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It's All About the Name: What Is the Imperative of Adopting Unique Names for Biologic and Biosimilar Therapeutics?

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TABLE OF CONTENTS

It's All About the Name: What Is the Imperative of Adopting Unique Names for Biologic and Biosimilar Therapeutics? Alliance for Safe Biologic Medicines

I. INTRODUCTION

The Alliance for Safe Biologic Medicines[1] (ASBM) believes that patient safety must be the top, non-negotiable priority guiding all policy decisions regarding biologics and biosimilars at both the federal and state levels if the new biosimilar pathway is to successfully serve patients in the United States. A unique United States Adopted Name or "USAN" (also referred to as a non-proprietary or generic name) for biologics will be a foundational element of the safety framework.

To these ends, the ASBM presents this paper on the need for distinct USANs for biologics as a reflection of the collective wisdom and insight of our diverse membership, representing patients, physicians, scientists, manufacturers, academics, and more.

It is our hope that in identifying key challenges and practical solutions, this paper will help facilitate a solution that ensures patient safety continues to remain at the forefront of every policy discussion about a biosimilar pathway for the United States.

POLICY RECOMMENDATIONS

- All biologics should receive distinct non-proprietary names.
- United States Pharmacopeia (USP) should work with FDA to adapt the product monograph system to accommodate the unique attributes of structurally-related, but distinct, biologic medicines.
- The non-proprietary name of a reference product and product/s biosimilar to it should have a common, shared root but have distinct and differentiating suffixes.
- Products designated interchangeable should have a distinct name from the reference product for which they are considered interchangeable to facilitate accurate attribution of adverse events.

II. BACKGROUND

Biologic medicines are used to treat a wide range of serious chronic and life threatening conditions, including cancer, multiple sclerosis, rheumatoid arthritis, and more.[2] Biologics are different than traditional chemical drugs in important ways that make copying them especially challenging and

present a set of safety considerations. While the U.S. Congress authorized an abbreviated approval pathway for traditional chemical drugs in 1984, prior to 2005, no abbreviated regulatory pathway to approve copies of biologic medicines had been established in any highly regulated country or jurisdiction.

In 2004, the European Union (EU) became the first highly regulated jurisdiction to authorize the establishment of a pathway for the approval of "biosimilars."[3] Since then, 13 biosimilar products have been approved for marketing in the EU.[4] Many countries outside of Europe have followed the European Medicines Association (EMA) lead in adopting a biosimilar pathway. Even the World Health Organization (WHO) has adopted standards for approval of biosimilar medicines. In 2010, the United States Congress gave FDA the authority to implement an approval pathway for biosimilars[5] and defined a framework that was similar to the EU, but distinct in certain regards (e.g. data exclusivity limits, interchangeability standard, and patent provisions were included in the new U.S. law but not in the EU framework).

Congress laid out some key parameters for the new pathway, but provided FDA with substantial discretion in defining and implementing a biosimilar approval process. FDA invited stakeholder input[6] in 2010 and again in 2012 following publication of an initial set of draft guidances[7] on February 9, 2012. However, many questions about the U.S. pathway were not addressed in the draft guidances and remain to be answered by FDA. One important question is how biosimilars will be named.

A biosimilar medicine is a drug designed to be similar to an approved, innovative biologic medicine. The patents of a number of the biologics are due to expire in the U.S., which has led to an increased interest in the development of biosimilars as a means of controlling health care costs. When a patent approaches expiry, the law permits other entities to attempt to reverse engineer, clinically develop, and manufacture biosimilars of the original medicine in order to seek FDA approval to enter the market when the patent expires.

Biosimilars are not direct copies of biologics and are therefore not considered generics. As will be discussed in more detail below, biologics are produced from proteins expressed by living cells and are made up of very large and complex molecules.[8] While copies of traditional chemical drugs are required to have an identical version of the active ingredient found in the original, this is currently not possible for biologics.[9] Biosimilars must be proven to be highly similar to an original biologic in terms of characteristics, safety, and efficacy, but subtle differences between the active ingredients are expected and allowed.[10]

Biologics can be extremely structurally complex. This complexity is important for patients because any twist or turn or kink in the molecular structure that is different than the original (reference) product could cause the patient's immune system to deem the medicine a foreign substance and mount an immune response.[11] A different cell line, different source of raw material, different medium in which the cells reproduce, etc., will all have an impact on the final product. Not all of the differences between the reference product and the biosimilar will matter for the patient; the key is to know which differences do matter. There is currently no analytical or animal model that

can reliably predict every difference that may matter and cause an unwanted immune response, and unwanted responses can be difficult to determine in the limited time frame and experience of pre-marketing evaluation.[12] Therefore, information from the post-market setting is essential to ensuring the safety of biologics.[13]

Accurate product identification is a fundamental element of any medicine safety system, and increases the ability to accurately attribute adverse events to the correct product.[14] Since all biologics are expected to be structurally distinct and these distinctions may have implications for patients, product identification is especially important. This can best be achieved by assigning a unique USAN to every biologic, and will advance the safety of patients who use biologics.

