**COUNCIL OF THE DISTRICT OF COLUMBIA**
**COMMITTEE ON HEALTH**
**COMMITTEE REPORT**
**1350 Pennsylvania Avenue, N.W., Washington, D.C. 20004**

**TO:** All Councilmembers

**FROM:** Councilmember Vincent C. Gray, Ward 7
Chairperson, Committee on Health

**DATE:** July 1, 2020

**SUBJECT:** Report on Bill 23-0430, the "Access to Biosimilars Amendment Act of 2020"

The Committee on Health, to which Bill 23-0430 was referred, reports favorably thereon and recommends approval by the Council.

## CONTENTS



## I. BACKGROUND & NEED

The stated purpose of Bill 23-0430 is to authorize licensed pharmacists to dispense interchangeable biological products, and to require notifications to physicians when interchangeable biological products are dispensed with certain exceptions. The "Access to Biosimilars Amendment Act of 2020" was introduced on September 17, 2019 by Councilmembers Mary Cheh, Brandon Todd, Anita Bonds, Charles Allen, Brianne Nadeau, Elissa Silverman, Vincent Gray, and Jack Evans at Committee of the Whole. The bill was also co-sponsored by Councilmembers Kenyan McDuffie and David Grosso.

A biosimilar is defined as a biological product that is identical in safety, and potency to an existing FDA approved biologic, known as a "reference product". Currently, there are 24 biosimilars approved by the US Food and Drug Administration (FDA). Unlike traditionally

chemically derived medicines, biologics are made from living organisms, making them effective in treating life threatening conditions such as cancer, rheumatoid arthritis, and diabetes. This legislation is needed to ensure patient safety for biologics designated as interchangeable by the FDA and to establish open communications between the pharmacy and prescribed to ensure that all those involved in a patients care know the exact course of treatment. It will also allow doctors to better monitor patients for changes in their disease activity or side effects after the substitution. This legislation will provide the necessary framework for residents of the District to obtain lower-cost options for the life-changing treatments they need.

## II. LEGISLATIVE CHRONOLOGY

| | |
|---|---|
| September 17, 2019 | B23-0430 Introduced by Councilmembers Cheh, Todd, Bonds, Allen, Nadeau, Silverman, Gray, and Evans at Committee of the Whole |
| September 17, 2019 | Referred to Committee on Health |
| September 27, 2019 | Notice of Intent to Act on B23-0430 Published in the District of Columbia Register |
| October 18, 2019 | Notice of Public Hearing Published in the District of Columbia Register |
| November 08, 2019 | Notice of Public Hearing Published in the District of Columbia Register |
| November 13, 2019 | Public Hearing on B23-0430 |
| July 1, 2020 | Consideration and vote on Bill 23-0430 |

## III. POSITION OF THE EXECUTIVE

**Shauna White, PharmD, RPH, MS, Executive Director of the District of Columbia Board of Pharmacy, Department of Health**, testified on behalf of the Executive, stating that the Department supports updating the Prescription Drug Price Information Act by adding "or interchangeable biological product" or in places after the word "generic equivalent"; however, she testified that when referencing interchangeable biologics, the Purple Book, which lists biological products licensed by the FDA under the Public Health Service Act, including any approved biosimilar and interchangeable biological products, should be used instead of the "Approved Drug Products with Therapeutics Equivalence Evaluations," referred to as the "Orange Book" in the legislation. She also recommended removing language requiring the Boards of Pharmacy and Medicine to maintain a link on their websites to the current list of biological products determined by the FDA to be interchangeable. She suggested that the Board of Pharmacy and Board of Medicine maintain direct links to the FDA on their respective websites, which will facilitate access to the primary source for drug references for biologics, biosimilars, and interchangeable products.

Finally, Director White recommended removing the requirement to notify a physician when a biosimilar is dispensed to a patient. She expressed that a more straightforward and streamlined approach would be for prescribers to indicate if substitution is permitted on the prescription or indicate the specific biologic, biosimilar, or interchangeable product they deem to be appropriate for their patient. This process, she stated, would serve as a safeguard in ensuring that the medical practitioner and pharmacist are or one accord. Director White thanked the Council for its proactive efforts and expressed that she looks forward to continuing work with the Mayor and Council in promoting safe, cost-effective alternatives to District residents.

## IV. COMMENTS OF ADVISORY NEIGHBORHOOD COMMISSIONS

The committee received no testimony or comments from Advisory Neighborhood Commissions.

## V. LIST OF WITNESSES AND SUMMARIES OF TESTIMONY

Public Witnesses

| | |
|---|---|
| 1. Monet Stanford, PharmD. | Pharmacy Government Relations and Regulatory Affairs, Kaiser Permanente Mid-Atlantic |
| 2. Angela Gochenaur | Director, State Government Affairs – Eastern Region, The Biotechnology Innovation Organization (BIO) |

Executive Witness

| | |
|---|---|
| Dr. Shauna White, PharmD, RPH, MS | Executive Director of the DC Board of Pharmacy |

**Monet Stanford, PharmD., Pharmacy Government Relations and Regulatory Affairs, Kaiser Permanente Mid-Atlantic**, testified in opposition of Bill 23-0430. She expressed that the legislation places onerous requirements on the substitution of interchangeable biosimilars, is imprudent, and does not improve the quality of life for the residents of the District of Columbia. On this note, she testified that it is not clear how this bill increases safety or reduces the financial burden on residents. If the proposed legislation were to move forward, she requested the consideration of several amendments (see testimony).

