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November 25, 2009

Dockets Management Branch (HFA-305)
Food and Drug Administration
5600 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA-2009-N-0295: Providing Effective Information to Consumers about Prescription Drug Risks and Benefits.

Dear Sir/Madam:

The Biotechnology Industry Organization (BIO) thanks the Food and Drug Administration (FDA) for the opportunity to submit comments on “*Providing Effective Information to Consumers about Prescription Drug Risks and Benefits.*” BIO believes that patients and healthcare professionals should have access to up-to-date, relevant, and accurate product information available in an easily accessible form in order to inform individual medical decisions and ensure the safe utilization of medications. Under current practice, patients may receive several different types of patient-oriented written communication at the time of dispensing – such as Consumer Medication Information (CMI), Medication Guides (MedGuide), and Patient Package Inserts (PPI) – that may be non-standardized and duplicative. In previous comments (*Appendix B*), BIO endorsed the development of a single written patient-oriented document to be used to communicate product benefit and risk information to patients. BIO believes this patient document should be drafted by the sponsor, reviewed and approved by FDA, and based on a template that has been validated through social-science research of patient comprehension. BIO also believes that technology should be leveraged to enhance dissemination and distribution of the most up-to-date patient labeling. We applaud the FDA for convening the September 24th-25th public workshop to identify the ideal attributes of the document and how it can be best distributed to patients. BIO is pleased to offer the following considerations to elaborate on our previous comments and workshop testimony.

BIO represents more than 1,200 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology products, thereby expanding

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

I. Prototype for a Single Patient-Oriented Written Communication

The workshop included a productive series of breakout sessions to evaluate the relative merits and weaknesses of four prototypes developed by FDA to explore different written approaches to conveying prescription drug information to consumers. FDA challenged stakeholders to identify common strengths across the various prototypes and think about how these attributes could be combined into a single “hybrid” prototype. A number of key themes emerged during the breakout sessions and subsequent summary that BIO believes should be reinforced and incorporated into future prototypes.

- *Includes the Full Context of Benefits and Risks:* The document should provide summary information of both the product’s benefits and risks and proper usage of the medication so patients can make informed decisions about their health. The balance between the benefits and risks of treatment will differ based on many factors, including each patient’s unique medical profile and engagement in his or her health. Both the Agency and industry recognize that drug safety is not absolute, but rather a matter of balancing benefits against risks, which can differ patient by patient, depending on their health history, personal choice, and individual circumstances. Therefore, BIO recommends that the prototype should provide patients with both risk and benefit information, because only then can patients make appropriately informed choices about a product’s use along with discussions with their health care professional. This information could be ordered in a logical flow of benefits based on indication and indication description, followed by important warnings and safety information, contraindications, administration information, and finally contacts for additional information.
- *Communicated Using Narrative, Layperson-Friendly Language:* Safety, benefit, and administration information should be provided in qualitative, narrative manner using language that can be easily read and understood by a patient who has the disease for which the medication is being prescribed. For example, rather than simply stating that the product is used for “ankylosing spondylitis” (prototypes #1, #2), the document should state that it treats ankylosing spondylitis and “reduces back pain, swelling, and improves mobility” (prototype #3). This additional benefit information provides useful information to the patient about what to expect from the therapeutic communicated in language that an average patient can fully understand. A similar approach is utilized in Vaccine Information Statements produced by the Centers for Disease Control and Prevention (CDC), which can serve as a useful model for the content of the FDA prototype.
- *Utilizes “Action-Driven” Wording:* The use of “action-driven wording” rather than generic headers helps to provide direction and clear advice for patients and healthcare providers on how to manage a risk. For example, the headers should provide clear direction in the event of an adverse reactions, such as “Call your Doctor Right Away if You Experience” (prototype #1), rather than simply stating “Serious Side Effects” (prototypes #2) or “What are the Risks?” (prototypes #3, #4). Signals should also be given to patients regarding the urgency in managing risks. For example, “Seek immediate medical care” suggests that a patient should contact a medical provider no

matter what day or time, while “Tell your doctor that you have experienced...” indicates that the patient could wait for routine office hours.

