BY ELECTRONIC DELIVERY

December 1, 2017

Ms. Maryann Sheehan
Director, Legislative and Regulatory Affairs
Division of Consumer Affairs
124 Halsey Street, 7th Floor
P.O. Box 45027
Newark, NJ 07102

Re: BIO Comments Regarding Gift Ban Rule

Dear Ms. Sheehan:

The Biotechnology Innovation Organization (BIO) welcomes this opportunity to submit comments regarding proposed rule, N.J.A.C. 13:45J, concerning "limitations on and obligations associated with the acceptance of compensation from pharmaceutical manufacturers." BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO's members develop medical products and technologies to treat patients afflicted with serious diseases, to delay the onset of these diseases, or to prevent them in the first place.

BIO supports the efforts by the Christie Administration to address the opioid crisis in New Jersey and applauds the national leadership that Governor Christie has shown on this critical issue. BIO and our member companies also fully support policies to ensure lawful, professional, and ethical interactions between prescribers, and manufacturers in a way that facilitates the advancement of medical science and improves patient care. However, we have significant concerns that this rule will increase the regulatory burden on manufacturers and providers, while having no impact on the opioid epidemic –the opposite of Governor Christie's stated goal when announcing the rule.

BIO is concerned that if adopted, as written, this proposed rule will:

- Severely curtail clinical research conducted in New Jersey by placing an unrealistically low cap on payments to clinicians conducting clinical trials in the state.
- Create a system that prevents valuable interactions between health care professionals and biopharmaceutical manufacturers, which is essential to communicating the most current and relevant information about life saving medicines.
- Place a tremendous administrative and operational burden on both prescribers and manufacturers due to the requirements needed to redesign processes, policies, procedures and systems to aid compliance.

BIO's detailed comments are outlined below.

"Bona fide Services" Cap will Curtail Research

BIO's concern with proposed rule N.J.A.C. 13:45J is that it may do nothing to improve patient care, and it could hurt, rather than help, medical science and biopharmaceutical innovation. More specifically, the proposed rule could potentially impede scientific exchange of information and clinical trial research in the State of New Jersey. Clinical trials are an essential part of drug development and are the cornerstone of the innovation process. The proposed rule does not provide for an exemption in "bona fide services" for engagements or interactions related to scientific exchange, clinical research or payments for conducting clinical trials. This proposed rule would limit the compensation clinicians may receive from all manufacturers to $10,000 annually. This would have a drastic adverse effect on research conducted in New Jersey, necessary sharing of scientific information, as well as an economic impact that the proposed rule fails to consider.

BIO believes the "Economic Impact" and "Jobs Impact" analyses noted in the beginning of the proposed rule are seriously flawed and do not recognize the contribution the biopharmaceutical makes to the state's fragile economy and the risk of causing an imbalance that would send jobs to neighboring states such as New York and Pennsylvania. The biopharmaceutical industry supports nearly 380,000 direct or indirect jobs in the State of New Jersey.[1] New Jersey is one of only two states in which the economic impact of the biopharmaceutical industry exceeds $100 billion.[2] Moreover, since 2004 the industry has ongoing or has completed at least 4,967 clinical trials in the State of New Jersey.[3] Clinical trials provide more than 3,700 jobs and add another $337 million to the state's economy. Manufacturers that believe research can be stymied by the state's policies if this rule is adopted, could potentially relocate to other states, or decide not to move into the state in the first place, resulting in a significant impact on tax revenue in the state. Moreover, research and clinical trials may be moved elsewhere, costing the state high-paying research jobs. Given the significant amount of economic contributions and investment the bio-pharmaceutical industry has made in the State of New Jersey, BIO urges the state to consider the overall impact this may have both on research and the economy.

Moreover, the context the rule lays out for the concept of "bona fide service agreements" does not recognize that many manufacturers enter into agreements for bona fide services such as research, symposia, advisory board, professional speakers bureaus, or continuing educational events with both providers and institutions. These contracts are often much higher than the $10,000 cap if an institution has contracted to conduct large clinical trials. Also, a provider working for an institution may appear to be receiving large remuneration based on the agreement with the institution, as well as the study being conducted, but often it is the institution receiving remuneration and the provider is receiving his or her salary from the institution. In addition, it is important to note that the specific nature of these proposed agreements and the required disclosures may impede the ability to conduct "blind" studies in clinical trials or even double-blind market research. The proposed definition of "pharmaceutical manufacturer's agent" could be so broad as to cover a market research company, which would have a function that is very different than actual marketing of a drug product.

