October 30, 2017

BY ELECTRONIC DELIVERY

Dennis E. Doherty, M.D., Chair
Healthcare Quality and Safety Expert Committee
U.S. Pharmacopeial Convention
12601 Twinbrook Parkway
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CC: Donna Bohannon, R.Ph.
Scientific Liaison
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RE: USP Drug Classification System, Second Round Public Comments

Dear USP Healthcare Quality & Safety Expert Committee,

The Biotechnology Innovation Organization (BIO) appreciates the opportunity to submit the following comments to the U.S. Pharmacopeial Convention (USP) Healthcare Quality and Safety Expert Committee (Expert Committee) in response to the second round of public comment on the USP Drug Classification System (USP DC), released September 25, 2017.[1] BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and in more than 30 other nations. BIO's members develop medical products and technologies to treat patients afflicted with serious diseases, to delay the onset of these diseases, or to prevent them in the first place. In that way, our members' novel therapeutics, vaccines, and diagnostics not only have improved health outcomes, but also have reduced healthcare expenditures due to fewer physician office visits, hospitalizations, and surgical interventions.

In response to the USP DC, BIO offers comments consistent with our comprehensive comments on the draft Version 7.0 Medicare Model Guidelines (MMG) and comments on last year's draft USP DC, both of which are included as appendices for the Expert Committee's reference. Our comments, as follows, also correspond to the call for additional feedback on how to make the USP DC more user friendly as expressed on the open-mic web meeting.[2]

[1] U.S. Pharmacopieal Convention (USP), Drug Classification (September 25, 2017), available at: https://www.usp.org/health-quality-safety/usp-drug-classification-system.
[2] During the October 12th Open-Microphone Web Meeting intended for Pharmaceutical Manufacturers, Beneficiaries and Patient Advocacy Groups, there were questions raised about how stakeholders intended to use the USP DC and sought feedback on how to make the USP DC more user-friendly.

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I. USP should provide additional context for how the USP DC is meant to be applied.

BIO agrees that the USP DC system is needed to account for the continuing expanded use of USP guidelines across the healthcare delivery system. Specifically, we are concerned about potential stakeholder confusion between the USP MMG and the USP DC, as the USP DC includes outpatient prescription drugs that could either be administered through the pharmacy benefit or the medical benefit. We believe that it is the duty of the Expert Committee to expressly detail how the USP DC should be used, particularly referencing that it is not an appropriate benchmark for medical benefit drug coverage. This context is important when considering the application of the USP DC for purposes of coverage benchmarks such as the Essential Health Benefits (EHBs). We urge USP to share these additional considerations to continue to inform stakeholders about the appropriate applications of the USP DC.

II. USP should detail how therapies are selected for inclusion and how the accuracy and comprehensiveness of the USP DC list is verified.

BIO continues to have concerns with the USP Guiding Principles used in the development of the MMG and the USP DC, as expressed in our previous comment letters. Mainly, we are concerned about how Food and Drug Administration (FDA)-approved therapies are identified for inclusion in the USP DC and the methods used to ensure accuracy and comprehensiveness before each release of the updated USP DC. The Guiding Principles note that the classification system is developed using pharmacotherapeutic evidence for an FDA-approved agent, but we further urge the Expert Committee to provide process specific information on how therapies are selected. Through such level of detail, stakeholders could provide additional feedback, identifying potential gaps in the therapies included in the USP DC and how to properly incorporate such treatments.

III. USP should improve the granularity and comprehensiveness of the USP DC list to appropriately capture treatments for distinct patient populations.

BIO appreciates the Expert Committee's efforts to increase the granularity of the USP DC through the inclusion of a vaccines and combination products lists, however, we have concerns around the level of detail provided about specific drugs within these lists and their application by stakeholder entities using the USP DC. We are concerned that the single entity list includes products that are not designated by the FDA for stand-alone use, as is the case for many antiviral therapies that are used in combination. While the USP DC does note in the single entity list that these products are used in combination, BIO finds that maintaining these under both lists could be problematic for stakeholders, particularly when applied for coverage benchmarks such as the EHBs. Instead, we suggest that the Expert Committee work to create a greater level of detail within a single list.

Further, we continue to ask the Expert Committee to advance the granularity and comprehensiveness of the USP DC, through consistency across categories and classes. BIO believes it is imperative that the Expert Committee avoid categories or classes that serve as a 'catch-all' and instead provide for distinct categories and classes that reflect the specific mechanism of action or targeted disease state, highlighting the pharmacokinetic differences of therapies. Such an approach will improve the utility of the USP DC for stakeholders by ensuring that it is reflective of the outpatient therapies appropriate to the patients for which it will be utilized. The following are examples of areas in which USP should consider such increased granularity. We urge the Expert Committee to continue to work with stakeholders to address these issues across the USP DC.

- As detailed in our 2016 Comments on the USP DC, the category of "Genetic or Enzyme Disorder: Replacement, Modifier, Treatment" should ensure all unique molecules approved to treat rare, genetic metabolic disorders are included, and further delineate classes within the category, as these are distinct drugs for a varying range of genetic diseases. Additionally, in these comments we referenced the example of the "Antineoplastics" category where the class of "Antineoplastics, other" includes treatments with significant pharmacological differences for the treatment of distinct patient populations. The Expert Committee should work to make further distinctions within these categories and classes.

- Within the "Immunological Agents" category, we request that the Expert Committee reconsider the placement of Janus kinase (JAK) inhibitors in the more appropriate "immunomodulator" class rather than be classified as an "immune suppressant." JAK inhibitors are used to treat immunological conditions such as rheumatoid arthritis (RA), and possess several key characteristics that distinguish this new and emerging class of medications for the treatment of immunological conditions, including the mechanism of action of the JAKs, the clinical properties of immune "suppression" vs. "modulation", and their pharmacodynamics and pharmacokinetic profile. This is an area where USP can work to better organize drugs into classes that are reflective of the clinical characteristics and therapeutic uses.

- For anticonvulsants, in some instances the USP DC includes categories with narrow classes that recognize the unique mechanism of action. However, the "Anticonvulsants, other" class includes a number of products that would be more accurately reflected if the class were relabeled "Synaptic Vesicle Glycoprotein 2A (SV2A) Agents". Such a change would more closely align the class with how other anticonvulsant classes, such as the "Glutamate Reducing Agents", "Sodium Channel Agents", and "Calcium Channel Modifying Agents", are grouped and characterized.