- *Formatted Clearly and Concisely:* We believe that there are benefits to using the “boxed” format used in prototype #1, similar to the current OTC “Drug Facts Box.” This format would be immediately recognized by patients and provide a level of consistency across drug classes that could help patient to easily find relevant drug information. Bulleted information, chunking, and use of white space would seem to make the format more accessible and understandable to patients. When possible, concise information limited to a single page or a two sided sheet of standard letter sized paper will make the document more straightforward and comprehensible to patients and will allow it to be printed in a variety of settings using off-the-shelf printers. Shortened, easier to understand information may also motivate patients to read the information and take a more active role in their health versus the current format.
- *Tiered Levels of Information:* The patient labeling document should only include the most important information that patients need to know to make informed decisions and use the medication safely and effectively. It should also direct patients to additional information should patients wish to access it through the manufacturer FDA website, manufacturer telephone number, and other appropriate points of contact.

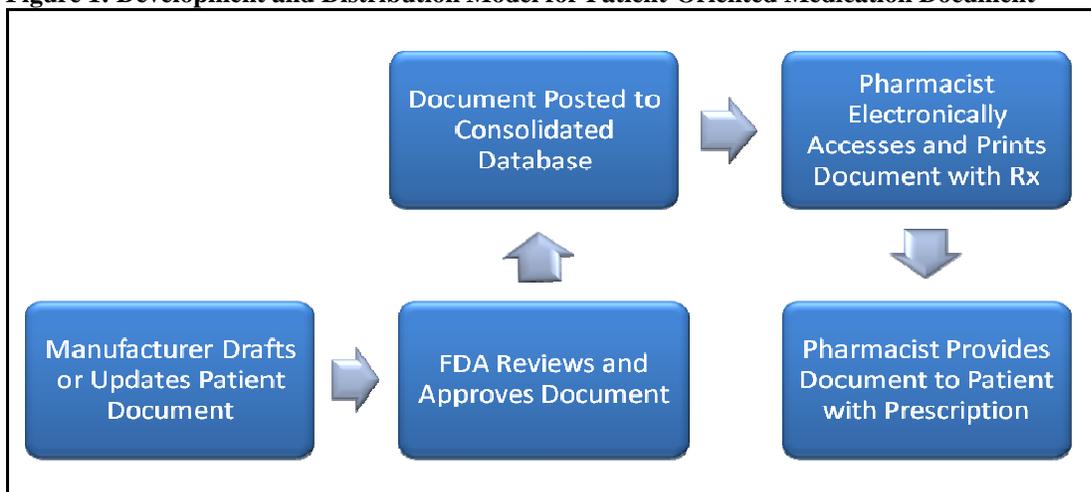
Please see Appendix A for an example of a “hybrid” prototype document that captures the various strengths listed above.

II. Electronic Distribution of the Patient-Oriented Written Document

In light of recent advances in information technology, FDA, manufacturers and pharmacists should leverage electronic systems to enhance the dissemination and accessibility of patient communications. BIO supports FDA’s decision that the most recent, FDA-approved, patient-oriented written document should be electronically accessible on a public website or database such as the National Library of Medicine’s DailyMed website in a similar manner to the professional labeling. This should provide prescribers with single point access to the U.S. Package Insert content as well as the content of patient labeling.

As noted above, one of the strengths of a short, concise, standard letter sized document is that it can be downloaded and printed in a variety of settings using off-the shelf printing technology. BIO believes that pharmacists should be able to electronically access and print the document from a consolidated database, thereby ensuring that the most up-to-date document is provided to the patient. To the extent practicable, existing pharmacy information technology and distribution systems should be utilized. We do recognize that this may involve some reengineering of existing pharmacy databases and workflow systems. However, these changes are technologically feasible and should be pursued by pharmacists and the FDA if it is in the best interest of the patient and can improve health outcomes.

