularies in Part D—aspects considered to be hallmarks of the program. As more medicines are subject to MFP over time, the factors that differentiate plans from one another will likely decrease, leading to fewer choices for patients.

In summary, ASBM advocates for policies that ensure the affordability and accessibility of medications and actively promote the paramount importance of patient safety. We believe that government policies that impact patient safety and access to medicines should be transparent, value the input of stakeholders, and incentivize innovation.

ASBM thanks you for the opportunity to provide comments.

Sincerely,



Michael S. Reilly, Esq.
Executive Director
Alliance for Safe Biologic Medicines

ASBM Steering Committee Members:

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