The rules, policies, guidance, and practices put in place by FDA around medicines operate like traffic laws to enable patients, doctors, pharmacists, and others to use these products safely. It is not appropriate to simply apply the rules used for generic drugs to the biosimilar process any more than it is appropriate to simply apply boating or train traffic laws to cars. Biologics and traditional chemical medicines are scientifically different in ways that have important implications for keeping patients safe.

All biologics – not just biosimilars– raise certain safety considerations simply by virtue of their more complex molecular structure. Biologics are often 200–1000 times the size of a small molecule drug. Their structural complexity, and the limitations in methods used to analyze them, make biologics more difficult to characterize and produce. In contrast to most medicines that are chemically synthesized and have structures that are known, biologics are complex compounds made from living cells and have highly complex structures that are not easily understood, characterized, or replicated.

Therefore, while small molecules can enter the human body and be unnoticed by the immune system, large molecules are always seen and the immune system must decide whether or not to mount an immune response. Thus, if the biologic is not quite right, the patient's immune system may decide the medicine is a foreign substance and take steps to neutralize and eliminate it.

Biologics are also highly complex to manufacture. Biologics are made using living cells, which are highly sensitive to their environment and the manufacturing process. A seemingly small change in the manufacturing process, or handling, container closure, etc., can alter the structure of the medicine. This change could cause the patient's body to decide the medicine is foreign and mount an immune response.

If it happens, the timing of an immune response for a biologic can vary widely. Some reactions occur immediately while the drug is being administered intravenously. In that case, the cause of the reaction is clear and the health care provider can take appropriate steps to address the problem. However, an immune response to a biologic may take time, becoming apparent nine to twelve months after the patient was first treated. In that case, it may be difficult for the doctor to know if it is a response to a medicine and to determine which medicine, or if it is simply a progression of the

disease. If the patient has been exposed to more than one version of a biologic medicine, it may be difficult to know which product, if any, caused the reaction.

Determining the source of the adverse reaction is clearly of primary importance to the patient being treated; however, it is also important for the safety of other patients who are or may be treated with the same medicine. In some cases, a biologic may have changed as a result of manufacturing, handling, etc., in a way that increases the likelihood of triggering an unwanted and unexpected immune response. Accurately and promptly identifying the source of the problem for the immediate patient can help prevent other patients from being exposed to the medicine until the problem is identified and resolved.

III. MAJOR ISSUES DISCUSSION

Biosimilars are coming to the U.S. As of the start of 2012, FDA had received 34 requests for pre-Investigational New Drug (IND) meetings regarding 11 reference (original) biologics. In light of patents expected to expire in 2013, FDA may approve a biosimilar before 2014.

As discussed above, biosimilars – unlike generic small molecule therapeutics – will not be identical to the reference products they attempt to copy. Furthermore, biological medicines tend to be highly sensitive to raw material sourcing, container closure systems (the syringe, the stopper, the needle), handling, etc., where small changes could alter the medicine in a way that triggers an immune response for some patients. Even if a given biosimilar and the reference product were identical at approval, over the lifecycle of the product, changes in raw materials, container closure systems, the manufacturing process, etc., could result in the products being substantially different from one another over time. Seemingly minor changes could have consequences for patients. It would be important to know which of the formerly identical products was received by the patient and may have caused the reaction.

Today in the U.S., if a specific biologic medicine is associated with an adverse event, the source of the problem is generally clear because there is no copy on the market. The doctor knows which product the patient received and the issue can be addressed promptly with the manufacturer and the FDA. However, with the arrival of biosimilars, both the sensitivity of biologics and the potential for delayed expression of an immune response present new challenges for accurately attributing an adverse event to a specific cause.