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[1] TEConomy Partners; for PhRMA. The Economic Impact of the US Biopharmaceutical Industry. Columbus, OH: TEConomy Partners; July 2017

[2] Ibid.

[3] http://www.phrma.org/research-in-your-backyard/research-in-new-jersey

In addition, BIO is concerned that the $10,000 cap is extremely low for effective advisory contracts with the best candidates, particularly if the providers are contracting for different services from different manufacturers. Fair market value for these professionals can far exceed the $10,000 cap. In addition, Scientific Advisory Boards (SABs) are typically comprised of medical providers and are an important means by which bio-pharmaceutical companies gain valuable information regarding what is working and not working in clinical treatments, what value a drug may bring or not bring to a patient community.

Manufacturers often learn key insights about particular drugs or compounds that they may discover are important for clinical development of new therapies for patients with unmet needs. Often only the best specialists and experts in their field are recruited for these SABs. Fair market value for these individuals can exceed the proposed cap especially as these experts may provide similar services for more than one manufacturer. SABs are meant to provide an honest discussion with the medical community regarding a product or potential new products in clinical development without the detailing activities of sales representatives that ultimately improve the quality of care and life of patients. Most typically, SABs are facilitated by professionals in Medical Affairs or by liaisons within the medical community, not members of traditional sales teams. However, the key element of SABs is that they are set up so that the health care providers can provide information to the manufacturer representatives, not the reverse. Many providers often are the elite experts in their field and may participate on multiple SABs from different companies. This $10,000 cap may hinder an SAB's effectiveness, and ultimately hinder participation in SABs of the highly respected professionals in their field. This policy could also result in SABs being conducted outside of the state.

In addition, there are significant clinical research organizations (CROs) that are based in New Jersey, including one entity that operates through Rutgers University. These organizations operate within current federal guidelines permitted under the Open Payments System operated by CMS (and discussed later in this response). The definition of research is broader, "Research includes a systematic investigation designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. This term encompasses basic and applied research and product development."[4] If New Jersey adopts this rule as drafted these functions could be seriously undermined. If indeed the rule is to be enacted, BIO recommends that the state adopt a categorical exemption for research and non-promotional activities in Section 1.4(a). Further, if the Division does not adopt a categorical exemption, then it is imperative that the definition is brought in line with the federal definition to ensure entities that are compliant with current federal regulations are not inadvertently forced out of the state.

BIO recommends that if the intent of the proposed rule is to cap the compensation a prescriber receives from a manufacturer for promotional activities, then the definition of bona fide services should be amended to include the specific promotional activities that the Governor intends to limit through such a cap. This approach would continue to allow the meaningful and appropriate exchange of scientific information which fuels innovation and improvements in care for patients.

Definition of "Modest Meals" Will Curtail Valuable Interactions

Biopharmaceutical manufacturers' interactions with health care prescribers are designed to improve the quality of care and ensure patient safety. Manufacturers use exchanges with health care practitioners as a means to provide valuable information, such

[4] 42 USC 403.902

as important information about a drug's risks and benefits, which may change over time as more post-marketing studies are completed. Also, these meetings provide an opportunity for a scientific exchange between pharmaceutical representatives and providers. Biopharmaceutical representatives provide updates on scientific information, and can receive valuable input about how the provider's patients are responding [or not] on certain medication, with the ultimate goal being the improvement of patient care. These communications enhance the patient's care and can improve proper medication adherence. The PhRMA Code sums up well the goals of these interactions and the materials provided. "Promotional materials provided to healthcare professionals by or on behalf of a company should: (a) be accurate and not misleading; (b) make claims about a product only when properly substantiated; (c) reflect the balance between risks and benefits; and (d) be consistent with all other Food and Drug Administration (FDA) requirements governing such communications."[5]

