BIO
BIOTECHNOLOGY
INDUSTRY ORGANIZATION

February 17, 2012

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-5060-P
P.O. Box 8013
Baltimore, MD 21244-8013

Re: Docket No. CMS-5060-P: Proposed rule implementing Section 6002 of the Affordable Care Act (Pub. L. 111-148, as amended by Pub. L. 111-152)

Dear Sir or Madam:

The Biotechnology Industry Organization (BIO) thanks the Centers for Medicare & Medicaid Services (CMS) for the opportunity to submit comments on the proposed rule published in the Federal Register on December 19, 2011.[1] This proposed rule would implement Section 6002 of the Affordable Care Act ("ACA")--which added section 1128G to the Social Security Act ("SSA" or "the Act")-- also known as Physician Payment Transparency Reporting or the "Sunshine Act." This proposed rule would require applicable manufacturers of drugs, devices, biologicals, or medical supplies covered by Medicare, Medicaid or the Children's Health Insurance Program (CHIP) to report annually to the Secretary certain payments or transfers of value provided to physicians or teaching hospitals ("covered recipients"). In addition, applicable manufacturers and applicable group purchasing organizations (GPOs) are required to report annually certain physician ownership or investment interests.

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, thereby expanding the boundaries of science to benefit humanity by providing better healthcare, enhanced agriculture, and a cleaner and safer environment.

As stated in our April 7, 2011 comments to CMS,[2] BIO supports the goals of the ACA in providing greater transparency regarding financial relationships with health care providers and we recognize the significant challenges presented in the implementation of these ACA provisions. BIO appreciates the significant step that CMS has taken in publishing the proposed rule, as our members are eager for guidance in their ongoing efforts to establish systems that will accurately and consistently reflect payments to physicians and teaching hospitals and result in

[1] 76 Fed. Reg. 78,742
[2] See, BIO's April 7, 2011 Comments to CMS on Section 6002 of the Affordable Care Act: http://www.bio.org/sites/default/files/20110407_affordable_care_act.pdf

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reported and published information that is meaningful to the public. It is also important to acknowledge that considerable hurdles remain for both CMS and manufacturers before publication of a cogent final rule enabling the achievement of compliance and transformation of congressional intent into reality.

Below, we briefly summarize and highlight our primary concerns in "General Comments", and discuss these issues in "Specific Comments". We also respectfully request a meeting with CMS to further discuss implementation of the Sunshine Act.

General Comments

Final Rule and Timing

While BIO appreciates CMS' efforts in publishing the proposed rule and the recognition in the preamble that no additional requirements beyond those specified in the ACA are warranted at this time, we have significant concerns that certain statutory provisions remain unaddressed or continue to be unclear, and that in some instances CMS appears to have expanded requirements beyond the scope of the statute. BIO supports CMS' conclusion that compliance with the ACA requirements cannot feasibly begin until a period of time after the regulation is finalized. However, given these significant issues of interpretation and amplification of the ACA requirements beyond reasonable expectations, BIO members feel strongly that a period of at least 180 days from publication of a final rule is necessary for compliance as well as the intent of broad transparency to be achieved.

Definitional Concerns

BIO focused on the need for clear definitions of fundamental terms during CMS' March 24, 2011 Special Open Door Forum and in our April 7, 2011 written comments. As detailed below, we continue to have substantial questions regarding definitions for several key terms, and are concerned with the lack of definition for others.

The ACA provisions turn on several pivotal definitions, including "applicable manufacturer"[3] and "covered drug" [or other covered product].[4] BIO remains concerned that "applicable manufacturer" has not been adequately defined and that the proposed rule is inconsistent with the clear statutory language as well as congressional intent. In particular, clarification is needed as to how the reporting requirements apply to manufacturers with foreign parents, partners, and ex-U.S. affiliates, as well as to the co-development and co-marketing arrangements that are prevalent in the biotechnology community. Similarly, we are concerned that the term "covered drug" [or other covered product] is interpreted overly broadly in the proposed rule and that the proposed definition of "common ownership"[5] also exceeds the

[3] Section 1128G(e)(2) [42 U.S.C. § 1320a-7g(e)(2)]
[4] Section 1128G(e)(5) [42 U.S.C. § 1320a-7g(e)(4) and (5)]
[5] 76 Fed. Reg. at 78,744 [Proposed 42 C.F.R. § 403.902]

scope of the statute and would impose an extremely broad and burdensome interpretation on manufacturers if not properly defined. These expansive definitions are likely to have unintended consequences, including the compilation of data that that does not serve the purpose, and, ultimately could undermine the purpose, of the Sunshine Act.

In addressing the "nature of [a] payment"[6] to a covered recipient, BIO is concerned that the proposed rule defines "research"[7] very narrowly, and that the proposal to capture specific details regarding payments for early discovery research is problematic.

With regard to defining "payment or other transfer of value",[8] BIO is also concerned that the proposed rule would improperly exceed the ACA language, which does not require reporting of an indirect payment to a recipient "where the applicable manufacturer is unaware of the identity of the covered recipient".[9] Further, CMS' proposed interpretation is not well-defined and infeasible. As a result of its vagueness, it may violate due process by placing manufacturers that comply in good faith in jeopardy of investigation or prosecution while chilling desirable conduct.

Reporting Concerns

With regard to manufacturer reporting of payments, BIO is concerned that the proposed method for the reporting of meals would result in inaccurate data. Accordingly, BIO proposes an alternate method that would be more representative of actual activities and consistent with established reporting methods and industry practices. BIO is also concerned that the proposed method for reporting payments to teaching hospitals and reporting payments to principal investigators ("PIs") is overly broad and would result in duplicative and inaccurate data.

BIO is also concerned that the proposed narrowing of the exclusion applicable to reporting payments provided indirectly to a covered recipient by a third party is overly expansive and could be interpreted to require reporting of payments that properly should be excluded by the statute, including payments made by independent third parties in the context of accredited Continuing Medical Education programs (CME), that would be contrary to the nature and established paradigm for CME.

Public Availability Not Addressed

BIO is concerned that the ACA requirement for public education, including background on industry-physicians relationships and information helpful to the average consumer,[10] is not addressed at all in the proposed rule. The development of this information is critical, as the

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[6] 76 Fed. Reg. at 78,748 [Proposed 42 C.F.R. § 403.902]
[7] 76 Fed. Reg. at 78,749 (Proposed 42 C.F.R. § 403.904]
[8] 76 Fed. Reg. at 78,750 [Proposed 42 C.F.R. § 403.904]
[9] 76 Fed. Reg. at 78,750 [Proposed 42 C.F.R. § 403.904]
[10] Section 1128G(c)(1)(C)(vii) [42 U.S.C. § 1320a-7g(c)(1)(C)(vii)]

goal of providing useful, understandable information to the public cannot be achieved otherwise.

