BIO
BIOTECHNOLOGY
INDUSTRY ORGANIZATION

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BY ELECTRONIC DELIVERY (Notice.comments@irscounsel.treas.gov)

CC:PA:LPD:PR (Notice 2011-9)
Room 5203
Internal Revenue Service
P.O. Box 7604
Ben Franklin Station
Washington, DC 20044

Re: Proposed Guidance Regarding Branded Prescription Drug Fee [Notice 2011-9]

Dear Mr. Commissioner:

The Biotechnology Industry Organization (BIO) is pleased to submit the following comments to the Internal Revenue Service (IRS) on the preliminary guidance in Notice 2011-9 regarding implementation of the new branded prescription drug fee in Section 9008 of the Patient Protection and Affordable Care Act (PPACA). BIO previously submitted comments regarding Notice 2011-9 on April 29, 2011. We hope that these additional comments will aid in the IRS's continuing efforts to implement Section 9008 in a manner that is fair and consistent with the statute.

I. Preliminary Assessment Process

BIO greatly appreciates the IRS's decision to offer manufacturers the opportunity to review the preliminary assessment of each manufacturer's share of the 2011 fee. The preliminary assessment process already has demonstrated utility by providing manufacturers insights into the government program valuation process used by the IRS to determine each manufacturer's preliminary fee amount. Based on that experience, BIO has identified additional recommendations that it believes will further improve the fee calculation process and which BIO urges IRS implement as soon as possible.

A. Greater Data Transparency

BIO urges the IRS to provide additional transparency regarding the sources of data that the IRS has used for this year's calculation and will use in the future to calculate each manufacturer's share of the annual fee going forward. BIO appreciates the challenges the IRS faces in amassing and processing the necessary data to carry out Section 9008's requirements and understands that the agency must gather data from a variety of sources. However, BIO's members face these same challenges as they attempt to verify the data on which the IRS bases its assessment and decide whether a dispute is warranted. The opportunity to file a dispute, while a

welcome addition to the fee assessment process, is meaningless if manufacturers lack access to the underlying data that is necessary to determine whether the preliminary fee amounts are calculated in accordance with the statute. More transparency into the underlying data will provide much needed tools to assist the IRS and manufacturers in ascertaining the amount of the fee that should be assessed to each manufacturer.

Manufacturers cannot conduct a meaningful analysis of the data used to calculate the preliminary assessment without a more specific description of the data used, or not used, to generate those assessments, as well as an opportunity to review those data directly. Without such information and access, manufacturers can only determine whether the amounts derived by the IRS are different from what the manufacturer itself anticipated, based on the manufacturer's own calculations. Where those differences are material, a manufacturer often can only hypothesize as to what the cause of that difference may be. And, even where there are no material differences, absent underlying data, a manufacturer cannot be certain that its accuracy is the result of anything but sheer luck – particularly in these early years of the fee. Such uninformed disputes, which may be the only option for a manufacturer faced with a large discrepancy in program sales amounts, are not an effective or efficient means for identifying and resolving actual errors in or concerns with the underlying data.

We urge the IRS to provide greater detail and availability as to its data sources, and omitted data sources, so that manufacturers can make informed, reasoned decisions regarding whether to dispute the IRS's assessment and thereby avoid disputes that result solely from confusion about which data were used and how the IRS arrived at its preliminary figures. Disputes informed by the actual source data used will be more productive for manufacturers and the IRS alike and will work to ensure the integrity of the fee calculation process. We recommend that IRS do so in the form of a guidance document, with details regarding the data elements, files and methodologies used to construct these values.

B. The Need for a Second Preliminary Assessment

BIO strongly believes that some process must be put in place to provide for a second preliminary assessment to address a number of concerns with the initial fee assessments issued in May. In addition to the lack of data transparency noted above, the May assessments also were calculated using what may be flawed sales valuation methodologies that fail to conform to the statutory requirements. Those methodologies include, but are not limited to:

- Valuation of Medicare Part B sales at ASP plus 5% or 6% (depending on whether the site of service is a hospital outpatient department of physician office, respective) rather than ASP, as specified by statute;
- Valuation of vaccines under the Medicare Part D program at the ingredient cost plus the vaccine administration fee, rather than at ingredient cost alone as specified by statute, in the case of PDE files submitted by plans that inappropriately include the

administration fee in the ingredient cost PDE field (a practice as to which CMS is aware);

- Valuation of Medicaid sales using Average Manufacturer Price (AMP) rather than the per-unit ingredient cost paid to pharmacies outlined in statute, which is particularly problematic where Medicaid is a secondary payer to Medicare Part B as it essentially results in a double-counting of these units under both Medicaid and Medicare Part B;
- Potential inappropriate inclusion of Medicaid managed care organizations utilization because there is no "per unit ingredient cost paid to pharmacies by States;"
- Valuation of sales to the Veterans Administration and Department of Defense that potentially and inappropriately include the Industrial Funding Fee and the Cost Recovery Fee; and
- Other errors and inconsistencies highlighted in our April 29 letter.