The need for clear, defined naming considerations and a system to implement an effective tracking and tracing of all biologics – not just biosimilars – stems from the potential of these products to be unexpectedly altered by the manufacturing process, handling, etc., in a manner that could cause unintended harm to patients. Whether the products that FDA approves will have the same name or a different name than the originator biologic will determine how well products can be traced back to a patient who has an adverse reaction.

In the following sections we will outline key components that must be addressed by the FDA to ensure that patients, physicians and pharmacists know which treatment is prescribed and more importantly which treatment does a patient receive.

A. Naming Provision, Track and Trace

Recommendation 1: All biologics should receive distinct non-proprietary names.

The impending arrival of biosimilars in the U.S. marketplace will expand the range of therapeutic options available to patients, but will also complicate pharmacovigilance. It is, therefore, paramount to differentiate between originator biologics and biosimilars to facilitate proper pharmacovigilance. Rigorous pharmacovigilance programs are needed to protect patients and ensure that any adverse events are quickly detected, reported, and attributed to the correct product and manufacturer. In the U.S., it is an obligatory step for the manufacturers of biologic medicines to submit comprehensive pharmacovigilance and risk management plans when applying for approval. This may be even more important for biosimilars, where the clinical safety and efficacy package is likely to be more limited at launch than that of the original biologic. Distinct names are an essential component of the tracking process.

As discussed above, it is important to understand that biosimilar and interchangeable biological products will be only similar to, but not the same as, an original reference product. From a patient and provider perspective, it would be inappropriate, unsafe, and misleading to allow biosimilar products to use the same name for biological products that are not exactly the same.

At the May 2012 FDA public hearing to discuss the biosimilar draft guidance, numerous stakeholders raised concerns about issues resulting from the biosimilar regulatory process, including naming. Many of the concerns reflected marketing dilemmas, system limitations, and reimbursement issues. These concerns should be considered by FDA only to the extent that they impact patient safety. FDA is the leading regulatory body in the world because it has remained singularly focused on ensuring that the products it approves are first and foremost "safe and effective."

Distinct non-proprietary names are a modest tweak to an existing system and thus present a cost-effective option for facilitating robust tracking and tracing. ASBM strongly believes that existing systems should account for, and accommodate, the use of distinct non-proprietary names for all biologic products. To the extent that any existing mechanisms used for tracking and tracing are unable to accommodate distinct non-proprietary names, it is imperative that we work to update or modify them so that the system fosters patient safety.

A survey of physicians conducted by ASBM revealed that 76 percent of physicians would assume that biologics with the same name are identical to one another. This mistaken assumption could lead to inappropriate switching of patients from one product to another, and adversely affect the health of patients.

Transparency also fosters accountability. Distinct non-proprietary names would increase the likelihood that adverse events are attributed to the correct product, by manufacturer. Receiving early reports of adverse events enables a manufacturer to promptly identify and correct any problem.

Any naming policy for biosimilar products must be a viable, long-term solution, not a short-term stopgap that fails to adequately address safety issues. Thus, it is important to make sure that this process is well thought-out and provides a solution focused on patient safety. In the following sections, we will outline key components of the naming issue that we believe will be helpful in creating an effective and safe pathway for biosimilar products in the U.S., while recognizing that we exist in a global market. We urge all stakeholders to thoughtfully consider the following points.

B. Limitations of Using the National Drug Code (NDC)

One option for biologic identification advanced by some stakeholders is using the National Drug Codes (NDCs) as a mechanism to identify the product and manufacturer. While NDCs are certainly valuable in their own context, they should not be viewed as a "silver bullet" that will comprehensively provide accurate identification of medicines received by a patient—either in patient records or in adverse event reports. NDCs prove to be problematic for the following reasons.

Doctors and patients are the primary source of adverse event reports. They know and remember medicines by name, not number. A recent survey of 380 physicians conducted by the Alliance for Safe Biologic Medicines found that more than 99% of physicians record the product name, not the NDC, in the patient record. While the NDC can be found by the physician in a variety of ways, this is an additional step that will increase the time it takes for a physician to record and report an adverse event, and will increase the opportunity for error. Being off by a single digit could render the information meaningless.