- Beyond the issues detailed above for the maintenance of the separate combination and single entity lists and considerations around antiviral drugs, we encourage USP to create separate and distinct classes for antiviral drugs based on the diseases they aim to treat. Instead of the broad "Antiviral Combinations" class, the Expert Committee should consider including the following classes: "Anti-HBV Agents", "Anti-HIV Agents", and "Anti-HCV Agents" to more appropriately detail these therapies to stakeholders who rely on the USP DC.

These are examples of areas where improvements can be made within the USP DC categorization and class designations to ensure an appropriate level of detail is included and relevancy in application. BIO urges the Expert Committee to use a single list that is reflective of information such as the targeted disease state, mechanism of action, and treatments that are approved in combination within categories and classes. We believe this approach will create a more user friendly USP DC that is reflective of how different products are used in patient care. We encourage the Expert Committee to continue to work with and seek stakeholder feedback on how to best define various categories and classes of drugs.

IV. USP should regularly update the USP DC to ensure accuracy as new therapies come to market and provide continued opportunities to collect recommendations and feedback from stakeholders.

BIO urges the Expert Committee to regularly make updates to and seek feedback on the USP DC. This is particularly important as new therapies become available that represent significant improvements in the standard of care and overall health outcomes, for instance for patients with cancer or rare diseases. During the October 12th open-mic web meeting, the issue of updates to the USP DC was raised and general suggestions were made around updates on a six-month basis. We believe, however, that updates should be made on a more frequent basis to appropriately inform stakeholders and insurance benchmarks reliant on the USP DC.

The Expert Committee should develop and publicly communicate a process for more consistent updates to respond to the approval of new treatments and avoid impeding patient access, while continuing to seek regular feedback from stakeholders. Such detail should include a planned timeframe for updates, or opportunities to suggest interim updates based on the approval of new therapies that should be included on the USP DC, and how stakeholders can participate and provide feedback. These elements are critical to transparent, constructive updates of the USP DC.

* * *

We appreciate the Expert Committee's attention to our comments and concerns in this round of updates to the USP DC. We look forward to continuing to work with the Expert Committee to ensure that the USP DC is reflective across therapies and ensure patient access to appropriate treatment. Should you have any questions, please contact me at 202-962-9200.

Sincerely,

/s/

Crystal Kuntz
Vice President,
Healthcare Policy and Research

/s/

Mallory O'Connor
Director,
Healthcare Policy and Federal Programs

Attachments

Appendix 1: BIO Comments, RE: Revision of USP Medicare Model Guidelines v7.0 for Benefit Years 2018-2022, November 2, 2016.

Appendix 2: BIO Comments, RE: Draft USP Drug Classification System, December 5, 2016.

November 2, 2016

Donna Bohanon, R.Ph. CPPS
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VIA ELECTRONIC DELIVERY

Re: Revision of USP Medicare Model Guidelines v7.0 for Benefit Years 2018-2020

Dear Members of the U.S. Pharmacopeial Convention Healthcare Quality Expert Committee:

The Biotechnology Innovation Organization (BIO) is pleased to submit the following comments to the U.S. Pharmacopeial Convention (USP) Healthcare Quality Expert Committee (the "Expert Committee") in response to the Draft Medicare Model Guidelines Version 7.0 (the draft "Model Guidelines") released October 3, 2016.[1]

BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and in more than 30 other nations. BIO's members develop medical products and technologies to treat patients afflicted with serious diseases, to delay the onset of these diseases, or to prevent them in the first place. In that way, our members' novel therapeutics, vaccines, and diagnostics not only have improved health outcomes, but also have reduced healthcare expenditures due to fewer physician office visits, hospitalizations, and surgical interventions.

BIO appreciates this opportunity to reiterate several issues that could limit patient access to vital therapies if left unaddressed in the Version 7.0 Final Model Guidelines. Our comments, described in detail below, are structured in two parts based on the current dual responsibilities of the Model Guidelines, as a benchmark for prescription drug coverage in both Medicare Part D and for health insurance plans subject to the Essential Health Benefits (EHB).[2] We were encouraged to see USP's release of the USP Drug Classification (DC) system on November 1, and we agree that such a system is necessary to account for the expanded manner in which USP guidelines are used in the healthcare system, including as part of the prescription drug coverage standard for plans subject to EHB.[3] BIO looks forward to the opportunity to provide feedback on the draft of this new system. In the interim, we urge USP to consider the comments we have included in section III of this letter as initial input into the development of this new system, as these comments identify the

[1] U.S. Pharmacopeial Convention (USP), USP Medicare Model Guidelines v7.0 (October 3, 2016), available at: http://www.usp.org/usp-healthcare-professionals/usp-medicare-model-guidelines/medicare-model-guidelines-v70 (last accessed October 10, 2016).
[2] Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation, 78 Fed. Reg. 12,834 (Feb. 25, 2013).
[3] USP, 2016 (November 1), USP Drug Classification: USP Drug Classification System, available at: http://www.usp.org/usp-healthcare-professionals/usp-drug-classification-system last accessed November 1, 2016).

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gaps in USP MMG, when used for the purposes of fulfilling the EHB standard, that we would expect the new classification system to address.

The Medicare Prescription Drug Improvement and Modernization Act of 2003 charged the Centers for Medicare and Medicaid Services (CMS) to cooperate with USP to develop a classification system to be used by Medicare Part D drug plans for formulary development.[4] Updated every three years, the resulting Model Guidelines "utilize pharmacotherapeutic evidence within the context of FDA [Food and Drug Administration] approved indications to create categories and classes…which characterize the statutory requirement for Medicare Part D plan benefit design to include drugs from each category and class."[5] BIO appreciates the inclusion of several drugs and biologicals approved by the FDA since the last update to the Model Guidelines. However, we are concerned that this draft Version 7.0 update does not provide the sufficient granularity and comprehensiveness within and across the categories and classes that is necessary to ensure that the Model Guidelines include the spectrum of therapies needed by a Medicare population with diverse health needs.

Additionally, BIO is concerned that the three-year update cycle allows a significant gap between when innovative therapies are available on the market and when the Model Guidelines reflect these innovations. In our comments below in response to the draft Model Guidelines, we urge USP to revise the MMG more frequently to support patients' timely access to new and innovative medications.

