BIO
BIOTECHNOLOGY
INDUSTRY ORGANIZATION

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BY ELECTRONIC DELIVERY

Sherry A. Glied
Assistant Secretary for Planning and Evaluation
Department of Health and Human Services
Hubert H. Humphrey Building, Room 447-D
200 Independence Avenue, SW
Washington, DC 20201

Re: Comparative Effectiveness Research (CER) Inventory

Dear Dr. Glied:

The Biotechnology Industry Organization (BIO) appreciates the opportunity to submit the following comments on the Office of the Assistant Secretary for Planning and Evaluation (ASPE) Request for Information (RFI) regarding the creation of an Inventory for Comparative Effectiveness Research (CER).[1] BIO represents more than 1,200 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 an industry committed to discovering new cures and ensuring patient access to them, BIO strongly supports efforts to increase the availability of accurate scientific evidence to inform clinical decision-making. When appropriately applied, CER can be a valuable tool that, together with a variety of other types of medical evidence, can contribute to improvements in health care quality. We are providing comment on the RFI to draw your attention to several policy issues raised by the proposed Inventory.

Establishing the Inventory Framework

BIO understands the value in creating a database to ensure that patients and their health care providers are armed with the best available information to assess the relative clinical benefits and risks of various treatment alternatives. However, BIO believes that ASPE's efforts to create a national inventory may be premature. It is imperative that policymakers first have the opportunity to deliberate on the standards and methodologies for conducting CER to help determine the criteria upon which to include relevant CER into the database. Additionally, these criteria will have a direct impact on the potential sources for identifying credible and

[1] 75 Fed. Reg. 41867 (July 19, 2010).

scientifically rigorous CER. Without the establishment of the definitions and standards required, BIO has concerns about the credibility of the information that may be included in the CER inventory.

Specifically, BIO is concerned that by instituting a framework and establishing potential requirements for which data qualify for inclusion in the CER inventory, ASPE could be establishing a *de facto* threshold for what constitutes credible CER. BIO believes that comprehensive and careful selection of evidence is an essential component of sound comparative effectiveness evaluation, and that the criteria used for selection of CER data to be included in the inventory must be thoroughly considered. There should be a detailed verification and validation process for all information included in the inventory, as well as specific criteria for which data are entered into the inventory.

The drafters of the Patient Protection and Affordable Care Act (PPACA) recognized the infrastructure and methodological gaps in the development of a CER framework in the United States, and established thoughtful mechanisms to address these issues by creating the Patient Centered Outcomes Research Institute (PCORI). In addition, PPACA created a methodology committee within PCORI to develop scientifically based methodological standards by which PCORI will conduct its research.[2]

BIO believes that PCORI is suited to develop an inventory, and that it will be well equipped with the appropriate tools and resources to take on this responsibility. Efforts to develop an inventory outside of the PCORI could potentially undermine the Institute, and be duplicative of ongoing federal activities, which is an inefficient use of resources.

In addition, the careful dissemination of CER findings is a critical component of the success of CER in the United States. Without appropriate interpretation of the findings of various CER studies, including discussion of the relevance to particular populations, CER could be misapplied, with potential negative effects on patient care. Thoughtful dissemination of CER findings may supplement the discussion of credibility and interpretation of results. PPACA addressed the dissemination of CER research findings by directing PCORI to work through the Office of Communication and Knowledge Transfer within the Agency for Healthcare Research and Quality (AHRQ) to create informational tools that organize and disseminate research findings.[3]

To that end, PCORI is directed to ensure that the research findings are conveyed in "a manner that is comprehensible and useful to patients and providers in making health care decisions; fully convey findings and discuss considerations specific to certain subpopulations, risk factors, and comorbidities, as appropriate; and include limitations of the research and what further research may be needed as appropriate."[4] It is imperative that the inventory convey CER findings in a manner that is consistent with these goals.

[2] PPACA § 6301(a) (adding Social Security Act (SSA) § 1181(d)(6)(a)).
[3] Id. § 6301(b) (adding Public Health Service Act § 937(a)(1)-(2)).
[4] Id. § 6301(a) (adding SSA § 1181(d)(8)).

Inventory Format and Categorization

Even after the methodological definitions and standards are established, and CER findings are appropriately framed, there remain significant challenges to the creation of an inventory. BIO believes that in order for an inventory to be both meaningful and successful, it must be accessible in a user-friendly, easily searchable format, and be updated on a "live" basis with the most recent information on each study (or related study) included in the database. The purpose of the CER inventory is to ensure that patients, doctors and decision makers have access to timely, relevant CER information.

In addition, the inventory should be categorized to ensure that stakeholders can easily identify, locate and differentiate the quality and applicability of relevant CER evidence. The database must be truly searchable across a number of study characteristics. The search functionality should recognize that study characteristics are not mutually exclusive because they may create contradictory search results. Additionally, the database should be searchable by several variables, including, but not limited to the following elements: 1) study design; 2) disease state; 3) patient population; and 4) comparators included. The PCORI methodology committee could also provide further input and guidance on what variables should be included in the database.

Further, significant coordination with AHRQ, the National Institutes of Health (NIH), and the PCORI will be needed to ensure that the data included in the inventory is consistent with all other government databases. Managing and maintaining the CER inventory will be an enormous undertaking, and careful consideration must go toward the development of this database. ASPE should look to existing government inventories, such as NIH's ClinicalTrials.gov, for insight on best practices regarding inventory maintenance and data input.

Conclusion

BIO encourages ASPE to proceed with caution on the creation of an inventory after fully evaluating the methodological and structural considerations that we have raised. BIO appreciates the opportunity to comment on the important issues raised by the ASPE RFI on the development of a CER inventory. If BIO can be of any assistance as you consider these comments, please do not hesitate to contact me at (202) 962-9200.

Respectfully submitted,

/s/

Laurel Todd
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