Figure 1: Development and Distribution Model for Patient-Oriented Medication Document



III. Additional Social Science Research is Needed

While stakeholder evaluation of the prototypes was a useful exercise, it will be important to conduct additional social science and behavioral research to validate average patient comprehension of specific proposed prototypes before any single template is adopted. BIO encourages FDA and other stakeholders to collaboratively sponsor research to advance the field of how to best present risk and benefit information to patients, including optimal format, content, verbiage, length, and patient comprehension expectations that can be applied across all drugs. For example, BIO would endorse the development of a consortium to finance, prioritize, and commission this research. Such a consortium or private-public partnership should include drug and biologics manufacturers, physician groups, pharmacy associations, patient organizations, and academic researchers, and could be coordinated through National Council on Patient Information and Education (NCPPIE), the Centers for Education & Research on Therapeutics (CERTs), or the Reagan- Udall Foundation for the FDA.

IV. Conclusion:

BIO appreciates this opportunity to comment on the FDA workshop “*Providing Effective Information to Consumers about Prescription Drug Risks and Benefits.*” We are encouraged by FDA’s ongoing evaluation of a single document solution for written patient-oriented medication information with a template informed and justified by relevant social science research in order to further enhance patient comprehension of a drug or biologic’s benefits and risks. We would be pleased to provide further input or clarification of our comments, as needed.

Sincerely,

/s/

Andrew J. Emmett
Director for Science and Regulatory Affairs
Biotechnology Industry Organization (BIO)

RHEUTOPIA (*ROO-TOH-PEE-AH*), ARIXALATE

approved by FDA in 2002

Why use this Product?

Rheutopia is a prescription medicine called a Tumor Necrosis Factor (TNF) blocker used to treat:

- Rheumatoid arthritis in adults (It reduces painful & swollen joints, slows joint damage, and improves the ability to move around and do physical activities.)
- Polyarticular juvenile rheumatoid arthritis in people older than 4 who did not have results from other medicines (It reduces pain, improves ability to move around, and decreases the number of painful joints.)
- Ankylosing spondylitis (It reduces back pain and swelling and improves the ability to move around.)
- Chronic plaque psoriasis in adults who may benefit from medicines or using ultraviolet light (It improves or clears up areas or clears up areas of skin with psoriasis.)

Important information to know:

Rheutopia affects your immune system which fights infections. It can make you more likely to get an infection or make an infection that you already have worse. Some people have died from infections.

Call your doctor right away if you experience:

- Fever, cough, flu-like symptoms, skin problems (red, warm, painful skin) or open sores. These can be signs of **serious infections**.
- Numbness, tingling, weakness, vision problems, or dizziness. If you have **nervous system problems** you may get new or worse symptoms.
- List symptoms You may have a higher chance of getting **lymph node cancer**.
- Bruising, fatigue, and pale skin. You may have **blood problems** and your body may not make enough blood cells to fight infection or to help stop bleeding.
- Shortness of breath, swelling of ankles or feet, or sudden weight gain: You may get **heart failure** or worsening heart failure. .
- Chest discomfort or pain, shortness of breath, joint pain or a rash on your cheeks or arms. These may be signs of **an immune reaction**.

Tell your doctor about side effects that do not go away or get worse such as:

- Injection (shot) site reactions (redness, rash, swelling, bruising), infections, headache, and runny nose.

You may report side effects to FDA at 1-800-FDA-1088.

Do not take these medicines with Rheutopia:

- Kineret (anakinra) - you are more likely to develop a serious infection.
- Any vaccinations (including a flu shot) - you may develop an infection. Tell your doctor that you take Rheutopia before you get any vaccine.

How do you use this Product?

