Biocom California

April 14, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Medicare Drug Price Negotiation Program: Initial Memorandum, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026, and Solicitation of Comments

Submitted electronically

Dear Administrator:

Biocom California appreciates the opportunity to offer comments on the initial guidance issued by the Centers for Medicare and Medicaid Services (CMS) for the implementation of the Medicare Drug Price Negotiation Program ("Negotiation Program")[1].

Biocom California 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 1,700 members dedicated to improving health and quality of life, Biocom California drives public policy initiatives to positively influence the state's life science community in the research, development, and delivery of innovative products. California's life sciences industry generates over $375 billion in annual economic activity, supports 435,000 jobs, and increases labor income by $115 billion per year[2].

While Biocom California supports the Inflation Reduction Act's (IRA) establishment of a $2,000 cap on out-of-pocket patient spending and the restructuring of the Medicare Part D benefit program, we have continuously raised strong concerns about the Medicare Negotiation provisions which will have a devastating impact on current and future biotechnology innovation. We believe that the IRA does not balance promoting patient affordability and the role of the biomedical community in bringing innovative medicines to market. As the advocate for California's life science sector, we understand the importance for stakeholders to inform and guide the establishment of the Negotiation Program and we offer our comments below:

[1] Federal Register, 87 FR 30963, pp. 30963-30966, May 20, 2022.
[2] Biocom California 2022 Economic Impact Report Databook. https://www.biocom.org/eir/

Biocom California is disappointed by the agency's decision not to accept comments on Section 30, *Identification of Selected Drugs for Initial Price Applicability Year 2026*. We believe stakeholders should have the opportunity to provide feedback on all aspects of this program. This initial approach to developing the framework sets an unfavorable precedent of limited communication and a lack of transparency between CMS and stakeholders. **We encourage the agency to consider comments on all sections of this initial guidance in order to prioritize transparency and engagement with stakeholders. We respectfully submit the following comments on Section 30 and request consideration:**

Identification of Qualifying Single Source Part D Drugs for Initial Price Applicability Year 2026

The guidance states that CMS will identify a potential qualifying single source drug by "all dosage forms and strengths of the drug with the same active moiety and the same holder of a New Drug Application (NDA), inclusive of products that are marketed pursuant to different NDAs." For biological products, CMS will consider "all dosage forms and strengths of the biological product with the same active ingredient and the same holder of a Biologics License Application (BLA) inclusive of products that are marketed pursuant to different BLAs."

Biocom California disagrees with CMS's approach to identifying a qualifying single source drug and its dosage forms and strengths by its common active moiety and common active ingredient for drugs and biologics, respectively. Instead, we suggest that CMS identify drugs and their dosage forms and strengths by referencing an NDA or BLA. The Food and Drug Administration's (FDA) application-based framework should act as a reference and be adopted such that a product approved or licensed under a new NDA or BLA (as opposed to a product approved or licensed under a supplement to an existing NDA or BLA) is a distinct qualifying single source drug. Utilizing this framework to distinguish products would be consistent with industry practice and incentivize innovation; unlike CMS's current definition of a "qualifying single source drug" which combines drug products by common active moiety and biological products by common active ingredient. Furthermore, utilizing FDA's application-based framework would enable CMS to more easily identify relevant dosage forms and strengths when aggregating Medicare expenditures and this would allow manufacturers to track the seven- or eleven-year "qualifying single source drug" clock more readily.

Orphan Drug Exclusion from Qualifying Single Source Drugs

In section 30.1.1, CMS explains that certain orphan drugs will be excluded when identifying qualifying single source drugs: "CMS will exclude a drug or biological product that is designated as a drug for only one rare disease or condition under section 526 of the [Food, Drug, and Cosmetics] FD&C Act and that is approved for only an indication (or indications) for such disease or condition." The limited scope of the orphan drug exclusion risks disincentivizing orphan drug research and development (R&D) and will impact a manufacturer's decision to continue follow-on R&D to expand a drug's indications to include additional rare diseases. The initial guidance also states, "CMS is considering whether there are additional actions CMS can take in its implementation of the Negotiation Program to best support orphan drug development." **Biocom California urges CMS to consider ways to expand the orphan drug exclusion to allow orphan drugs and biological products with multiple rare disease indications to qualify for the exclusion**. By expanding the scope of orphan drug exclusion, CMS would continue to support and incentivize the development of orphan drugs and rare disease R&D.

