BIO
BIOTECHNOLOGY
INDUSTRY ORGANIZATION

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BY ELECTRONIC DELIVERY

Maria Ellis
Executive Secretary for MEDCAC
Centers for Medicare & Medicaid Services
Office of Clinical Standards and Quality
Coverage and Analysis Group
S3–02–01
7500 Security Boulevard
Baltimore, MD 21244

Re: Request for Comments Regarding Evidentiary Characteristics of Coverage with Evidence Development

Dear Ms. Ellis:

The Biotechnology Industry Organization (BIO) appreciates this opportunity to respond to the Medicare Evidence Development & Coverage Advisory Committee's (MEDCAC) questions regarding the evidentiary characteristics of coverage with evidence development (CED). BIO is the largest trade organization to serve and represent the biotechnology industry in the United States and around the globe. BIO represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology products.

As a representative of members dedicated to developing new therapies and ensuring access to them, BIO supports the use of CED when it is used to help patients gain access to otherwise unavailable drugs, biologicals and other therapies. Our members invest billions of dollars each year in clinical research to develop and disseminate evidence to help guide the effective use of their therapies. This investment generally continues after the Food and Drug Administration's (FDA's) stringent drug and biological approval requirements are met and often includes post-marketing studies required by FDA. We also support the dissemination of this evidence, as appropriate, to further clinical knowledge and enhance and improve the clinical decision-making process.

Before responding to MEDCAC's panel voting questions,[1] we believe it is important to address more broadly the applicability of CED to drugs and biologicals. The Centers for Medicare and Medicaid Services (CMS) should not second-guess FDA's drug approval decisions by requiring additional post-approval studies of a drug or biological for "medically accepted indications," as defined by statute or pursuant to longstanding Medicare guidance, as FDA has already determined that the products are safe and effective. CED is not necessary or appropriate for FDA-approved uses of drugs and biologicals that are approved for use in the Medicare population, including disabled and patients older than age 65. Moreover, the Social Security Act's definition of "drugs or biologicals" requires that each drug or biological be included or approved for inclusion in the United States Pharmacopoeia or be "approved by the pharmacy and drug therapeutics committee (or equivalent committee) of the medical staff of the hospital furnishing such drugs and biologicals for use in such hospital."[2] These requirements, combined with FDA approval, provide additional assurance that the therapy has been thoroughly reviewed by independent experts prior to coverage.

In addition, CED should not be applied to drugs and biologicals that are used for "medically accepted indications" of drugs or biologicals used in anti-cancer chemotherapeutic regimens, which include the FDA-approved uses as well as uses that are listed in certain compendia or are supported by peer-reviewed literature.[3] Medicare also has long granted its contractors authority to determine that unlabeled uses of other drugs are "medically accepted" based on "the major drug compendia, authoritative medical literature and/or accepted standards of medical practice."[4] By using authoritative compendia and medical literature to define "medically accepted indications," the statute and Medicare's guidance protect beneficiaries' timely access to drugs and biologicals while also ensuring that Medicare's coverage policies are truly evidence-based.

Finally, FDA and CMS each have separate and distinct mandates that CMS must adhere to in any redesign of the CED policies. While BIO supports the two agencies working together to ensure patients have access to needed therapies, it is critical that the unique missions of these two agencies remain distinct, and not be comingled or compromised in the course of CED application. Congress deliberately bestowed FDA and CMS with distinct authorities and standards for approval and coverage decisions respectively, consistent with the different missions and constituencies of the agencies. FDA has the appropriate combination of expertise and resources to review and approve study design and results of clinical trials needed to demonstrate that drugs and biologicals are safe and effective. CMS should not attempt to use its limited resources to duplicate these capabilities. The industry should not be put into a "double jeopardy" situation (i.e., CMS should not apply CED to those products that are already subject to REMs or other post-market studies required by the FDA).

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[1] Centers for Medicare and Medicaid Services. MEDCAC Meeting 5/16/2012 - Evidentiary Characteristics for Coverage with Evidence Development (CED). Available at: http://www.cms.gov/medicare-coverage-database/details/medcac-meeting-details.aspx?MEDCACId=63&TimeFrame=7&DocType=All&bc=AgAAYAAAAAAA&

[2] SSA § 1861(t)(1).

[3] SSA § 1861(t)(2)(B).