- Read the detailed “Instructions for Using Rheutopia” that come in the package
- Take Rheutopia only as your doctor told you
- Call your doctor, pharmacist, or 1800 RHEUTOPIA if you are having trouble giving yourself shots
- Store Rheutopia in the refrigerator at 36 to 46°F
- Do not drop or crush the glass syringe
- Do not shake

Inactive ingredients:

- **Single-use prefilled syringe:** sucrose, sodium chloride, L-arginine hydrochloride, sodium phosphate monobasic monohydrate, sodium phosphate dibasic anhydrous.
- **Vial:** mannitol, sucrose, tromethamine.

For more information on Rheutopia

- Visit www.fda.more-information.gov
- Call [manufacturer] toll-free 1-800-_____ from __ a.m. to __p.m. (ET) Monday to Friday.

This document summarizes the most important information about Rheutopia. If you would like additional information, talk with your doctor. Medicines are sometimes prescribed for purposes other than those listed in here.

RHEUTOPIA (ROO-TOH-PEE-AH), ARIXALATE

approved by FDA in 2002

Indication and benefit information is described in layperson-friendly narrative language that explains the condition and expected outcomes

Why use this Product?

Rheutopia is a prescription medicine called a Tumor Necrosis Factor (TNF) blocker used to treat:

- Rheumatoid arthritis in adults (It reduces painful & swollen joints, slows joint damage, and improves the ability to move around and do physical activities.)
- Polyarticular juvenile rheumatoid arthritis in people older than 4 who did not have results from other medicines (It reduces pain, improves ability to move around, and decreases the number of painful joints.)
- Ankylosing spondylitis (It reduces back pain and swelling and improves the ability to move around.)
- Chronic plaque psoriasis in adults who may benefit from medicines or using ultraviolet light (It improves or clears up areas or clears up areas of skin with psoriasis.)

Important “black box warnings” can be prominently displayed

Important information to know

Rheutopia affects your immune system which fights infections. It can make you more likely to get an infection or make an infection that you already have worse. Some people have died from infections.

Additional safety information - described in a narrative, layperson friendly fashion - is included in a tiered fashion with serious adverse events followed by less-serious, common AEs.

Call your doctor right away if you experience:

- Fever, cough, flu-like symptoms, skin problems (red, warm, painful skin) or open sores. These can be signs of **serious infections**.
- Numbness, tingling, weakness, vision problems, or dizziness. If you have **nervous system problems** you may get new or worse symptoms.
- List symptoms You may have a higher chance of getting **lymph node cancer**.
- Bruising, fatigue, and pale skin. You may have **blood problems** and your body may not make enough blood cells to fight infection or to help stop bleeding.
- Shortness of breath, swelling of ankles or feet, or sudden weight gain: You may get **heart failure** or worsening heart failure.
- Chest discomfort or pain, shortness of breath, joint pain or a rash on your cheeks or arms. These may be signs of an **immune reaction**.

“Action headers” provide direction and clear advice for patients and healthcare providers on how to manage a risk

Tell your doctor about side effects that do not go away or get worse such as:

- Injection (shot) site reactions (redness, rash, swelling, bruising), infections, headache, and runny nose.

You may report side effects to FDA at 1-800-FDA-1088.

Contraindications and direction for use sections helps to support safe use of the product

Do not take these medicines with Rheutopia:

- Kimeret (anakinra) - you are more likely to develop a serious infection.
- Any vaccinations (including a flu shot) - you may develop an infection. Tell your doctor that you take Rheutopia before you get any vaccine.

Additional contact information is provided for patients seeking more detailed information

How do you use this Product?

- Read the detailed “Instructions for Using Rheutopia” that come in the package
- Take Rheutopia only as your doctor told you
- Call your doctor, pharmacist, or 1800 RHEUTOPIA if you are having trouble giving yourself shots
- Store Rheutopia in the refrigerator at 36 to 46°F
- Do not drop or crush the glass syringe
- Do not shake

This section provides important information on the purpose and limitations of written patient information

Inactive ingredients:

- **Single-use prefilled syringe:** sucrose, sodium chloride, L-arginine hydrochloride, sodium phosphate monobasic monohydrate, sodium phosphate dibasic anhydrous.
- **Vial:** mannitol, sucrose, tromethamine.