**Angela Gochenaur Director, State Government Affairs – Eastern Region, The Biotechnology Innovation Organization (BIO)**, testified in support of Bill 23-0430 because it contains important provisions that consider the special and complex characteristics of biological medicines. He expressed that unlike traditional chemically derived medicines, biologics are made from living organisms that are effective in treating life-threatening diseases and conditions such as cancer, rheumatoid arthritis, and diabetes. He stated that given the unique and complex nature

of biologics, current state generic substitution laws must be updated to address five key principles to ensure patient safety:

- Substitution should occur only when the FDA has designated a biologic product as interchangeable
- The prescribing physician should be able to prevent substitution
- The pharmacy dispensing the interchangeable biologic product must communicate with the prescribing physician concerning the substitution
- The patient, or the patient's authorized representative, should, at a minimum, be notified of the substitution
- The pharmacist and the physician should keep records of the substitution

## VI. IMPACT ON EXISTING LAW

Bill 23-0430 amends the District of Columbia Prescription Drug Price Information Act, effective September 10, 1976 (D.C. Law 1-81; D.C. Official Code § 48-801.01 *et seq.*) by clarifying that "Biological product" shall have the same meaning as provided in 42 U.S.C. § 262 and that "Interchangeable biological product" means a biological product that is licensed and determined by the United States Food and Drug Administration to meet the standards for interchangeability under 42 U.S.C. § 262(k)(4); or determined to be biosimilar or interchangeable with a reference biological product as stated in the latest edition of or supplement to the United States and Food and Drug administration's ("FDA") publication, "Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations" (known as the Purple Book).

Bill 23-0430 also amends D.C. Law-181 by requiring the Boards of Pharmacy and Medicine to maintain a link on their websites to the current list of biological products determined by the FDA to be interchangeable with a specific biological product. Lastly the bill requires that within 5 business days after dispensing a biological product to a patient, a dispensing pharmacist or the pharmacist's designee communicate to the prescriber the specific biological product dispensed, including the name and manufacturer of the biological product.

## VII. FISCAL IMPACT

Funds are sufficient in the fiscal year 2020 through fiscal year 2023 budget and financial plan to implement the bill.

## VIII. SECTION BY SECTION ANALYSIS

Section 1 States the short title of Bill 23-430.

Section 2 Amends the District of Columbia Prescription Drug Price Information Act, effective September 10, 1976 (D.C. Law 1-81; D.C. Official Code § 48-

801.01 *et seq.*) by clarifying that "Biological product" shall have the same meaning as provided in 42 U.S.C. § 262 and that "Interchangeable biological product" means a biological product that is licensed and determined by the United States Food and Drug Administration to meet the standards for interchangeability under 42 U.S.C. § 262(k)(4); or determined to be biosimilar or interchangeable with a reference biological product as stated in the latest edition of or supplement to the United States and Food and Drug administration's ("FDA") publication, "Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations" (known as the Purple Book).

This section also amends D.C. Law-181 by requiring the Boards of Pharmacy and Medicine to maintain a link on their websites to the current list of biological products determined by the FDA to be interchangeable with a specific biological product. It requires that within 5 business days after dispensing a biological product to a patient, a dispensing pharmacist or the pharmacist's designee communicate to the prescriber the specific biological product dispensed, including the name and manufacturer of the biological product. Lastly this section strikes and inserts phrases to reflect the addition of biosimilars.

Section 3 Adopts the fiscal impact statement

Section 4 States the Act will take effect following Mayoral approval, Congressional review, and publication in the District of Columbia Register.

## IX. COMMITTEE ACTION

Bill 23-430, the "Access to Biosimilars Act of 2020." The meeting was called to order at 9:10 a.m. after a quorum was present consisting of Committee Chairperson Vincent C. Gray and Councilmembers Brianne K. Nadeau, David Grosso and Mary M. Cheh. Bill 23-430 was the third item on the agenda.

After discussing the chronology and purpose of the bill, Chairperson Gray gave brief remarks, and opened the floor for discussion. Councilmember Cheh, who introduced the legislation, noted the legislation would allow a pharmacist to substitute a biosimilar for a brand name biologic, therefore providing District residents with improved access to life-saving medication and reducing the overall costs associated with biologics by increasing competition. She noted that this has been the experience from nearly every other state in the U.S. and much of the rest of the world and that this legislation increases access in a way that is patient-centered and scientifically sound.

Hearing no further discussion, Chairperson Gray moved the print and report, with leave for staff to make technical and editorial changes. The vote on the print and report were unanimous. (Chairperson Gray and Councilmembers Grosso, Cheh and Nadeau voting "aye", Councilmember Todd being absent) The meeting adjourned at 9:43 a.m.

## X. ATTACHMENTS

A. Secretary's Notice
B. Bill 23-0430 as Introduced
C. Hearing Notice and Witness List
D. Copies of Written Testimony
E. Fiscal Impact Statement
F. Legal Sufficiency Memorandum
G. Committee Print of Bill 23-0430

# ATTACHMENT A

# COUNCIL OF THE DISTRICT OF COLUMBIA
# 1350 Pennsylvania Avenue, N.W.
# Washington D.C. 20004

Memorandum

To : Members of the Council

From : Nyasha Smith, Secretary to the Council

Date : September 18, 2019

Subject : Referral of Proposed Legislation

Notice is given that the attached proposed legislation was introduced in the Committee of the Whole on Tuesday, September 17, 2019. Copies are available in Room 10, the Legislative Services Division.

TITLE: "Access to Biosimilars Amendment Act of 2019 ", B23-0430

INTRODUCED BY: Councilmembers Cheh, Todd, Bonds, Allen, Nadeau, Silverman, Gray, and Evans

CO-SPONSORED BY: Councilmembers McDuffie and Grosso

The Chairman is referring this legislation to the Committee on Health.

