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NEW YORK STATE BAR ASSOCIATION
FOOD, DRUG AND COSMETIC LAW SECTION AND
HEALTH LAW SECTION COMMITTEE ON MEDICAL RESEARCH AND BIOTECHNOLOGY

MEMORANDUM IN SUPPORT OF AN AMENDMENT TO NEW YORK'S PHARMACY LAW PROVISIONS RELATED TO BIOSIMILARS

Approved by the New York State Bar Association Executive Committee
November 2015

Executive Summary

The Food, Drug and Cosmetic Law Section and the Health Law Section Committee on Medical Research and Biotechnology of the New York State Bar Association, for the reasons set forth in this memorandum, supports amendments to New York's Pharmacy Laws to permit the automatic substitution of interchangeable biosimilar products for their reference biological counterparts and dispensing highly similar biosimilar products consistent with the Biologics Price Competition and Innovation Act (BPCIA). We believe amendments to New York's Pharmacy Laws, as provided below, are necessary, because New York's current Pharmacy Laws exclude biological products from the definition of "drugs" and do not address how pharmacists should handle substitution for interchangeable biosimilars or dispense highly similar biological products by prescription. Without modification to New York's Pharmacy Laws, we believe interchangeable biosimilar products would likely require a new prescription, contrary to the BPICA. In particular, FDA's first-approved biosimilar product, Zarxio® (filgrastim-sndz) is a highly-similar biosimilar that may be dispensed by pharmacies in response to an initial prescription for the reference product, Neupogen® (filgrastim), assuming a patient's prescriber writes a prescription for Zarxio®. In the future, the developing biosimilars industry hopes to submit and have FDA approve interchangeable biosimilar products that may be automatically substituted for the reference biological product without the prescriber's intervention to write a new prescription, e.g., if prescribed as Neupogen® or filgrastim. Our proposed legislation would provide necessary definitions for both highly-similar biosimilars and interchangeable biosimilars, as well as a new provision to affirmatively provide prescribers with access to their patient's pharmacy records for dispensing all drug and biological products down to the lot number, permitting more accurate adverse event reporting and attribution to the appropriate

medication(s). We hope that this elegant yet simple solution will be adopted by additional states, as they look for ways to address adverse event reporting for biological and other medical products, which has been raised as an issue in the context of drug products.[1]

I. History of Biosimilars

The BPCIA establishes a pathway for subsequent or follow-on biologics to obtain approval based upon a showing of "biosimilar[ity]" to a currently approved product. *See* 42 U.S.C. § 262(k). Biosimilars have been approved in other countries with robust regulatory systems, such as Canada, Europe, and Japan since on or about 2009, but the United States is unique to include the possibility for a biosimilar product to be determined to be interchangeable with the reference product. A product is "biosimilar" to a reference product if such product is "highly similar to the reference product notwithstanding minor differences in clinically inactive components" and "there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product." Data demonstrating biosimilarity must be derived from (i) analytical, (ii) animal studies (including the assessment of toxicity); and (iii) a clinical study or studies. *Id.* § 262((k)(2)(A)(i)(I)(aa)-(cc).

A biosimilar may also be deemed to be "interchangeable", if a showing is made that the biosimilar "can be expected to produce the same clinical result as the reference product in any given patient," and "for a biological product that is administered more than once to an individual, the risk in terms of safety or diminished efficacy in alternating or switching between use of the [biosimilar] and the reference product is not greater than the risk of using the reference product

[1] Specifically, a number of innovator biological product companies have asserted that adverse events tend to be attributed to innovator drug products even after the product has multiple generic products, because the actual product dispensed and lot number are not recorded in adverse event forms by physicians.

without such alteration or switch." *Id.* § 262(k)(4)(A)-(B). A product that is found to be interchangeable with respect to a reference product may also "be substituted for the reference product without the intervention of the health care provider who prescribed the reference product." *Id.* §§ 262(i)(3), (k)(6).