Additionally, in situations where an approved indication falls within the scope of an orphan drug designation but there is no corresponding orphan exclusivity, CMS cannot rely on FDA's databases as they track orphan exclusivity, rather than a designation, to determine eligibility for orphan drug exclusion. **Biocom California suggests that CMS establish a process that enables manufacturers to submit evidence demonstrating that an indication falls within an orphan drug designation in situations where the agency is unable to determine eligibility for the exclusion based on FDA's databases.** We encourage CMS to establish this process in a timely manner so that manufacturers can gather evidence supporting eligibility for the orphan drug exclusion in advance of the first selected drug publication date.

Furthermore, under FDA regulations, a manufacturer may voluntarily withdraw a requested or granted orphan drug designation at any time and the withdrawal is publicized. **We ask CMS to clarify that, when determining eligibility for the orphan drug exclusion, the eligibility will be based on orphan drug designation *at the time of selection* and will not reference any prior designation that has been withdrawn.** This practice would continue to protect the scope of orphan drugs eligible for the exclusion.

Lastly, Biocom California asks CMS to clarify that, where an orphan drug loses eligibility for the orphan drug exclusion, the seven- or eleven-year "qualified single source drug" clock runs from *the date on which the drug lost eligibility for the exclusion*. An orphan drug that loses eligibility for the orphan drug exclusion due to an expansion of indications for a second rare disease could be immediately eligible for negotiations. **This would further disincentivize drug developers from investing in rare disease R&D and we ask CMS to clarify these details in order to mitigate the risk that the Negotiation Program will deter necessary orphan drug development.**

<u>Exception for Small Biotech Drugs</u>

Per the IRA, a drug is exempt from negotiation for initial price applicability years 2026, 2027, and 2028 if the drug meets the exception for small biotech drugs ("Small Biotech Exception"). For initial price applicability year 2026, wherein only Part D drugs will be selected for negotiation, this exception requires that in 2021, "the Total Expenditures under Part D for the qualifying single source drug (1) were equal to or less than one percent of the Total Expenditures under Part D for all covered Part D drugs; and (2) were equal to at least 80 percent of the Total Expenditures under Part D for all covered Part D drugs for which the manufacturer of the drug had a [Coverage Gap Discount Program] CGDP agreement in effect during 2021."

The Small Biotech Exception is a critical protection that recognizes the need for small biotech drugs to be exempt from negotiation. Therefore, Biocom California asks CMS to make the Small Biotech Exception permanent and to release transparent and predictable guidance that assists small biotech companies in applying for the exception. CMS has indicated that the current Small Biotech Exception information collection request (ICR) is focused only on initial price applicability in the year 2026 and the agency has not publicly announced which 2021 total expenditure data it will utilize to determine eligibility for the exception. **Without this information, it is challenging for small biotech manufacturers to determine whether a submission will be needed in the current or future years, and we suggest that CMS clearly state the specific criteria manufacturers should reference when determining whether to apply for the Small Biotech Exception. For initial price applicability year 2026, we recommend that manufacturers who believe they qualify for the Small Biotech Exception should apply and be approved for this exception this year regardless of whether the drug meets the test of a high spend drug under Sec. 1192 (d)(1)[3].** This will benefit small biotech manufacturers who have a limited number of products on the market.

[3] Social Security Act § 1192(d)(1)

Section 30.2.1 of the guidance states: "To receive consideration for the Small Biotech Exception for initial price applicability year 2026, the Submitting Manufacturer must submit the Small Biotech Exception Information Collection Request Form using the CMS Health Plan Management System (HPMS) by the deadline established by CMS; CMS anticipates that this deadline will be in June 2023 but will publish a specific deadline on the CMS IRA website in the future. This due date will be in advance of the date on which CMS is required to publish the list of selected drugs for initial price applicability year 2026 and will allow sufficient time for CMS to consider whether the qualifying single source drug qualifies for the Small Biotech Exception."

Biocom California appreciates the agency's transparency in providing an anticipated date for the deadline to submit for the Small Biotech Exception. **We ask that CMS publish the specific June 2023 deadline date on the IRA website as soon as possible so manufacturers can have adequate notice of the ICR form submission date and can plan their efforts accordingly. Additionally, we ask CMS to clearly specify the review and response timelines (in situations where the agency does and does not grant the exception) for submitting manufacturers as far in advance of September 1, 2023, as possible.** If a negative determination is granted, CMS's response should include 1) a rationale in sufficient detail explaining how the determination was made and 2) information regarding which expenditure data was referenced that led to a negative determination.