NDCs are not uniformly used in medical billing. While private health insurance accounts for more than 64% of insured people,[15] claims submitted to private payers do not uniformly require NDC or even have a data field for NDCs. Only 30 of the 50 potential mini-Sentinel data partners investigated have access to NDCs and for those that have it, the error or missing data in this field is 32%.[16]

Federal claims data, another important source of pharmacovigilance information, do not uniformly include NDC numbers. For example, Medicare and Medicaid inpatient claims rarely include the NDC number of drug products or biologics administered

during hospital treatment.[17] Retail pharmacy claim forms under Medicare Part D do include NDC numbers, but Medicare Part B claim forms for physician-administered drugs—covering the vast majority of administered biologics—are billed by the Health Care Common Procedure Coding System (HCPCS) codes, not by the NDC number.[18] Although NDCs are increasingly provided on Medicaid claims as a result of a requirement in effect in many states, they are still not provided all of the time.[19]

Further, NDCs are not uniformly available on the prescription labels. Without the NDC number on a prescription label, it is much more difficult to trace a product in the event of an adverse effect incident. Additionally, there are doubts on the

accuracy of recorded NDCs. An NDC number consists of up to 11 digits.[20] That means there are 100 billion possible variations of that 11-digit number and there is little way for a potential reporter to know the manufacturer or product simply by looking at this string of numbers. Even if a reporter has familiarity with the system, there is a greater likelihood of mistakes or accidental changes that would prevent proper identification.

A final point on the use of NDCs should be highlighted. In naming, tracking, and tracing, redundancy is extremely important. This point is further supported by the fact that often times NDC identification is absent or inaccurate on medical claim forms. To support a more efficient system, ASBM suggests the use of both the NDC number and the distinct nonproprietary name to ensure accurate pharmacovigilance.

Nonproprietary naming is easier for providers, patients, and billing administrators to remember and associate with specific products. Requiring both would go a long way towards providing a check against errors. Each of these factors would help to reduce the likelihood of incorrect data entry and, ultimately, the chance that an adverse event would be associated with the incorrect product.

C. European Experience

The European Union (EU) was the first jurisdiction to authorize a formal regulatory pathway for Biosimilars. However, a number of the jurisdictions outside of Europe that followed the EMA framework deviated to some extent on the process of product naming. The experience with naming in both the EU and several countries that chose to take a different approach can be instructive.

The 2005 Guidelines from the EMA state that it should be recognized that, by definition, similar biological medicinal products are not generic medicinal products, since it could be expected that there would be subtle differences between similar biological medicinal products from different manufacturers.[21] Indeed, these differences may not be fully apparent until there is greater experience with the biosimilar outside of the clinical trial setting. Therefore, in order to support pharmacovigilance monitoring, the specific medicinal product given to the patient should be clearly identified.[22]

In the EU, most biosimilars approved to date have the same INN (International Non-proprietary Name or generic name) as the reference product, which has created challenges for tracking and tracing biologics in Europe. In the case of epoetin alpha, the EMA subsequently required that all prescribers record the brand name in addition to the INN so as to ensure traceability going forward.[23] However, what the EMA giveth on one hand, the EU member state authorities are in the process of taking away. Specifically, a number of countries in Europe are requiring physicians to prescribe by INN and prohibiting the inclusion of a brand name, thus making accurate tracing of biologics in

the event of an adverse event impossible.[24] This situation could have been avoided if the EU had implemented a system in which biosimilars were required to hold a distinct INN.

The European Commission recently introduced a directive requiring EU member states to ensure that biological medicines are clearly identified by name of the product and the batch number. The 2012 EU pharmacovigilance directive is the biggest change to the regulation of human medicines in Europe since 1995. It is now a legal requirement for EU Member States to take all necessary measures to clearly identify the biological medicines that are prescribed, dispensed, and sold in their country. Furthermore, member states are empowered to impose requirements for achieving such identification requirements on doctors, pharmacists, and other healthcare professionals

D. FDA Naming Precedence for Biologics

We hope that the FDA approach to name biosimilars may be influenced by the naming approach undertaken for two recent biologics approved through the 351(a) BLA pathway: Sanofi's Zaltrap[25]and Teva's Neutroval.[26] Both of these products are related to previously approved products: Regeneron's Eylea and Amgen's Neupogen, respectively. For both of these new approvals, the FDA assigned unique non-proprietary names that were created by adding a prefix and a hyphen to a root non-proprietary name: ziv-aflibercept and tbo-filgrastim.