In light of these significant issues, which impact both the methodologies and data derived from such methodologies used, as well as the short timeframe available for filing disputes, BIO strongly recommends that the IRS issue a second preliminary assessment to manufacturers. This second preliminary assessment could address the errors and issues raised by manufacturers and provide additional detail on the sources of data that the IRS used in calculating its preliminary assessment. A second assessment would ensure that obvious errors in the data have been corrected before each manufacturer's share of the fee is finalized and becomes due.

In the absence of a second preliminary assessment, BIO suggests that the IRS include in the 2012 preliminary assessment a mechanism for adjusting the fee amount due in that year to reflect the correction of any errors underlying each manufacturer's 2011 finalized fee liability. The IRS already plans to include such an adjustment process to account for a lag in data processing by the Centers for Medicare and Medicaid Services (CMS). A similar adjustment of each manufacturer's 2012 liability would thus seem to be an appropriate means of ensuring that each manufacturer pays its fair share of the fee imposed under Section 9008 for 2011.

C. Stakeholder Meeting with the IRS and Relevant Agencies

To further assist the IRS in administering Section 9008 and to enhance the transparency, efficiency, and accuracy of the fee calculation process, BIO also requests that manufacturers and other stakeholders be given the recurring opportunity to meet with representatives of the IRS and other relevant agencies such as CMS, the Department of Defense, and the Department of Veterans' Affairs. Such a meeting would provide a valuable forum for agency representatives to describe the data and calculation process, as well as for the government and manufacturer representatives to exchange ideas for streamlining and improving the fee calculation process. Simply put, those who are closest to the data from both government and industry certainly would benefit from a meeting to discuss the data and calculation process. BIO encourages the IRS to organize this type of meeting as soon as possible.

D. Preliminary Assessment in Future Years

BIO strongly recommends that the IRS institutionalize the issuance of the preliminary assessment and issue a similar preliminary assessment each year, providing sufficient time for manufacturers to assess whether the data used are accurate and whether a dispute is warranted. Although the process of assessing each manufacturer's share will likely be streamlined in the future as the IRS and manufacturers gain experience with the fee calculation, BIO's members have greatly valued the opportunity to evaluate the IRS's preliminary assessment this year and believe that both manufacturers and the IRS will benefit if manufacturers have the opportunity to do so each year. Once the process has been streamlined and a consistent methodology and data sources are identified, the inputs should remain identical from year-to-year absent new opportunities for notice and comment. This consistency will allow manufacturers to more accurately predict future liabilities for budgeting and forecasting purposes, as well as allow for accurate basis of disputes as discussed previously.

II. Adjustment Process

Section 9008(b)(1) provides that the annual fee is to be based on sales to the specified government programs in the "preceding calendar year." Because of the expected delay in data processing by CMS, the IRS proposes instead to base the annual fee on sales in the second year preceding the year in which the fee is apportioned. Then, "[b]ecause the use of the second preceding year, rather than the immediately preceding year, as the sales year may affect the amount of the fee paid by any particular covered entity, the fee due in every year after 2011 will include an adjustment amount."[1] Under the proposed guidance, this adjustment "is applied only with respect to the amount of the fee otherwise payable by the relevant covered entity in the year in which the adjustment is calculated, and is not a refund, credit, or recalculation of a fee payable by any covered entity in any preceding fee year."[2]

BIO is concerned that the current guidance may require manufacturers to factor the proposed adjustment into their accounting for the year in which it is applied, which will greatly complicate manufacturers' efforts to make a proper accounting of their annual fee liability each year. Treatment of the adjustment amount as a refund or credit would address these concerns. BIO therefore urges the IRS to reconsider its proposed guidance in Notice 2011-9 and proposes the following revised and underscored language be used instead:

- "Because the use of the second preceding year, rather than the immediately preceding year, as the sales year may affect the amount of the fee paid by any particular covered entity, the fee due in every year after 2011 will include an adjustment amount and that adjustment is an obligation of the previous year."

[1] Notice 2011-9, at 4.
[2] *Id.* at 5.

- "The adjustment amount is applied only with respect to the amount of the fee otherwise payable by the relevant covered entity in the year in which the adjustment is calculated, and is considered to be a refund, credit, or recalculation of a fee payable by any covered entity in any preceding fee year."

III. Amendments to Form 8947

In its April 29th letter, BIO requested that the IRS provide additional guidance regarding how manufacturers should amend their submissions on Form 8947. With our members having completed their first round of Form 8947 submissions, we now reiterate our request for guidance on how manufacturers should amend these submissions in future years. If the IRS maintains its proposed compliance schedule for the 2012 fee, the time will greatly increase between filing Form 8947 and receipt of a preliminary assessment. This increase means taxpayers may be more likely to catch correctible errors before the IRS generates a preliminary assessment. A clear process for amending Form 8947 submissions is critical to ensuring that the data manufacturers submit is as accurate as possible, thereby preventing avoidable errors and time-consuming corrections later in the process.

We appreciate this opportunity to submit additional comments regarding Notice 2011-9 and look forward to continued dialogue with the IRS and other relevant agencies on these important issues. Please contact Laurel Todd at (202) 962-9220 if you have any questions regarding our comments. Thank you for your attention to this important matter.

Respectfully submitted,

/s/

Laurel Todd
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