I. Process for the Development of the Model Guidelines: Implementing the Guiding Principles

As an initial issue, BIO raises significant concerns with USP's process for making a draft Version 7.0 publicly available. In early October, USP posted a draft Version 7.0 MMG, but then removed that version of the document a short time later, without any notification to stakeholders that a different version had replaced it or why the updated version was necessary in the first place. Moreover, there were significant discrepancies between the two documents, including that: there were examples added and removed from various categories and classes; and the drug-specific information was changed for certain therapies between the first and second versions. This incident raises concerns as it reflects a broader opacity in the USP process for drafting updated MMG versions, in particular with regard to USP's choice of examples. It also raises broader concerns, discussed in more detail in the remainder of this section, with the thoroughness and comprehensiveness with which USP reviews newly-approved FDA products for inclusion in the updated MMG version. In the short term, we urge USP to explain why two different drafts of Version 7.0 were posted online in a matter of days, and the cause of the differences between these versions. Moving forward, BIO asks USP to consider the recommendations included in the balance of this letter to improve the process and implementation of future USP MMG versions.

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[4] Medicare Prescription Drug Improvement and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2085; Social Security Act § 1860D-4(b)(3)(C)(ii).
[5] USP. 2013. Guiding Principles USP Medicare Model Guidelines v6.0 Therapeutic Information and Formulary Support Expert Committee. Rockville, MD: USP, Available at: http://www.usp.org/sites/default/files/usp_pdf/EN/healthcareProfessionals/2013_usp_mg_guiding_principle.pdf.

As USP describes, the draft Version 7.0 MMG were developed in accordance with the Guiding Principles, which have been established through the previous Model Guideline revisions. Specifically, the Guiding Principles note that the MMG revisions are developed utilizing pharmacotherapeutic evidence for an FDA-approved agent. Additionally, the draft Version 7.0 Draft Model Guidelines includes a list of associated drug examples that aligns with the Part D drugs on the CMS Formulary Reference File (FRF).

As a threshold question, we ask the Expert Committee to provide further details on the exact process by which therapies that have gained FDA approval since the development of Version 6.0 of the MMG are identified, and what mechanisms are utilized to verify the accuracy and comprehensiveness of this list before the initial Version 7.0 was released. This is an important question as stakeholders expect USP to go to great lengths to ensure the inclusion of all eligible drugs in a timely manner, both given: (1) the importance of the USP MMG standard to Medicare Part D (discussed in section II(A) below) and to the EHB prescription drug coverage standard (discussed in section III below); and (2) the infrequency with which the MMG are currently updated (i.e., only every three years) (discussed in section II(B) below). However, a review to align the CMS FRF to the Version 7.0 Draft Model Guidelines identified that Part D drugs and vaccines included in the FRF that are not reflected in the draft Version 7.0. Thus, at a minimum, BIO urges USP to revisit the FRF listing to ensure that all Part D drugs and vaccines are included as examples in the Version 7.0 Model Guidelines, particularly for the classes of clinical concern and vaccines.

Additionally, the Guiding Principles note that "USP will advise CMS on issues it discovers during the revision process that are relevant to implementing the USP Medicare Model Guidelines."[6] Given that implementation of the USP MMG has a direct impact on patient access to needed therapies, BIO asks USP to consider sharing a summary of the issues transmitted to CMS under this provision of the Guiding Principles. This information can inform stakeholders' comments in response to the draft Model Guidelines as well as comments to CMS with regard to how the Agency might best address any issues USP raises.

II. The Role of the Model Guidelines in Medicare Part D Prescription Drug Plans

A. <u>The USP categories and classes should be more detailed to adequately represent the drugs needed by enrollees in Medicare Part D prescription drug plans.</u>

BIO urges USP to consider the scope, comprehensiveness, and granularity of Version 7.0 to ensure that the updated Model Guidelines accurately reflect an evolving standard of care across prescription drug categories and classes. With regard to the MMG scope, this requires the Expert Committee to make both positive updates—which result in the addition of therapies—to reflect new-to-market medicines, as well as negative updates, which result in the removal of therapies that no longer reflect the standard of care. BIO asks the Expert Committee to identify the process by which the Model Guidelines are reviewed, and positive

[6] USP, Guiding Principles: USP Medicare Model Guidelines v7.0 (March 22,2016), available at: http://www.usp.org/sites/default/files/usp_pdf/EN/healthcareProfessionals/2016_usp_mmg_guiding_principles.pdf (last accessed October 10, 2016).

and negative updates made, such that stakeholders can more constructively engage with USP to improve and streamline the process in the future.

The Model Guidelines need to keep pace both with therapeutic advancements and with the changing medical needs of the patient populations to which they are applied. BIO recognizes that 16 percent of beneficiaries are eligible for Medicare based on disability status not age.[7] Thus, more than 9 million Medicare beneficiaries[8] are younger than 65 years-old and have healthcare needs that may differ significantly from those of the traditional, 65 years-old and older, Medicare population. To ensure that this younger population has access to the therapies most appropriate for them, the categories and classes in the Model Guidelines must be sufficiently broad in scope.

In addition, BIO reiterates concerns with regard to the comprehensiveness of Version 7.0, described in more detail in section I. Given the update schedule for the Model Guidelines—every three years—we urge USP to confirm that Version 7.0 includes all relevant therapies that have been FDA-approved since Version 6.0, and to release additional information on the process used to identify such therapies and consider them for inclusion. Greater visibility into this process will improve stakeholders' ability to constructively engage with USP to ensure accuracy and efficiency moving forward.

Moreover, BIO urges the Expert Committee to increase the granularity within the categories and classes to ensure that the healthcare needs of the entire Medicare population are met. This can be particularly critical to improve access to medically-appropriate therapies for patients with rare diseases. Overall, increased granularity will help to identify therapies used for distinct purposes or conditions, and distinguish among therapies with clinically-relevant differences. In the remainder of this section, we identify several examples of draft Version 7.0 categories and classes in which greater granularity is necessary to improve the ability of the Version 7.0 Model Guidelines to act as an appropriate standard for comprehensive prescription drug coverage under Medicare Part D. These examples are not exhaustive, but the sheer number is a clear indication of the need for the Expert Committee to work closely with stakeholders in finalizing Version 7.0 to improve the granularity of this classification system overall.