Limited Applicability of Sunshine Law

A majority of BIO members are start-up companies with development stage drugs and biologicals. Some of these companies engage in co-development activities with established companies that may have other marketed products. It is BIO's understanding that the statute and proposed regulations do not apply to companies with no FDA-approved products as they would have no covered products. CMS should clarify that a manufacturer is not subject to the reporting provisions unless or until the manufacturer has a product that has been approved for commercial distribution in the United States (including territories, possessions and commonwealths). It would be useful if CMS can confirm this.

Report Submission and Review

BIO is concerned that without further guidance from CMS a 45 day review period will not provide enough time for covered recipients and applicable manufactures to accurately review the reported data prior to publication. Given that the proposed rule does not establish a formal dispute resolution process, it is not clear what steps would be taken by CMS and applicable manufacturers and covered recipients to ensure errors are addressed appropriately. BIO believes CMS should provide further guidance concerning the dispute resolution process and allow for comment before setting the review period at the minimum length required by the Act.

Specific Comments

Timing and Manufacturer Challenges

In the preamble to the proposed rule, CMS acknowledges that a final rule was not available for applicable manufacturers to be able to begin collecting complete data on January 1, 2012.[11] CMS requested comment on the amount of time applicable manufacturers will need following publication of a final rule in order to begin complying with the data collection requirements of section 1128G of the SSA and CMS' regulations. BIO notes that the ACA was signed into law in March 2010, contemplating that rulemaking would have been completed by October 1, 2011, following consultations with various stakeholders, including affected industry.[12] We appreciate that CMS requests comment on the timeline for compliance, and that the Agency is engaging in notice and comment rulemaking in order to fully and fairly address the issues raised by the ACA.

Nonetheless, while CMS suggests that ninety days was contemplated by Congress for preparation, the implementation timeline reasonably would have been expected to be

[11] 76 Fed. Reg. at 78,743

[12] Section 1128G(c)(1)(A) and (C)(2) [42 U.S.C. § 1320a-7g(c)(1)(A)-(C)]

substantially longer, given that the time from passage of the ACA to January 1, 2012 was close to two years. BIO, other stakeholders, and members of Congress have repeatedly voiced concerns about the timeline for applicable manufacturers to achieve compliance with the ACA, given the nature of the issues to be clarified and complexities of developing internal company systems to track this information. Despite time pressures, BIO firmly believes that it is most important to get this done right, rather than just quickly.

BIO believes that at least 180 days from CMS' publication of a final rule will be necessary for manufacturers to incorporate the specific details and nuances of a final rule into existing internal systems that are currently employed to capture data for the purposes of voluntary reporting, or reporting required by other regulators. The operational challenges in creating and revising applicable compliance processes, policies and procedures, and making functional changes to Information Technology (IT) and other internal tracking systems and reporting systems to facilitate mandatory collection of data cannot be minimized. For example, manufacturers need to amend travel and expense reporting systems and other tracking and reporting systems to reflect the specific provisions of the proposed rule. Such changes may require the engagement of vendors, amending software licenses and necessitate audits or other actions. The implementation of some functional changes can take six months or even longer, taking into account the need for auditing and training of employees, vendors and consultants. Depending upon the ultimate language included in the final rule, manufacturers may also be required to request detailed data from clinical research organizations and other parties that manage and correspondingly make payments related to clinical trials.

Manufacturers may be dependent upon timely and accurate tracking and reporting systems to be implemented by third parties for certain information that may need to capture more detailed spend data than has typically been collected. Further, because the collection and reporting of payment information currently required under certain state laws and now under the ACA are intertwined, interdependent, and yet somewhat different, manufacturers should be afforded sufficient time to ensure that the correct sets of information are collected and reported to each separate governmental entity.

Even though manufacturers can use the proposed rule as a guide to begin to address compliance issues, the requirements will remain a moving target until CMS assesses stakeholder input, addresses the many remaining open issues, and publishes a final rule. Accordingly, manufacturers will not be able to truly establish the systems that will result in fully compliant data until there is a final rule. The proposed rule requests comments from the public on dozens of issues, and in some instances, proposes both a first and an alternative approach. This uncertainty makes it virtually impossible to implement the systems until a final rule publishes.

Further, expansion of certain of the reporting requirements beyond what BIO believes are reasonable interpretations of the statute raises systems challenges that had not been contemplated previously. If the expansive definitions CMS proposes are published in a final rule, companies that had not anticipated being required to report would simply not have

enough time to adapt to the new rules. Even for the many manufacturers who have spent a considerable amount of time--for many, more than two years--designing and implementing systems to track and report payments to covered recipients, post-final rule implementation will be time-consuming.

BIO members strongly believe that at a compliance date of at least 180 days from publication of a final rule is necessary. Further, BIO recognizes that CMS may consider alternatives, such as a phased in approach, whereby payment information that is already collected by manufacturers for other regulators, e.g., certain states, would be reported to CMS initially, and other requirements that will take longer to meet would be added to reporting requirements over time. While, as discussed below, BIO believes that the proposed definitions of terms--including "covered drug," "applicable manufacturer" and "common ownership"--are overly broad, and that the proposed scope of "research" is unexpectedly narrow, if CMS were to finalize these definitions, at least a year would be necessary for manufacturers to adopt such new requirements. Alternatively, a phasing-in of such requirements could represent a more feasible approach. If CMS were to adopt such an approach, it would be necessary for CMS to clearly set forth exactly what data elements would need to be reported in each phase. BIO would be pleased to provide further input to CMS in this regard.

Applicable Manufacturer

The statute defines an "applicable manufacturer" as "a manufacturer of a covered drug, device, biological, or medical supply *which is operating* in the United States, or in a territory, possession, or commonwealth of the United States.[13] A "manufacturer of a covered drug, device, biological, or medical supply" is defined in turn as "any entity which is engaged in the production, preparation, propagation, compounding, or conversion of a covered drug, device, biological, or medical supply (or any entity under common ownership with such entity which provides assistance or support to such entity with respect to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered drug, device, biological, or medical supply)."[14]

CMS proposes to define an "applicable manufacturer" as "an entity that is—
(1) Engaged in the production, preparation, propagation, compounding, or conversion of a covered drug, device, biological, or medical supply for sale or distribution in the United States, or in a territory, possession, or commonwealth of the United States; or (2) Under common ownership with an entity in paragraph (1) of this definition, which provides assistance or support to such entity with respect to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered drug, device, biologicals, or medical supply for sale and distribution in the United States, or in a territory, possession, or commonwealth of the United States."[15]

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[13] Section 1128G(e)(2) [42 U.S.C. § 1320a-7g(e)(2)] (emphasis added.)
[14] Section 1128G(e)(9) [42 U.S.C. § 1320a-7h(e)(9)]
[15] 76 Fed. Reg. at 78,767 (Proposed 42 C.F.R. § 403.902)

BIO does not believe CMS has the authority to adopt a definition of "applicable manufacturer" that extends to entities that are not "operating in the United States." The definition of "applicable manufacturer" proposed by CMS is inconsistent with the clear statutory language limiting scope to entities operating in the U.S. Under the statute, an entity is an "applicable manufacturer" only if it is a manufacturer of a covered product "which is operating in the United States." Despite the "operating in" requirement's central place in the statutory definition of "applicable manufacturer," the proposed rule disregards that significant statutory language, and further, adds an expansive definition that would allow an entity to be covered if it makes a covered product "for sale or distribution" in the United States. This new definition improperly shifts the emphasis of the definition from the extent of an entity's operations in the United States to the destination of the covered product, a concept that is entirely absent from and irrelevant to the statutory definition of an "applicable manufacturer."