We also encourage the agency to develop a dispute resolution process that enables manufacturers to respond to and appeal a negative determination. As part of this process, CMS should engage in a dialogue and small biotech companies should have the opportunity to provide additional data to support their application for the exception before CMS provides a final determination. **If a manufacturer has previously received the Small Biotech Exception and there has been no significant change in the manufacturer's circumstances, Biocom California asks that manufacturers need not reapply for the Small Biotech Exception in subsequent years and, instead, inform CMS annually that no changes have occurred.**

Lastly, Biocom California would like to underscore the importance of maintaining the confidentiality of proprietary information; especially when submitted as part of the Small Biotech Exception ICR. **We ask that CMS provide more specific information regarding its approach for publicly sharing which small biotech drugs qualify for the exception. In order to promote transparency and consistency, we recommend the agency publish a summary list of the small biotech drugs and manufacturers that qualify each year.** Any additional information detailing how or why a specific manufacturer's drug qualified should only be released with the manufacturer's consent as this will ensure proprietary information remains protected.

Requirements for Manufacturers of Selected Drugs for Initial Price Applicability Year 2026

In section 40.1, CMS states that it "will make reasonable efforts to make the final text of the Agreement available to the public before the selected drug list for initial price applicability year 2026 is published." **Biocom California requests that CMS publicly release and provide an opportunity to comment on the text of the Negotiation Program Agreement as soon as possible, and well in advance of September 1, 2023, when CMS publishes the selected drug list.** It is imperative that manufacturers have an adequate opportunity to review the agreement and understand their specific obligations since they are subject to civil monetary penalties (CMPs) if in violation of the agreement's terms. Furthermore, advanced notice of the agreement is necessary for manufacturers to establish new processes in order to comply with the terms of the agreement.

Confidentiality of Proprietary Information

In section 40.2.1, CMS explains that it "intends to implement a confidentiality policy that is consistent with existing requirements for protecting proprietary information, such as Exemption 4 of [the Freedom of Information Act] FOIA." The guidance states that R&D costs and recoupment, unit costs of production and distribution, pending patent applications, market data, revenue and sales volume data will be considered proprietary. Conversely, data on prior Federal funding, approved patent applications, exclusivities, and FDA applications and approvals will be considered non-proprietary since this data is publicly available. **Biocom California acknowledges and agrees with the information that will be considered proprietary versus non-proprietary. However, we believe there is a need for CMS to further explain how it intends to protect a manufacturer's confidential information and establish more robust safeguards to ensure that the agency is adequately handling proprietary information submitted as part of the negotiation process. We suggest that CMS focus on developing data privacy and security protection protocols that include robust storage and controls that limit access to confidential information to CMS staff on a "need-to-know" basis.**

Furthermore, the initial guidance outlines that "CMS is required to publish the explanation for the MFP [maximum fair price] by March 1, 2025, for initial price applicability year 2026 (see section 60.6.1 of this memorandum). In this public explanation and any other public documents discussing the MFP, CMS intends to make high-level comments about the data submitted to CMS, without sharing any proprietary information reported to CMS under section 1193(a)(4) for purposes of the negotiation." **Biocom California appreciates CMS's discretion and intention to only make high-level comments regarding the submitted data. However, the possibility of inadvertently disclosing confidential information is possible. In order to avoid such a disclosure, we suggest CMS allow manufacturers the opportunity to review a draft explanation of the MFP prior to its publication and dispute any confidentiality concerns. This will ensure that manufacturers are comfortable with the information disclosed and no proprietary information is inadvertently released.**

In section 40.2.2, the Primary Manufacturer is barred from disclosing "any information in the initial offer or any subsequent offer by CMS, the ceiling price contained in any offer, or any information contained in any concise justification provided with an offer," as well as "any information exchanged verbally during the negotiation period." CMS also proposes to require that manufacturers destroy information if the drug or biologic no longer qualifies as a selected drug. However, Congress, through the IRA, did not authorize CMS to impose these mandatory non-disclosure and information-destruction provisions. These provisions violate manufacturers' rights to free speech and are not necessary to administer or monitor compliance with the Negotiation Program. Moreover, this practice would put manufacturers at an unnecessary disadvantage that hinders the program's administration, efficiency, and consistency. **In order to facilitate a fair and transparent negotiation process, we ask CMS to remove the non-disclosure and information-destruction provisions.**