- The "Immunological Agents" category lists "Immune Suppressants" as a class, but as currently designed, does not distinguish between the disparate pharmacological, physiological, and clinical effects of the therapies it includes. To be consistent with the approach the Expert Committee has taken in the past in the "Antiretroviral" category, BIO recommends USP revise the Immunosuppressant category to create four distinct classes: post-transplant; biological disease modifying antiheumatic drugs (DMARDs); non-biological DMARDs; and other therapies.

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[7] Medicare Payment Advisory Commission (MedPAC), A Data Book: Health Care Spending and the Medicare Program (May 2016), Chart 2-1 "Aged beneficiaries accounted for the greatest share of the Medicare population and program spending, 2012, p.19, available at: http://medpac.gov/docs/default-source/data-book/june-2016-data-book-health-care-spending-and-the-medicare-program.pdf?sfvrsn=0 (last accessed October 10, 2016).
[8] Id. at p.15 (calculation of 16 percent of 57 million).

- USP includes therapies in the "Antineoplastics, Other" 'catch-all' class of the "Antineoplastics" category that have significant pharmacological differences and treat distinct patient populations (e.g., the indications are as diverse as B-cell chronic lymphocytic leukemia versus osteosarcoma, with diverse mechanisms of action and diverse recommendations with regard to treating sequencing). In the absence of greater granularity in this category and class, the Medicare coverage standard that relies on the MMG would not be sufficient to protect patient access to the various therapies it includes.

- The draft Version 7.0 maintains the Version 6.0 category "Immunological Agents," with a class for "Immunomodulators." This class acts as a "catch all" for many therapies that treat disparate diseases, including rare diseases. For example, the therapies that the Expert Committee includes in this category treat conditions as diverse as chronic granulomatous, multiple sclerosis, and inflammatory bowel diseases, including new therapies with a unique gut-selective mechanism of action that inhibits tissue-specific trafficking of lymphocytes in the gastrointestinal tract. Given that the Model Guidelines form the basis for the Medicare Part D coverage standard, there is a persistent concern that plan formularies may not cover a sufficient breath of therapies to treat Medicare beneficiaries' healthcare needs. To address this, the Expert Committee should consider creating separate classes for immunomodulators within the "Immunological Agents" category based on the disease they are approved to treat and their mechanism of action.

- New respiratory therapies for patients with Chronic Obstructive Pulmonary Disease (COPD) have been approved by the FDA since the last USP cycle. The USP class of "Respiratory Tract Agents, Other", which sits under the "Respiratory Tract/Pulmonary Agents" category, has become too broad to recognize clinically-meaningful differences in products, specifically combination therapies. A key feature of COPD is airflow obstruction that progressively worsens over time, leading to dyspnea and other debilitating symptoms. Inclusion of combination ICS/LABA and LAMA/LABA examples in the same USP class (i.e., "Respiratory Tract, Other") may prohibit treatment options recommended by the GOLD (Global Initiative for Chronic Obstructive Lung Disease) guidelines. These guidelines outline an incremental approach to pharmacologic treatment for COPD, involving the use of combinations of drug classes with different or complementary mechanisms of action, including regular maintenance treatment with one or more long-acting bronchodilators as the disease progresses.[9] One mechanism USP can use to address this issue is to create two new USP classes within the broader category: (1) Bronchodilator, Inhaled Corticosteroid Containing Combinations (ICS/LABAs listed in "Respiratory Tract, Other") and (2) Bronchodilator, Anticholinergic Containing Combinations (LAMA/LABAs listed in "Respiratory Tract, Other") to align with the treatment options recommended by the GOLD guidelines. The reassignment of examples currently included in "Respiratory Tract, Other" class to the appropriate classes will align

[9] The *Global Strategy for Diagnosis, Management, and Prevention of COPD*, Global Initiative for Chronic Obstructive Lung Disease (GOLD), 2016. Available from: http://www.goldcopd.org/

available treatment options for patients as they present and/or progress in the care continuum.

- The draft Version 7.0 MMG are not sufficiently granular to take into account the new class of opioid analgesics with FDA-recognized abuse-deterrent properties (ADFs), instead opting to retain the broader "long-acting" and "short-acting" classes of opioid analgesics from the Version 6.0 MMG. We note that such a specific class is warranted based on FDA's recognition of the distinction of ADFs in labeling guidance[10] as well as in the Agency's Opioid Action Plan.[11] Moreover, opioid abuse is a growing issue in the U.S., and recent research has shown that Medicare beneficiaries have among the highest and most rapidly growing prevalence of opioid use disorder.[12] Emerging clinical evidence demonstrates the potential role ADFs can play in curbing opioid abuse and overdose.[13] In addition, there are a significant number of chronic pain patients, many of them elderly, who may be misusing their long-acting opioids by manipulating them for medical reasons, such as to aid in swallowing,[14] and not recognizing that this dangerously converts a long-acting opioid into a short-acting opioid. Moreover, evidence demonstrates the diversion of products from seniors, and the majority of prescription pain relievers used for non-medical purposes are obtained from family or friends.[15] In the absence of a specific ADF class of opioid analgesics, the Version 7.0 MMG may contribute to slower patient access to these therapies and will not reflect important evolutions in the standard of care for Medicare Part D beneficiaries.

- The draft Version 7.0 Model Guidelines retain the Version 6.0 format in which only a single class of "Anti-Hepatitis C (HCV) Agents" is identified in the broader category of "Antivirals." This single class is not sufficient to capture significant advances in the standard of care that have been approved by the FDA since Version 6.0 was finalized. Namely, cures—rather than "treatments"—for HCV have come to market over the last two years, and represent a significant stride forward in combating this disease, which represents a substantial public health burden for the Medicare

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[10] FDA's final April 2015 "Abuse-Deterrent Opioids" guidance not only encourages companies to conduct studies establishing a product's abuse-deterrent properties, but where these properties are supported through relevant studies, the guidance also encourages the inclusion of the abuse-deterrent information on the product's labeling. See FDA. 2015 (April). Abuse-Deterrent Opioids—Evaluation and Labeling Guidance for Industry, available at: http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm334743.pdf (last accessed October 25, 2016).

[11] FDA News Release, 2016 (February 4), Califf, FDA Top Officials Call For Sweeping Review of Agency Opioids Policies, available at http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm484765.htm (last accessed October 25, 2016).

[12] Lembke, A., and Chen, J. H. 2016 (September). Use of Opioid Agonist Therapy for Medicare Patients in 2013, *JAMA Psychiatry* 73(9):990-992.