For more information on Rheutopia

- Visit www.fda.more-information.gov
- Call [manufacturer] toll-free 1-800-_____ from _____ a.m. to _____ p.m. (ET) Monday to Friday.

This document summarizes the most important information about Rheutopia. If you would like additional information, talk with your doctor. Medicines are sometimes prescribed for purposes other than those listed in here.

Revised 11/2009

Revision date helps to notify patients of recently updated information

APPENDIX B: BIO Comments on FDA's Consumer Medication Information (CMI) Initiative,
April 29, 2009



1201 Maryland Avenue SW, Suite 900, Washington, DC 20024
202-962-9200, www.bio.org

April 29, 2009

Dockets Management Branch (HFA-305)
Food and Drug Administration
5600 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA-2008-N-0038

Dear Sir/Madam:

The Biotechnology Industry Organization (BIO) thanks the Food and Drug Administration (FDA) for the opportunity to submit comments on the FDA's Consumer Medication Information (CMI) Initiative. BIO believes that patients and healthcare professionals should have access to up-to-date, relevant, and accurate product information available in an easily accessible form in order to inform individual medical decisions and ensure the safe utilization of medications. Under current practice, patients may receive several different types of patient-oriented written communication at the time of dispensing – such as Consumer Medication Information (CMI), Medication Guides (MedGuide), and Patient Package Inserts (PPI) – that may be non-standardized and duplicative. BIO encourages FDA to collaborate with stakeholders to develop a single patient-oriented medication document with standardized format and content informed by social science and behavioral research to be used to communicate product information to patients.

BIO represents more than 1,200 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology products, thereby expanding the boundaries of science to benefit humanity by providing better healthcare, enhanced agriculture, and a cleaner and safer environment.

BIO's healthcare members understand the need for patients and physicians to have up-to-date, relevant, and accurate information about the benefits and risks of a drug or biologic so they can make well-informed choices about therapy. The professional physician label is the cornerstone of every prescribing decision and includes important benefit/risk information to guide medical decision-making. However, the professional label is written in a manner intended for physicians and other medical professionals. Additional consumer-friendly written materials can be useful to help patients understand the benefits and risks of a product, to increase patient compliance, and to help inform patients when a follow-up with their physician may be warranted.

Under current practice, a patient being dispensed a medication at a pharmacy or other healthcare setting may receive a combination of several separate documents including a CMI prepared by a third-party vendor, and/or a FDA-approved MedGuide, or a PPI. Patients may also receive product information from the brief summary section of direct-to-consumer advertising. These different types of written patient-oriented communications are the result of a series of laws, regulations, and guidance documents spanning several decades. The most notable of these is a 1996 law (P.L. 104-180) which established a voluntary private-sector initiative to provide useful written information for patients of new prescriptions 95% of the time by 2006. As demonstrated by a 2008 evaluation of CMI, the initiative has struggled to meet that goal.¹ The evaluation found that the quality and comprehensibility of CMIs can be variable; the format and content can be difficult for patients to read; and the information provided may be duplicative of other formats. This can contribute to suboptimal comprehension of important prescribing information. BIO is encouraged by FDA's ongoing evaluation of new initiatives to provide patients with the tools they need to understand and manage their medications to achieve optimal compliance and health outcomes.

I. A SINGLE PATIENT-ORIENTED WRITTEN COMMUNICATION:

BIO supports efforts to streamline this process to ensure that patients receive high quality and easily understandable medication information, and is pleased to offer the following recommendations.