The preamble to the proposed rule likewise disregards the statute's text, stating instead that "we believe that any entity manufacturing covered drugs, devices, biologicals, or medical supplies for sale or distribution in the U.S. . . . should be subject to the requirements of section 1128G of the Act," because the "opportunity for undue influence or inappropriate relationships caused by payments or transfers of value to covered recipients is the same for manufacturers of drugs, devices, biologicals, or medical supplies sold or distributed in the United States regardless of where the product is actually manufactured."[16] The decision to exclude entities that are not operating in the United States from the statute's coverage was made by Congress, and BIO does not believe CMS has the authority to read that limitation out of the statute.

Although the statute does not define what it means for an entity to be "operating in the United States," CMS' proposed definition of "applicable manufacturer" would sweep broadly enough to cover entities that Congress is unlikely to have intended to cover. For example, where an entity has no physical presence in the United States, maintains tax and corporate separation from the United States, and has few or no additional contacts with the United States, the entity is not "operating in the United States" and should not be covered under the statute as an "applicable manufacturer." Although such an entity may be involved in the production of covered products that are eventually sold in the United States, Congress's decision to set the definition of "applicable manufacturer" apart from the definition of a "manufacturer of a covered drug, device, biologicals, or medical supply" reinforces that the "operating in the United States" requirement is a separate and independent requirement that must be met regardless of whether a company is involved in the production or sale of covered products later sold or distributed in the United States.

In addition, CMS' proposed definition of "applicable manufacturer" is inconsistent with limits on the jurisdictional reach of federal statutes. Even if the statute's "operating in" language could be read to extend the statute's coverage to companies that have only attenuated contacts with the United States, CMS's interpretive authority is limited by the longstanding

[16] 76 Fed. Reg. at 78,744

presumption against reading federal statutes to apply outside United States borders. The presumption assumes that Congress did not intend for a statute to apply outside the territorial jurisdiction of the United States unless it expresses its affirmative intent that the statute should apply abroad.[17] Congress did not include any such affirmative statement of intent in the ACA. Indeed, the statute's requirement that an entity be "operating in the United States" in order to be covered indicates that Congress intended the statute to apply only where a manufacturer has significant contacts within the United States.

The presumption against extraterritorial application is reinforced where applying the statute abroad would lead to conflicts with foreign law and other effects that Congress is unlikely to have intended. Applying this statute to foreign conduct may conflict with requirements imposed by other jurisdictions to manufacturers operating outside of the U.S. For example, requiring manufacturers under the jurisdiction of the European Union (EU) to submit the personal data of EU physicians or other individuals (including US physicians whose data are stored in the EU) to the federal government may force manufacturers to violate a number of EU privacy laws, including prohibitions on (1) transferring personal data to a third country that does not have adequate privacy protections (which the EU considers the United States),[18] (2) disclosing personal data to a third party without a "legitimate" justification, such as individual consent,[19] or (3) processing personal data without notifying the country's privacy regulator.[20]

Alternative mechanisms for reporting would be more faithful to the statute while still carrying out Congress's intent. Congress intended the ACA to shed light on payments made by manufacturers of products sold and distributed in the United States to the physicians and teaching hospitals that prescribe or purchase their products, and receive reimbursement for the use of those products in the United States. In most cases, the alternative definition of "applicable manufacturer" proposed above will capture the payments that Congress intended to capture. We recognize, however, that some entities that would not be "applicable manufacturers" under that alternative definition may still make payments that CMS would view as within the scope of the statute, including certain payments by an applicable manufacturer's non-covered foreign affiliate. In such cases, CMS could carry out Congress's intent by exercising its statutory discretion[21] to require additional reporting by the applicable manufacturer affiliated with these non-covered foreign entities. By way of example, CMS could require an applicable manufacturer to disclose any reportable payments made by a foreign affiliate at the

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[17] *See, e.g., EEOC v. Arabian American Oil Co.*, 499 U.S. 244 (1991); *Morrison v. National Australia Bank Ltd.*, 130 S. Ct. 2869 (2010).

[18] *See* Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data, art. 25-26, 1995 O.J. (L 281) 31 (1995).

[19] *See* Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data, art. 7, 1995 O.J. (L 281) 31 (1995).

[20] *See* Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data, art. 18-19, 1995 O.J. (L 281) 31 (1995).

[21] *See* 42 U.S.C. § 1320a-7h(a)(1)(A)(viii)

applicable manufacturer's request or direction. This type of additional reporting category would effectively capture the payments that Congress intended to make public while respecting the limits on the scope of the law imposed by the statute's language.

Finally, in regard to the "applicable manufacturer" definition, it is BIO's understanding that the statute and proposed regulations do not apply to companies with no FDA-approved products as they would have no covered products. Indeed, the vast majority of BIO members are start-up companies with investigational drugs and biological. As stated in our April 7, 2011 comments, it would be useful if CMS would confirm, in the preamble to the final rule, that a manufacturer is not subject to the reporting provisions unless or until the manufacturer has a product that has been approved for commercial distribution in the United States (including territories, possessions and commonwealths).

Common Ownership

Under the statute, an entity that is not itself an applicable manufacturer can nonetheless be brought within its scope if it is under "common ownership" with an applicable manufacturer and provides "assistance or support" to such entity with respect to production, preparation, marketing, or other activities listed in the statute.[22] CMS proposes to implement the first prong of this requirement by defining "common ownership" as occurring "when the same individual, individuals, entity, or entities, directly or indirectly, own any portion of two or more entities."[23] CMS has alternatively proposed to define a minimum ownership threshold at which two or more entities would be considered under common ownership, and asks whether a threshold of five percent is appropriate. BIO firmly believes the proposed threshold is not appropriate. Both the absence of any threshold and a proposed minimal threshold (any threshold less than 50 percent) are unreasonable and would seriously impair bona fide research and development funding for companies that are not "applicable manufacturers" themselves and do not have their own "covered products".

While BIO supports CMS' efforts to address financial relationships in the proposed rule, BIO believes that the proposed definition of "common ownership" is overly broad; inconsistent with commonly used and accepted definitions of common ownership; and does not take into account whether there is in fact an element of control. The proposed thresholds would have a damaging impact on start-up companies that engage in co-development activities with established companies that have marketed products, including covered drugs and biologics.