[13] Coplan, et al., *The Effect of an Abuse-Deterrent Opioid Formulation on Opioid Abuse-Related Outcomes in the Post-Marketing Setting*, Clinical Pharmacology & Therapeutics, 100(3): 275-86 (2016).

[14] Pergolizzi Jr, J. V., R. Taylor Jr., S. Nalamachu, R. B. Raffa, D. R. Carlson, R. K. Varanasi, and E. A. (2013). Challenges of treating patients with chronic pain with dysphagia (CPD): physician and patient perspectives. *Current Medical Research & Opinion*, 30(2): 191-202.

[15] Substance Abuse and Mental Health Services Administration (SAMHSA), *Results from the 2013 National Survey on Drug Use and Health: Summary of National Findings*, NSDUH Series H-48, HHS Publication No. (SMA) 14-4863, available at: http://www.samhsa.gov/data/sites/default/files/NSDUHresultsPDFWHTML2013/Web/NSDUHresults2013.pdf (last accessed October 30, 2016).

population. Thus, this single class incorporating both the older treatments and the newer cures obscures the substantial, clinically-meaningful differences between these medicines and can negatively impact patient access to the latter (e.g., without differentiation, plans could only cover the older treatments and still be in compliance with the Medicare Part D coverage standard). To address the scientific and clinical realities between the older treatments and cures, the Expert Committee should create two HCV-related classes in the "Antivirals" category in the final Version 7.0 Model Guidelines: (1) Interferon and Peginterferon-based treatments (IFN, PEG-IFN)[;]"[16] and (2) "direct-acting antiviral (DAA)."

- The draft Version 7.0 Model Guidelines maintain the various Version 6.0 dyslipidemics classes within the broader "Cardiovascular Agents" category. However, these existing classes do not capture evolutions in the standard of care for patients with, or at high risk for, cardiovascular disease (CVD). Since Version 6.0 was finalized, proprotein convertase subtilisin kexin 9 (PCSK9) Inhibitors, already recognized as a new class of dyslipidemics, have been approved by the FDA. These monoclonal antibodies are designed to mimic a natural mutation that some people have in the PCSK9 gene, whereby blocking PCSK9 allows the liver to dramatically reduce LDL-C levels. To ensure that the Version 7.0 Model Guidelines are sufficiently comprehensive and granular to reflect the existing standard of care, the Expert Committee should consider including a new class within the "Cardiovascular Agent" category: "Dyslipidemics, Proprotein Convertase Subtilisin Kexin 9 (PCSK9) Inhibitors." PCSK9 inhibitors offer the unique ability to completely inhibit the target, leading to reliable and predictable LDL lowering versus any other dyslipidemic, and therefore warrant a unique classification within the MMG. Such an update to the Version 7.0 Model guidelines would assist Medicare Part D plans in developing drug formularies that are in alignment with the 2016 American College of Cardiology (ACC) Expert Consensus Decision Pathway regarding the use of non-statin agents for LDL-C lowering, including PCKS9 inhibitors.[17]

- As proposed, the "Dermatological Agents" category is overly broad, and the lack of classes obscures meaningful clinical differences among the included therapies. The various medicines included in this category represent several different mechanisms of action and FDA-approved indications, which are characteristics that are significant in the clinical setting. In fact, since Version 6.0 was finalized, new classes of dermatological agents, with novel mechanisms of action, have emerged. Thus, the lack of differentiation into classes within the category does not reflect the current standard of care nor does it accurately capture clinically-meaningful differences among existing and emerging therapies. To address this, the Expert Committee

[16] The Expert Committee should take into account that certain therapies and therapeutic regimens are "not recommended" by the American Association for the Study of Liver Diseases (AASLD) clinical guidelines, including "PEG-IFN/ribavirin with or without sofosbuvir, simeprevir, telaprevir, or boceprevir." See American Association for The Study of Liver Diseases and Infectious Diseases Society of America, 2016 (July 6), Recommendations for Testing, Managing, and Treating Hepatitis C: Not Recommended Regimens In HCV Treatment, available at: http://hcvguidelines.org/full-report/not-recommended-regimens-hcv-treatment (last accessed October 30, 2016).
[17] Lloyd-Jones, D. M., *et. al*. 2016. 2016 ACC Expert Consensus Decision Pathway on the Role of Non-Statin Therapies for LDL-Cholesterol Lowering in the Management of Atherosclerotic Cardiovascular Disease Risk. *Journal of the American College of Cardiology* 68(1):92-125.

should consider significantly differentiating this category into numerous classes. For example, USP could create a class for each of the following agents: anti-acne; anti-biotic; antibacterial; antifungal; anti-inflammatory; antineoplastic/anti-metabolic; antihistamine; anti-rosacea; anti-xerotic; and monoclonal antibodies and anti-cytokine agents. The Expert Committee also should consider a "catch all" class for therapies that cannot be grouped into the newly created classes (USP has employed this type of class in other categories in Version 7.0).

- The draft Version 7.0 MMG fails to list all 25 unique molecules approved to treat rare, genetic metabolic disorders in the "Genetic or Enzyme Disorder: Replacement, Modifier, Treatment" category. Moreover, draft Version 7.0 places all listed therapies into a *single* drug category, which fails to consider the fact that the genetic mutations that cause the pathophysiology of each disease are distinct, and therefore manifest as inherently different, devastating, rapidly progressing conditions, each of which requires a targeted therapeutic intervention.[18] Especially in the absence of distinct classes within the "Genetic or Enzyme Disorder: Replacement, Modifier, Treatment" category, USP must, at minimum, list each unique therapy approved to treat a single genetic metabolic disorder to ensure Part D beneficiaries are able to access these critical therapies. We also note that not all therapies that have been approved to treat genetic or enzyme disorders since January 1, 2014 are included in draft Version 7.0 under this category.[19] In general, BIO is concerned that USP's approach to updating the MMG between versions is not sufficiently comprehensive, which may result in significant, detrimental consequences for patient access to needed care. We reiterate our recommendation that USP provide additional details with regard to how newly-approved therapies were identified and considered for inclusion in draft Version 7.0, and work with stakeholders to ensure that the final Version 7.0 comprehensively reflects all FDA-approved therapies that patients may need.