However, BIO is concerned that the imposition of a $15 limit on modest meals in §13:45J-1.2 is extremely low and should be eliminated in favor a broader, more flexible definition, or be raised substantially. For instance, a simple pizza for lunch could cost more than $15, and this could lead to manufacturers reducing visits because the requirements are arbitrarily set at such a low bar, or alternatively it could lead to providers reducing the number of calls per year, because they can only meet during lunch and manufacturers are unable to provide them with as much. BIO believes that the state should consider language that is similar in nature to that adopted in Massachusetts for the definition of "modest meals." In Massachusetts, "'modest meals and refreshments' is defined as food and/or drinks provided by or paid for by a pharmaceutical or medical device manufacturing company or agent to a health care practitioner that, as judged by local standards, are similar to what a health care practitioner might purchase when dining at his or her own expense."[6] This definition is sufficiently broad so that geographic differences are accounted for while still limiting the amount spent on meals. Meals near the major cities are much more expensive than those in rural areas. Fifteen dollars is an extremely low expectation for the provision of dinner, especially one catered at an event such as at continuing education or other events that may include a dinner. As noted above, costs from one city or town to the next can vary widely in a state such as New Jersey. The cost of a meal near New York City or Philadelphia may be much higher than the cost of a meal further away near the Delaware border.

It is important to consider that presentations to providers and their staff by company representatives are educational in nature and facilitate a dialogue about the product and its on-label use. These communications enhance not only prescriber knowledge, but patient care as well. As an example, a BIO member manufactures a product that is an inhaled nitric oxide delivered in the Neonatal Intensive Care Unit (NICU) via a device. The company's representatives visit hospitals to help educate the respiratory department staff on the proper set up and use of the device, which can be critical in a hospital that uses this product on a more infrequent basis. The meal simply facilitates that educational exchange and product discussion, which if it didn't occur, could lead to complications for the patient due to improper set up and use of the device.

There could also be a chilling effect on communications addressing rare diseases or oncology where medicine is rapidly evolving. For example, with the large number of ongoing clinical trials in oncology—across different tumor types and cancers caused by specific genetic mutations—there is legitimate reason to be concerned that the proposed rule's

[5] http://phrma-docs.phrma.org/sites/default/files/pdf/phrma_marketing_code_2008.pdf
[6] http://www.mass.gov/eohhs/docs/dph/regs/105cmr970.pdf

restrictions on educational activity will hamper providers from receiving the latest scientific updates and clinical trial information on emerging and cutting-edge treatment options for the patients with unmet needs, such as for rare diseases. Again, meals facilitate these educational exchanges.

Additionally, BIO is concerned that the list of exemptions is not adequate to account for activities related to exchange of scientific information, as well as several, FDA-regulated, non-promotional activities that might take place related clinical trials, Risk Evaluation and Mitigation Strategies (REMS), investigational drugs, or medical/trade conferences. The rule appears to exclude non-promotional meetings and interactions from the exemptions for "modest meals." Section 13:45J-1.4 "Permitted Gifts and Payments", appears to only permit "modest meals" in cases of continuing education events when the meals "facilitate the educational program to maximize the prescriber learning" or "to non-faculty prescribers through promotional activities." Non-promotional meetings and interactions would not be covered in these two scenarios, yet these meetings could include, for example, scientific exchanges to discuss a drug's REMS, which are required by the Food and Drug Administration (FDA). We urge the Division to modify this section to explicitly allow for meals related to non-promotional activities or at the very least increase the dollar amount limitation to account for reasonable costs associated with meals, tax and gratuity with a mechanism to account for inflationary changes over time.

Moreover, BIO is also concerned that the definition of "immediate family member" is overly broad. It is unrealistic to expect that such individuals should be automatically known to manufacturers at meetings that are not meant to include such individuals. For example, an individual interviewing for a position, but is not yet an employee of a manufacturer, may not reveal to the manufacturer that they are related to a physician, particularly if that individual happens to be the grandparent or other relative that is included in §13:45J-1.3, but is generations away from the physician. The same could be true at conferences or educational programming that have nothing to do with promotion of a product. For example, many companies, through their philanthropic endeavors, may provide for educational forums regarding disease-states, such as HIV/AIDS. These programs might focus on prevention of the disease in at-risk populations with no mention of products. These sessions would often include refreshments, or could incorporate dinner or receptions for participants. It would be impossible for the company to know who is an immediate family member under this definition. As a result, this rule could have a chilling effect on nonproduct-related endeavors. We urge the Division to remove this provision from any final rule.