The establishment of collaborative relationships between large biopharmaceutical companies and pre-commercial companies is an historical practice and an important piece of the backbone of the biotechnology industry. These science-based relationships have led to the discovery of many breakthrough and lifesaving drugs and biologicals for patients. Such collaborations provide needed funding for research and development activities at the pre-commercial

[22] 76 Fed. Reg. at 78,744

[23] 76 Fed. Reg. at 78,744 [Proposed 42 C.F.R. § 403.902].

company. Typically the research and development is the responsibility of the pre-commercial company and commercialization and marketing of a "covered product" is the responsibility of the larger biopharmaceutical company which already has the infrastructure for and experience with commercializing and marketing products. Typically the pre-commercial company has little or no control over the marketing of the "covered product", as exemplified by the fact that they may not employ, directly or indirectly, a sales force. Pre-commercial companies should not be considered to be under "common ownership" with an "applicable manufacturer" and potentially subject to the statute merely based on a larger company's non-controlling equity investment in the pre-commercial company. If as a result of the proposed CMS rule, a research and development stage company could be obligated to comply with these rules, it would add a level of infrastructure and cost that would undercut these very important financial investments in pre-commercial companies and further diminish financing of innovative research and development.

BIO therefore supports a definition of "common ownership" that would set the minimum threshold at a 50% or greater equity interest, or a lesser equity interest if coupled with the holding of sufficient seats on the Board of Directors of the entity to direct or control the entity. Absent a 50% or greater equity interest, or a lesser equity interest coupled with controlling seats on the Board of Directors, a less than 50% interest would not provide the power or ability to control the other company. This proposed modification to CMS' proposed "common ownership" definition reflects the standard corporate law definition of common control, as well as the standard used by the Securities and Exchange Commission to define common ownership and common control.[24] Setting the threshold at less than 50% where it is not coupled with the power to control the Board of Directors will seriously undermine the ability of pre-commercial companies to access capital for their discovery and development programs.

Adoption of a reasonable threshold for the "common ownership" definition would properly exclude reporting by a company which itself has no approved drugs or biologicals, unless there is a significant common ownership or control relationship and the company clearly provided assistance or support to the applicable manufacturer. To do otherwise could trigger a potential chilling effect on such collaborative agreements, which are essential for incentivizing innovative research.

BIO also believes that it's very important that CMS allow for entities under common ownership to choose to report separately or to combine their information in a consolidated report. CMS

[24] The Securities and Exchange Commission (SEC) uses a 5% ownership interest to define "affiliate" status, but not common control. It should be further noted that the noted "affiliate" definition is used only for the limited purpose of defining when a shareholder might have the reasonable possibility of greater access to "inside information". Again, the SEC does not assume that a mere 5% ownership interest provides a shareholder with common ownership or control. Notably, the 50% ownership level also tracks standard corporate governance and accounting practice under generally recognized accounting principles that determine when income and expenses should be consolidated (17 CFR § 210).

proposes that separate reporting by each "applicable manufacturer" be mandatory.[25] This would be technically difficult for many companies that have separate legal entities of which each would be considered "applicable manufacturers" and which often utilize separate financial systems. Equally, if not more important, is the fact that the identity of the separate entities is often very different from the umbrella name that is known to and recognized by the general public. For some companies, consolidated reporting may be less difficult and should be an option. Thus, we recommend that CMS permit, but not require, applicable manufacturers under common ownership to file a consolidated report with a single certification.

Covered Drug, Device, Biologicals, or Medical Supply

CMS proposes limiting covered drugs and biologicals to those that need a prescription to be dispensed.[26] BIO supports CMS efforts to focus the proposed rule and reporting on prescription products, but requests that CMS reconsider the result that would allow some manufacturers of non-prescription products (e.g., OTC or other consumer directed and purchased products) to be exempted from reporting, but require others—such as companies with prescription drugs and biological -- to report payments related to any product. Many manufacturers have complex corporate structures with separately operated entities supporting non-prescription healthcare products or services which should reasonably be treated the same as manufacturers who manufacture only OTC drugs or other non-covered products. For example, an applicable manufacturer could have separate operations, including separate sales, marketing and research teams that focus solely on the development and distribution of non-covered products and they may interact with different physician specialties. As CMS recognized in the preamble, physicians and teaching hospitals have less influence over patients' choice of OTC products. Further, the inclusion of data about non-prescription products and services for some, but not all, manufacturers could lead to confusing information being made available to the public.

Associated Covered Drug, Device, Biologicals, or Medical Supply

The Act states that reports from applicable manufacturers should identify the name of a covered drug or biologic if a payment is related to "marketing, education, or research specific to" the covered product.[27] CMS' proposed rule recognizes that not all payments are related to a specific product, and proposes that a specific drug be identified if the transfer of value is "reasonably associated" with a product. CMS also states that the name reported should be the name the product is marketed by, for familiarity to consumers, or if there is not yet a marketed name, the scientific name. CMS proposes that applicable manufacturers report the scientific name only in the event that a covered drug, device, biological, or medical supply does not yet have a market name. For the reasons set forth below, BIO urges CMS to make clear that there are a range of activities, in particular those related to potential business development activities, that do not require the reporting of a specific drug name.

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[25] 76 Fed. Reg. 78, 744 and 76 Fed. Reg. 78, 770

[26] 76 Fed. Reg. 78, 744-45

[27] Section 1128G(a)(1)(A)(vii) [42 U.S.C. § 1320a-7h(a)(1)(A)(vii)]

BIO asks CMS to confirm that applicable manufacturers are not required to report an associated product name for payments and transfers of value related to pre-commercial products. Under the statute, manufacturers are required to report the name of an associated drug or biological only when a given payment "is related to marketing, education, or research specific to a *covered* drug, device, biological, or medical supply."[28] The definition of "covered" products is limited to those products for which payment is available under Medicare, Medicaid, or CHIP. Because pre-commercial products are only eligible rarely for payment under one of those programs (usually in the context of an investigational drug exemption), in almost all cases these products do not qualify as "covered" products and are not subject to associated product reporting under the statute. Moreover, information about payments related to pre-commercial products is highly sensitive, as Congress recognized when it included a provision allowing for delayed publication of research payments made prior to FDA approval. The statute's limitation on associated product reporting likewise promotes appropriate protection of sensitive information about the compounds that manufacturers are researching. We ask CMS to confirm that the associated product reporting provision does not extend to payments related to pre-commercial products (e.g., compounds and uses).

Nature of Payment

The ACA requires the reporting of 15 types of payments/transfers.[29] CMS proposes that payments be categorized based on the "dictionary definition" of the statutory terms.[30] BIO is concerned that standard dictionary definitions are not sufficient to clarify terminology that is not standard, where different interpretations exist within the biopharmaceutical community, and where the types of payments listed involve considerable overlap. For example, payments for consulting on research projects could be treated as consulting fees or research, and an "honorarium" may also be considered a consulting fee. Clear definitions will help provide certainty and consistency among reporting manufacturers. CMS should prevent duplicative reporting and help manufacturers report this information in a meaningful and consistent manner. CMS must provide clear definitions that are applicable to the reporting requirements found in the proposed rule in order to guide data collection.