While numerous questions remain for biosimilar products, especially regarding product naming and standards for interchangeability, FDA's potential or at least "placeholder" approach to biosimilar labeling was revealed in the approval of Zarxio®. Zarxio®'s labeling does not state that the product is a biosimilar, nor does it state that the product has not been found to be interchangeable with the reference product. While initial FDA draft guidance indicated that a clear statement that the product has (or has not) been determined to be interchangeable is "necessary for a health professional to make prescribing decisions." *See* FDA, Draft Guidance for Industry, Scientific Considerations in Demonstrating Biosimilarity to a Reference Product, 20-21 (Feb. 2012), FDA's revised guidance now omits this language, suggesting that FDA's *Purple Book: Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations* ("the Purple Book", a book that lists approved biological products, including biosimilars), will adequately informs prescribers of each biosimilar's reference product and interchangeability determination. The proposed changes to New York's Pharmacy Laws incorporate the Purple Book into a new New York interchangeable biosimilars formulary, in a similar fashion to how generic drugs are pooled from FDA's *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book", a book that lists approved drug products, including generic drugs that may be automatically substituted for their reference product). Such new provisions are necessary to enable pharmacists to freely substitute interchangeable biosimilar products for the reference product in

the same way that generic drugs may be automatically substituted for their reference product; New York's current Pharmacy Laws only address generic drugs, not highly similar and interchangeable biosimilar products, as they are new under the BPCIA.

II. New York

New York's Pharmacy Laws provide for automatic substitution of generic versions for prescription drugs, assuming the generic version costs less than the reference product. New York's Pharmacy Laws establish a mechanism to establish a formulary of generic drugs, drawn from the Orange Book. An FDA "AB-rated" generic drug may be automatically substituted for the reference product without intervention of a patient's prescriber, because FDA has approved the generic drug as pharmaceutically and therapeutically equivalent to the reference product based on bioequivalence and other data. New York's Pharmacy Laws, however, currently have no provisions to address the automatic substitution of interchangeable biosimilar products nor how highly similar biosimilar products will be dispensed. The amendments provided below will define highly similar versus interchangeable biosimilar products and provide for a mechanism to automatically substitute interchangeable biosimilar drugs products as intended under the BPCIA. Similarly, the provisions will permit pharmacists to discuss biological and biosimilar choices for patients and facilitate communications with patients' prescribers much as they do for other prescription drug and medical device products. The proposed amendments to New York's Pharmacy Laws build upon amendments made in other states for their pharmacy laws, providing a superior yet more efficient mechanism to track actual prescriptions dispensed to patients (including lot numbers) that may be accessed by a patient's prescriber, yielding more accurate adverse event reporting for both drug and biological products. We believe that if this mechanism is adopted by New York and other states, physicians will provide FDA and other public health

authorities with more accurate track-and-trace mechanisms to more effectively attribute adverse events to actual products dispensed, resulting in better public health decisions related to these products. And perhaps most importantly, our proposed mechanism requires minimal extra work for pharmacists in contrast to the systems proposed in other states that are much more time intensive and less effective, especially for reporting down to lot information.

III. Other States

To date, fifteen states have amended their Pharmacy Laws to allow the automatic substitution of interchangeable biosimilar products and dispensing of highly similar biological products. Many of these states enacted provisions in 2015 with the advent of FDA's approval or Zarxio® (see attached list we have been tracking) and others are in the works that were facilitated by consensus language for substitution of interchangeable biosimilar products for their reference product developed by the Biological Industry Organization (BIO), the Pharmaceutical Research and Manufacturers of America (PhRMA), and the Generic Pharmaceutical Association (GPhA) (minus one member), Express Scripts (ESI), supported by 24 biological manufacturers. None of the states have adopted the consensus language exactly as written, in part because each state's pharmacy laws are different.

The consensus language requires that prescribers may require no automatic substitution of interchangeable biosimilars if prescribed "dispense as written" and the following:

> Within a reasonable time following the dispensing of a biological product, the dispensing pharmacist or the pharmacist's designee shall communicate to the prescriber the specific product provided to the patient, including the name of the product and the manufacturer. The communication shall be conveyed by making an entry in an interoperable electronic medical records system or through an electronic prescribing technology or a pharmacy record that is electronically accessible by the prescriber. OTHERWISE,

> the pharmacist shall communicate the biologic product dispensed to the prescriber, using facsimile, telephone, electronic transmission, or other prevailing means, provided that communication shall not be required where:
>
> • There is no FDA-approved interchangeable biologic for the product prescribed; or
>
> •a refill prescription is not changed from the product dispensed on the prior filling of the prescription.