Attachment

cc: General Counsel
Budget Director
Legislative Services

# ATTACHMENT B

Councilmember Brianne K. Nadeau

Councilmember Mary M. Cheh

Councilmember Elissa Silverman

Councilmember Brandon T. Todd

Councilmember Vincent C. Gray

Councilmember Anita Bonds

Councilmember Jack Evans

Councilmember Charles Allen

A BILL

IN THE COUNCIL OF THE DISTRICT OF COLUMBIA

To amend the District of Columbia Prescription Drug Price Information Act to authorize licensed pharmacists to dispense interchangeable biological products, and to require notifications to physicians when such interchangeable biological products are dispensed.

BE IT ENACTED BY THE COUNCIL OF THE DISTRICT OF COLUMBIA, That this act may be cited as the "Access to Biosimilars Amendment Act of 2019."

Sec. 2. The District of Columbia Prescription Drug Price Information Act, effective September 10, 1976 (D.C. Law 1-81; D.C. Official Code § 48-801.01 *et seq.*), is amended as follows:

(a) Section 2 (D.C. Official Code § 48-804.51) is amended by adding new paragraphs (1A) and (2A) to read as follows:

"(1A) "Biological product" shall have the same meaning as provided in 42 U.S.C. § 262.

"(2A) "Interchangeable biological product" means a biological product that is:

"(A) Licensed and determined by the United States Food and Drug Administration to meet the standards for interchangeability under 42 U.S.C. § 262(k)(4); or

"(B) Determined to be therapeutically equivalent as stated in the latest edition of or supplement to the United States Food and Drug Administration's publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" ("Orange Book").".

(b) Section 301 (D.C. Official Code § 48-803.01) is amended by adding a new subsection (d) to read as follows:

"(d) The Boards of Pharmacy and Medicine shall maintain a link on their websites to the current list of biological products determined by the FDA to be interchangeable with a specific biological product.".

(c) Section 302 (D.C. Official Code § 48-803.02) is amended as follows:

(1) The section heading is amended to read as follows:

"Sec. 302. Dispensing of generically equivalent drug product or interchangeable biological product.".

(2) Subsection (a) is amended by striking the phrase "generically equivalent drug product" wherever it appears and inserting the phrase "generically equivalent drug product or interchangeable biological product" in its place.

(3) Subsection (b) is amended by striking the phrase "drug by generic name" and inserting the phrase "drug by generic name or interchangeable biological product" in its place.

(d) Section 303(2) (D.C. Official Code § 48-803.03) is amended by striking the phrase "generically equivalent drug product" and inserting the phrase "generically equivalent drug product or interchangeable biological product" in its place.

(e) Section 303a(a) (D.C. Official Code § 48-803.03a) is amended by striking the phrase "drug substitution" and inserting the phrase "drug substitution, including an interchangeable biological product" in its place.

(f) Section 304 (D.C. Official Code § 48-803.04) is amended by striking the phrase "substituted under this subchapter," and inserting the phrase "substituted under this subchapter, including the substitution of an interchangeable biological product,"

(g) Section 305 (D.C. Official Code § 48-803.05) is amended as follows:

(1) Subsection (a) is amended by striking the phrase "under this subchapter" and inserting the phrase "under this subchapter, including the substitution of an interchangeable biological product" in its place.

(2) Subsection (b) is amended by striking the phrase "generically equivalent drug products drugs" and inserting the phrase "generically equivalent drugs products or an interchangeable biological product" in its place.

(h) A new section 306 (D.C. Official Code § 48-803.06) is added to read as follows:

"Sec. 306. Pharmacist notification to prescriber of substitution of interchangeable biological product.

"(a) Within 5 business days after dispensing a biological product to a patient, the dispensing pharmacist or the pharmacist's designee shall communicate the specific biological product dispensed, including the name and manufacturer of the biological product, to the prescriber; however, the communication shall not be required if the FDA has not approved an

interchangeable biological product for the biological product prescribed to the patient or a refill prescription is not changed from the biological product dispensed on the most recent filling of the prescription.

"(b)(1) Except as provided under subsection (c) of this section, the communication required under subsection (a) of this section shall be provided by making an entry that is electronically accessible to the provider through:

"(A) An interoperable electronic medical records system;

"(B) An electronic prescribing technology; or

"(C) A pharmacy benefits management system.

"(2) Making an entry through a mechanism listed in paragraph (1) of this subsection is presumed to provide the communication to the prescriber required under subsection (a) of this section.

"(c) If the mechanisms listed in subsection (b)(1) of this section are unavailable, the communication required under subsection (a) of this section may be provided by facsimile, telephone, electronic transmission, or other means.".

Sec. 3. Fiscal impact statement.

The Council adopts the fiscal impact statement in the committee report as the fiscal impact statement required by section 4a of the General Legislative Procedures Act of 1975, approved October 16, 2006 (120 Stat. 2038; D.C. Official Code § 1-301.47a).

Sec. 4. Effective date.

This act shall take effect following approval by the Mayor (or in the event of veto by the Mayor, action by the Council to override the veto), a 30-day period of congressional review as provided in section 602(c)(l) of the District of Columbia Home Rule Act, approved December

24, 1973 (87 Stat. 813; D.C. Official Code § 1-206.02(c)(l)), and publication in the District of Columbia Register.