Providing Access to the MFP

In section 40.4, CMS details the ways in which a Primary Manufacturer may provide access to the MFP by either "(1) ensuring that the price paid by the dispensing entity when acquiring the drug is no greater than the MFP; or (2) providing retrospective reimbursement for the difference between the dispensing entity's acquisition cost and the MFP" within 14 days. **Biocom California supports CMS's proposed MFP rebate approach and appreciates the agency's flexibility for manufacturers. In order to facilitate access to the MFP, we ask that CMS make available the necessary datasets for manufacturers to ensure that the MFP discount is being provided on an MFP-eligible product to an MFP-eligible patient.**

Additionally, the initial guidance does not specify when the 14-day retrospective reimbursement timeframe begins, and **we ask CMS to confirm that the proposed 14-day period begins on the date on which the manufacturer has validated the eligibility of an MFP-eligible individual. We also urge the agency to lengthen this timeframe and seek additional stakeholder input to determine a more appropriate timeline. Given the new processes that still need to be developed as part of the Negotiation Program, we ask CMS for maximum flexibility to ensure program compliance.**

Manufacturer Specific Data

Section 50.1 of the initial guidance outlines the selected drug data requirements to be reported by the Primary Manufacturer to CMS by October 2, 2023. These elements include 1) "research and development costs of the Primary Manufacturer…and the extent to which the Primary Manufacturer has recouped those costs;" 2) "current unit costs of production and distribution…averaged across the Primary Manufacturer and any Secondary Manufacturer(s);" 3) "prior Federal financial support for novel therapeutic discovery and development with respect to the selected drug;" 4) "data on pending and approved patent applications, exclusivities recognized by the FDA, and applications and approvals under section 505(c) of the FD&C Act or section 351(a) of the PHS Act;" and 5) "market data and revenue and sales volume data for the selected drug in the United States for the Primary Manufacturer and any Secondary Manufacturer(s) (with the exception of costs related to the acquisition of the selected drug, which would be reported only for the Primary Manufacturer)."

While we appreciate CMS outlining the exact manufacturer-specific data required, it is unclear what the agency's expectations are regarding data quality and how it intends to assess these factors without standardizing each element. For example, R&D costs related to the selected drug may have been incurred via disease-specific research programs that evaluated multiple drugs with varying indications. It would be difficult for a manufacturer to calculate the exact R&D costs for a selected drug that was part of a larger disease research program. **In an effort to provide clear data that aligns with the relevant information CMS requires, we suggest that the agency allow manufacturers to 1) submit the information which they believe is most relevant and aligns with these required elements and 2) provide a justification for the manufacturer-specific data they submitted.**

Moreover, we urge CMS to reconsider its proposal that if the selected drug has patents and exclusivities that will last for several years, CMS may consider adjusting the preliminary price downward. This proposal, which the agency did not provide a rationale for, will likely discourage innovation by penalizing innovators from obtaining patents. Additionally, the proposal fails to consider a key value of the patent right as a patent is a quid pro quo situation. In exchange for the right to exclude for a limited period of time, the inventor must fully disclose their invention such that the public can benefit from it and expand on it. Therefore, a patented product creates an economic value derived from its improved technological features and social value through its public disclosure. **We recommend CMS consider the value associated with a patented product and urge the agency not to use patent coverage as a downward adjustment factor.** Further, the CMS proposal may be inconsistent with the United States' obligation under the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement[4]. Specifically, Article 30 of the TRIPS agreement requires that each member state "not unreasonably conflict with a normal exploitation of the patent and … not unreasonably prejudice the legitimate interests of the patent owner." Adjusting a price downward in view of patent coverage appears to be inconsistent with this TRIPS requirement.

[4] Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994)

Lastly, Biocom California also asks CMS to clarify how it intends to consider pending patent applications as a negotiation factor when determining a preliminary price. We discourage the agency from utilizing pending applications as a factor to downward-adjust prices since these may not always mature into a full patent and do not guarantee protection for the product.