CMS also states in the proposed rule that applicable manufacturers may, if they choose, submit with their data a document describing the assumptions they used when categorizing payments.[31] BIO agrees with CMS that submission of an assumptions document should be voluntary.[32]

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[28] Section 1128G(a)(1)(A)(vii) [42 U.S.C. § 1320a-7h(a)(1)(A)(vii)]
[29] Section 1128G(a)(1)(A)(i)-(viii) [42 U.S.C. § 1320a-7g(a)(1)(A)(i)-(viii)]
[30] 76 Fed. Reg. at 78,748
[31] 76 Fed. Reg. at 78,748
[32] 76 Fed. Reg. at 78,748

The ACA's list of nature(s) of payment includes "any other transfer of value."[33] BIO seeks clarification as to whether material transfers, e.g., providing a protein to a teaching hospital for general research, would be considered a transfer of value. The biopharmaceutical industry has discovered many, if not a majority of, new biologics through discovery research collaborations and the sharing of proprietary biologic materials with academic researchers—many who are employed at teaching hospitals and many of whom are physicians. These early discovery research arrangements are frequently unsuccessful, cost all involved internal resources, and are most often unfunded. The parties typically share confidential information and proprietary materials, sometimes coupled with an exchange of development and commercialization rights for any new discoveries. While the vast majority of these arrangements lead to more questions and scientific data, sometimes they result in key breakthroughs and new medical advances for patients. It is critical that this research be encouraged.

These material transfers are typically not part of any commercial or marketing plan nor do they involve development of a product. They would typically precede development and involve discovery of a new product or product use. Many biotech companies enter into hundreds of these relationships each year and they are and have been vital to the success of the biotech industry. The actual transfer involved in these relationships is only a transfer of the material that is the subject of research—it has no inherent value, and any value attached to it would occur at a much later date, if ever. The physicians and teaching hospitals involved in the collaboration conduct research with no relationship to a covered or marketed drug or biological.

For these reasons, BIO requests that CMS clarify that such material transfers or other discovery research collaborations that do not involve funding are not considered a "transfer of value" and accordingly, are not subject to reporting under the ACA.

Food and Beverage

The ACA lists "food" as a nature of payment.[34] In this regard, CMS seeks comment on the most equitable and least burdensome way of reporting the costs of food and beverages provided by a manufacturer to a covered recipient. CMS proposes that an in-office meal be attributed to/divided among all of the covered recipients in a practice, even if not present at a meal in an office.[35]

BIO believes that CMS' proposed method would result in inaccurate reported data, as some covered recipients may not attend a particular in-office meal; may not even be present on a particular day; or may attend the in-office presentation and choose not to partake in the meal. A physician in a practice may even have a completely different practice area than that which is the topic of discussion/associated with a meal. In these instances, the meal should not be attributed to that physician.

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[33] Section 1128G(a)(1)(A)(vi)(XV) [42 U.S.C. § 1320a-7g(a)(1)(A)(vi)-(XV)]
[34] Section 1128G(a)(1)(A)(vi)(VI) [42 U.S.C. § 1320a-7g(a)(1)(A)(vi)-(VI)]
[35] 76 Fed. Reg. at 78,748

Further, food may be consumed by other office staff who are not covered recipients, resulting in inflated meal costs if the proposed rule were applied. For example, a lunch for 10 people might cost $100, and might be consumed by one physician, eight office staff members, and one employee of an applicable manufacturer. If attributed entirely to the one attending physician, a meal would be reported as costing $100, rather than the actual cost per person of $10. This approach is not only misleading, but also inconsistent with many state disclosure laws, including Massachusetts, Minnesota, and Washington, DC, where the food cost is calculated based on the manufacturer's employee, physicians and other relevant attendees.[36]

The proposed approach for allocating meal values to physicians would result in inaccurate representations of physician interactions. CMS' proposed approach would require applicable manufacturers to report a value associated with the meal that in fact would almost never be representative of the value actually conferred on the physicians. On the one hand, the value would be artificially increased by not allocating the total value of the meal among all individuals actually partaking in the meal, including office staff and others. On the other hand, the value would be artificially decreased by requiring manufacturers to allocate portions of the value of the meal to individuals who did not even partake in the meal (which could significantly skew the data when interacting with physicians who are members of very large practices comprised of tens or, in some cases, hundreds of physicians).

With these two considerations operating simultaneously (as currently contemplated by CMS), the value that manufacturers would be required to report, and that would be made publicly available, would often be far from an accurate representation of the value actually conferred upon each physician. These results would not achieve the intent of the ACA, which is to provide accurate transparency of industry relationships with physicians and teaching hospitals.

BIO proposes that manufacturers be provided the flexibility to calculate the value of food by calculating the food cost over the number of confirmed attendees used to confirm a catering order and reporting the appropriate calculated cost for each covered recipient. Such flexibility in calculation is supported by principles of valuation, considers the practical aspect that catered food must be confirmed in advance of a meeting, and is consistent with historical reporting to several U.S. states.

Research

The Act identifies "research" as one of the 15 types or "nature[s] of [the] payment".[37] The preamble and proposed rule address the complexities and array of payment methods involved in research and CMS requests comments on whether its proposed method for reporting

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[36] See, e.g., Massachusetts Executive Office of Health and Human Services , Department of Public Health "*FAQs Pharmaceutical and Medical Device Manufacturer Code of Conduct*," at FAQ (2)(11): http://www.mass.gov/eohhs/docs/dph/quality/healthcare/pharm-medical-device-conduct-faq.pdf.

[37] Section 1128G(a)(1)(A)(vi)(IX) [42 U.S.C. § 1320a-7h(a)(1)(A)(vi)(IX)]

research payments is viable and not overly burdensome, and whether an alternative method is preferable.[38] BIO has comments on several research payment reporting issues, as well as related exclusions from reporting.

First, CMS proposes to limit the research category to what it refers to as bona fide research activities, including clinical investigations, which are subject to both a written agreement and a research protocol.[39] BIO proposes that the definition of research be broadened to include research that is subject to either a written agreement or a research protocol, as much discovery research (i.e., pre-clinical/development work) is conducted pursuant to a protocol or a research agreement, but not both. Discovery is an integral, and critical, component of the research process; it is the first step in finding innovative solutions for the treatment of disease. As such, payments for discovery research should be properly considered part of "research" and eligible for the relevant delay in publication to protect the proprietary information of the parties conducting it. BIO urges CMS to consider the chilling effect that premature disclosure of discovery work can have on the willingness of drug manufacturers and other entities to collaborate, or to make strategic investments of money and resources in innovation.

