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BY ELECTRONIC DELIVERY

Cynthia Tudor, Ph.D.
Director, Medicare Drug Benefit Group
Centers for Medicare & Medicaid Services
Mail Stop C4-13-01
7500 Security Boulevard
Baltimore, MD 21244

Re: Medicare Prescription Drug Benefit Manual – Draft Chapter 6

Dear Dr. Tudor:

The Biotechnology Organization (BIO) appreciates this opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) Draft of Chapter 6 of the Medicare Part D Manual ("Draft Chapter 6"), released on the CMS web site on September 13, 2006. BIO is the largest trade organization to serve and represent the biotechnology industry in the United States and around the world. BIO represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers, and related organizations in the United States. BIO members are involved in the research and development of health care, agricultural, industrial and environmental biotechnology products.

BIO represents an industry that is devoted to discovering and ensuring patient access to new and innovative therapies. BIO strongly supports the Medicare Part D prescription drug benefit, and we appreciate CMS' significant efforts to implement this program. Many of the therapies developed by

biotechnology companies target conditions that primarily affect seniors. We continue to encourage CMS to focus on patient access in its ongoing implementation of this important program. This is particularly important as CMS continues to evaluate plan formularies to ensure that Part D enrollees have meaningful access to critical therapies and as CMS continues to find better ways to ensure that Part B and Part D provide Medicare beneficiaries with a comprehensive and seamless benefit.

BIO supports CMS' overall approach to formulary review. In particular, BIO:

- supports CMS' use of the Medicare Current Beneficiary Survey as one benchmark in reviewing Part D formularies, but encourages CMS to ensure that the therapies needed by individuals with rare disorders also are met;
- supports CMS' recognition of the critical importance of plan formularies including all or substantially all therapies in the "Six Classes of Clinical Concern;"
- remains concerned about the implementation of the specialty tier for "high-cost" drugs and biologicals;
- requests that CMS reconsider the timeframe for the consideration of new drugs and biologicals;
- appreciates CMS' policy that plans exempt enrollees currently taking a drug or biological from mid-year formulary changes; and
- urges CMS to continue to focus on ways to ensure that the coordination of Part B and Part D do not result in coverage gaps for beneficiaries, particularly with respect to home infusion therapies and the administration of Part D vaccines.

We have commented on each of these areas in more detail below.

I. Formulary Review – Section 30.2.7

BIO supports CMS' ongoing efforts to provide a rigorous review of Part D plan formularies. BIO encourages CMS to continue to ensure that plans are covering the most widely used medications for the most common conditions. We are concerned, however, that CMS' policy of using data from the 2002 Medicare Current Beneficiary Survey (MCBS) and the Office of Inspector General (OIG) study on the transition of dual eligibles to Part D may overlook the existence and

importance of innovative drugs that are new to the market and that, by extension, are not yet widely used (or were not yet widely used in 2002) and will not be found in either of the data sources. We support CMS' efforts to ensure that formularies include the commonly used drugs, yet we also want to emphasize the importance of CMS' formulary review including an analysis of newer therapies as well as therapies needed by individuals with rare disorders.

A significant percentage of biological therapies on the market are designed to treat rare diseases and disorders, such as Idiopathic Pulmonary Fibrosis or Gaucher's disease. We are concerned that reliance on a list of common drugs could fail to ensure that enrollees with rare diseases or disorders have access to medically appropriate therapies. Even if such lists include some of these types of therapies, they will not include the range of drugs and biologicals to which enrollees will need access. Patients with rare diseases and disorders should have the same access to medically necessary drugs to treat their conditions as do patients with common conditions. We urge CMS to clarify that an assessment of the availability and tier position of therapies for uncommon conditions will be a critical component of the formulary process.