While BIO has always had concerns about the granularity of categories and classes in the Model Guidelines for the entire Medicare Part D population, these concerns have become more acute since the elimination of the formulary key drug designation, which had provided another level of granularity that helped to ensure robust formularies.

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[18] The category includes therapies for the following rare, genetic metabolic disorders: alpha-1 antitrypsin deficiency, bile acid synthesis disorders, congenital sucrase-isomaltase deficiency, cystinosis, Fabry disease, Gaucher disease, hereditary tyrosinemia type 1, homocystinuria, mucopolysaccharidosis (MPS) type I (Hurler syndrome), MPS type II (Hunter syndrome), MPS type VI (Maroteaux-Lamy syndrome), peroxisomal disorders including Zellweger spectrum disorders, phenylketonuria, primary biliary cholangitis, severe combined immunodeficiency associated with ADA deficiency, and urea cycle disorder. It also includes a molecule approved for exocrine pancreatic insufficiency (EPI), which can be caused by certain rare disorders, such as Shwachman-Diamond syndrome and cystic fibrosis, but is not an inherited metabolic disorder like the others in the category. While nearly all of the therapies approved to treat these conditions are a single molecule, there are four unique FDA-approved alpha-1 proteinase inhibitor therapies for alpha-1 antitrypsin deficiency, two unique FDA-approved cysteamine bitartrate therapies for cystinosis, and six unique FDA-approved pancrelipase therapies for EPI.

[19] For example, the following therapies were approved on or after January 1, 2014, but are not included in the "Genetic and Enzyme Disorders" category of the draft Version 7.0 MMG: asfotase alfa (Strensiq) for perinatal/infantile- and juvenile-onset hypophosphatasia; uridine triacetate (Xuriden) for hereditary orotic aciduria; and elosulfase alfa (Vimizim) for mucopolysaccharidosis (MPS) type IVA (Morquio A syndrome). Additionally, we note that certain therapies that have been on the market for years have never been incorporated in the MMG, including but not limited to: alglucosidase alfa (Lumizyme and Myozyme) for Pompe disease.

B. The USP Model Guidelines must be revised frequently to support timely access to innovative medicines.

Frequent updates to the Model Guidelines are crucial to both its role in the Medicare Part D program and the EHB standards. Every American covered by these two programs should have timely access to innovative therapies. Although the MMG is meant to be revised "from time to time to reflect changes in therapeutic uses of covered Part D drugs and the additions of new covered Part D drugs,"[20] the infrequency with which the USP updates its categories and classes, in practice, presents a significant barrier to accessing these medications.

BIO appreciates that USP itself has urged CMS to adopt an annual revision process for the Model Guidelines.[21] BIO wholeheartedly shares USP's concerns that the three-year revision cycle is not consistent with the intentions of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 and believes that, similarly, the intention of the EHB provisions was to ensure that the American public has timely access to new therapies. BIO is concerned that, in the absence of timely updates to the USP, patients will lack access to innovative medicines, such as first-in-class drugs, that are not represented in existing categories or classes. Therefore, we urge USP to update the Model Guidelines at least annually. Similarly, we ask that greater detail be provided around the process for updating and the methodology around the use of the CMS FRF Alignment File as a crosswalk tool for the Model Guidelines. Increased transparency into the crosswalk methodology is especially important so that stakeholders can better understand and alert USP and CMS to any inconsistencies.

III. The Role of the Model Guidelines in the Coverage of Prescription Drugs Under EHB

BIO reiterates our appreciation that USP is addressing a long-standing concern of the industry's in developing a novel classification system that will complement the MMG but respond to the expanded use of USP guidelines throughout the healthcare sector, including as part of the prescription drug coverage standard for plans subject to EHB. Because the USP Model Guidelines were originally created for use by Medicare Part D prescription drug plans, BIO has maintained concerns that the categories and classes may not adequately represent the range of drugs needed by the populations seeking coverage under the EHB. This is because the age, socioeconomic status, medical conditions, and health care needs of individuals in the EHB population are dramatically different than those of the Medicare Part D population. Throughout the remainder of this section, we identify the specific concerns with using the MMG as a standard of EHB plans and provide comments that we ask USP to consider in completing the development of the new classification system such that it will address long-standing concerns.

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[20] Social Security Act § 1860D-4(b)(3)(C)(ii).
[21] USP. 2011. *Final Report, Summary of Methodology and Approach: USP Model Guidelines v5.0*. Rockville, MD: USP, Available at: http://www.usp.org/sites/default/files/usp_pdf/EN/healthcareProfessionals/2011-03-11methodologyandapproach.pdf.

BIO is concerned that the draft Model Guidelines' categories and classes do not sufficiently reflect the entire range of drugs that are needed by, and appropriate for, the patient population that will be covered by insurance plans subject to the EHB (including those served by health insurance Exchanges or those in the Medicaid expansion population covered through Alternative Benefit Plans). We do recognize that the Model Guidelines have made important progress, however, many issues persist. For example, prescription contraceptives are not included as a specific class in the draft Model Guidelines, yet the impact of limiting patient access to these drugs is most significant in, and almost exclusive to, the young and middle-aged adult population. Similarly, though diabetic macular edema is the most frequent cause of blindness for the young and middle-aged adult population, there is no category or class for the vascular endothelial growth factor (VEGF) products that have approved indications to treat the most serious causes of blindness. By using the USP categories and classes to define the floor for the EHB drug coverage standard, CMS may inadvertently leave individuals who require therapies that are disproportionately needed by the non-Medicare population, like prescription contraceptives and VEGF products, highly vulnerable.

Not only will more categories and classes of medicines be required to meet the needs of an EHB population, but more granularity is necessary to account for distinct therapies with clinically relevant differences, such as selective serotonin reuptake inhibitors (SSRIs) and serotonin-norepinephrine reuptake inhibitors (SNRIs). Although listed in the same USP class, extensive clinical evidence exists on the differences between SSRIs and SNRIs in the treatment of depression. Two separate pharmacological classes for these agents would better ensure that patients suffering from depression have access to the treatment most appropriate for them. Particularly when used as the formulary classification system for a benefit without protected classes, such as the EHB, it is critical that the therapeutic classes provide greater granularity.