[4] Medicare Benefit Policy Manual, ch. 15, § 50.4.2.

BIO appreciates CMS' attempt to solicit stakeholders' input regarding its CED policies and understands that CMS leadership is seeking comments to help develop new guidance on CED. We urge CMS to make any change to CED in response to, or as a result of, the MEDCAC meeting, subject to an additional notice and comment period so that stakeholders have the opportunity to comment on specific changes being proposed.

Below, BIO responds to MEDCAC's five panel voting questions on CED.

Question 1: Are there significant, practical differences between binary and non-binary coverage paradigms? If the answer favors "Yes" please discuss the advantages and disadvantages of non-binary paradigms.

While BIO believes there are significant and practical differences between binary and non-binary coverage paradigms, we note that the definition of a non-binary coverage paradigm as provided by CMS is unclear. As stated in the meeting notice, a non-binary coverage paradigm is defined as a "qualified coverage decision that may evolve as evidence base changes over time, with planned reconsideration based on the achievement of pre-specified clinical outcomes."[5] Based on CMS' experience with CED to date, BIO is not aware of the metrics CMS uses for "reconsideration" of CED, and we are not aware whether or how reconsideration of a national coverage determination (NCD) applying CED is "planned." We also note that there is no guidance on how an item or service "graduates" from CED after the appropriate amount of evidence has been collected. This lack of clarity underscores the need for transparency and highlights the importance of stakeholder input in any application of CED. For example, CMS must be clear about why CED for a given technology is considered necessary, and identify, *a priori,* the outstanding evidentiary questions required to be resolved. In addition, CMS needs to carefully weigh the additional costs and burdens imposed on stakeholders with the types of studies it considers sufficient for CED purposes. For example, CMS must consider whether a prospective observational CED study using primary data is truly necessary when a retrospective study based on existing secondary data sources (*e.g.,* claims or EMR data) might suffice given CMS's evidentiary needs. Without a clear understanding—by all stakeholders involved—of the evidentiary questions and requirements, clinical trials, registries, and other methods of collecting evidence may not be designed in the most efficient manner to address those requirements and patients' access to needed therapies may be delayed as the additional evidence is gathered.

The non-binary paradigm has a few notable disadvantages, the first being that it creates a less predictable coverage and reimbursement environment. It is critical that CMS recognize that current Medicare policies encourage innovation and continued research by giving patients a choice of new therapies and new uses of therapies and creating a relatively stable and predictable coverage and reimbursement environment, which is particularly critical for many of BIO's emerging company members who depend on private equity investment to fund drug

[5] Centers for Medicare and Medicaid Services. MEDCAC Meeting 5/16/2012 - Evidentiary Characteristics for Coverage with Evidence Development (CED). Available at: http://www.cms.gov/medicare-coverage-database/details/medcac-meeting-details.aspx?MEDCACId=63&TimeFrame=7&DocType=All&bc=AgAAYAAAAAAA&

development. As CMS recognized when it first developed principles for applying CED,[6] the need to provide for a predictable coverage and reimbursement environment is still relevant today, and should therefore be reflected in new guidelines. If, under a newly designed CED policy, manufacturers are unclear about the rationale for CMS' application of CED, investment in new medical technologies may be severely interrupted, and patient access to improved drugs and biologicals may be delayed. Any application of CED must be developed in a clear and predictable manner, with opportunity for public comment, to ensure that CMS reaches an appropriate decision. Thus, to ensure transparency and the opportunity for stakeholder input, CED should occur only within the auspices of the NCD process, which has procedures to garner input from stakeholders and has protections in place to ensure that inappropriate coverage determinations do not occur.

A second disadvantage to a non-binary paradigm is the potential for additional costs to be incurred by all stakeholders. The drug development and FDA review and approval process require significant investment by manufacturers. CED or other non-binary coverage decisions only add to those costs. Currently, there is no designated funding source for CED efforts. As discussed by the Medicare Payment Advisory Committee (MedPAC) in its July 2010 report to Congress, this lack of a designated funding source for CED efforts results in inconsistency, confusion, and most importantly, delay in the initiation of data collection efforts.[7]

In addition to the added costs CED imposes upon manufacturers, CMS should also weigh the additional costs to providers, in terms of the additional time and burden to collect additional evidence. Physicians who participate in clinical trials often donate considerable amounts of time and resources to evaluating patients' eligibility for trials, data collection, and drug administration services that frequently are not reimbursed by trial sponsors. To date, the costs of performing studies required by CED policies, including maintenance of registries and collection of data, have largely fallen on providers and manufacturers. BIO therefore urges CMS to exercise caution and work with stakeholders to ensure that any application of CED is truly necessary and is implemented in the most economical manner possible. We also urge CMS to revise its payment policies to reimburse providers for the costs of performing the data collection activities required by CED.