Evidence about Clinical Benefit for the Selected Drug

As noted in section 50.2, CMS will "consider evidence about alternative treatments to the selected drug, as available, including:

1. The extent to which the selected drug represents a therapeutic advance compared to existing therapeutic alternatives for the selected drug and the costs of such existing therapeutic alternatives;
2. FDA-approved prescribing information for the selected drug and its therapeutic alternatives;
3. Comparative effectiveness of the selected drug and its therapeutic alternatives, including the effects of the selected drug and its therapeutic alternatives on specific populations (including individuals with disabilities, the elderly, the terminally ill, children, and other patient populations, herein referred to as "specific populations"); and
4. The extent to which the selected drug and the therapeutic alternatives to the drug address unmet medical needs for a condition for which treatment or diagnosis is not addressed adequately by available therapy."

Additionally, CMS will not use "evidence from comparative clinical effectiveness research in a manner that treats extending the life of an elderly, disabled, or terminally ill individual as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill" and certain uses of quality-adjusted life-years (QALYs) will not be used in the negotiation process. Furthermore, in section 60.3 *Methodology for Developing an Initial Offer*, when developing a starting point for the initial offer, CMS proposes to utilize the net price for identified therapeutic alternatives and, after the review of the clinical evidence, adjust this price to develop a "preliminary price." At this point, CMS will then consider the manufacturer-specific data to adjust the preliminary price upward or downward. When there is no therapeutic alternative CMS would adjust the starting point based on how the selected drug fills an unmet medical need.

Biocom California supports CMS's proposed approach of prioritizing a selected drug's therapeutic benefit and negotiation factors related to therapeutic alternatives, comparative effectiveness, and unmet need. Ensuring such evidence is appropriately weighted in the MFP will more appropriately reward products that have enhanced patient care and will help maintain the investment in promising R&D and clinical programs. **Since CMS proposes to adjust the starting point for the initial offer based on its review of clinical benefit evidence, Biocom California encourages an approach that places a greater emphasis on a range of high-quality robust evidence, including real-world evidence (RWE), and prioritizes information submitted by manufacturers with expertise in their therapeutic areas. We suggest the agency provide additional clarifying information about how it will evaluate alternative treatment evidence from different stakeholders and how that data will be considered when determining the MFP.** Lastly, in order to promote a transparent negotiation process, we ask CMS to provide manufacturers with details regarding the agency's evaluation of evidence related to therapeutic alternatives and discuss this analysis with manufacturers before CMS's initial offer in February 2024.

Negotiation Process

In section 60, CMS outlines the methodology and negotiation process that it intends to use to "achieve the lowest maximum fair price for each selected drug." After the written initial offer from CMS is presented to the Primary Manufacturer, the negotiation process would begin as described in section 60.4 of the initial guidance. As part of this process, the Primary Manufacturer may provide an optional written counteroffer (if CMS' written initial offer is not accepted) that must be submitted no later than 30 days after the date of receipt of the written initial offer. CMS may then provide a written response to the optional written counteroffer and, if the Primary Manufacturer's counteroffer is not accepted by the agency, up to three possible in-person or virtual negotiation meetings may take place. At the conclusion of these meetings between the Primary Manufacturer and CMS, the agency will provide a final written offer to the manufacturer, and they must either accept or reject this final offer before the end of the negotiation period.

Biocom California encourages an open and transparent dialogue between CMS and the Primary Manufacturer when determining the MFP. As part of the Negotiation Process, we believe CMS should begin at the MFP ceiling price instead of negotiating upwards from the lowest MFP. We also suggest the agency consider circumstances when drugs should be priced as close as possible to the MFP ceiling in order to avoid imperiling patient access. Additionally, to facilitate a transparent negotiation process, we ask CMS to provide 1) a meaningful justification of its initial offer, 2) its response to any counteroffer, and 3) afford the manufacturer a legitimate opportunity to comment on the response before the MFP is set. As part of this justification, we would ask the agency to provide a rationale as to how it arrived at the offer or response, including an explanation of how the decision is supported by the negotiation factors, how those factors were considered and weighted, and any additional information that was utilized as a part of the decision. Disclosing the basis of an offer or response would promote a robust and effective dialogue that informs more targeted discussions during the negotiation process.