- *A Single Document Solution:* BIO supports the development of a single patient-oriented medication document for drugs and biologics to be provided at the time of dispensing. A single document solution based on a uniform template would promote consistent information and formatting of patient information. Such consistency should seek to increase patient comprehension by creating a common format with which patients could become familiar over time, so they could recognize where to find relevant information in the document regardless of the product or class. A single written communication may also serve to stimulate patients' communication with their health care provider about their medication regimen. BIO does not advocate the creation of yet another duplicative document for dispensers to distribute to patients, but envisions that this document would

¹ Kimberlin & Winterstein *Expert and Consumer Evaluation of Consumer Medication Information - 2008* Final Report to the U.S. Department of Health and Human Services and the Food and Drug Administration, November 4, 2008, http://www.fda.gov/cder/news/CMI/final_report.pdf

replace the current complement of patient documents, except in cases where MedGuides are required, as discussed below. For the purposes of these comments, we will refer to this proposed, standardized single document as the “Patient-oriented Medication Document” or PMD.

- *Written by the Sponsor:* BIO believes that the PMD should be initially drafted by the drug sponsor. Drug and biologics manufacturers, along with FDA, have the most detailed knowledge of the benefits, risks, and unique scientific characteristics of a given product. Because drug and biologics manufacturers are responsible for the surveillance and continuous review of marketed products’ benefit-risk profile, they are in the best position to develop and routinely update the content of the PMD. Much like the current process for developing professional and patient labeling, the sponsor should initially draft the PMD, followed by FDA review, including written comments from FDA to the manufacturer regarding any Agency proposed changes to the labeling language. Sponsors may wish to contract with a third party to assist in drafting and/or distributing the PMD, but ultimate decisions regarding content should rest with the sponsor and FDA.
- *Based on a Pre-determined Template Specifying Content and Format:* BIO believes that FDA should establish a uniform template through regulation and guidance that specifies the content and format of the PMD. The template should be determined after consulting with relevant stakeholders; should be based on the results of social science and behavioral research on patient comprehension of medication information; and should be implemented only if supported by such research. The template should be drafted in a manner that promotes standardization while also retaining a level of flexibility so that new approaches can be adopted as research and technology advance.
- *Reviewed and Approved by FDA:* As with all labeling, the PMD must be reviewed and approved by the FDA. Recent history has suggested that private sector initiatives to streamline and standardize CMI have not met their goals, and that FDA should take a greater role ensuring the future quality and consistency of the proposed PMD. FDA should approve the document as part of the pre-market approval process and a process should be established for approval of revisions to the document as necessary, e.g. when new benefit/risk information emerges. BIO believes the review process and timeframes should be the same as other changes to the labeling and should be integrated into the Good Review Management Principles and Practices.
- *Communicated within the Full Context of Benefits and Risks:* All drugs and biologics carry both benefits and risks that must be carefully weighed by patients and their doctors. The balance between the benefits of treatment and the risks of potential side effects will differ based on many factors, including the nature of the treatment and the condition, and each patient’s unique medical profile. Both the Agency and industry recognize that drug safety is not absolute, but rather a matter of balancing benefits against risks. Likewise, patients should be able to make therapeutic choices based on complete information. Therefore, BIO recommends that the template for the single PMD should provide patients with both risk and benefit information, because only then can patients make appropriately informed choices about a product’s use. FDA and stakeholders should also explore formatting options to make new benefit and safety information more prominent so that it is brought to a patient’s attention.