II. Inclusion of "All or Substantially All" Therapies in the Six Protected Categories – Section 30.2.5

BIO appreciates and strongly supports CMS' decision to extend its "all or substantially all" guidance into the 2007 plan year and encourages CMS to make it permanent. Many of the therapies developed by BIO members serve the needs of very sick and extremely vulnerable Medicare patients. As CMS has recognized, the needs of these beneficiaries require special attention under Part D. It is critical that beneficiaries with chronic diseases such as HIV and cancer have access to a wide range of drugs and biologicals in certain therapeutic categories and classes. BIO greatly appreciates CMS' continued implementation of this "all or substantially all" requirement. We believe that this approach plays a critical role in assuring that many of the most vulnerable Medicare beneficiaries have access to the therapies they need.

The therapies used to treat these diseases typically are not interchangeable. A plan that includes a limited number of therapies from the antineoplastics category, for example, will necessarily be discriminating against individuals with certain types of cancer. Cancer treatment is complex, and the types of agents used continue to evolve rapidly. Antineoplastics may be used for more than one organ system, for more than one type of cancer, for different stages

of diseases, and often in combination with other agents. Thus, it is critical that CMS continues its policy requiring all of these therapies be on a plan's formulary. This will ensure that the full range of these therapies are available to Medicare beneficiaries.

BIO remains concerned that the April 17, 2006 deadline for determining which products are eligible for the "all or substantially all" requirement unfairly discriminates against beneficiaries who need access to innovative treatments and therapies. A key requirement of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA)[1] is to assure that plans provide beneficiaries access to all medically necessary treatments. Yet the April 17 cut-off date unfairly may deny patients' access to medically necessary new drugs. Part D plans must include all or substantially all therapies in the six protected categories. Thus, Medicare beneficiaries reasonably expect, and are entitled to, a benefit structure that aligns with currently available therapies, or at the very least, with the beginning of their benefit period. BIO is concerned that the April 17, 2006 date could leave patients without access to critical, life-saving therapies that come onto market more than eight months prior to the beginning of the benefit period.

Last year, CMS established a cut-off date of January 1, 2006, so that the "all or substantially all" policy applied to all drugs and biologicals on the market as of that date. BIO urges CMS to change the proposed April 17, 2006 cut-off date so that all or substantially all products within the six protected categories must be included in the plans' formularies, no matter when they come to market. At the very least, CMS should establish January 1, 2007 as the cut-off date, similar to its policy for last year. Medicare patients deserve to have a drug benefit that keeps pace with the latest in the standard of care.

BIO supports CMS' prohibition on the implementation of prior authorization or step therapy requirements for patients already stabilized on drugs or biologicals within one of the six categories, as well as the extension of this policy in circumstances where a plan cannot determine at the point-of-sale whether the enrollee currently is taking the drug or biological. We also urge CMS to prohibit prior authorization and step therapy for those beneficiaries who have previously tried but failed to respond to one or more drugs in a class of clinical concern.

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[1] See MMA, Pub. L. No. 108-173 (2003).

We also support CMS' continued policy that HIV/AIDS drugs not be subject to utilization management tools at all, with a very limited exception. We urge the agency to extend this approach to the drugs and biologicals in the other protected classes as well. We strongly urge CMS not to permit plans to impose additional utilization management tools on these six drug classes in a manner that will impede patient access in any way.

BIO also requests that CMS modify its statement that "Part D plan sponsors may not implement prior authorization or step therapy requirements *that are intended to steer beneficiaries to preferred alternatives within these classes* for enrollees who are currently taking a drug."[2] We are concerned that plans may interpret this phrase as permitting prior authorization or step therapy requirements for an enrollee currently taking a drug or biological as long as the plan couches those requirements in a manner that is not, on its face, intended to steer the enrollee to preferred alternatives in the class. In its 2006 guidance on the "all or substantially all" classes, CMS stated its expectation that, for patients already stabilized on a drug, "plans would not use management techniques like prior authorization or step therapy, *unless a plan can demonstrate extraordinary circumstances*."[3] We encourage CMS to take this approach in finalizing Draft Chapter 6 for 2007 and subsequent years to ensure that patients have full access to therapies in these six classes.