Lastly, the initial guidance specifies that, only in the case where CMS rejects a counteroffer, the agency will extend an invitation for a negotiation meeting within 30 days of receipt of the counteroffer. **Biocom California asks that the agency fulfill its commitment to responding to counteroffers within 30 days and allow the Primary Manufacturer at least 30 days to comment on CMS's response before the MFP is set.** These actions would further support a consistent and transparent negotiation process and prevent the MFP from being finalized based on an error or lack of information.

Removal from the Selected Drug List Before or During Negotiation, or After an MFP is in Effect

In section 70, CMS explains that a drug will be removed from the selected drug list and no longer subject to the negotiation process when the agency determines that "(1) the FDA has approved a generic drug under section 505(j) of the FD&C Act that identifies as its reference listed drug a product that is included in the selected drug, or the FDA has licensed a biosimilar biological product under section 351(k) of the PHS Act that identifies as its reference product a product that is included in the selected drug; and, (2) the generic drug or biosimilar biological product, as applicable, is marketed pursuant to such approval or licensure." CMS intends to review prescription drug event (PDE) data to determine whether a generic drug or biosimilar biological product is approved and marketed. The agency will consider a generic or biosimilar to be marketed when PDE data reveals that the manufacturer has engaged in bona fide marketing of that drug or product.

Biocom California disagrees with the agency's use of "bona fide marketing" as this is a subjective assessment of "robust and meaningful competition" and the initial guidance lacks objective, clear criteria defining this standard. We suggest CMS abandon "bona fide marketing" and, instead, consider a product's market date as the date on which a generic or biosimilar is marketed and the date on which CMS *determines* that a generic or biosimilar has been marketed.

Per CMS's Medicaid Drug Rebate Program (MDRP) Data, "market date" is defined as "the earliest date the drug was first marketed under the application number by any labeler[5]." The MDRP "market date" is a familiar term for both CMS and manufacturers and would allow for a consistent application and less burdensome adoption of this standard as part of the Negotiation Program.

Furthermore, the use of PDE data raises timing concerns as there will be a delay between the actual date of marketing and the date of CMS's determination that a product has been marketed since some time is required for sales to be reflected in this data. Furthermore, when a new product is available and actively marketed, it takes time for the widespread adoption of the product by providers and for patients to transition to the generic or biosimilar. During this uptake period, this information will not be immediately reflected in the PDE data once a generic or biosimilar is on the market.

Manufacturer Compliance and Oversight

In section 90.2, *Monitoring of Access to the MFP*, the initial guidance explains that "CMS intends to require that the Primary Manufacturer establish safeguards to ensure the MFP is available to MFP-eligible individuals and to pharmacies, mail order services, and other dispensers on units of the selected drug for which there are Secondary Manufacturers, as described in section 40.4 of this memorandum." Additionally, CMS explains that "each component of the pharmaceutical supply chain may have a role in making the MFP available to MFP-eligible individuals, but it is ultimately the Primary Manufacturer's responsibility to ensure access to the MFP."

Biocom California is concerned with the large responsibility placed on the Primary Manufacturer to ensure that entities across the entire supply chain have made the MFP available to MFP-eligible individuals. When there are multiple Secondary Manufacturers involved such as repackers and relabelers, it is unrealistic to hold the Primary Manufacturer solely responsible for the compliance of these entities. Furthermore, Primary Manufacturers do not have visibility into a Secondary Manufacturer's information, thus making this policy nearly impossible to comply with. The initial guidance explains that a manufacturer who does not comply with certain Negotiation Program deadlines and requirements could be subject to excise tax liability or CMPs. **We do not believe that Primary Manufacturers should be penalized due to a lack of data access and business practices that they cannot enforce. We strongly suggest that CMS not hold a Primary Manufacturer responsible for ensuring the compliance of Secondary Manufacturers and, instead, Secondary Manufacturers should be held responsible and subject to CMPs themselves if they do not provide access to the MFP. Lastly, we ask CMS to require other stakeholders (i.e., providers, health plans, etc.) to make data available so that manufacturers can comply with the MFP effectuation.**

[5] CMS, MDRP Data Guide § 5.15 (Apr. 2022).

We appreciate the opportunity to provide feedback on behalf of our members and thank you for your time and diligence in examining our comments. Please contact Biocom California's Associate Manager of Regulatory Policy, Zoe Bilis, at zbilis@biocom.org for additional information or questions. We look forward to continuing to work with you on this matter.

Sincerely,

Joe Panetta
President and CEO
Biocom California