Patients also face additional CED-related costs in the form of a potential for decreased access to care, specifically in cases where the patient does not qualify for the required clinical

[6] Guidance for the Public, Industry, and CMS Staff, National Coverage Determinations with Data Collection as a Condition of Coverage: Coverage with Evidence Development, July 12, 2006. The eight principles governing the application of CED as articulated in the guidance document are: a) National Coverage Determinations (NCDs) requiring CED will occur within the NCD processes, which is transparent and open to public comment; b) CED will not be used when other forms of coverage are justified by the available evidence; c) CED will in general expand access to technologies and treatments for Medicare beneficiaries; d) CMS expects to use CED infrequently; e) CED will lead to the production of evidence complementary to existing medical evidence; f) CED will not duplicate or replace the FDA's authority in assuring the safety, efficacy, and security of drugs, biological products, and devices; g) CED will not assume the NIH's role in fostering, managing, or prioritizing clinical trials; h) Any application of CED will be consistent with federal laws, regulations, and patient protections.

[7] Medicare Payment Advisory Committee. July 2010 Report to Congress: Chapter 1, "Enhancing Medicare's Ability to Innovate." Available at: http://www.medpac.gov/chapters/Jun10_Ch01.pdf

trial, or cannot travel to study sites. For example, many Medicare beneficiaries are ineligible to participate in clinical trials due to age, comorbidities, or complications. Some beneficiaries, particularly those in rural areas or with limited incomes, may choose not to participate if the trial would require them to travel long distances to receive care. Many beneficiaries may be discouraged from participating in trials that would require them to change physicians. Beneficiaries must continue to have access to appropriate therapies, regardless of whether they participate in clinical trials. Therefore, we urge CMS to clarify that any application of CED will be used to expand access to care in clinical trials, but will not limit carriers' discretion to cover the same uses of the items or services outside the trials.

The additional costs incurred as a result of a poorly designed and vague CED policy or inappropriate application of CED may culminate in a chilling effect on innovation, harming patient care both now and in the future. If these issues are not addressed in future CED guidance, uncertainty about reimbursement for medical technologies could interfere with private market research priorities, slowing the development of new life-saving therapies. Thus, BIO urges CMS to recognize that imposing additional clinical research requirements may limit manufacturers' ability to continue to innovate, especially for therapies for the Medicare population. BIO recommends that CMS minimize these burdens whenever possible.

Although there are several significant disadvantages to a non-binary paradigm, there is one very notable advantage: it can provide coverage for items and services that would otherwise not be covered by Medicare. In most instances, the Medicare statute already provides an effective framework for determining the appropriate coverage of drugs and biologicals. However, BIO supports CED in those situations when it is used to increase patient access to critical drugs and biologicals, and other items and services, without affecting the existing statutory framework.

Question 2: Can an evidentiary threshold be defined to invoke CED? If the answer favors "Yes" please discuss how this threshold should be identified. If the answer favors "No" please discuss the impediments and recommend strategies to overcome them.

BIO believes that it would be inappropriate for CMS to apply a single evidentiary threshold to invoke CED for all types of items and services because the coverage determination process involves complex judgments and values, and interventions are highly variable. For example, the level of evidence that CMS may require for drugs, biologics, devices, or medical procedures will vary based on the characteristics of these interventions. Each of these items or services requires different standards for approval, which in turn, warrant different research questions. Even within a given category of technology, evidentiary requirements may vary based on factors including, but not limited to, those identified in Question 3.

BIO continues to believe that CED should rarely be applied to drugs and biologicals, especially for their FDA-approved indications. These therapies are subject to a rigorous FDA review and approval process, and their approved labeling and prescribing information clearly describes the population for which each therapy is approved and incorporates the data supporting each indication. As discussed above, there is already a well-established

evidentiary threshold for recognition of medically accepted indications for on and off-label use of drugs and biologicals. BIO maintains that these requirements are sufficient for most drugs and biologicals, and that CED is inappropriate for most products within the typical coverage analysis.

