March 6, 2006

Mark McClellan, M.D., Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Department of Health and Human Services
Washington, D.C. 20201

Re: 2007 Draft Guidelines for Formularies

Dear Administrator McClellan:

The Biotechnology Organization (BIO) appreciates this opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) "2007 Draft Guidelines – Formularies" (Draft Guidelines), released February 23, 2006, pursuant to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). 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. We support extending Medicare coverage to all drug and biological therapies, regardless of how they are

administrated. BIO 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.

BIO supports CMS' overall approach to formulary review, relying on best practices in the private sector both in Pharmacy and Therapeutics (P&T) committee operations and formulary list developments. In particular, BIO supports CMS' recognition of the critical importance of plan formularies including all or substantially all therapies in the "Six Classes of Clinical Concern." While BIO supports CMS' efforts to ensure plans are covering the most widely used medications for the most common conditions, via use of data like the Medicare Current Beneficiary Survey, we encourage CMS to ensure that new therapies and therapies needed by individuals with rare diseases are also made available to beneficiaries. BIO is concerned about the implementation of the specialty tier for "high-cost" drugs and biologicals. BIO also requests that CMS reconsider the timeframe for the consideration of new drugs and biologicals. Finally, BIO asks CMS to clarify its approach to the review of Drug Utilization Review practices as well as to provide information about how CMS expects to monitor formulary changes for the 2007 year.

I. Inclusion of "All or Substantially All" Therapies in the Six Protected Categories

BIO 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.

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 continue its policy requiring all of these therapies be on a plan's formulary. This will ensure that the full range of these therapies be available to Medicare beneficiaries.

BIO greatly appreciates CMS' continued implementation of their "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.

However, BIO is 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 MMA is to assure that plans provide access to all medically necessary treatments. Yet the April 17 cut-off date may unfairly deny patients' access to these necessary treatments. Part D plans must include all or substantially all of the therapies in each of 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 proposed 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 products 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. CMS should establish January 1, 2007 as the cut-off date, similar to its policy for last year. At the very least, CMS should clarify that a post April 17, 2006 formulary submission will undergo the same or preferably an expedited review process to achieve formulary position. BIO understands that a requiring a running formulary review process may not be practical; however, Medicare patients deserve to have innovative biopharmaceuticals reviewed timely and a drug benefit that keeps pace with the latest standard of care.

BIO supports CMS' proposed prohibition on plans implementing 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 proposal to enrollees where a plan cannot determine at the point-of-sale whether the enrollee is not currently taking the drug or biological. 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 CMS to extend this approach to the drugs and biologicals in the other protected classes as well. We are concerned that CMS is requesting suggestions on tools that plans could implement to manage these drug classes. 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.

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".[1] 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*."[2] We encourage CMS to take this approach in its final 2007 formulary guidance in order to ensure that patients have full access to therapies in each of these six classes.

Finally, we encourage CMS to include coverage of extended release therapies where an immediate-release therapy is on formulary. Sometimes, it is incremental innovation that makes a significant difference in patients' lives, which can improve patient compliance, safety and tolerability. CMS appears to recognize the potential advantages of unique dosage forms in the Draft Guidance but the exceptions to this proposal would effectively deprive patients of any meaningful access to these important technologies. We encourage CMS' to recognize the important difference that these types of therapies may offer patients by explicitly requiring coverage of extended release therapies even if an immediate release

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[1] Draft Guidance at 7 (emphasis added).

[2] 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).

therapy is on the formulary when the agency finalizes the Draft Guidance with respect to the "Six Classes of Clinical Concern."

Also noted is the CMS request for feedback related to current managed care strategies that could be implemented within the context of standards that apply to the six classes of clinical concern and that would allow plan sponsors the flexibility to manage these drug classes where appropriate. Given the potential for feedback in this area to significantly alter the meaning, application and value of proposed and existing standards that apply to the six classes of clinical concern and the vulnerable patients who benefit from this policy, BIO recommends that CMS undertake separate notice and comment rulemaking before any further consideration is given to the application of managed care strategies in the context of the six classes of clinical concern.

II. Formulary Review for Commonly Used Drugs

BIO supports CMS' efforts to ensure that plans are covering the most widely used medications for the most common conditions. However, we are concerned that CMS' policy of using data from the 2002 Medicare Current Beneficiary Survey (MCBS) and the 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 in the first two quarters of 2005) 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 the inclusion of new therapies and 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 new therapies and of therapies for uncommon conditions will be a critical component of the formulary process.

We also are concerned by the suggestion that patients newly placed on a protected drug therapy might not receive the same level of protection as those who were previously on the same drug therapy. Differential treatment of newly diagnosed from previously diagnosed beneficiaries is not consistent with the policy articulated by the guidance and would create an unacceptable and indefensible 'second class' of Medicare enrollee.

III. Specialty Tiers

BIO is concerned about the policies CMS proposes 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. While we question the statutory authority for any such specialty tier, if CMS continues to allow this approach, 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.

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 – which 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"[3] 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' proposed 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. CMS proposes that, in this circumstance, "a plan does not need to identify a preferred drug for that category or class."[4] This runs directly counter to CMS' statement earlier in the Draft Guidance, reiterating the 2006 formulary guidance:

> "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."[5]

CMS goes on to explain that its formulary review will "focus on identifying drug categories that may substantially discourage enrollment of certain beneficiaries by placing drugs in non-preferred tiers in the absence of commonly used therapeutically similar drugs in more preferred positions."[6] 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 any 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.

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[3] Draft Guidance at 6.
[4] *Id.*
[5] Draft Guidance at 4.
[6] *Id.*

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.[7] CMS' continued implementation of the specialty tier, which eliminates the ability of an enrollee to seek a tiering exception for high-cost biologicals, is inconsistent with the statute.

III. Formulary Inclusion of New Drugs and Biologicals

BIO requests that CMS reconsider its proposed requirement that a plan's 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 make decisions on 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 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. Drug Utilization Review Practices

We note that CMS has not listed review of plan Drug Utilization Review ("DUR") practices in the Draft Guidance. We are interested in whether CMS intends to review plans' DUR practices for 2007, and we would encourage the agency to do so.

V. Formulary Changes

[7] SSA § 1860D-4(g)(2).

We also note that CMS has not indicated how it will handle formulary changes made during the course of the year. We encourage CMS to monitor these changes on an ongoing basis and ask that the agency establish a clear and public process for monitoring changes to plan formularies.

VI. Conclusion

BIO appreciates CMS' consideration of these comments and would welcome the opportunity to discuss them in depth. Please contact Jayson Slotnik 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/

Jim Greenwood
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Biotechnology Industry Organization