# ATTACHMENT C

**COUNCIL OF THE DISTRICT OF COLUMBIA**
**COMMITTEE ON HEALTH**
**NOTICE OF PUBLIC HEARING**
**1350 PENNSYLVANIA AVE., N.W., WASHINGTON, D.C. 20004**

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**COUNCILMEMBER VINCENT C. GRAY, CHAIRPERSON**
**THE COMMITTEE ON HEALTH**

**ANNOUNCES A PUBLIC HEARING ON**

**BILL 23-0326, THE "POSTPARTUM COVERAGE ACT OF 2019"**

**BILL 23-0360, THE "CONTINUING NUTRITION EDUCATION AMENDMENT ACT OF 2019"**

**BILL 23-0416, "BETTER ACCESS FOR BABIES TO INTEGRATED EQUITABLE SERVICES ACT OF 2019"**

**BILL 23-0430, THE "ACCESS TO BIOSIMILARS AMENDMENT ACT OF 2019"**

**WEDNESDAY, NOVEMBER 13, 2019**
**12:00 P.M., ROOM 412, JOHN A. WILSON BUILDING**
**1350 PENNSYLVANIA AVENUE, N.W.**
**WASHINGTON, D.C. 20004**

Councilmember Vincent C. Gray, Chairperson of the Committee on Health, announces a Public Hearing on Bill 23-0326, the "Postpartum Coverage Act of 2019", Bill 23-0360, the "Continuing Nutrition Education Amendment Act of 2019", Bill 23-0416, the "Better Access for Babies to Integrated Equitable Services Act of 2019", and Bill 23-0430, the "Access to Biosimilars Amendment Act of 2019." The hearing will be held on Wednesday, November 13, 2019, at 12:00 p.m., or immediately following the Committee on Health and Committee on Education's joint hearing, in Room 412 of the John A. Wilson Building.

Bill 23-0326, the "Postpartum Coverage Act of 2019", extends postpartum inpatient and outpatient benefits to at least a year after childbirth.

Bill 23-0360, the "Continuing Nutrition Education Amendment Act of 2019", requires continuing education for certain health occupations on the subject of nutrition.

Bill 23-0416, the "Better Access for Babies to Integrated Equitable Services Act of 2019", adds provisions to the Comprehensive Newborn Screening Program to establish discharge standards and authorizes penalties for failure to comply with the standards or perform the necessary screens. It would also authorize the Department of Health to collect information from hospitals and birthing facilities to create a report card regarding compliance with newborn screening requirements, lactation support services, parent education, discharge standards, and clinical quality measures. It also creates a Perinatal

and Infant Health Advisory Committee that would advise on ways to reduce preterm birth and newborn screening activities.

Bill 23-0430, the "Access to Biosimilars Amendment Act of 2019", authorizes licensed pharmacists to dispense interchangeable biological products, and requires notifications to physicians when such interchangeable biological products are dispensed. An interchangeable biological product is a biological product licensed by the US Food and Drug Administration to meet the standards of interchangeability under federal law and determined to be therapeutically equivalent by the USFDA.

The Committee invites the public to testify at the roundtable. Those who wish to testify should contact Malcolm Cameron, Committee Legislative Analyst at (202) 654-6179 or mcameron@dccouncil.us, and provide your name, organizational affiliation (if any), and title with the organization, preferably by 5:00 p.m. on Monday, November 11, 2019. Witnesses should bring 15 copies of their written testimony to the roundtable.

The Committee allows individuals 3 minutes to provide oral testimony in order to permit each witness an opportunity to be heard. Additional written statements are encouraged and will be made part of the official record. Written statements may be submitted by e-mail to mcameron@dccouncil.us or mailed to: Council of the District of Columbia, 1350 Pennsylvania Ave., N.W., Suite 113, Washington D.C. 20004.

**COUNCIL OF THE DISTRICT OF COLUMBIA**
**COMMITTEE ON HEALTH**
**NOTICE OF PUBLIC HEARING**
**1350 PENNSYLVANIA AVE., N.W., WASHINGTON, D.C. 20004** **Abbreviated/Revised**

**COUNCILMEMBER VINCENT C. GRAY, CHAIRPERSON**
**THE COMMITTEE ON HEALTH**

**ANNOUNCES A PUBLIC HEARING ON**

**BILL 23-0326, THE "POSTPARTUM COVERAGE ACT OF 2019"**

**BILL 23-0360, THE "CONTINUING NUTRITION EDUCATION AMENDMENT ACT OF 2019"**

**BILL 23-0430, THE "ACCESS TO BIOSIMILARS AMENDMENT ACT OF 2019"**

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Bill 23-0326, the "Postpartum Coverage Act of 2019", extends postpartum inpatient and outpatient benefits to at least a year after childbirth.

Bill 23-0360, the "Continuing Nutrition Education Amendment Act of 2019", requires continuing education for certain health occupations on the subject of nutrition.

Bill 23-0430, the "Access to Biosimilars Amendment Act of 2019", authorizes licensed pharmacists to dispense interchangeable biological products, and requires notifications to physicians when such interchangeable biological products are dispensed. An interchangeable biological product is a biological product licensed by the US Food and Drug Administration to meet the standards of interchangeability under federal law and determined to be therapeutically equivalent by the USFDA.

The Committee invites the public to testify at the hearing. Those who wish to testify should contact Malcolm Cameron, Committee Legislative Analyst at (202) 654-6179 or

mcameron@dccouncil.us, and provide your name, organizational affiliation (if any), and title with the organization, preferably by 5:00 p.m. on Monday, November 11, 2019. Witnesses should bring 15 copies of their written testimony to the hearing.

The Committee allows individuals 3 minutes to provide oral testimony in order to permit each witness an opportunity to be heard. Additional written statements are encouraged and will be made part of the official record. Written statements may be submitted by e-mail to mcameron@dccouncil.us or mailed to: Council of the District of Columbia, 1350 Pennsylvania Ave., N.W., Suite 113, Washington D.C. 20004.