In order to determine an appropriate threshold for each application of CED, CMS should work collaboratively with stakeholders representing the full range of expertise and values in evaluating the existing evidence, assessing the need to collect additional evidence, and constructing studies that can be used under CED NCDs. Because this process would be sensitive to the unique issues raised by each particular intervention, it is critical that CMS work closely with all stakeholders involved. It is equally critical that CMS establish a well-defined and transparent CED policy that is initiated only after clearly communicating the reasons for applying CED and identifying the research questions justifying application of CED. These communications should be understood by all interested stakeholders, and the timeline for sufficient evidence development should be part of the ongoing dialogue between CMS, stakeholders, and appropriate expert advisors, such as clinical epidemiologists and scientists. Thus, any new guidance on CED should describe CMS' proposed process for communication with manufacturers and other relevant stakeholders prior to the opening of a national coverage analysis and the potential application of CED, and its proposed process for involving them in an open and transparent dialogue as the issue is considered and the research questions are generated.

Question 3: How would an evidentiary threshold to invoke CED be influenced by the following?

- **a. whether the item or service is a diagnostic v. a therapeutic technology;**
- **b. the severity of the disease;**
- **c. the safety profile of the technology;**
- **d. the availability of acceptable alternatives for the same disease/condition;**
- **e. other factor(s);**
- **f. a combination or tradeoff involving two or more of the above?**

Each of the items above influences the possible application of CED; however, these are just examples of the factors affecting use of CED. Other items to consider include patient preference, possible side effects, quality of life measures, among other factors. Moreover, each of these factors contributes to the unique context of the specific technology being considered. BIO believes that in order for CED to be applied appropriately, the process must be flexible and accommodating as opposed to mechanistic and prescriptive. We discuss the different factors in more detail below.

As noted in Question 2, evidentiary questions are likely to vary based on the type of technology being considered for coverage. It is important to note that these evidentiary questions will differ both across and within technology categories, *i.e,* diagnostic versus

therapeutic technologies. MEDCAC's existing guidelines[8] address how evidence should be evaluated based on the type of technology, and include a separate appendix specifically focused on evaluating evidence for diagnostic tests. These guidelines acknowledge that unlike pharmaceutical and biological assessments, "direct proof of effectiveness of diagnostic tests is usually unavailable," and recognize that "the design and evaluation of trials related to diagnostic tests tends to be more difficult than those for therapies because the 'gold standard' of truth is frequently missing in these trials or the source of patients may be unrepresentative (*e.g.*, by stage of disease or site of care)."[9] As a result, the Committee is instructed to answer a set of questions which "collectively determine whether there is convincing indirect evidence that the test will lead to better health outcomes." These questions include:[10]

- Is the evidence adequate to determine whether the test provides more accurate (*i.e.*, measures of specificity and sensitivity) diagnostic information? Thus, when the alternative under consideration is another diagnostic strategy, MEDCAC will specifically need to decide "whether the estimated accuracy of a test in a study is likely to be distorted by a substantial degree of bias or whether the limitations of the study are sufficiently minor that it is possible to draw conclusions about the accuracy of the test."
- If the test changes accuracy, is the evidence adequate to determine how the changed accuracy affects health outcomes? MEDCAC acknowledges that "improved accuracy leads to effective treatment for more people who truly have the disease, while helping to avoid unnecessary treatment in people who would not benefit from it."

Thus, as MEDCAC itself, acknowledges, the evidentiary thresholds must be considered differently for a drug versus a diagnostic.

With respect to the threshold for diagnostics, CMS must recognize the practical limitations on data development inherent in the diagnostic industry. Product life cycles, payment levels, and investment returns may not support the capital necessary for large scale, randomized controlled clinical trials. Expectations for data generation prior to reconsideration must be consistent with these realities.