The Proposed Requirements Would Duplicate and Conflict with Existing Requirements

BIO member companies and other biopharmaceutical manufacturers already have extensive compliance programs that ensure compliance with the Federal anti-kickback statute, Federal Sunshine Act, and the Health and Human Services Office of Inspector General's (OIG's) "Federal Compliance Program Guidance for Pharmaceutical Manufacturers." The subject of the guidance also pertains to communications with healthcare providers and "gifts" of the nature the proposed rule intends to regulate. The OIG said within the guidance that compliance with the PhRMA Code of Conduct[7] "will substantially reduce the risk of fraud and abuse and help demonstrate a good faith effort to comply with the applicable federal health care program requirements." The preamble to the

[7] http://phrma-docs.phrma.org/sites/default/files/pdf/phrma_marketing_code_2008.pdf

proposed rule N.J.A.C. 13:45J, states that these proposed "prohibitions closely mirror those set forth in the Pharmaceutical Research and Manufacturers of America (PhRMA) [voluntary] Code of Ethics for their member companies with respect to gifts to prescribers."[8] When the PhRMA Code was developed, it was anticipated to be a voluntary, but reasonable, approach to interactions with healthcare providers. Many BIO members are compliant with the PhRMA Code as they are also members of PhRMA. However, many of BIO's members do not have the resources for large scale marketing efforts but must still act in good faith within the guidance issued by the OIG. Indeed, the Department of Justice may prosecute any companies that violate those guidelines.

Despite the proposed rule's stated intention to "mirror the PhRMA Code," it far exceeds the Code, particularly by not providing a clear exemption for research and for placing a $10,000 industry cap for "bona fide services." As a result, this proposed rule could disproportionately harm smaller manufacturers. While the proposed rule requires providers to develop processes and systems to track their remuneration from manufacturers, it essentially requires manufacturers to develop a system to track the remuneration of all manufacturers, to ensure their own payments do not surpass the provider's limits. BIO does not believe this to be a reasonable approach. First, development of such as system would be extremely difficult, particularly because it would be unknown who would be the caretaker of such a system, or how the manufacturers would be forced to report. Second, this type of system is fundamentally different than the federal Sunshine rules because it would require tracking payments to physicians on an ongoing basis throughout the year, not after the fact. Many of these interactions involve complex marketing strategies, which are considered proprietary trade secrets that are protected by the New Jersey Uniform Trade Secrets Act that Governor Christie signed into law in 2012,[9] as well as federal case law and the US Constitution.

Biopharmaceutical manufacturers already must comply with Federal Sunshine rules that require reporting to the Centers for Medicare and Medicaid Services (CMS) Open Payments System.[10] Manufacturers that provide remuneration under the *de minimis* threshold limit of $10.49 do not need to report those payments, while those that provide in aggregate more than the upper threshold $104.90 to a physician must report each of their payments to health care professionals. Neither providers nor manufacturers have the ability to measure the payments of other manufacturers. As mentioned above, the Open Payments System has specific exemptions in addition to those under the $10.49 *de minimis* threshold, such as research. The broader definition of research under the federal program is meant to include items directly associated with non-promotional activities.

However, given the additional requirements included in this proposed rule, BIO hopes the Division will try to ease the burden on providers as much as possible. The current Open Payments System encompasses data that is submitted by manufacturers regarding payments to physicians [and not nurse practitioners or physician assistants]. Currently, physicians can voluntarily review their information for accuracy, but not all do. The state could endorse a system that encourages prescribers that are captured by the federal system to review the data annually.

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[8] Proposed rule, N.J.A.C. 13:45J, Page 4. 2017.

[9] N.J. Stat. §§56:15

[10] https://www.cms.gov/openpayments/

The Proposed Rules Should Provide for a Delay for Administrative Preparation

If the state decides to move forward with the rule, at a minimum we recommend that the state delay implementation to allow providers and manufacturers adequate time to implement procedures and technology to comply with the rule. Given the proposed rule's operational and administrative challenges, providers and manufacturers would need a minimum six-month, if not more, readiness period to secure adequate financial and human resources, modify existing or develop new processes and systems, and communicate and train staff to be able to comply with the rule.

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Thank you for the opportunity to comment on the proposed rule, N.J.A.C. 13:45J. If the Division intends to implement this rule, BIO is prepared to work with you regarding the most effective means of ameliorating opioid abuse in New Jersey. However, we do not believe the rule, as drafted, would not accomplish these goals and we urge the Department to withdraw the rule or make necessary changes to ensure the valuable exchanges between providers and manufacturers are not unduly restricted, and research and innovation is preserved. If you have any questions, please do not hesitate to contact me at 202-962-9200.

Sincerely,

/s/

Patrick Plues
Vice President
State Government Affairs