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**COUNCILMEMBER VINCENT C. GRAY, CHAIRPERSON**
**THE COMMITTEE ON HEALTH**

**ANNOUNCES A PUBLIC HEARING ON**

**BILL 23-0326, THE "POSTPARTUM COVERAGE ACT OF 2019"**

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**1350 PENNSYLVANIA AVENUE, N.W.**
**WASHINGTON, D.C. 20004**

## WITNESS LIST

**BILL 23-0326, THE "POSTPARTUM COVERAGE ACT OF 2019"**

Public Witnesses

| | |
|---|---|
| 1. Mary Revenis, MD | DC American Academy of Pediatrics |
| 2. Chidiogo Anyigbo, MD, MPH, FAAP | Fellow, General Academic Pediatrics, Children's National Hospital |

Executive Witness

| | |
|---|---|
| Melisa Byrd | Senior Deputy Director/Medicaid Director, Department of Health Care Finance |

**BILL 23-0360, THE "CONTINUING NUTRITION EDUCATION AMENDMENT ACT OF 2019"**

Public Witnesses

| | |
|---|---|
| 1. Nichole Jannah | Research Associate, Milken Institute School of Public Health, The George Washington University |
| 2. Taylor Dodson | Student, Harvard Law School |
| 3. Meedie Bardonille RN, MSN, PCCN-K | Chair, DC Board of Nursing |
| 4. Andrea A. Anderson, MD, FAAFP | Chair, DC Board of Medicine |
| 5. Neal Barnard, MD, FACC | President, Physicians Committee for Responsible Medicine |

Executive Witness

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|---|---|
| Dr. Jacqueline Watson, DO MBA | Chief of Staff, Department of Health |

**BILL 23-0430, THE "ACCESS TO BIOSIMILARS AMENDMENT ACT OF 2019"**

Public Witnesses

| | |
|---|---|
| 1. Monet Stanford, PharmD. | Pharmacy Government Relations and Regulatory Affairs, Kaiser Permanente Mid-Atlantic |

Executive Witness

| | |
|---|---|
| Dr. Shauna White, PharmD, RPH, MS | Executive Director of the DC Board of Pharmacy |

# ATTACHMENT D

KAISER PERMANENTE®

Mid-Atlantic Permanente Medical Group, P.C.
Kaiser Foundation Health Plan of the Mid-Atlantic States, Inc.

# OPPOSE B23-0430: Access to Biosimilars Amendment Act of 2019

November 11, 2019

Councilmember Vincent C. Gray
Chair, Committee on Health
Council of the District of Columbia
1350 Pennsylvania Avenue NW
Suite 406
Washington, DC 20004

Dear Councilmember Gray:

Thank you for the opportunity to provide comments on *B23-0430: Access to Biosimilars Amendment Act of 2019*. Kaiser Permanente of the Mid-Atlantic States region provides and coordinates complete health care services for over 769,000 members through 32 medical office buildings in Maryland, Virginia, and the District of Columbia. Kaiser Permanente is a total health organization composed of Kaiser Foundation Health Plan of the Mid-Atlantic States, Inc. and the Mid-Atlantic Permanente Medical Group, P.C., an independent medical group comprising approximately 1,600 physicians who provide or arrange care for patients throughout the area, and Kaiser Foundation Hospitals, which contracts with community hospitals for the provision of hospital services to our patients.

**Kaiser Permanente opposes the overall enactment of B23-0430. Legislation that places onerous requirements on the substitution of interchangeable biosimilars is imprudent and does not improve the quality of life to the residents of the District of Columbia.** It is not clear in which way this bill increases safety or reduces the financial burden on residents of the District of Columbia. Biologics — drugs derived from living organisms used to treat conditions such as rheumatoid arthritis, multiple sclerosis, and certain cancers — are the fastest growing component of prescription drug spending.[1] Shortly after the rise in popularity of biologics, follow-on products, known as biosimilars, were developed in a manner similar to the role generic drugs play on the traditional market. Because of the unique molecular structure of biological products, the Food and Drug Administration (FDA) evaluates and approves these products through a parallel regulatory pathway established by the federal Biologics Price Competition and Innovation Act of 2009 (BCPI).

For approval, biosimilars and their reference products must produce the same degree of safety, purity and potency. The BCPI establishes evidentiary thresholds to determine if products considered to be biosimilar to the reference products are interchangeable amongst themselves. Additionally, the Affordable Care Act mandates an interchangeable product may be substituted downstream for the reference product without

[1] Kristen Joyce, "Drug Policy 101: Biosimilars" Kaiser Permanente Institute for Health Policy, January 1, 2019, https://www.kpihp.org/issue-areas/drug-policy-101/drug-policy-101-biosimilars/

the intervention of the prescriber.[2] Providers and their patients can be assured that an FDA-approved interchangeable product has been thoroughly tested and met rigorous standards for approval.[3] Most importantly, to date, the FDA has not designated any approved biosimilars as interchangeable. Thus, the proposed legislation codifies a process that is premature and rather unnecessary.

If the proposed legislation does move forward, we request your consideration of the following amendments and comments, which we believe minimally necessary to optimize safety and improve the well-being of the residents of the District of Columbia.

**(1) We urge the Committee to delete proposed lines 44-46:**

~~"Determined to be therapeutically equivalent as stated in the latest edition of or supplement to the United States and Food and Drug Administration's publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" ("Orange Book")."~~

**COMMENT:** B23-0430 indicates within the definition of interchangeable biological product its reference text as the FDA's Orange Book. That text identifies therapeutically equivalent drug products as approved by the FDA for traditional small molecule drugs. However, more appropriate is the FDA's Purple Book, which lists all biological products, including any biosimilar and interchangeable biological products, licensed by FDA under the Public Health Service Act (PHS). It includes whether a biological product licensed under section 351(k) of the PHS Act has been determined by FDA to be biosimilar to or interchangeable with a reference biological product.

Thus, we suggest in the alternative that this proposed Section be amended to provide that:

(B) "Determined to be biosimilar or interchangeable with a reference biological product as stated in the latest edition of or supplement to the United States and Food and Drug Administration`s publication, "Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations"("Purple Book")."