While we believe that this consensus language was a positive step toward more states amending their pharmacy laws to permit dispensing biosimilar products and in particular interchangeable biosimilars, we found that these provisions have weaknesses that we could improve upon for New York. As provided below, our proposal would incorporate the concept of reporting biosimilar dispensing in a patient's interoperable health record or electronic prescribing technology when available, yet requiring that more detailed information be provided in a patient's prescription, including the lot number, which can readily be added at the time of prescription. Our proposal would obviate the need for communicating the biologic product dispensed to the prescriber, using facsimile, telephone, electronic transmission, or other prevailing means in the absence of an interoperable health record or electronic prescribing means, which currently are not available throughout New York. Accordingly, our key provision that is comparable to this consensus language reads:

> Following the dispensing of a prescription, the dispensing pharmacist or the pharmacist's designee shall communicate the specific product provided to the patient, including the non-proprietary and any proprietary name of the product, manufacturer, and lot number. The communication shall be conveyed by making an entry in an interoperable electronic medical records system or through an electronic prescribing technology, or a pharmacy benefits management system, or pharmacy record that is electronically accessible by the prescriber, if available. The pharmacist shall record the name of the manufacturer and the

production lot number of the product dispensed on the original prescription.

As noted below, there are other conforming amendments to New York's Pharmacy Laws including provisions for providing a prescribing physician access to the physician's pharmacy records for more accurate adverse event reporting and the development of a formulary for interchangeable biosimilars, when available.

IV. Proposed Amendments to New York's Pharmacy Laws to Permit Dispensing Biosimilar Products

-Proposed Biosimilars Bill-

An Act Amending Education Law Article 137, Pharmacy and Public Health Law § 206 to Allow for the Substitution of an Interchangeable Biological Product and Enhanced Prescriber Communications for Substitution of Generic Drugs and Interchangeable Biological Products

Education Law, Article 137 Pharmacy

§ 6802. Definitions.

27. "Biological product" means:"

a. Articles defined as a "biological product" in subsection (i) of section 351 of the Public Health Service Act (42 U.S.C. § 262(i)).

b. Articles that refer to a subset of drugs manufactured in or extracted from biological sources rather than chemically synthesized and can be made of sugars, proteins, nucleic acids, complex combinations of these substances, or may be living entities such as cells and tissues.

c. Examples of biological products include viruses, therapeutic serums, toxins, antitoxins, vaccines, blood, blood components or derivatives, allergenic products, immunoglobulins, products containing cells or microorganisms, gene therapy, and most therapeutic protein products (except any chemically synthesized polypeptide), including monoclonal antibodies, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.

d. The single biological product licensed under subsection (a) of section 351 of the Public Health Service Act (42 U.S.C. § 262(a)) against which a biological product is evaluated in an application submitted under subsection (k) of the Public Health Service Act (42 U.S.C. § 262(k)) is called the "reference product". Healthcare professionals can prescribe biosimilar and interchangeable biological products as they would prescribe other medications by writing the proprietary name or nonproprietary name on the prescription.

28. "Biosimilar product" means:

a. Articles defined as a "biosimilar product" in subsection (i) of section 351 of the Public Health Service Act (42 U.S.C. § 262(i))

b. FDA has determined under subsection (k) of the Public Health Service Act (42 U.S.C. § 262(k)) is highly similar to a U.S.-licensed reference product notwithstanding minor differences in clinically inactive components, and there are no clinically meaningful differences in terms of safety, purity, and potency between the biosimilar and the reference product.

c. A biosimilar product is not an interchangeable biological product and cannot be substituted for a reference biological product without a new prescription from the Prescriber for the biosimilar product.

29. "Interchangeable Biological Product" means:

a. Articles that meet the definition of a biosimilar product.

b. Articles that further meet the definition of "interchangeable" as defined in subsection (i) of section 351 of the Public Health Service Act (42 U.S.C. § 262(i)).

c. FDA has determined under subsection (k) of the Public Health Service Act (42 U.S.C. § 262(k)) can be expected to produce the same clinical result as the reference product in any given patient and, if administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between the use of the biological product and reference product is not greater than the risk of using the reference product without such alternation or switch. FDA will list interchangeable biological products in the "Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations," referred to as the "Purple Book."

d. Under Federal law, an interchangeable biological product can be substituted for the reference product without intervention of the healthcare provider who prescribed the reference product.