Likewise, treatments for diseases with different severity levels may require different levels of evidence. Where a disease is serious or life-threatening, limitation of coverage to patients within a registry or clinical trial may have a negative impact on patients' health and possibly their prospects of survival. Furthermore, it might in some cases have implications for public health (with respect, for example, to certain infectious diseases). In such cases, use of CED should be limited; *i.e.,* the threshold for invoking CED should be high. Furthermore, again, it is important to note that CMS should not duplicate FDA's efforts. FDA's drug approval process appropriately takes into account severity of disease: "[FDA's] procedures reflect the

[8] Medicare Coverage Advisory Committee Operations and Methodology Subcommittee. "Process for Evaluation of Effectiveness and Committee Operations." Revised (initial meeting): July 21, 2005, Revised and approved (by CMS): January 12, 2006.
[9] *Ibid.*
[10] *Ibid.*

recognition that physicians and patients are generally willing to accept greater risks or side effects from products that treat life-threatening and severely-debilitating illnesses, than they would accept from products that treat less serious illnesses. These procedures also reflect the recognition that the benefits of the drug need to be evaluated in light of the severity of the disease being treated."[11]

A technology's safety profile will also affect the evidentiary bar the product must reach. As noted previously, drugs and biologics must be approved by FDA, so data and information on the product's safety will already been evaluated and continue to be scrutinized following FDA approval. Congress provided the Agency with additional authorities to enhance the safety and effective use of these products.. For example, the FDA Amendments Act of 2007 provided FDA with additional authority to require post-market labeling changes and clinical studies and to mandate Risk Evaluation and Mitigation Strategies (REMS). These authorities are carefully balanced to address the determination and maintenance of a benefit-risk balance for drugs and biologicals. Additionally, unlike other types of technologies, evidence on both safety and efficacy of many drugs and biologicals are collected and made available to clinicians through an array of medical compendia, which CMS itself uses to identify medically accepted indications for drugs and biologicals.

The availability of acceptable treatment alternatives also has an effect on evidentiary requirements. This is particularly relevant for rare diseases and orphan drugs, where it is often the case that few or no alternative treatments are available. Many therapies targeting rare or orphan diseases do not have an evidence base defined for the general population due to the vulnerabilities, small size, heterogeneity, and other characteristics of these patient populations, and access to the most appropriate course of treatment must be preserved. Congress has recognized these difficulties, and sought to increase access to these treatments via the Orphan Drug Act. Additionally, FDA considers the existence of other therapies in its review and approval process, in the context of accelerated approval fast track, and priority review.

As mentioned above, there are other, patient-centric factors that should affect evidentiary standards, and these must be appropriately weighed when applying CED. Medicare policy has consistently placed high value on patient preference in choosing providers and has recognized that providers must have the flexibility to tailor the appropriate course of treatment for each patient based on individual patient preferences and clinical circumstances. MEDCAC itself recognizes such factors when evaluating evidence: "The [MEDCAC] greatly values information on the effect of treatments on quality of life, functional status and other relevant aspects of health."[12] As such, CMS should consider patient preference and quality of life measures in developing evidentiary requirements in CED. The presence or absence of potential side effects should also be considered in developing the evidentiary framework for a new technology. Serious side effects can have a significant impact on patients' ability to continue a therapy, and can play an important role in patient decision-making. In addition, patient heterogeneity and

[11] 21 C.F.R. Part 312, Subpart E.
[12] Medicare Coverage Advisory Committee Operations and Methodology Subcommittee. "Process for Evaluation of Effectiveness and Committee Operations." Revised (initial meeting): July 21, 2005, Revised and approved (by CMS): January 12, 2006.

differential response to treatment is an emerging and complex science. In determining the need for CED, this issue is critical to assess and can only be done on a case-by case-basis as a global evidence base of the underlying science emerges.

These factors do not exist in a vacuum. In fact, consideration of each factor may involve tradeoffs with other factors. In situations where there are few or no treatment alternatives, patients and providers may assign less weight to product safety profiles than in situations where there are more alternatives. Likewise, if a patient has a serious and life-threatening health issue, such as late stage cancer, and there are limited treatment options, the FDA is appropriately prepared to evaluate these combinations of factors and in many cases, accept a higher level of risk. Again, CMS should not duplicate FDA efforts by requiring additional post-approval studies of a drug or biological for its approved indications, as FDA is required to take these same trade-offs into account. As FDA has stated, "While the statutory standards apply to all drugs, the many kinds of drugs that are subject to them and the wide range of uses for those drugs demand flexibility in applying the standards. Thus FDA is required to exercise its scientific judgment to determine the kind and quantity of data and information an applicant is required to provide for a particular drug to meet them."[13]

It is critical that CMS use these and other factors when evaluating the appropriateness of CED for an item or service, and BIO appreciates CMS' recognition of these factors as it considers changes to CED policies. BIO emphasizes that, to justify the application of CED, it is critical for CMS to demonstrate that a research gap exists which frustrates physician and patient efforts to identify the most medically appropriate therapy. CED can be an important tool to help patients and their doctors make clinical decisions only if it is used judiciously.