We also encourage CMS to include coverage of extended release therapies where an immediate-release therapy is on formulary and coverage of a unique dosage form of an existing chemical entity already on formulary. Sometimes, it is incremental innovation that makes a significant difference in patients' lives, such as the development of extended release formulations of existing therapies or the development of a unique method of administration. We encourage CMS' to recognize the importance difference that these types of therapies may offer patients when the agency finalizes Draft Chapter 6 with respect to the "Six Classes of Clinical Concern."

Finally, we request that CMS clarify the exception to the substantially all requirement regarding the "same active ingredient or moiety." We are concerned that plans may interpret moiety to mean something other than the FDA

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[2] Draft Chapter 6 at 15 (emphasis added).

[3] CMS Guidance, "Why is CMS requiring 'all or substantially all' of the drugs in the antidepressant, antipsychotic, anticonvulsant, anticancer, immunosuppressant and HIV/AIDS categories," posted at http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/FormularyGuidanceAllorSubAll.pdf (emphasis added).

definition of this term. Therefore, we suggest that in the final Chapter 6 CMS make clear that moiety has the same meaning as used by FDA in its definition of "new molecular entity." We also suggest that this exception only apply where there exists an AB-rated generic for the specific product(s) in question, consistent with the intent of addressing products that have the "same active ingredient or moiety."

III. Specialty Tiers – Section 30.2.4

BIO is concerned about the policies CMS has proposed with respect to the specialty tier for 2007. In particular, permitting a plan to place all therapies with negotiated prices greater than $500 per month on the specialty tier grants plans too much discretion in setting negotiated prices and allows the inclusion of far too wide a range of therapies on the specialty tier. As BIO understands CMS' rationale for permitting such a specialty tier, the intent was at least in part to protect plans from the cost of having to place all high-cost therapies on the preferred formulary tier, either directly or through the exceptions process. CMS previously had suggested that plans would be allowed to include in this tier only very high cost therapies. Establishing a threshold amount of $500 goes far beyond this apparent intent by establishing a threshold well below that used by most plans and by allowing plans to include a wide range of drugs and biologicals. Although we question whether it is appropriate to establish a threshold at all for the specialty tier, if CMS does establish such a threshold BIO requests that CMS substantially increase the threshold amount for the specialty tier in order to more appropriately limit the significant effect this tier has on patient access to critical therapies. CMS' proposed threshold will facilitate the proliferation of specialty tiers at a much lower cost threshold than exists in among 2006 plans.

We also ask that CMS more clearly define the way in which plans should calculate the threshold amount. Draft Chapter 6 states that "[o]nly Part D drugs with plan negotiated prices that exceed $500 per month may be placed in the specialty tier." This allows plans considerable discretion in setting negotiated prices at a level that qualifies a particular therapy for specialty tier inclusion. Instead, we suggest that, if CMS must establish a threshold amount for the specialty tier, CMS permit plans to include a drug on the specialty tier only where the lower of (1) the plan's negotiated price for the drug, or (2) the wholesale acquisition cost for the drug minus any rebates or other price concessions provided to the Part D plan sponsor from the drug's manufacturer is above the threshold amount.

Patients who need therapies that are placed in a specialty tier tend to be particularly medically vulnerable. In addition, because of the distinctive structure of the Part D benefit, these patients are uniquely at risk because of the cost-sharing structure of Part D. Although many Medicare beneficiaries are unlikely to hit the "donut hole" or coverage gap at all, or only late in the year, patients needing high cost and unique therapies are likely to encounter the "donut hole" early in the calendar year and to incur the donut hole's substantial out-of-pocket expenses over a very short period of time. It is likely to be extremely difficult for these patients to absorb these significant out-of-pocket expenses all at once. With CMS' proposed threshold for the specialty tier – that is lower than most plans have used for 2006 – many more patients will be subject to the specialty tier and the typically higher cost-sharing associated with such a tier.

