Biotechnology Innovation Organization
1201 New York Ave., NW
Suite 1300
Washington, DC 20005
202-962-9200

June 27, 2024

The Honorable Chiquita Brooks-LaSure Administrator
Centers for Medicare & Medicaid Services Department of Health and Human Services
Baltimore, MD 21244–1850

RE: Small Biotech Exception and Biosimilar Delay Information Collection Request (ICR) Form for Initial Price Applicability Year (IPAY) 2027 (CMS-10844, OMB 0938-1443)

Dear Administrator Brooks-LaSure:

The Biotechnology Innovation Organization (BIO) appreciates the opportunity to comment on the Small Biotech Exception and Biosimilar Delay Information Collection Request (ICR) for Initial Price Applicability Year (IPAY) 2027 (CMS-10844, OMB 0938-1443) issued by the Centers for Medicare & Medicaid Services (CMS).

BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and in more than 30 other nations. BIO's members develop medical products and technologies to treat patients afflicted with serious diseases, to delay the onset of these diseases, or prevent them in the first place. As a result, our members' novel therapeutics, vaccines, and diagnostics not only have improved health outcomes but also have reduced healthcare expenditures due to fewer physician office visits, hospitalizations, and surgical interventions. BIO membership includes biologics and vaccine manufacturers and developers that have worked closely with stakeholders across the spectrum, including the public health and patient advocacy communities, to support policies that help ensure access to innovative and life-saving medicines and vaccines for all individuals.

Small Biotech Exception

Small biotech manufacturers are at the forefront of America's innovation ecosystem. At BIO, we represent hundreds of biopharmaceutical manufacturers, with the vast majority of our members being small manufacturers who are working on some of the most

important and cutting-edge scientific and medical research. Emerging biotech manufacturers are exceptionally productive, taking into account their lower market capitalization, and are responsible for nearly 80 percent of clinical drugs in the pipeline. Many of these companies have yet to achieve a revenue stream and rely on private capital and outside investment to fund their clinical trials and research. Ensuring that these manufacturers benefit from the small biotech provisions in the Inflation Reduction Act (IRA) is critical as America seeks to maintain its global competitiveness in this strategically important growth sector. Even more important is ensuring that these small manufacturers have the policy and regulatory environment they need to bring the next generation of medicines to the patients whose lives can be transformed by breakthroughs in new treatments and therapies.

Importantly, the Small Biotech Exception recognizes that small biotech manufacturers with a single product that represents most of their Medicare revenue would be disproportionately impacted by Medicare "negotiation," which could have an immediate and tangible impact on the ability of such manufacturers to invest in future R&D – and in areas that predominantly affect the Medicare population. Our specific recommendations follow.

Dispute Resolution Process and Notice of Qualification. We continue to urge CMS to establish a dispute resolution process in implementing the small biotech exception, whereby the manufacturer should have the opportunity to respond to and appeal a negative determination by CMS. A robust dispute resolution process is necessary to provide critical protections for small biotech manufacturers against potentially arbitrary or inconsistent decisions.

We also recommend that CMS initiate the small biotech exception ICR process earlier in the year to allow sufficient time for a dispute resolution process to conclude prior to the February 1, 2025, deadline for CMS to select drugs for negotiation. Per the Draft Guidance for IPAY 2027, small biotech exception eligibility determinations are rendered after publication of the selected drug list. Initiating the small biotech exception process earlier would allow sufficient time for a robust dispute resolution process. And we note that such an approach would be consistent with the flexibilities afforded under the revised Part D Manufacturer Discount Program, where CMS provided an opportunity for manufacturers to obtain a preliminary determination regarding their eligibility for phased-in discounts as a specified manufacturer or small specified manufacturer.

Clear Definition of Acquired. As BIO has recommended in previous years, CMS should include a definition for what it means to be "acquired" pursuant to Sec. 1192(d)(2)(B)(ii). CMS should consider defining an acquisition as the transfer of substantially all assets of the manufacturer. Further, CMS should specify whether the acquiring manufacturer meeting the definition of a specified manufacturer will be determined at the time of acquisition.

Biosimilar Delay

High Likelihood Determination. BIO strongly believes that biosimilar manufacturers should be granted a meaningful opportunity to request a delay in the selection of a reference product for negotiation. As BIO has stated in previous comments, it is critical that the "high likelihood" determination is accurate and relies on all of the most recent available information that bears on the likelihood of market entry within the requisite time period. To that end, BIO requests that CMS consider the following criteria in determining that there is a high likelihood that a biosimilar will be licensed and marketed before February 1, 2027:

- One or more court or patent office decisions establishing the invalidity, unenforceability, or non-infringement of any potentially applicable unexpired patent; *or*
- A legal agreement that permits the biosimilar manufacturer to market the biosimilar; *or*
- A biosimilar manufacturer certifies that, to the best of its knowledge, there are no valid patents that will be infringed upon once the biosimilar is launched.

Addition of Questions to ICR. Following on the comments above, we recommend that CMS add questions to the ICR that ask for the submission of patent office decisions and that ask the manufacturer to certify, to the best of its knowledge, that no valid patents would be infringed upon once the biosimilar is launched.

In addition, we request that an intent to submit a BLA be added to the list of questions regarding whether a biosimilar will be "licensed" by Feb. 1, 2027, in support of the determination of whether a drug is likely to come on the market within two years of what would otherwise have been the reference biological product's selection date. Finally, we request that CMS include a question allowing manufacturers to write an additional

narrative or submit additional information related to the high likelihood determination if the manufacturer deems that such information may support these determinations.

Thank you for your consideration of these comments. We look forward to ongoing dialogue with you on these important issues.

Sincerely,

/s/

Crystal Kuntz
Senior Vice President, Healthcare Policy & Research