**(2) We urge the Committee to delete proposed lines 77-86:**

~~(b) "A new section 306 (D.C. Official Code 48-803.06) is added to read as follows:~~
~~"Sec. 306. Pharmacist notification to prescriber of substitution of interchangeable biological product."~~

~~(a) "Within 5 business days after dispensing a biological product to a patient, the dispensing pharmacist or the pharmacists designee shall communicate the specific biological product dispensed, including the name and manufacturer of the biological product, to the prescriber; however, the communication shall not be required if the FDA has not approved an interchangeable biological product for the biological product prescribed to~~

[2] US Code, Title 42, Section 262[i][3]
[3] "Prescribing Biosimilars and Interchangeable Products" Food and Drug Administration., October 31, 2017 https://www.fda.gov/drugs/biosimilars/prescribing-biosimilar-and-interchangeable-products

~~the patient or a refill prescription is not changed from the biological product dispensed on the most recent filling of the prescription."~~

**COMMENT:** We do not believe physician notification is necessary for these FDA-approved drugs. Large drug companies may disagree and push for post-dispensing notification, as they prefer to steer the conversation with physicians without pharmacists' input on appropriate substitution. The vast majority of our prescriptions are written by Kaiser Permanente physicians and filled at our owned and operated pharmacies. Laws aiming to protect patient safety should not needlessly create barriers to biosimilar use. With electronic prescribing, our physicians already have the capability to access pharmacy records and with a system that is safe and effective, notification is not necessary. Where pharmacies are not connected to physician offices, notification would need to occur via telephone or fax, as proposed, and we also consider that an unnecessary barrier.

If safety concerns exist regarding interchangeable biosimilars, like all drugs with FDA approval, they are already mandated to enter Phase IV post-marketing surveillance once available. Adverse reactions can be reported to MedWatch by prescribers, pharmacists and patients at any time to gather data for the FDA to determine if broader safety concerns are present.

**(3) Since we believe physician notification is unnecessary, the language in proposed lines 87-98 may be deleted:**

~~"(b)(1) Except as provided under subsection (c) of this section, the communication required under subsection (a) of this section shall be provided by making an entry that is electronically accessible to the provider through:~~

~~(A) An interoperable electronic medical records system;~~

~~(B) An electronic prescribing technology; or~~

~~(C) A pharmacy benefits management system.~~

~~(2) Making an entry through a mechanism listed in paragraph (1) of this subsection is presumed to provide the communication to the prescriber required under subsection (a) of this section.~~

~~(c) If the mechanisms listed in subsection (b)(1) of this section are unavailable, the communication required under subsection (a) of this section may be provided by facsimile, telephone, electronic transmission, or other mean.".~~

**COMMENT:** Pharmacies receive prescriptions in a variety of ways from multiple sources. Some may be through interconnectivity between physician offices and pharmacies and other methods will not support that approach. For pharmacies that can initiate communication directly from their dispensing software, not allowing for feasible methods of communication will increase the administrative burden on healthcare workers and detract from time spent providing direct patient care. As such, if this section is not deleted, we ask that the language in proposed lines 87-95 be amended to provide that:

"(b)(1) Except as provided under subsection (c) of this section, the communication required under subsection (a) of this section shall be provided by making an entry that is electronically accessible to the provider through:

(A) An interoperable electronic medical records system;

(B) An electronic prescribing technology;

(C) A pharmacy benefits management system; *or*

*(D) An electronic pharmacy record system."*

(2) Making an entry through a mechanism listed in paragraph (1) of this subsection is presumed to provide the communication to the prescriber required under subsection (a) of this section."

**(4) Please consider adding a sunset provision to notification language that may be written into legislation. That may provide a more informed opportunity to assess uncertainty regarding the perceived value of physician notification.**

For these reasons, Kaiser Permanente requests an unfavorable Committee report on the legislation as proposed. Please feel free to contact me at monet.stanford@kp.org or (301) 552-5571, if you have any questions or require additional information.

Thank you for your time and consideration.

Sincerely,

Monet Stanford, PharmD
Pharmacy Government Relations and Regulatory Affairs
Kaiser Foundation Health Plan of Mid-Atlantic States, Inc.

4000 Garden City Drive
New Carrolton, MD 20785

Biotechnology Innovation Organization

**Testimony in Support of Bill 23-0430, The "Access to Biosimilars Amendment Act of 2019"**

**November 13, 2019**

**The Biotechnology Innovation Organization (BIO)**
**Washington, DC**

Chairman Gray and distinguished members of the District of Columbia Health Committee, the Biotechnology Innovation Organization (BIO) is pleased to express our strong support for B23-0430, sponsored by Councilmember Cheh. BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology products.

BIO supports B23-0430 because it contains important provisions that take into account the special and complex characteristics of biologic medicines. Unlike traditional chemically derived medicines, biologics are made from living organisms making them effective in treating life threatening diseases and conditions such as cancer, rheumatoid arthritis and diabetes. Pharmacy substitution with these special medicines should therefore ensure patient safety by limiting substitution to biologics designated as interchangeable by the U.S. Food and Drug Administration and by establishing open communications between the pharmacy and prescriber as a way to ensure all those involved in a patient's care know exactly the course of treatment for that patient.

With the enactment of the Biologic Price Competition and Innovation Act of 2009 (BPCIA), the United States Food and Drug Administration (FDA) has authority to approve and regulate lower-cost biologic medicines known as biosimilar and interchangeable biologic products. States must therefore update current generic substitution legislation to allow for substitution of these new biologic therapies. However, given the unique and complex nature of biologics, current state generic substitution laws must be updated to address five key principles to ensure patient safety.