Furthermore, BIO seeks clarification that the cost-sharing associated with the specialty tier must be limited to 25%. We are concerned that CMS' statement that the requirement is 25% "or actuarially equivalent for plans for with decreased or no deductible basic alternative benefit designs"[4] would allow plans to increase the cost-sharing percentage for the specialty tier beyond 25%. We also urge CMS to carefully monitor cost-sharing levels for the specialty tier, as we note that several plans have established specialty tier cost-sharing well in excess of 25% for 2006, contrary to CMS' 2006 instructions to plans.

BIO also is concerned about CMS' policy allowing plans to place all therapies within a particular category or class, as long as all therapies in that category or class meet the criteria for inclusion in the specialty tier. In Draft Chapter 6, CMS states that, in this circumstance, "a plan does not need to identify a preferred drug for that category or class."[5] This directly contradicts CMS' statement later in Draft Chapter 6:

> "Best practice in existing formularies and preferred drug lists generally place drugs in a less preferable position only when drugs that are therapeutically similar (i.e., drugs that provide similar treatment outcomes) are in more preferable positions on the formulary."[6]

CMS goes on to explain that its formulary review will "focus on identifying drug categories that may substantially discourage enrollment of certain beneficiaries by

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[4] Draft Chapter 6 at 15.
[5] *Id.*
[6] Draft Chapter 6 at 16.

placing drugs in non-preferred tiers in the absence of commonly used therapeutically similar drugs in more preferred positions."[7] BIO strongly supports this approach to formulary review and urges CMS to reconsider this approach to the specialty tier so that a plan's implementation of such a tier does not further result in a plan benefit design structured in a manner that substantially discourages the enrollment of Medicare beneficiaries with certain disorders. BIO is concerned that the implementation of the specialty tier be done in a manner that minimizes the inherent discriminatory nature of such a tier. Allowing plans to exclude all therapies for treatment of a particular disorder from the preferred formulary tier certainly would seem to discourage the enrollment of certain groups of beneficiaries.

Finally, we reiterate our concern about the specialty tier more generally. The MMA specifically grants Part D enrollees the right to request an exception to a plan's tiered cost-sharing structure.[8] CMS' continued implementation of the specialty tier, eliminating the ability of an enrollee to seek a tiering exception for high-cost biologicals, is inconsistent with the statute.

IV. Formulary Inclusion of New Drugs and Biologicals – Section 30.1.5

BIO requests that CMS reconsider its requirement that a plan's pharmacy and therapeutics (P&T) committee make reasonable efforts to review each new chemical entity within 90 days of its market release and make decision on each new chemical entity within 180 days of its release onto the market, unless the plan provides a clinical justification for not making such a determination. BIO represents an industry that is devoted to discovering new and innovative therapies and ensuring patient access to them. Our members continually are developing promising new medicines. It is imperative that these new therapies be available to Medicare beneficiaries in a timely manner so that they may have the advantage of life-saving and life prolonging innovations. We urge CMS to require that P&T committees consider new therapies within 90 days. We also ask that CMS require P&T committees to consider new indications for existing therapies within 90 days of the approval of the new indication. Where CMS permits an extended period by allowing plans to provide clinical justifications for the delay, we urge CMS to publish written guidance to plans regarding acceptable bases for and active resolution of any delays. This will help to ensure that the timeframe for the

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[7] *Id.*
[8] SSA § 1860D-4(g)(2).

consideration of new therapies is meaningful and that Part D benefits are comprehensive and appropriately reflect evolving standards of care, including new and innovative therapies. In addition, we request that CMS clarify that "new chemical entity" is intended to include biologicals approved under a biologics license application (BLA).

IV. Formulary Changes – Section 30.3

BIO appreciates CMS' efforts to establish a clear and public process for plan formulary changes. In particular, BIO strongly supports the agency's requirements that, for most mid-year formulary changes, plans exempt enrollees currently taking the affected drug from the formulary change for the remainder of the plan year. BIO believes this policy will provide important continuity of therapy for medically vulnerable beneficiaries. We also believe this policy is critical to limiting plans' ability to "bait-and-switch" by enticing enrollees to enroll based on one formulary and then changing that formulary mid-year. We encourage CMS to continue to monitor plan formulary changes on an ongoing basis.