With regard to reporting of payments related to research, BIO appreciates CMS' understanding of the complexities and array of payment methods that would make it too burdensome for drug manufacturers to determine the exact amount a physician covered recipient might receive in connection with a manufacturer's payment to a research institution. However, BIO believes that the method proposed by CMS is broader than the statutory language and could result in double reporting. It would also result in public confusion and misunderstanding as to how research is conducted, and the relationship between a manufacturer and a physician who is a principal investigator. Specifically, the proposed method of reporting that would attribute research payments to the PI could unintentionally misrepresent the relationships and benefits of payments in the research process. The conduct of research is complex and highly regulated, and as CMS notes, involves multiple parties and forms of payment.

Any teaching hospital or non-teaching hospital (or other recipient) to which research payments are made utilizes or engages physician investigators, among others, to help it carry out the full range of trial-related responsibilities. To report the full amount paid to the entity as a payment to the PI implies a level of benefit or control by the PI equal to that of the contracting entity. BIO believes that in the great majority of cases this would not be accurate, and would oversimplify and misrepresent the relationships in the research process.

BIO is also concerned that this method of reporting will result in confusing and inconsistent data, as payments made directly to teaching hospitals will be reported differently than payments made to non-teaching hospitals, and may also be seen as payments directly to the PI. Further, we are concerned that this proposal exceeds the statutory language: Congress directed reporting of payments to physicians and teaching hospitals, and specifically did not expand the

[38] 76 Fed. Reg. at 78,749; 78,769-78,770 (Proposed 42 C.F.R. § 403.904(e)).
[39] 76 Fed. Reg. at 78,769 (Proposed 42 C.F.R. § 403.904(e)(2))

scope to non-teaching hospitals. We note in this regard, however, that under the statutory special rule for certain payments or other transfers of value,[40] such payments would be reported in the name of the covered recipient where the payment is made at the request of or designated on behalf of a covered recipient.

BIO therefore proposes, in accordance with the requirements of the statute, that payments made to a covered recipient should be reported only under the name of that covered recipient. For example, when a manufacturer makes a payment to a teaching hospital to fund research conducted at the hospital, that payment should be reported only under the name of the teaching hospital; likewise, payments made directly to a PI to carry out investigator-sponsored research should be reported only under the name of the physician. We also propose that payments made to an entity that is not a covered recipient, such as payments to a non-teaching hospital to fund investigator-sponsored research, should be reportable if they are made at the request of or designated on behalf of a covered recipient, such as the PI. BIO also recommends that such information be posted in a manner that makes it clear that the payment is for the purpose of conducting research. We urge CMS to adopt this approach, which captures all of the research spending that Congress intended manufacturers to report while remaining faithful to the language of the statute.

BIO recognizes CMS' concern that reporting the name of the teaching hospital alone may in some cases fail to capture the full extent of the relationship between the manufacturer and other covered recipients, particularly the individual physician principal investigator(s) running the study. However, we believe that the relationships between the manufacturer and the physicians involved with the study can also be captured through the reporting of payments that the manufacturer makes under agreements with those physicians, including expenditures for travel to and meals at investigator meetings and service on study boards. In short, if CMS wishes to make public the extent of the manufacturer's relationship with the physicians associated with the study, that goal is best accomplished by clear reporting of the benefits actually received by those physicians.

The proposed rule does not directly address the reporting of expenditures on travel and meals for PIs and other members of a study team who attend investigator meetings and other study-related board meetings. BIO proposes that where these expenditures are part of the payment to the host institution under the clinical trial agreement, any payments related to the meeting should be included in the manufacturer's reporting of payments for the clinical trial under the regular research payment rules proposed above. In contrast, where the expenditures are made under a separate agreement with the investigator or other individual physician participating in the study, BIO believes that these payments should be separately reported, as they represent payment for a discrete service by an individual, separate from the actual conduct of the trial itself. With respect to these separate expenditures on individual physicians, BIO proposes that CMS give manufacturers the flexibility to allocate the cost of meals and travel associated with

[40] Section 1128G(a)(1)(B) [42 U.S.C. § 1320a-7h(a)(1)(B)]

meetings among covered recipients in a manner that is reasonable and consistent with the statute.

Finally, BIO requests that CMS clarify the reporting obligations, if any, of licensor and licensee when a compound or drug is licensed for research purposes (other than co-development or co-promotion.) Specifically, we recommend that CMS establish that a licensee's payments are not reportable by the licensor unless the licensor controls the payments. Likewise, we request that CMS also clarify that a licensee's payments are not reportable by the licensee unless the licensee is an applicable manufacturer (i.e., has a covered drug).

Third Party Payments

Under the statute, an applicable manufacturer's transfer of an economic benefit to a covered recipient through a third party is not considered to be a reportable "payment or transfer of value" if the applicable manufacturer is unaware of the identity of the covered recipient who received the benefit from such third party.[41] In addition, where an applicable manufacturer provides a "payment or other transfer of value" to a third party at the request of or designated on behalf of a covered recipient, the statute directs that the reporting be in the name of the covered recipient.[42]

The preamble to the proposed rule, in addressing "Indirect Payments Through a Third Party," could be read to suggest that whether a payment by a third party is reportable hinges solely on whether a manufacturer has "actual knowledge of, or acts in reckless disregard of, the identity of the covered recipient."[43] BIO believes that such an interpretation would exceed the statutory mandate and would not be feasible in many common situations. BIO believes that the intent and the language of the statute are consistent in limiting reporting to those payments made directly to teaching hospitals and physicians and those payments made to others at the request of or designated on behalf of a covered entity or individual.

The statute was never intended to cover payments that may be made indirectly where the manufacturer has no control over who the recipient may be. It would not be sensible or feasible to attribute a payment to a manufacturer if the manufacturer does not direct the payment to be made to a specific recipient, but may find out the identity at a later date, perhaps because the information is publicly available. Indeed, such a vague and expansive standard would potentially render the statute constitutionally infirm in that manufacturers would often have no way of knowing, at the time a payment is made, whether their failure to track and report that payment would eventually violate the law.

BIO urges CMS to clarify the scope of an applicable manufacturer's obligation to report payments made to third parties in a manner fully consistent with the statutory text.

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[41] 42 U.S.C. §1320a-7h(e)(10)(A)
[42] Section 1128G(a)(1)(B) [42 U.S.C. §1320a-7h(a)(1)(B)]
[43] 76 Fed. Reg. at 78,751

Specifically, we propose that when a physician or teaching hospital requests that an applicable manufacturer make a payment to a third party on the covered recipient's behalf, such payments should be reported under the name of the covered recipient in accordance with the statutory rule regarding payments made "at the request of or designated on behalf of a covered recipient."

In contrast, when an applicable manufacturer makes a payment or other transfer of value to an entity that is not a covered recipient, and the third party ultimately transfers some or all of that amount to a covered recipient, BIO proposes that the manufacturer would be obligated to report that payment only if the manufacturer has (1) actual knowledge of the identity of the recipient at the time the manufacturer makes the payment to the third party and (2) the ability to direct (or otherwise control) the payment to the covered recipient.

