BIO
BIOTECHNOLOGY
INDUSTRY ORGANIZATION

September 30, 2010

Ms. Heather C. Maloy
LMSB Commissioner
Internal Revenue Service
1111 Constitution Avenue, NW
Washington, D.C. 20224

Dear Ms. Maloy,

As President and CEO of the Biotechnology Industry Organization (BIO) and on behalf of our more than 1,100 biotechnology companies, academic institutions, state biotechnology centers and related organizations in all 50 U.S. states, I am writing to express the views of America's biotechnology companies regarding implementation of the biopharmaceutical manufacturers fee (hereinafter "fee") enacted into law as part of comprehensive health reform (Section 9008 of the Patient Protection and Affordable Care Act as amended by the Health Care Education and Reconciliation Act).

Representatives of BIO and our member companies recently met with IRS and Treasury officials to discuss many of the views and concerns expressed in the attachment to this letter. We appreciated the opportunity to share our perspective on an issue of great importance to America's innovative, research-based biotechnology companies and we hope that the views expressed herein will help to inform the IRS and Treasury as you promulgate your formal guidance.

The fee is novel in many respects and, as such, presents a number of technical implementation issues. Given these challenges, we are hopeful that the IRS, Treasury and the specified government agencies will work closely with industry to ensure that the fee is implemented in as fair and transparent a manner as possible.

Please find attached a series of recommendations that we believe will help to accomplish this important goal. We look forward to continuing a dialogue on these implementation issues in the weeks and months to come.

Sincerely,

James C. Greenwood
President and CEO
Biotechnology Industry Organization

cc: Bryon Christensen
Deputy Tax Legislative Counsel
U.S. Department of the Treasury

Douglas Shulman
Commissioner of Internal Revenue
Internal Revenue Service

Michael F. Mundaca
Assistant Secretary of the Treasury for Tax Policy
U.S. Department of the Treasury

I. Scope of Fee and Assessment/Payment Process

A. Orphan Drug Exemption Requires Clarification

Issue: The statutory definition of "branded prescription drug sales" specifically excludes products with respect to which the orphan drug tax credit was "allowed for any taxable year under section 45C of the Internal Revenue Code of 1986." However, it is unclear whether a product is eligible for this exclusion where the credit was allowable for the product under §45C but the credit was not claimed. As you are aware, there are a variety of reasons why a credit would be allowable but not be claimed or allowed, despite the orphan drug credit's applicability.

Suggestion: Treasury guidance should provide that a product's revenue be excluded from branded prescription drug sales when the product was eligible for the orphan drug credit under §45C, but the credit was not claimed.

An interpretation of "allowed" as "allowable" in the guidance will be more reflective of Congressional intent and will negate the need for companies to amend prior year returns in order to claim and report the orphan drug credit. The process of amending past returns would be both time consuming and administratively burdensome for taxpayers and the Service.

Additionally, some small companies receiving credit allocations under the Therapeutic Discovery Project Tax Credit (Section 9023 of the Patient Protection and Affordable Care Act) are not allowed to claim the orphan drug credit under §45C in order to benefit from this tax credit program. Consequently those companies will be prohibited from claiming the orphan drug credit in 2009 and 2010, resulting in a potential inclusion of their revenue in the branded prescription drug sales base. The guidance should clarify that this product revenue is excluded.

B. Companies Need Sufficient and Specific Information to Evaluate Accuracy of Assessment

Issue: The biopharmaceutical manufacturers fee is unique in that, unlike other excise taxes or industry fees, an individual company's assessment is based on the company's share of the total branded drug and biologic sales to specific government programs. As such, a company is not likely to possess sufficient information on its own to validate the accuracy of its assessment. Given this fact, we believe it is incumbent upon the government to provide detailed information to each covered entity in a manner that allows the entity to conduct a timely evaluation of the data upon which its assessment is based. Additionally, for financial reporting reasons, companies must have the ability to estimate their fee on a quarterly basis beginning in the first quarter of 2011.

Suggestion: Treasury should work with Centers for Medicare and Medicaid Services (CMS), Department of Defense (DOD) and the Veterans Administration (VA) to ensure that data is available for each company's sales, by National Drug Code (i.e. NDC-11) and government program, so that this information can be shared with the company as part of the assessment process. We support a trial run in 2010 based on 2009 data so that companies can gain an understanding of how their fee is determined and have an opportunity to point out potential errors or inadequacies in the process prior to the first real assessment in 2011. We also strongly support the concept of a preliminary invoice so as to give companies sufficient opportunity to address any inaccuracies in the specified program sales data before a final assessment is issued. This would help to both promote accuracy and minimize the disruption that could occur if large discrepancies are discovered after final assessments are issued.

C. Materiality Threshold for Contesting Invoiced Amount Should be Low

Issue: Another consequence of the fee structure is that gross inaccuracies in one company's assessment could result in a change in liability for all the other covered entities. As such, it is in the interest of both the government and the industry to collect the most accurate data possible from the specified programs in order to minimize the need for subsequent adjustments to the assessments issued.

Suggestion: We support the concept of establishing a materiality threshold below which a company could not challenge the fee assessment issued to it. While we understand that absolute precision may not be possible, we believe this threshold should be low, such as 0.5% of the invoice amount. Covered entities may be more comfortable with a somewhat higher threshold if the government provides detailed data as to how their fee was calculated. This information must include each covered entity's sales on a specified program by program and NDC-11 basis, as well as the total specified government sales in the aggregate for each government program across all covered entities and products. A trial run would help to establish the appropriate materiality threshold as well.