V. Medicare Part B and Medicare Part D Coverage Issues – Section 20.2.2 and Appendix B

BIO appreciates CMS' efforts to coordinate the benefits available through Part B and Part D, and we urge CMS to continue its efforts to eliminate the gaps in coverage for beneficiaries that result from coordination challenges between the Part B and Part D benefits. Specifically, we urge CMS to reconsider the coverage policies that continue to impede beneficiary access to home infusion therapies as well as to vaccines that are Part D drugs.

As we have discussed in our comment letter to CMS regarding Draft Chapter 5 of the Prescription Drug Benefit Manual, home infusion therapies pose a critical coverage gap for Medicare beneficiaries. Because Medicare fails to provide coverage for the services necessary to administrate home infusion therapies, the fact that Part D coverage is available for many home infusion drugs is rendered meaningless. CMS has precluded Part D plans from paying for the professional services and supplies necessary for the administration of home infusion therapies.[9] In many cases, there is no other Medicare coverage available for these supplies and services. Currently, home infusion is covered infrequently under Part B, and only certain homebound beneficiaries may receive assistance

[9] Draft Chapter 6, Appendix B at 9.

with nursing services and limited equipment and supplies under Part A. For many Medicare beneficiaries, payment for these supplies and services is not available, and the beneficiary must pay for these supplies and services out-of-pocket. Instead, many beneficiaries will forgo medically necessary therapies or remain in the hospital or seek care in a physician's office or hospital outpatient setting.

Home infusion provides a cost effective alternative for patients who otherwise would need to seek treatment in outpatient clinics, physician offices, or inpatient stays. Forcing patients to seek care in provider settings often results in increased costs to Medicare. For example, a patient in a rural area who must travel a long distance to a provider site may forgo recommended treatment only to suffer an acute episode requiring otherwise avoidable Medicare expenditures. We urge CMS to reconsider the approach that precludes payment under Part D for the supplies and services necessary to make home infusion a reality for many patients.

Coverage of home infusion therapies under Part D was an important step forward in the provision of meaningful and comprehensive coverage for Medicare beneficiaries. In addition to asking CMS to establish policies that permit more effective coordination of Part B and Part D with respect to home infusion, BIO requests that CMS greatly expand the list of common home infusion drugs contained in Draft Chapter 6. This draft list excludes many commonly used home infusion therapies, as well as therapies needed by beneficiaries with rare diseases and disorders. We are concerned that the failure to provide a more comprehensive list of home infusion therapies will result in Part D formularies that do not adequately reflect the range of home infusion therapies eligible for coverage under Part D. At the very least, we urge CMS to clarify that this list establishes a minimum threshold for Part D coverage and that those therapies needed in a home infusion setting by beneficiaries with rare diseases and conditions also should be included on Part D formularies.

Another significant challenge in the coordination of Part B and Part D is coverage of administration fees for Part D vaccines. In order for beneficiaries to have meaningful access to vaccines that qualify as Part D drugs, Medicare must provide coverage for the administration of these vaccines. Congress expressly included vaccines in the statutory definition of Part D drugs. Congress intended for Part B and Part D together to provide a seamless benefit. Beneficiaries are not afforded meaningful access to vaccines where the costs of administering those vaccines are not also covered by Medicare. BIO strongly urges CMS to remedy this problem and to clarify that payment is available under Part B for the administration of Part D vaccines. One option would be for CMS to issue a

HCPCS code for Part D vaccine administration, consistent with the codes already available for administering Part B vaccines.

VI. Conclusion

BIO appreciates CMS' consideration of these comments and would welcome the opportunity to discuss them with you in depth. Please contact me at (202) 312-9273 if you have any questions regarding our comments. Thank you for your attention to this very important matter.

Respectfully submitted,

/s/

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