For example, payments made to a CME provider who then employs a physician as a CME speaker should be excluded, given that true CME, provided by an accredited provider, does not allow manufacturer control in choosing speakers. It has been long accepted policy and practice that a manufacturer supporting a continuing medical education (CME) program does not have any control or influence over the choice of speakers for a program. This is essentially the foundation of accredited CME, and has been recognized by the Accreditation Council for CME (ACCME), as well as by the Food and Drug Administration (FDA).[44] To require a manufacturer to report a payment via an accredited CME provider to a speaker—purely because the manufacturer later sees the speaker's name listed on a program agenda, or even if the proposal for CME is given to the manufacturer with the speakers previously chosen by the CME provider—would be inconsistent with the established CME paradigm and result in misleading data.

Another concern arises in regard to CMS' proposed language that "awareness of the identity of the covered recipient by an agent of the applicable manufacturer will be attributed to the applicable manufacturer."[45] CMS does not define "agent" in the proposed rule. BIO recognizes that there are many situations in which manufacturers may engage third parties that could be considered agents of the manufacturer where such an awareness standard is appropriate, such as situations in which a manufacturer engages a contract sales force to market and sell its products on its behalf in the United States, or a third party to manage the logistics of its speaker program. We are concerned, however, that such a general standard, that is not expressly

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[44] ACCME, Preamble to the ACCME Standards for Commercial Support (2012) *available at* http://www.accme.org/sites/default/files/null/SCS%20Toolkit%201_181_SCS_Preamble_20120207.pdf (noting that the mission of ACCME is to enhance physician education, minimize commercial bias, and apply its accreditation standards in a manner consistent with FDA and other government agencies); *See also,* FDA, Guidance for Industry-Supported Scientific and Educational Activities, 62 Fed. Reg. 64,093 (Dec. 3, 1997) *available at* http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM125602.pdf (setting forth the factors FDA will consider in evaluating the appropriateness of industry-supported educational activities and recognizing the role of major accrediting organizations in monitoring such activities).

[45] 76 Fed. Reg. at 78,751

defined, could inadvertently require applicable manufacturers to track and report third parties' interactions with covered recipients in situations not contemplated by the statute.

For example, manufacturers often provide financial assistance to academic or training institutions for residents and fellows to attend educational conferences. In accordance with applicable industry standards, this financial support is provided on the condition that the institution will select which physician receives the funds and that the manufacturer will not have any control or influence over selection of the recipient. Likewise, manufacturers frequently engage independent market research companies to conduct blinded market research where, for legitimate business reasons, the manufacturer does not control the selection of the covered recipients that participate and is unaware of their identities. Because the type of situation described above is neither uncommon, nor would raise any concerns for the type of public transparency called for by the statute, we urge CMS to expressly exclude from reporting indirect payments to covered recipients unless they are made with the manufacturer's actual knowledge of the covered recipient's identity at the time the payment is made to the third party and the manufacturer can direct or control the payment to the covered recipient.

Exclusion for Educational Materials

The statute provides an important exclusion for "educational materials that directly benefit patients or are intended for patient use."[46] In the proposed rule, CMS solicited comment on whether materials provided to covered recipients for their own education should be excluded from reporting as educational materials that "directly benefit patients."[47] BIO firmly believes that such materials, which include medical textbooks, reprints of scientific and medical journal articles, and clinical treatment guideline sheets, directly benefit patients by ensuring that their doctors have access to up-to-date information regarding new medicines, therapies, and treatment options. Excluding educational materials for physicians from reporting obligations will ensure that patients continue to receive treatment from physicians informed on the latest standards and developments in their fields. We urge CMS to interpret the educational materials exclusion to cover such materials.

Exclusion for Corporate Development Interactions

BIO has significant concerns that CMS' proposed rule seeks to expand the scope of the reported and posted information to include information regarding early drug development that may be proprietary/confidential. Such research and drug development is the backbone of the innovative manufacturers that BIO represents, and the discovery of lifesaving treatments depends upon this early stage research. Requiring reporting of confidential commercial information and trade secrets would not serve the underlying transparency goals of the Sunshine Act and may cause harm to the commercial interests of covered manufacturers. In

[46] Section 1128G(e)(10)(B)(iii) [42 U.S.C. § 1320a-7h(e)(10)(B)(iii)]
[47] 76 Fed. Reg. at 78,751

the proposed rule, CMS states that the Sunshine Act seeks to shed light on the financial relationships between manufacturers and physicians in order to "dissuade inappropriate conflicts of interest from developing."[48] This goal may be served, however, without compromising the proprietary nature of some of the information involved. Public posting of certain commercially sensitive information, or the ability to acquire certain commercially sensitive information through a Freedom of Information Act (FOIA) request, would have a potentially negative impact on companies that far outweighs the public's interest in transparency regarding interactions between manufacturers and covered recipients. This is especially true for companies that are publicly traded, in the U.S. or in other markets. To this end, BIO would request that CMS make clear that any information that is provided to CMS to comply with the ACA requirements would not be subject to disclosure under FOIA.

In addition, BIO asks CMS to clarify that certain commercially sensitive information is not subject to reporting under the Sunshine Act. For example, manufacturers routinely enter into agreements with highly knowledgeable physicians to analyze the products and pipelines of companies targeted for potential acquisition, in-licensing or collaboration. Under the proposed rule, CMS would require a manufacturer to report the name of a physician participating in such a review, even though such products are not currently owned by the reporting company nor related to promotion or marketing of a covered product. This type of disclosure would alert competitors that a company is considering pursuing acquisition or development of a specific company or product. Manufacturers generally engage key opinion leaders early in the drug development process to assist in the process of identifying and developing treatments that will best serve the needs of patients. Revealing which expert physician a company is engaging to analyze certain pipelines or products of target companies would similarly make public and alert competitors about a manufacturer's acquisition or development plans. This unintended consequence of the proposed rule could significantly chill research collaborations.

Similarly, if a manufacturer conducts a dinner meeting with personnel from a company with which they are in discussions for purposes of in-licensing, out-licensing, acquisitions, or mergers, and physicians in the role of employed medical directors attend, such a meal could be reportable under the proposed rule, since the physician employees of one company would not fit under the employee exception for the other company. Again, this information would reveal confidential drug development/business plans of the reporting manufacturer. Similar concerns arise where, after a collaboration agreement is concluded between two companies, there is a business meeting between the companies and one company serves a meal to the other company. A strict reading of the statute could require disclosure of the value of the meal offered to a physician employee of the collaborating company by the company hosting the meeting, but such a meal is provided in the context of a routine business meeting and has no relationship to promotion or marketing of a product. Such payments are outside the intended scope of the statute and risk exposure of sensitive commercial information to competitors.

We urge CMS to exclude such payments from manufacturers' reporting obligations. While the potential harm from publication of this information is great, the public benefit from such

[48] 76 Fed. Reg. at 78,743

disclosures would be minimal. Information about manufacturer payments to physicians for services that involve business decisions unrelated to currently marketed products are unlikely to provide insight into physicians' prescribing patterns or clinical decision making. Accordingly, BIO believes that interactions between manufacturers and physicians should not be reportable when the manufacturer does not own or have any contractual interest in the product to which the interaction relates. In any event, to protect confidentiality to the greatest extent possible, BIO proposes that payments for such interactions be categorized generally as "associated research spending".