Additionally, drugs used to treat certain conditions, such as agents when used for weight loss or agents when used to promote fertility, are excluded from Medicare Part D coverage under the Medicare statute,[22] and thus excluded from the USP categories and classes. This is troubling because one out of every eight deaths in America is caused by an illness directly related to obesity, leaving millions of Americans at risk from a preventable and treatable disease.[23] Yet despite the prevalence of this epidemic and the significant medical advances that have been made in the development of obesity drugs, specific categories and classes for obesity therapies are excluded from the Model Guidelines because of a CMS interpretation of the Medicare Part D statute's limitation on coverage of weight loss drugs. This has the effect of limiting the EHB patient population's access to these therapies because of a Medicare Part D coverage rule that has no relevance in the commercial or Exchange marketplace. Even if certain commercial and Medicaid Alternative Benefit Plans choose to cover these therapies, without inclusion as a category or class for which all EHB plans must offer coverage, many enrollees will be denied access to therapies that can significantly mitigate their risks from this serious health condition.

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[22] Social Security Act § 1860D-2(e); *id.* § 1927(d)(2).
[23] Carmona, R. H. 2003. *The Obesity Crisis in America*. U.S. Surgeon General Testimony Before the Subcommittee on Education Reform Committee on Education and the Workforce United States House of Representatives. Washington, DC. Available at: http://www.surgeongeneral.gov/news/testimony/obesity07162003.html.

BIO believes that increasing the comprehensiveness and granularity of the Model Guidelines—or doing so in the context of the new classification system—will improve access to needed therapies for patients who are covered by plans subject to EHB because it will broaden the number of covered drugs under the EHB's "one drug per USP category and class" minimum coverage standard. This is crucial to ensuring that plans do not discourage enrollment of certain patients by excluding needed therapies from plan formularies. BIO reiterates its concern that even with expanded coverage, patient access is threatened by the imposition of stringent utilization management techniques, such as specialty tier cost-sharing, prior authorization, and step therapy/fail-first protocols. Therefore, not only must USP categories and classes, as a part of the EHB minimum coverage standard, accurately reflect the treatments needed by the exchange population, but CMS must require meaningful oversight of plans' prescription drug benefit designs as well.

IV. Conclusion

We appreciate your attention to these concerns as you finalize the Version 7.0 Model Guidelines. We look forward to working with the Expert Committee to ensure that Version 7.0 reflects all of the innovative therapies needed by the Medicare Part D population, including those that have emerged in the years since Version 6.0 was implemented, as well as takes into consideration its role in ensuring that individuals enrolled in health plans subject to the EHB have access to the full range of drugs and biologicals they need. Please feel free to contact me if you have any questions or if we can be of further assistance.

Sincerely,

/s/

Laurel L. Todd
Vice President
Healthcare Policy & Research

December 5, 2016

Donna Bohanon, R.Ph. CPPS
Therapeutic Information and Formulary Support Expert Committee
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cc: Kevin Counihan
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BY ELECTRONIC DELIVERY

RE: Draft USP Drug Classification System

Dear Members of the U.S. Pharmacopeial Convention Healthcare Quality Expert Committee:

The Biotechnology Innovation Organization (BIO) is pleased to submit the following comments to the U.S. Pharmacopeial Convention (USP) Healthcare Quality Expert Committee (the "Expert Committee") in response to the draft USP Drug Classification (DC) system (the draft "USP DC") released November 1, 2016.[1] BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and in more than 30 other nations. BIO's members develop medical products and technologies to treat patients afflicted with serious diseases, to delay the onset of these diseases, or to prevent them in the first place. In that way, our members' novel therapeutics, vaccines, and diagnostics not only have improved health outcomes, but also have reduced healthcare expenditures due to fewer physician office visits, hospitalizations, and surgical interventions.

In this letter, BIO offers high level comments on various aspects of the draft USP DC. Many of these comments are echoed in our comprehensive comments in response to the draft Version 7.0 Medicare Model Guidelines (MMG), which we have attached as an appendix for the Expert Committee's ease of reference.[2]

BIO is encouraged by the release of the USP DC as we agree that such a system is necessary to account for the expanded manner in which USP guidelines are used in the healthcare system. However, as an initial matter, we urge USP to provide additional context with regard to how the USP DC is meant to be used. Specifically, we note that stakeholders' familiarity with USP MMG translates to an association of the USP drug classification systems with therapies covered under the pharmacy benefit. However, the

[1] U.S. Pharmacopeial Convention (USP), Drug Classification (November 1, 2016), available at: http://www.usp.org/usp-healthcare-professionals/usp-drug-classification-system (last accessed November 7, 2016).
[2] The Appendix begins on p. 5.

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draft USP DC includes outpatient prescription drugs that could be administered under a pharmacy or medical benefit, which may create confusion among stakeholders.

Moreover, while there may be ambiguity with regard to the use of the USP DC in the context of therapies covered under a pharmacy benefit, it is clear that the classification system is inappropriate, and should not be referred to as a benchmark, for medical benefit drug coverage, which the Expert Committee should consider stating outright. This context is critical to ensure that the USP DC is used in a manner consistent with its purpose and composition. BIO also asks USP to provide additional information on efforts to work with CMS, and other relevant organizations, to implement the USP DC in the context of pharmacy benefit drug coverage, including the timeline for such efforts. A better understanding of these details will help stakeholders to tailor future feedback and work with CMS (and others) to implement the USP DC in a manner consistent with its development.

Since the USP DC were developed based on the USP Guiding Principles for establishing Categories and Classes, BIO reiterates the concerns with these principles that we expressed in the context of our comments in response to the USP MMG Draft Version 7.0.[3] Specifically, the Guiding Principles note that the classification system is developed utilizing pharmacotherapeutic evidence for an FDA-approved agent. However, it is unclear exactly how therapies that have gained FDA approval are identified for purposes of inclusion in the USP DC and what mechanisms are in place to verify the accuracy and comprehensiveness of this list before the initial USP DC was released. BIO urges the Expert Committee to provide additional information on this process specific to the USP DC development to allow stakeholders to comment on mechanisms to improve and streamline the process in the future. Additional information also will improve stakeholders' ability to identify potential gaps in the therapies included in the USP DC; such gaps may have real-world impact on patient access to needed medicines, and thus, should be addressed before the USP DC is finalized.