D. Dispute Resolution Timelines Should be Clearly Outlined

Issue: Treasury guidance will need to establish a process, including timelines, by which covered entities can contest their assessment.

Suggestion: We expect that companies will require an adequate period of time in which to contest the assessment issued by Treasury. We believe that the amount of time that a company will need to evaluate its assessment should be inversely proportional to the amount and specificity of the data it receives regarding its covered sales. We suggest no less than 45 days to contest a preliminary assessment and no less than 60 days to contest a final assessment. A trial run would help to establish if these suggested timelines are adequate. This process may be particularly difficult in the first few years of the fee and for those mid-sized companies that may not have the in-house resources of larger companies. As such, it may be prudent to provide more extended timelines during the first year or two of the fee.

E. Treasury Should Clarify Effect of Treating the Fee as an Excise Tax

Issue: The statutory language of the fee specifies that the fee will be treated as an excise tax under subtitle F of the Internal Revenue Code "with respect to which only civil actions for refund under such subtitle shall apply." Further, the Joint Committee on Taxation's description of the provision states "Thus, the fees may be assessed and collected using the procedures in subtitle F without regard to the restrictions on assessment in section 6213."

Suggestion: Treasury should include in its guidance an explanation of the practical effect on a covered taxpayer of the statutory language treating the fee as an excise tax under subtitle F of the Internal Revenue Code. Specifically, the guidance should clarify if there are any circumstances under which a taxpayer contesting its fee assessment could avail themselves of the U.S. Tax Court procedures normally available to taxpayers.

II. Agency Data Collection Issues

A. Treasury Should Urge CMS to Issue Guidance

Issue: Treasury will rely on agencies such as CMS to provide it the relevant information regarding individual company sales data relative to the overall sales to the specified government programs. However, many companies likely to be impacted by the fee are seriously concerned that CMS as well as the other relevant government agencies may not currently possess the ability to identify all government sales by covered entity at the program-by-program and NDC-11 level. There are numerous circumstances within Medicare Parts B and D as well as Medicaid where these data could be difficult to gather accurately.

Suggestion: We urge Treasury to encourage CMS to issue guidance detailing how it will determine government sales in the covered programs on a covered entity-by-entity basis, and by NDC-11. We believe such transparency will provide an opportunity for covered entity input on the data gathering process and fewer disputes with Treasury over assessment amounts.

B. Guidance Should Recognize that a Drug's Manufacturer May Not Always Possess Legal Title to the NDC

Issue: There could be circumstances where the entity whose NDC is on the product may not be the only entity involved in the manufacture and sale of the drug. One example is where the entity that physically manufactures the drug and/or owns its underlying new drug application (NDA) or biologic license application (BLA) is distinct from the manufacturer that markets and sells the product and whose NDC is on that product. It is not uncommon in the biotech sector for collaborations and partnering agreements whereby the company with the NDC may not be the company that manufactures and/or owns the underlying FDA approval for the product.

Suggestion: As discussed above, we request that Treasury provide each manufacturer with sales data by NDC-11 and government program. Such data will not only permit validation of the data, as discussed above, but will also provide the granularity needed to quantify the portion of the assessment generated by any product subject to a collaboration. The partners to a collaboration can decide for themselves, according to the terms of whatever documents govern their relationship, how they will allocate the levy on an economic basis.

C. Guidance Should Clarify how Re-Packager NDCs Will Be Treated.

Issue: Re-packagers of products have a separate NDC, but under Medicare Part B they would be included under a J-code. It is unclear how re-packager NDCs would be treated since they are not the manufacturer, but do own the NDC.

Suggestion: We suggest that Treasury work with CMS to ensure that Part B utilization is reported in such a way that it accounts for re-packagers.

D. A Mechanism is Needed to Ensure that Medicare Part B Devices Billed as Drugs Are Not Covered by the Fee

Issue: Some medical devices are currently billed as drugs under Medicare Part B.

Suggestion: We suggest that Treasury work with CMS to ensure that these products are not included as applicable sales under the manufacturer fee calculation, including providing manufacturers with the opportunity to self-identify these products to CMS and Treasury.

E. Every Effort Should be Made to Avoid a Significant "Data Lag"

Issue: Due to how and when the specified government programs collect and report their data, it is possible that a significant data lag could occur, resulting in an assessment being issued based on sales data that no longer reflects actual sales to the program. For example, we understand it is possible that the initial assessment in 2011 could be based on 2009 data if the specified program data for 2010 is not available in a timely manner.

***Suggestion*:** We are concerned that a significant data lag would result in an inaccurate calculation of a given manufacturer's liability for the fee. New product introductions and patent expiration can significantly impact a company's sales from year-to-year. We urge Treasury to work with CMS and other programs to ensure that the data upon which the assessment is based is as timely as possible, and thus that each assessment is consistent with statutory language and intent.

F. Treasury Must Work with CMS to Eliminate Duplicate Utilization

Issue: A single beneficiary may be eligible for multiple programs with applicable utilization. For example, a beneficiary may participate in both the Medicare Part B and Medicaid programs as a "dual eligible," and where that is the case, both the Medicare Part B and Medicaid data would indicate coverage and expense for a given branded prescription drug.

***Suggestion*:** We suggest that Treasury work with CMS and other entities responsible for data reporting to eliminate the risk for potential double counting of utilization between programs, while also ensuring that any manufacturer rebates paid on the Medicaid utilization are fully accounted for as a reduction in the government's overall expenditures.