In both cases, FDA concluded that a nonproprietary name for these new approvals should be distinct from previously approved, structurally-related products, explaining that a distinct name will minimize medication errors by: (1) preventing patients from receiving a product different than intended to be prescribed; and (2) reducing confusion among healthcare providers who often consider use of the same nonproprietary name to mean that the biological products are clinically indistinguishable. The FDA has also concluded that unique nonproprietary names will facilitate post-marketing safety monitoring by providing a clear means of determining which product is dispensed to patients. Also, "due to the fact that health care providers may use non-proprietary names instead of proprietary names when prescribing and ordering products, and pharmacovigilance systems often do not require inclusion of proprietary names, the use of distinct proprietary names is insufficient to address these concerns."[27]

Although it should be noted that the FDA has expressed that this naming approach should not be taken as a naming convention to be applied to biosimilars, we believe that this does embody a patient-safety focused approach to naming that could be efficiently applied to biosimilars.

E. Role of Public Standards

Recommendation 2: USP should work with FDA to adapt the product monograph system to accommodate the unique attributes of structurally-related but distinct biologic medicines.

Public standards, such as the United States Pharmacopeia (USP) monographs, are an important component of ensuring consistent identity, potency, purity, and quality of medicines that are no longer covered by valid patents. To date, relatively few USP monographs have been published for biologic medicines (e.g., insulin, somatropin), but it is anticipated that the number will increase as patents expire on biotech medicines. The USP is a stakeholder in product nomenclature because its monographs link a given product to the non-proprietary name in a monograph chapter in order to define the public quality standards. Indeed, these compendia standards are considered enforceable for the purposes of the misbranding and adulteration provisions of the Food, Drug and Cosmetic Act.[28]

We are concerned, however, that USP has indicated in submissions to the FDA and elsewhere that the issuance of a monograph should dictate the nomenclature for a biologic medicine.[29] We encourage USP to work collaboratively with FDA to adapt the product monograph system to the unique attributes of structurally related, but distinct, biologic medicines. Such medicines will share some, but not necessarily all, elements of their biochemical identity and quality attributes with an originator product, and so it makes sense that such products might be linked through common public standards even if they are not named identically. As stated previously, FDA has indicated that there are important public health considerations that may merit a distinguishable nomenclature for structurally related biologics. Because these medicines will likely share a common root name, it would appear feasible to adapt the monograph system to accommodate prefixes or suffixes while still permitting the enforcement of common standards. We hope that a creative solution to the question of product nomenclature and public standards can be identified through consultation and collaboration among FDA, USP and other stakeholders.

IV. RESPONSE TO THE ISSUES

A. Defining Success: Functional Measures for a Naming Protocol

Biosimilars present an opportunity to reduce the cost of access to important medicines; however, biologics, because of their fundamental features, present some important challenges. The naming protocol adopted by FDA can play an important role in helping to:

1) Facilitate prompt identification and resolution of product problems;

2) Facilitate manufacturer accountability; and

3) Avoid incorrectly implying that the molecules are identical.

V. IMPACT OF POLICY RECOMMENDATIONS

Recommendation 3: The non-proprietary name of a reference product and product/s biosimilar to it should have a common, shared root but have distinct and differentiating suffixes.

In response to FDA's May 2012 hearing on the Draft Guidances and continued solicitation for input on naming conventions, ASBM believes that the following recommendations would lead to a safe and accurate tracking and tracing system that limits patient harm caused by adverse events emanating from the use of biosimilars.

ASBM, in consultation with its member partners, steering committee, and National Advisory Board, believes there are a wide variety of naming conventions that could be used to provide unique and distinct identification for all biological products in order to facilitate accurate attribution of adverse events. It is our view that one effective solution would be to have the reference product and the biosimilar product share a root and have a distinct and differentiating suffix. This two-pronged approach allows for relationships between products to be indicated via the shared root and yet each product to be traced to a specific manufacturer via the distinguishing suffix. Distinct naming also avoids improperly suggesting that products are exact or identical copies.

During the policy discussions on naming at the FDA hearings and public conferences, several policy measures have been discussed and proposed. Two popular options are pursing a shared root and distinct prefix with a nonproprietary name, and implementing an entirely distinct nonproprietary name. ASBM has explored these options and has the following considerations.