Despite the progress made, BIO believes that the USP DC is still not sufficiently comprehensive or granular to adequately represent the prescription drugs that many patients need (especially in the EHB benchmark construct of the greater of one drug per USP category or class or one drug per category and class of the State benchmark plan). On the issue of comprehensiveness, we ask the Expert Committee to be more consistent across the USP DC with regard to including a broad list of examples across classes. For example, some classes, like the "molecular target inhibitors" class under the "Antineoplastics" category, have nearly exhaustive lists while other USP classes under the same category, such as the "monoclonal antibody/antibody-drug conjugate" class, do not present as many illustrative examples for providers and plans.[4]

In addition to the need for increased comprehensiveness, BIO urges the Expert Committee to improve the granularity of the USP DC as well. For example, we note that USP includes therapies in the "Antineoplastics, Other" 'catch-all' class of the "Antineoplastics" category that have significant pharmacological differences and treat distinct patient populations (e.g., the therapeutic indications of drugs listed in this class are as diverse as B-cell chronic lymphocytic leukemia versus osteosarcoma, with diverse mechanisms of action and diverse recommendations with regard to treating sequencing).

[3] See Appendix at p. 2.
[4] Draft USP DC at pp.15-16.

As another example, we ask the Expert Committee to consider the "Genetic or Enzyme Disorder: Replacement, Modifier, Treatment" category. Each of the 25 unique molecules approved to treat rare, genetic metabolic disorders should be included in the category. In fact, in response to the USP MMG draft Version 7.0, we also noted that not all therapies approved to treat genetic or enzyme disorders since January 1, 2014 are listed.[5] Further, each of these targeted therapeutic interventions are included within a *single* drug category, which fails to consider that discrete mutations cause each genetic or enzyme disorder that manifests as inherently different, devastating, rapidly progressing conditions.[6] Thus, BIO continues to urge the Expert Committee to improve the granularity and comprehensiveness of this category and class, as well as improve granularity across the draft USP DC generally. In the absence of unique classes in this category, we request that each unique therapy approved to treat a genetic or enzyme disorder is listed.

Similarly, we note that the draft USP DC does not consistently include combination products within its classification system. For example, the current draft does not incorporate any oral contraception combination products. This exclusion may result in the diminished utility of the final USP DC to its end users: namely, payers and providers. BIO asks USP to address this issue in the final iteration of the USP DC to ensure the system more accurately reflects the outpatient prescription therapies appropriate for the patient populations for which it will be utilized.

In general, BIO agrees with the Expert Committee that the likely use of the USP DC will necessitate annual updates. However, we urge the Expert Committee to finalize the details of such a process. For example, it is unclear what similarities the process will bear to the USP MMG update—which takes place only every three years—including how stakeholders can participate and provide feedback throughout the year. It also is unclear if the annual update will run on the same timeframe, and a draft updated version released for stakeholder feedback, each year. BIO would recommend such standardization to improve the predictability of the process, and in turn, improve stakeholders' ability to participate.

Finally, though BIO recognizes that the use of the USP DC as a benchmark for prescription drug coverage is not the purview of the Expert Committee, it is nonetheless important that the Expert Committee finalize the USP DC with its intended use in mind, as is done for the USP MMG. In fact, it is with the use of the USP DC in mind that it was created. BIO continues to contend that the classification system used as a minimum prescription

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[5] For example, the following therapies were approved on or after January 1, 2014, but are not included in the "Genetic and Enzyme Disorders" category of the draft Version 7.0 MMG: asfotase alfa (Strensiq) for perinatal/infantile- and juvenile-onset hypophosphatasia; uridine triacetate (Xuriden) for hereditary orotic aciduria; and elosulfase alfa (Vimizim) for mucopolysaccharidosis (MPS) type IVA (Morquio A syndrome). To the extent that the Expert Committee continues to incorporate outpatient prescription drugs that are likely to be covered under the medical benefit (e.g., physician-administered therapies), we also note that sebelipase alfa (Kanuma®) has been approved since January 1, 2014 but is not included in the draft USP DC. Additionally, we note that certain therapies that have been on the market for years have never been incorporated in the MMG, including but not limited to: alglucosidase alfa (Lumizyme and Myozyme) for Pompe disease.

[6] The category includes therapies for the following rare, genetic metabolic disorders: alpha-1 antitrypsin deficiency, bile acid synthesis disorders, congenital sucrase-isomaltase deficiency, cystinosis, Fabry disease, Gaucher disease, hereditary tyrosinemia type 1, homocystinuria, mucopolysaccharidosis (MPS) type I (Hurler syndrome), MPS type II (Hunter syndrome), MPS type VI (Maroteaux-Lamy syndrome), peroxisomal disorders including Zellweger spectrum disorders, phenylketonuria, primary biliary cholangitis, severe combined immunodeficiency associated with ADA deficiency, and urea cycle disorder. It also includes a molecule approved for exocrine pancreatic insufficiency (EPI), which can be caused by certain rare disorders, such as Shwachman-Diamond syndrome and cystic fibrosis, but is not an inherited, rare metabolic disorder like the others in the category. While nearly all of the therapies approved to treat these conditions are a single molecule, there are four unique FDA-approved alpha-1 proteinase inhibitor therapies for alpha-1 antitrypsin deficiency, two unique FDA-approved cysteamine bitartrate therapies for cystinosis, and six unique FDA-approved pancrelipase therapies for EPI.

drug coverage benchmark for plans subject to EHB must be comprehensive and sufficiently granular to capture all of the therapies patients enrolled in these plans may need. We recognize—and appreciate—that the USP DC contains more pharmacy benefit categories than the USP MMG, including the addition of an anti-obesity category. This represents the potential broader applications of the USP DC outside of confines of Medicare Part D.

However, as we noted above, the draft USP DC includes some prescription drugs that are likely covered under the medical benefit, which may confuse an assessment of the comprehensiveness of EHB plans' drug coverage under the pharmacy benefit. Thus, while we appreciate the broader inclusion of pharmacy benefit therapies under the USP DC, USP must clarify the role of the system in the pharmacy benefit context and acknowledge the inappropriateness of utilizing the system in the medical benefit context—discussed above—before it finalized and utilized.

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We appreciate your attention to these concerns as you finalize the USP DC. We look forward to working with the Expert Committee to ensure that the USP DC reflects all of the innovative therapies needed by patients, as well as takes into consideration its role in ensuring that individuals enrolled in health plans subject to the EHB have access to the full range of drugs and biologicals they need. Please feel free to contact me if you have any questions or if we can be of further assistance.

Sincerely,

/s/

Laurel L. Todd
Vice President
Healthcare Policy & Research