**BIO Principles on the Substitution of Biologic Products**

**Substitution should occur only when the FDA has designated a biologic product as interchangeable.** Only in this situation can patients and their physicians be assured that all

reasonable efforts have been undertaken to assess the possible adverse effects on a patient, in terms of diminished safety or effectiveness, when one biologic product is substituted for another. In these cases, the FDA will have more thoroughly evaluated the possibility for immunogenic reactions, side effects, and other safety or efficacy differences to help ensure that a patient will react favorably to a given treatment if there is a substitution of an interchangeable biologic for an innovator product, or vice versa.

**The prescribing physician should be able to prevent substitution.** The prescribing physician is in the best position to evaluate a patient's treatment history and options, and thus it is important for the treating physician to be able to designate exactly which product he/she believes should be dispensed to the patient. Product determinations should include a patient's values and preferences following informed discussion of the interchangeable biologic product's risks, benefits, and uncertainties. By permitting prescription pads to contain the phrase "dispense as written," or "brand medically necessary," the physician can control the delivery of biologic products at the outset and be better able to manage potential patient side effects.

**The pharmacist dispensing the interchangeable biologic product must communicate with the prescribing physician concerning the substitution.** Even though interchangeable biologics are safe and expected to produce the same clinical result, it remains the case that patients could react differently to an interchangeable biologic than if they were given the innovator product. This is due to the complex nature of biologic products and how they work in the human body. In these circumstances, the treating physician must know that the products were substituted at the point of dispensing in order to appropriately assess a patient's experience and further treatment options. Moreover, it is in the interest of public health to be advised of which biologic is being administered as it will facilitate attribution to the proper product for adverse event reporting.

**The patient, or the patient's authorized representative, should, at a minimum, be notified of the substitution.** Often times patients managing chronic medical conditions have tried multiple treatment regimens with their physician to get to a point of comfortably managing the condition while minimizing side effects to the greatest extent possible. In these cases, patients are generally aware of which treatments work best in their unique circumstances. Providing notice to the patient, or in some cases – depending upon current state law – requiring patient consent, of the intent to switch gives that patient the opportunity to discuss with the pharmacist or physician past treatment experiences so that any potential future problems can be avoided.

**The pharmacist and the physician should keep records of the substitution.** Because many biologic medicines are used to treat chronic conditions that can change over time, it is important for a patient's treatment team to have records that document how and when a patient was treated with biologic therapies. These records will also provide insight down the road should an adverse reaction or disease evolution occur.

All of the aforementioned principles can be found in B23-0430. For these reasons, we strongly support and urge the committee to move forward with the legislation on behalf of BIO and our member companies. Thank you Chairman Gray and members of the Health Committee for this opportunity to express our support for B23-0430. If you have any questions please contact me at agochenaur@bio.org or 202-870-9747.

Respectfully Submitted,

Angela Gochenaur

Director, State Government Affairs - Eastern Region

The Biotechnology Innovation Organization (BIO)
1201 Maryland Ave., SW
Suite 900
Washington, DC 20024

**Medical Society of the District of Columbia**

**Testimony Before**

**The Committee on Health**

**On The**

**Access to Biosimilars Amendment Act of 2019**

**Bill 23-0430**

**Angus Worthing, M.D.**

**Member, MSDC**

**November 13, 2019**

**12:00 P.M.**

# Access to Biosimilars Amendment Act of 2019

## Bill 23-0430

Good afternoon Chairman Gray and members of the Committee. My name is Angus Worthing, and I am grateful for the opportunity to testify on behalf of the Medical Society of the District of Columbia in favor of Bill 23-430, the Access to Biosimilars Amendment Act of 2019.

I have been practicing medicine in the District of Columbia since 2003 and I am a resident of Ward 3. In addition to my rheumatology practice in downtown DC, I am a Clinical Assistant Professor of Medicine at Georgetown University Medical School. Briefly, my background in this topic includes treating patients with biologic drugs including biosimilars, publishing a white paper on biosimilars on behalf of my specialty society, the American College of Rheumatology, and speaking about biosimilars at Food and Drug Administration public meetings while previously serving as chair of the ACR's Government Affairs Committee.

As written, this legislation sets up an effective process to 1) authorize licensed pharmacists to dispense and substitute interchangeable biological products, and 2) require pharmacists to notify prescribers when interchangeable biological products are dispensed through substitution. The MSDC strongly supports the bill and commends Councilmember Cheh and her 7 colleagues for introducing it.

B23-430 will be an effective way to lower drug prices in the District, and this is the right time to enact it. Biologic drugs represent only 2% of all US prescriptions but 37% of net drug spending, and in the past several years, biologics accounted for over 90% of growth in US drug spend. [1] High drug prices reduce my patients' access to effective treatments because their copayments are often based on the drug price. In my clinic, when a patient with rheumatoid arthritis can't afford their biologic medication, they lose access to breakthrough treatments that not only relieve joint pain but also reduce the risk of joint damage, joint

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[1] Roy, A. Biologic Medicines: The Biggest Driver Of Rising Drug Prices. Forbes. Mar 8, 2019

replacement surgery, disability, other problems like health heart attacks and a shortened lifespan. Even worse, if they start taking a biologic medication and their symptoms improve, but then their out of pocket costs rise and they stop taking their biologic for a period of time, there is a risk that if and when they restart the medication their immune system may react to the drug, making it ineffective or cause an allergic reaction. Biologic drugs are used in many other diseases like cancer, multiple sclerosis, lupus, Crohn's Disease, ulcerative colitis, and skin psoriasis. In my view, biosimilars represent the most feasible, medically-acceptable way to lower biologic drug prices. Since pharmacists dispense many biologics, authorizing pharmacists to substitute and dispense interchangeable biosimilars will improve patients' access to these medicines, while also helping lower the cost of this class of drugs.