First, a shared root and distinct prefix in the nonproprietary name would provide the benefit of demonstrating a relationship between the reference and biosimilar product. Further, including a distinct prefix would assist in identifying a specific manufacturer. Yet, we conclude that the use of a prefix would prove to be a less effective tool for purposes of a pharmacovigilance search for a related product. Second, entirely distinct nonproprietary names have the benefit of ensuring that the products will not be confused with one another and can be directly traced to a manufacturer. However, this approach provides no indication or notation that the products are related, which would hamper attempts to search for a class effect.[30]

Ultimately, physicians and pharmacists must be able to identify any biologic product a patient receives, especially in the case of an adverse event. ASBM believes that an approach where the reference product and the biosimilar share a root and have a distinct and differentiating suffix is the most functional approach. However, we are open to alternative ways of achieving the same objective. We think that patients are better served when physicians and pharmacists are in agreement on potential threats to patient safety and work together to identify an approach that benefits patients. For that reason, input from the pharmacy community will be important to successful implementation of a solution.

We strongly believe that unique USANs will reduce the risk of misidentification and create a system of accountability for manufacturers to stand by their products. In our opinion, this is the best way to ensure long-term safety for patients.

A. Related Issues – Interchangeability

Recommendation 4: Products designated interchangeable should have a distinct name from the reference product for which they are considered interchangeable to facilitate accurate attribution of adverse events.

To date little is known about how the process of substituting a biosimilar for the reference product can impact the patient's immune system. The designation of "interchangeability" is a concept that is unique to the United States. In the European Union, Canada, and elsewhere, biosimilars are mainly approved as "stand-alone" therapies. For example, in Canada, biosimilars are referred to as "Subsequent Entry Biologics." These countries also oppose the automatic substitution of a prescribed biologic with a biosimilar.

- The EMA has noted that previous exposure to similar or related proteins can lead to a pre-sensitization and cause an immune response.[31]
- The Center for Drug Evaluation and Research (CDER) warns that there is a significant potential for repeated switches to impact safety and effectiveness.[32]

Currently, no biosimilar product has been approved as interchangeable with its originator reference product.

With this background in mind, ASBM believes that it is extremely important that FDA continues with a measured review of the issue and that they proceed with caution to ensure patient safety is the driving factor when discussing interchangeability. Further, all biological products, including those designated as interchangeable, should be given distinct non-proprietary names. Any suggestion that all biosimilars should be designated as interchangeable is contrary to sound science and the U.S. statute, which defines distinct standards for biosimilarity and interchangeability.

FDA has indicated that it will require additional clinical studies when a manufacturer requests its biosimilar to be deemed "interchangeable." Even if clinical studies were sufficient to determine "interchangeability," such a determination would only be valid for that point in time. FDA is aware that the similarity between the reference product and its interchangeable biologic product may change over time as a result of manufacturing, environmental, and other changes, impacting one or both products. This potential divergence post-approval must be addressed with sound policy, including a commitment to distinct names for all biologics, regardless of an interchangeability designation.

In light of the state of scientific knowledge today, implementation of an interchangeability standard will be extremely challenging and should be done with the need for accurate tracking and tracing in mind.

VI. CONCLUSION

The aforementioned points reflect the Alliance for Safe Biologic Medicines' overriding concern to ensure that patient safety is the non-negotiable priority of the biosimilars pathway in the U.S. It would only take one major preventable adverse event to upset and derail the promise of the biosimilars program.

To reiterate, effective implementation of the biosimilar pathway in the U.S. must include measures to ensure accurate and efficient attribution of adverse events.

1) Traceability measures, including unique nonproprietary names for all biologic therapies, transparent product labels, and patient/physician notification will enable clinical assessment and adverse event reporting.

2) A designation of interchangeability does not negate the need for distinct identification of all biological products. Biologic medicines are highly sensitive to raw material sourcing, manufacturing process, container closure systems, handling, etc. Similarity between a reference product and its interchangeable biologic product may change over time; thus, the need for clear product identification – by manufacturer – is as great for products designated as 'interchangeable' as it is for all other biologic medicines.

The Alliance fully appreciates the efforts of the FDA to consult with various stakeholders as it continues to formalize its guidance on the regulatory pathway for biosimilars in the U.S. Our goal is to continue to be a resource for FDA as this process continues. There is wonderful, life-saving potential available through biologic products, but we must be vigilant and watchful to ensure that patient safety is our number one goal as we move toward a fully operational biosimilar pathway here in the United States.

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The Alliance for Safe Biologic Medicines (ASBM) is an organization composed of diverse healthcare groups and individuals from patients to physicians, innovative medical biotechnology companies, and others who are working together to ensure patient safety is at the forefront of the biosimilars policy discussion. It is the mission of ASBM to serve as an authoritative resource center of information for policy makers, regulators, the healthcare community, and the general public on the issues surrounding biologic medications.

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