Amendment Explained: New York's Pharmacy Laws define "Drugs" but not biological products. Biological products, however, are a subset of drugs. The concept of an interchangeable biological product is similar but different than a generic drug and requires differentiation from a biosimilar product, which would require a new prescription for dispensing. These definitions are based on prior consensus language in other states (GPhA, BIO, PhRMA endorsed) as well as FDA's language from its "Purple Book": Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations.

§ 6810. Prescriptions.

5. Records of all prescriptions filled or refilled shall be maintained for a period of at least five years and upon request made available for inspection and copying by a representative of the department or prescribing doctor. Such records shall indicate date of filling or refilling, doctor's name, patient's name and address and the name or initials of the pharmacist who prepared, compounded, or dispensed the prescription, and manufacturer and the production lot number of the product dispensed or the products used in compounding the original prescription. Records of prescriptions for controlled substances shall be maintained pursuant the requirements of article thirty-three of the public health.

6.

a. Every prescription written in this state by a person authorized to issue such prescription shall be on prescription forms containing one line for the prescriber's signature. The prescriber's signature shall validate the prescription. Every electronic prescription shall provide for the prescriber's electronic signature, which shall validate the electronic prescription. Imprinted conspicuously on every prescription written in this state in eight point upper case type immediately below the signature line shall be the words: "THIS PRESCRIPTION WILL BE FILLED GENERICALLY OR WITH AN INTERCHANGEABLE BIOLOGICAL PRODUCT UNLESS PRESCRIBER WRITES 'd a w' IN THE BOX BELOW". Unless the prescriber writes d a w in such box in the prescriber's own handwriting

or, in the case of electronic prescriptions, inserts an electronic direction to dispense the drug as written, the prescriber's signature or electronic signature shall designate approval of substitution by a pharmacist of a drug product pursuant to paragraph (o) of subdivision one of section two hundred six of the public health law. No other letters or marks in such box shall prohibit substitution. No prescription forms used or intended to be used by a person authorized to issue a prescription shall have 'd a w' preprinted in such box. Such box shall be placed directly under the signature line and shall be three-quarters inch in length and one-half inch in height, or in comparable form for an electronic prescription as may be specified by regulation of the commissioner. Immediately below such box shall be imprinted in six point type the words "Dispense As Written". Notwithstanding any other provision of law, no state official, agency, board or other entity shall promulgate any regulation or guideline modifying those elements of the prescription form's contents specified in this subdivision. To the extent otherwise permitted by law, a prescriber may modify only those elements of the prescription form's contents not specified in this subdivision. Notwithstanding any other provision of this section or any other law, when a generic drug <u>or interchangeable biological product</u> is not available and the brand name drug originally prescribed is available and the pharmacist agrees to dispense the brand name product for a price that will not exceed the price that would have been charged for the generic <u>or interchangeable biological product</u> substitute had it been available, substitution of a generic drug <u>or interchangeable biological product</u> will not be required. If the generic drug <u>or interchangeable biological product</u> is not available and a medical emergency situation, which for purposes of this section is defined as any condition requiring alleviation of severe pain or which threatens to cause disability or take life if not promptly treated, exists, then the pharmacist may dispense the brand name product at his regular price. In such instances the pharmacist must record the date, hour and nature of the medical emergency on the back of the prescription and keep a copy of all such prescriptions.

b. The prescriber shall inform the patient whether he or she has prescribed a brand name or its generic <u>or interchangeable biological</u> equivalent drug product.

c.

<u>Following the dispensing of a prescription, the dispensing pharmacist or the pharmacist’s designee shall communicate the specific product provided to the patient, including the non-proprietary and any proprietary name of the product, manufacturer, and lot number. The communication shall be conveyed by making an entry in an interoperable electronic medical records system or through an electronic prescribing technology, or a pharmacy benefits management system, or pharmacy record that is electronically accessible by the prescriber, if available. The pharmacist shall record the name of the manufacturer and the production lot number of the product dispensed on the original prescription.</u>

d. The provisions of this subdivision shall not apply to a hospital as defined in article twenty-eight of the public health law.

e. No prescriber shall be subjected to civil liability arising solely from authorizing, in accordance with this subdivision, the substitution by a pharmacist of a drug or interchangeable biological product pursuant to paragraph (o) of subdivision one of section two hundred six of the public health law.