- *Clearly State Role and Limitations of Patient Information:* As beneficial as written information targeting patients can be, it is also important that patients understand that it does not replace advice from their physician. Accordingly, FDA should require that the PMD state that it is an-FDA approved summary of the full FDA-approved labeling; that it may not be comprehensive in addressing all patient needs and situations; and that discussions with their personal physician regarding their medication remain important. Consistent with the requirements for a MedGuide (21 CFR, part 208.20), the PMD should also include a statement similar to “Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide” followed by a statement that patients should ask health professionals about any concerns, and a reference to the availability of professional labeling.
- *MedGuides Should Serve as the Single Document for Drugs Subject to REMS:* BIO recognizes that MedGuides are a statutory concept codified under the FDA Amendments Act of 2007 (P.L. 110-085) for certain products subject to a Risk Evaluation and Mitigation Strategy (REMS). BIO believes that the MedGuide document should serve as the single patient document for products subject to REMS, in place of the proposed PMD. MedGuides generally focus on a particular adverse event(s) of concern, and can facilitate more thorough communication of the unique risks and mitigation considerations of the REMS products to inform and prevent serious side effects or to promote adherence to directions for use. However, in reference to the point above, we note that the MedGuide regulations (21 CFR, part 208) may need to be amended to allow for more comprehensive product information to be communicated in the complete context of its benefits and risks, and, depending upon the results of social science research, to facilitate patient understanding of the information in a format patients recognize. We also note that regulations mandating PPIs for certain drugs, such as oral contraceptives and estrogen products, may need to be considered to accommodate a single document solution.
- *Implementation Schedule:* If supported by the outcome of social science and behavioral research, the implementation of a single, FDA-approved PMD for applicable products will require formidable effort from both FDA and industry. Given the considerable workload necessary for industry to develop these documents and for FDA to review them, BIO believes that it is important that there be an appropriate, phased implementation schedule for applicable products. This schedule could be similar to the staggered timeframe approach used to implement the 2006 Physician Labeling Rule.

II. SOCIAL SCIENCE & BEHAVIORAL RESEARCH:

BIO believes that there is a need for additional social science and behavioral research around patient comprehension of written patient medication information. Such research should inform future efforts to streamline the format and content of the PMD template.

BIO encourages FDA and other stakeholders to collaboratively sponsor research to advance the field of how to best present risk and benefit information to patients, including optimal format, content, verbiage, length, and patient comprehension expectations that can be applied across all

drugs. For example, BIO would support the development of a consortium to finance, prioritize, and commission this research. Such a consortium or private-public partnership should include drug and biologics manufacturers, physician groups, pharmacy associations, patient organizations, and academic researchers, and could be coordinated through National Council on Patient Information and Education (NCPIE), the Centers for Education & Research on Therapeutics (CERTs), or the Reagan- Udall Foundation for the FDA. This research should:

- Focus on patient comprehension of various formats (tabular, Q&A, visual graphics, etc), content, verbiage, length, and delivery of written patient communication.
- To the extent practicable, be generalizable across a wide range of product classes.
- Focus on performance-based testing of patient comprehension, rather than basic content based-testing.
- Evaluate effectiveness of patient information systems in place in other countries.
- Involve a broad demographic of the U.S. population in a variety of settings.
- Future research could evaluate alternative means of communication for patient sub-populations such as the blind or illiterate who may not be able to utilize written documents.

BIO recognizes that a handful of drug sponsors with MedGuides subject to REMS are required to conduct evaluations of the effectiveness of the MedGuides within 18 months of approval. These smaller, individual, and varying evaluations may be useful to inform the labeling for those specific REMS products, but may not be appropriate for answering the broader social science research questions that are needed to realize the goals of the CMI Initiative. The 18 month MedGuide evaluations are intended to address the risk management strategies related to a single product, which usually has unique characteristics, risks, and patient populations. As a result, the outcomes of these evaluations may not be generalizable to other classes of products and the broader healthcare delivery system. Additionally, the REMS evaluations would not include the input of key stakeholders including pharmacists, patient advocates, and other manufacturers not subject to REMS. For these reasons, the 18 month evaluation of REMS MedGuides evaluations should not replace research needed to determine the format and content of a universal patient-oriented medication document. As noted above, a broad, consortium-driven social science review of patient-oriented documents and patient comprehension should be considered. Individual MedGuide evaluations should be limited in scope and conducted in a manner that is least burdensome for patients and pharmacists.