Public Availability

The ACA requires that the publicly available information regarding payments to covered recipients contain background information on industry-physician relationships[49] and that the Secretary "ensure that the information made available to the public is presented in the appropriate overall context."[50] This is an important provision, highlighting the need to assure that the information to be provided publicly is preceded and accompanied by clear, objective background, directed to the target audiences, and that the information presented is clearly defined and explained, so that it is meaningful and understandable.

CMS requests feedback regarding the type of information to be reported to the public, including background on industry-physician relationships, as well as how the data collected from manufacturers can be presented in a way that is most understandable to consumers. As BIO has stated previously, the information presented by CMS should focus on improving the public's understanding of the need for collaboration between U.S. physicians and the life sciences industry. BIO strongly recommends that CMS conduct focus group research and consult with experts to ensure that the information presented is useful and not misleading. We also proposed that CMS establish a taskforce comprised of representatives from industry, the provider community and public advocacy groups to advise on the development of the required background information on industry-physician relationships to be posted on the website.

BIO is concerned that the proposed rule does not address the inclusion of background information on industry-manufacturer relationships, as required by the statute. CMS has taken this first step in asking the question to stakeholders, but additional serious attention to this issue is imperative in seeking to achieve the goals of the statute. BIO suggests that CMS issue a second proposed rule to address public information and obtain stakeholder comments.

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[49] Section 1128G(c)(1)(C) [42 U.S.C. § 1320a-7g(c)(1)(C)]
[50] Section 1128G(c)(1)(A) [42 U.S.C. § 1320a-7g(c)(1)(A)]

Pre-Disclosure Review

In an effort to decrease the need for corrections, CMS proposes that applicable manufacturers may, prior to submitting data to CMS, provide each covered recipient with information that the reporting entity plans to submit to CMS.[51]

Manufacturers should not be required to provide covered recipients with direct access to their data either prior to ("pre-disclosure") or after data submission to CMS. Development of a company-specific, secured database accessible to covered recipients would be costly and administratively burdensome for manufacturers. Further, in the pre-disclosure context, there is simply not enough time between the close of the annual data collection period and the report submission deadline to facilitate an effective manufacturer-driven pre-disclosure process. BIO recognizes that some companies voluntarily may opt to provide covered recipients with information in advance of submission to CMS, and that others may allow access to data year-round. However, BIO believes that these should be offered to covered recipients at the option of the manufacturer, and not required.

45-Day Review Period

The statute requires that applicable manufacturers, applicable GPOs, covered recipients, and physician owners or investors have 45 days to review the data submitted to CMS before they are made available to the public.[52] BIO appreciates that the review of manufacturer data by covered recipients may provide a means of identifying reporting errors and confirming data accuracy; however, BIO believes that there are serious challenges associated with the post-disclosure review timeline proposed by the agency, as well as the process for identifying and addressing disputed dollar amounts.

BIO disagrees with CMS's recommendation that all disputes and corrections be made within the 45 day time period following report submission. BIO commends CMS on its broad base of recommended strategies for alerting physicians to the availability of data; however, even with this multi-channel communication, many covered recipients will likely not learn about the data review until well into the 45-day review period. Further, some covered recipients may fail to contact a manufacturer with a question regarding a reported payment until the last possible day. These actions will leave companies with inadequate time to respond fully and accurately to a question or a dispute.

BIO requests that CMS provide additional opportunities to communicate on the review process to make certain that disputes are handled appropriately and efficiently. As currently proposed, the review process offers little guidance on how CMS plans to handle outstanding disputes, or how reporting entities should respond to potentially erroneous claims from covered recipients. Given that the review period is the primary opportunity to correct errors or contest the data

[51] 76 Fed. Reg. at 78,753

[52] Section 1128G(c)(1)(C)(ix) [42 U.S.C. § 1320a-7g(c)(1)(C)(ix)]

submitted prior to public disclosure, BIO is hopeful that CMS will not be pressured into releasing a final rule without establishing safeguards to ensure accurate reporting to the public.

Delayed Publication

The ACA provides for delayed publication of payments or other transfers of value from applicable manufacturers to covered recipients made pursuant to product research or clinical investigations.[53] Delayed publication would be available for transfers of value provided in the context of bona fide research or investigation activities, which, if made public, would damage the reporting entities' proprietary interest. However, the proposed rule limits the types of products for which publication delay is available in a way that will impair the development of advances in patient care in many significant areas of health care.

CMS proposes to allow for delayed publication for research activities that concern "research on, or development of new drugs, devices, biologicals, or medical supplies"[54] and delayed publication for development and clinical investigations are "limited solely to new drugs, devices, biologicals, and medical supplies."[55] A delay in publication would not be available to applicable manufacturers for transactions related to OTC drugs and OTC devices/medical supplies. While these may not be covered products, CMS' proposed rule would encompass payments to covered recipients related to these products, if made by an applicable manufacturer. This creates a double standard – where such payments would be reported, but would not benefit from a similar delay in publication.

Clearly, product development and clinical investigation – and the confidentiality thereof - is critical to new innovations that benefit patients in these areas. Merely the publication of a particular expert physician's name in connection with a known industry product can signal to competitors the direction of development or investigation.

BIO believes innovation in these areas could be harmed if manufacturers must disclose these transfers of value with no delay. We therefore urge CMS to broaden the definition of products for which publication delay is allowed.

Animal Health Products

CMS states in the preamble that the purpose of the ACA is to "permit patients to make better informed decisions when choosing health care professionals and making treatment decisions". However, the proposed rule could be interpreted to encompass payments related to animal health products by an applicable manufacturer of covered products. Reporting payments arising from interactions with veterinary health professionals, or veterinary teaching schools, is beyond the scope of congressional intent and would not support the purpose of the ACA.

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[53] Section 1128G(c)(1)(E) [42 U.S.C. § 1320a-7g(c)(1)(E)]
[54] 76 Fed. Reg. at 78,756 [Proposed 42 C.F.R. § 403.910]
[55] 76 Fed. Reg. at 78,756 [Proposed 42 C.F.R. § 403.910]

BIO requests that CMS clarify in the final rule that payments to veterinary health professionals or veterinary schools are explicitly excluded from the ACA reporting requirements. The exclusion would be limited, as there are only about 30 accredited veterinary schools in the U.S., but the confusion avoided would be considerable.

Conclusion

BIO very much appreciates this opportunity to comment on CMS' proposed rule to implement the Sunshine Act, as these issues are of significant importance to our member companies. We respectfully request a meeting with CMS to further discuss the issues and challenges raised by the proposed rule, and will contact you to follow up in this regard. If you have any questions regarding these comments, please contact Sandi Dennis at

Sincerely,

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