Amendment Explained: New York's Pharmacy Laws permit the substitution of generic equivalent drugs but does not explicitly include interchangeable biological products. These amendments would permit a pharmacist to substitute an interchangeable biological product for a reference biological product as it does for generic equivalent drugs without civil liability. These amendments also add a provision for pharmacists to include manufacturer and lot number information in all prescriptions filled and affirmative rights for prescribers to obtain records of prescriptions filled by their patients, leading to enhanced pharmacovigilance data for manufacturers and the public health system. These provisions are based in part on prior consensus language in other states (GPhA, BIO, PhRMA endorsed) for the inclusion of interchangeable biological products and use of electronic reporting for certain interchangeable biological product dispensing. These requirements will enable physicians to more accurately report adverse events at the pharmacy level or through electronic prescription methods if available.

§ 6816 Omitting to label drugs, or labeling them wrongly

1. a. Any person, who, in putting up any drug, medicine, or food or preparation used in medical practice, or making up any prescription, or filling any order for drugs, medicines, food or preparation puts any untrue label, stamp or other designation of contents upon any box, bottle or other package containing a drug, medicine, food or preparation used in medical practice, or substitutes or dispenses a different article for or in lieu of any article prescribed, ordered, or demanded, except where required pursuant to §6816-a of this article, or puts up a greater or lesser quantity of any ingredient specified in any such prescription, order or demand than that prescribed, ordered or demanded, except where required pursuant to paragraph (g) of subdivision two of section three hundred sixty-five-a of the social services law, or otherwise deviates from the terms of the prescription, order or demand by substituting one drug for another, except where required pursuant to §6816-a of this article, is guilty of a misdemeanor; provided, however, that except in the case of physicians' prescriptions, nothing herein contained shall be deemed or construed to prevent or impair or in any manner affect the right of an apothecary, druggist, pharmacist or other person to recommend the purchase of an article other than that ordered, required or demanded, but of a similar nature, or to sell such other article in place or in lieu of an article ordered, required or demanded, with the knowledge and consent of the purchaser. Upon a second conviction for a violation of this section the offender must be sentenced to the payment of a fine not to exceed one thousand dollars and may be sentenced to imprisonment for a term not to exceed one year. The third conviction of a violation of any of the provisions of this section, in addition to rendering the offender liable to the penalty prescribed by law for a second conviction, shall forfeit any right which he may possess under the law of this state at the time of such

conviction, to engage as proprietor, agent, employee or otherwise, in the business of an apothecary, pharmacist, or druggist, or to compound, prepare or dispense prescriptions or orders for drugs, medicines, or foods or preparations used in medical practice; and the offender shall be by reason of such conviction disqualified from engaging in any such business as proprietor, agent, employee or otherwise or compounding, preparing or dispensing medical prescriptions or orders for drugs, medicines, or foods or preparations used in medical practice.

b. The provisions of this section shall not apply to the practice of a practitioner who is not the proprietor of a store for the dispensing or retailing of drugs, medicines, and poisons, or who is not in the employ of such a proprietor, and shall not prevent practitioners from supplying their patients with such articles as they may deem proper, and except as to the labeling of poisons shall not apply to the sale of medicines or poisons at wholesale when not for the use or consumption by the purchaser; provided, however, that the sale of medicines or poisons at wholesale shall continue to be subject to such regulations as from time to time may be lawfully made by the board of pharmacy or by any competent board of health.

c. The provisions of this section shall not apply to a limited pharmacy which prepares a formulary containing the brand names and the ~~generic~~ nonproprietary names of drugs and of manufacturers which it stocks, provided that it furnishes a copy of such formulary to each physician on its staff and the physician signs a statement authorizing the hospital to supply the drug under any ~~generic or~~ nonproprietary name listed therein and in conformity with the regulations of the commissioner of education.

2. For the purposes set forth in this section, the terms prescription, order or demand shall apply only to those items subject to provisions of §6810(1) of this chapter. The written order of a physician for items not subject to provisions of §6810(1) of this chapter shall be construed to be a direction, a fiscal order or a voucher.

Amendment Explained: New York's Pharmacy Laws mentions drugs, which includes the subset of biological products as defined above. The term "generic name" is replaced with "nonproprietary name" to include biological products.