An additional concept that warrants further social science research is the “Drug Facts Box” format. Some stakeholders have suggested that a Drug Facts Box may enhance patient comprehension and make safety and efficacy information more patient friendly. BIO believes that the concept may hold promise and that the format should be further explored. However, the Drug Facts Box or a similar summary should only be included as an element of the single PMD if justified by the results of robust patient comprehension research. We are concerned that the Drug Facts Box approach could make it extremely difficult to provide meaningful information in such a small space. Current PPIs already contain information that is distilled down from the physician labeling and to reduce that further may dilute important product information to the extent that it is of little use. Research needs to be conducted to determine the type of qualitative or quantitative safety and efficacy information that can be presented in the Drug Facts Box. For example, presentation of clinical trial results in the drug facts box and comparison across products may lead patients to draw inappropriate conclusion of the data.

Furthermore, the risk of a patient reading only the Drug Facts Box and not reading any additional, more detailed and thorough information could result in patients making uninformed decisions about medicines. For that reason, BIO believes that a “Drug Facts Box” cannot and should not include all patient-oriented information relevant to proper administration of a medicine. If research were to support the use of a Drug Facts Box, we would suggest that FDA consider a tiered approach where a “Drug Facts Box” or a similar summary appears at the beginning of the PMD and is followed by more extensive information for patients that wish to access more detailed information. FDA should also explore the potential for the Drug Facts Box or PMD to replace the brief summary required for direct-to-consumer print advertising.

III. DISSEMINATION OF THE PATIENT MEDICATION DOCUMENT:

In addition to streamlining the content and format of the PMD, greater efforts should be taken to ensure that the document is distributed to patients efficiently and effectively. BIO recommends that if a patient is supposed to receive the PMD with their prescription, then it should be provided with each prescription that is dispensed. This will help educate patients on emerging information regarding the benefits and risks of the product, and how to manage the medication on an ongoing basis.

In light of recent advances in information technology, BIO believes that manufacturers and pharmacists should leverage electronic systems to enhance the dissemination and accessibility of patient communications. BIO believes that the proposed FDA-approved PMD should be electronically accessible on a public website, such as the manufacturer’s product site, the FDA web page, and/or a National Library of Medicine database. In order to disseminate the most up-to-date information, pharmacists should be able to electronically access, distribute, and print the PMD from a consolidated database. To the extent practicable, existing pharmacy information technology and distribution systems should be utilized.

IV. THE ROLE OF WRITTEN PATIENT COMMUNICATIONS IN AN INPATIENT SETTING:

BIO also recognizes that the role and dynamic of written patient communications can change depending on the healthcare setting where the product is dispensed or administered. This is particularly true in hospitals, infusion centers, and cancer or dialysis clinics where the medication is generally administered directly by a healthcare provider who is physically present to educate a patient on the product’s benefits and risks and answer questions. In fact, many biologic products are administered by healthcare professionals in such settings. This raises unique challenges and opportunities regarding benefit/risk communication and the distribution of written patient communications.

BIO recommends that manufacturers be permitted to develop and distribute a PMD for a drug or biologic regardless of where it is dispensed, so that it can be made available to the patient whether or not the product is intended to be administered directly by a healthcare professional. BIO believes that physicians and other healthcare providers should consider utilizing the document with each patient, subject to the provider’s professional judgment and practice of medicine. Healthcare providers may find that these documents can serve as valuable educational

tools or visual instructions to complement spoken directions to patients. However, we also recognize that written communications can have inherent limitations in an inpatient setting, such as in an emergency situation when a patient is unresponsive. We do note, however, that certain products subject to REMS are required to have the MedGuide distributed to the patient prior to each administration of the medication, and those products should continue to comply with all required elements of the REMS.

CONCLUSION:

BIO appreciates this opportunity to comment on FDA's Consumer Medication Information Initiative. We encourage FDA to consider a single document solution for written patient-oriented medication information with a template informed and justified by relevant social science research in order to further enhance patient comprehension of a drug or biologic's benefits and risks. We would be pleased to provide further input or clarification of our comments, as needed.

Sincerely,

/S/

Andrew J. Emmett
Director for Science and Regulatory Affairs
Biotechnology Industry Organization (BIO)