Question 4: How would an evidentiary threshold to invoke CED be influenced if the outstanding questions focused only on the generalizability of a strong but narrow evidence base to

i. additional settings;

ii. additional practitioners;

iii. broader clinical indications for related or unrelated diseases?

An example of a related condition might include a different stage of the same cancer. An example of an unrelated condition might include the use of a cancer drug for a rheumatologic disease.

In the case of additional settings, we envision an injectable or infusible drug being made available for a patient to use at home, or a procedure that had been only available in the inpatient setting being available in the hospital outpatient department. In either of these situations, BIO reiterates the importance of a transparent process that incorporates stakeholder comment on whether the additional settings raise discrete clinical issues and specific evidentiary questions that justify application of CED.

[13] 21 C.F.R. Part 314.105, Subpart C.

Part (iii) of this question includes off-label medically accepted uses of unlabeled drugs and biologicals, and BIO again notes that there is already an established threshold for off-label uses of drugs and biologics—particularly for cancer products—through the statutory provisions regarding use of compendia to identify medically accepted indications. Congress intended for Medicare beneficiaries to have access to all appropriate therapies in their battles against cancer, and the existing statute[14] establishes an efficient and evidence-based decision-making process for determining which uses Medicare must cover. Therefore, any application of CED should in no way interfere with the statute's assurance of access to these important therapies.

Question 5: Can an evidentiary threshold be defined to trigger an evidentiary review to determine if CED should cease, continue or be modified? Please discuss whether the factors identified in Questions 3 and 4 are relevant to Question 5. If the answer favors "Yes" please discuss how this threshold should be identified. If the answer favors "No" please discuss the impediments and recommend strategies to overcome them.

BIO believes that an evidentiary threshold could be defined to trigger an evidentiary review to determine whether CED should cease, continue, or be modified. BIO continues to stress, as we have in previous comments, the importance of a predictable, transparent, and clearly defined CED policy. The outstanding research questions must be identified at the outset of CED, the process must be clear and understandable, and each data collection activity must have a clearly defined end point. Stakeholders must know at what point enough evidence is collected to trigger a review for full coverage. Additionally, BIO believes strongly that CED studies should not be an open and undefined data gathering exercise: CED decisions should have clearly defined timeframes for reconsideration of the evidence. We acknowledge that while this timeline may be different for various products or services, it should be part of the ongoing dialogue between CMS, the interested stakeholders, and appropriate expert advisors, such as clinical epidemiologists and scientists.

As discussed above, BIO believes that different technologies require different evidentiary thresholds. CMS should not apply a one-size fits all approach to these different technologies, or even within the realm of drugs and biologicals, as noted in question 3. We therefore recommend that CMS recognize the relevance of the principles established in the 2006 guidance document and use these as a foundation for improving the CED policy. In particular:

- CED should not be used when other forms of coverage are justified by the available evidence.
- CED should, in general, expand access to technologies and treatments for Medicare beneficiaries.
- CMS should use CED infrequently.
- CED should lead to the production of evidence complementary to existing medical evidence, and should not duplicate existing studies.
- CED should not duplicate or replace the FDA's authority in assuring the safety, efficacy, and security of drugs, biological products, and devices.

[14] SSA § 1861(t)(2).

The principles of the 2006 document were developed after careful consideration of stakeholder comments, are still relevant today, and warrant further consideration throughout this process of updating CED.

Conclusion

BIO again wishes to thank MEDCAC for the opportunity to comment on the evidentiary characteristics of CED. We hope that MEDCAC will continue to solicit input from stakeholders and will develop a CED policy that is transparent and predictable. We reiterate our belief that drugs and biologicals are already subject to the stringent FDA approval process and other statutory requirements, and thus CED is not appropriate for the FDA-approved uses of drugs and biologicals—or for off-label uses of chemotherapy and other drugs that are covered within the existing statutory framework. BIO does support the use of CED to expand patient access to therapies that would not otherwise be available.

Please feel free to contact Alyson Pusey at 202-449-6384 (apusey@bio.org) if you have any questions regarding this matter.

Respectfully submitted,

/s/

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