§6816-a When substitution is required

1. A pharmacist shall substitute a less expensive drug product containing the same active ingredients, dosage form and strength as the drug product prescribed, ordered or demanded, provided that the following conditions are met:

(a) The prescription is written on a form which meets the requirements of §6810(6) of this article and the prescriber does not prohibit substitution, or in the case of oral prescriptions, the prescriber must expressly state whether substitution is to be permitted or prohibited. Any oral prescription that does not include such an express statement shall not be filled; and

(b) The substituted drug product is contained in the list of drug products established pursuant to paragraph (*o*) of subdivision one of §206 of the public health law; and

(c) The pharmacist shall indicate on the label affixed to the immediate container in which the drug is sold or dispensed the name and strength of the drug product and its manufacturer unless the prescriber specifically states otherwise. The pharmacist shall record on the prescription form the brand name or the name of the manufacturer of the drug product dispensed.

2. In the event a patient chooses to have a prescription filled by an out of state dispenser, the laws of that state shall prevail.

No Amendment Required: Because biological products are a subset of drugs, this section does not appear to require modification if Public Health Law § 206 is amended as provided below or with similar language to include interchangeable biological products in the substitutable drug product list. The concept of "less expensive" is a function of New York developing a list of drugs and drug prices to make such a determination for substitution decisions by pharmacists/pharmacies.

Public Health Law § 206. Commissioner; general powers and duties. 1. The commissioner shall:

(o) establish and publish a list of drug products, each of which shall meet the following conditions:

(1) The drug product has been certified or approved by the commissioner of the Federal Food and Drug Administration as being safe and effective for its labeled indications for use, and a new-drug application, biological license application, or an abbreviated new-drug application approved pursuant to the Federal Food, Drug, and Cosmetic Act is held for such drug product; and

(2) The commissioner of the Federal Food and Drug Administration has evaluated such drug product as pharmaceutically and therapeutically equivalent and has listed such drug product on the list of approved drugs products with the therapeutic equivalence evaluations, provided, however, that the list prepared by the commissioner shall not include any drug product which the commissioner of the Federal Food and Drug Administration has identified as having an actual or potential bioequivalence problem; or.

(3) The commissioner of the Federal Food and Drug Administration has evaluated such biological product as highly similar to a U.S.-licensed reference product and for which the FDA has determined that there are no clinically meaningful differences between the biosimilar and the reference product and that can be expected to produce the same clinical result as the reference product in any given patient and, if administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between the use of the biological product and reference product is not greater than the risk of using the reference product without such alternation or switch and has listed such biological product as an interchangeable biologic for a reference product on the list of licensed biological products with reference product exclusivity and biosimilarity or interchangeability evaluations, provided, however, that the list prepared by the commissioner shall not include any biological product which the commissioner of the Federal Food and Drug Administration has identified has having an actual or potential biosimilarity or interchangeability problem.

Amendment Explained: This section of the New York Public Health Laws directs the commissioner to establish and publish a list of drug products that FDA has deemed as pharmaceutically and therapeutically equivalent to a reference drug but does not include a similar provision for interchangeable biological products. This proposed amendment permits interchangeable biosimilar products to be added to that list, which is relevant for determining substitution when the interchangeable biosimilar product is less expensive than the reference product.

Education Law, Article 137 Pharmacy

§ 6817. New Drugs.

[~~5. This section shall not apply to any drug which was licensed under the federal virus, serum, and toxin act of July first, nineteen hundred two (32 Stat. 728) or is licensed under section two hundred sixty-two of the public health service act of July first, nineteen hundred forty-four (58 Stat. 682), or under the federal virus, serums, toxins, antitoxins and analogous products act of March fourth, nineteen hundred thirteen (37 Stat. 832).~~]

Amendment Explained: New York's Pharmacy Laws previously excluded biological products from the definition of new drugs. This amendment removes that provision to now include biological products and permit the substitution of interchangeable biosimilar products for reference biological products.

CONCLUSION

The proposed amendments to New York's Pharmacy Laws will provide New York pharmacists with the appropriate mechanism to dispense biological products, including highly similar biosimilar and interchangeable biosimilar versions, along with enhanced information available to prescribers to report adverse event information more effectively, providing a model for other states to follow.