The provision in B23-430 that requires pharmacists to notify physicians about substitution is important because it will allow doctors to monitor patients for changes in their disease activity or side effects after the substitution. When one of my patients starts taking a biosimilar, I need to know so that I can effectively take care of them, and if needed, report safety events to the FDA about drugs coming out of this new FDA approval pathway. The time frame for notification within 5 days is reasonable from a medical standpoint based on the dosing frequency of biologics, and it is in line with legislation enacted by 49 states.

The Medical Society encourages the Council to pass this legislation in this session. The FDA finalized the approval pathway for medications to be evaluated for interchangeability just this spring, and at least 1 clinical trial testing a drug for interchangeability is already underway. So, biosimilars will likely gain interchangeability designation soon, and this legislation will provide the necessary framework for residents of the District to obtain lower-cost options for the life-changing treatments that they need.

As a physician, it is a privilege to be here today and be able to advocate on behalf of my patients and the thousands of individuals likewise situated. I look forward to your questions. Thank you.

**Government of the District of Columbia**
**Department of Health**

**Public Hearing on**

**B23-0430, the "Access to Biosimilars Amendment Act of 2019"**

**Testimony of**

**Shauna White, PharmD, RPH, MS**
**Executive Director**
**District of Columbia Board of Pharmacy**

**Before the**

**Committee on Health**
**Council of the District of Columbia**
**The Honorable Vincent C. Gray, Chairperson**

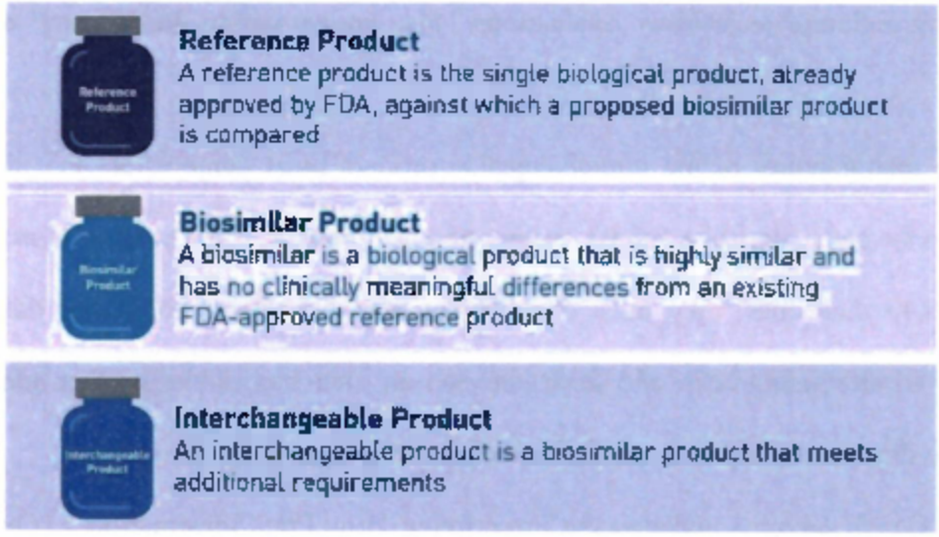
November 13, 2019
12:00 PM
Room 412
The John A. Wilson Building
1350 Pennsylvania Avenue, NW

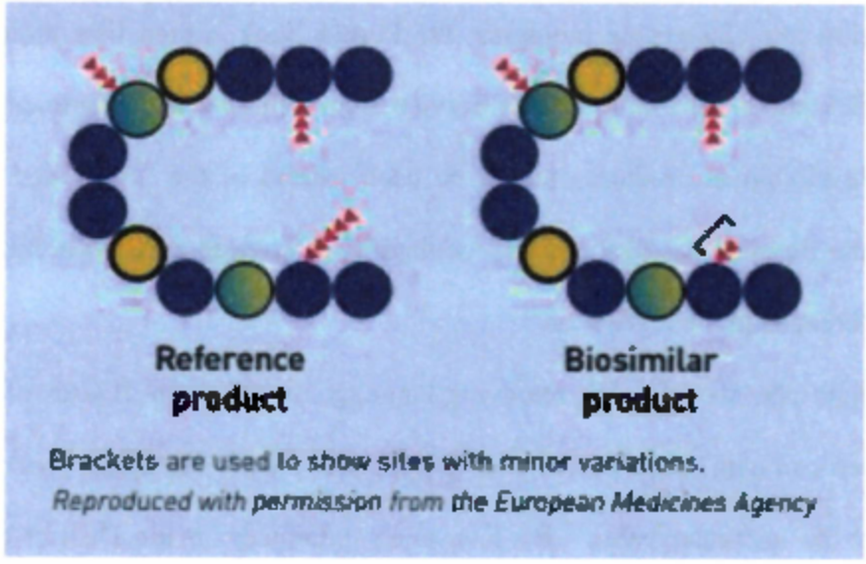
Good afternoon, Chairman Gray, members of the Committee on Health, residents, and advocates. I am Dr. Shauna White, Executive Director of the District of Columbia Board of Pharmacy. On behalf of Dr. LaQuandra S. Nesbitt, Director of the District of Columbia Department of Health (DC Health), I am pleased to provide testimony on Bill 23-430, the "Access to Biosimilars Amendment Act of 2019."

The proposed legislation calls for the amendment of the Prescription Drug Price Information Act to allow pharmacists to dispense interchangeable biological products and to require notifications to physicians when interchangeable biological products are dispensed to patients. The bill also requires the Board of Pharmacy and the Board of Medicine to maintain a link on their website of a current list of biological products determined to be interchangeable with a specific biological product.

A biosimilar is defined as a biological product that is highly similar to and has no clinically meaningful difference from an existing United States Food and Drug Administration (FDA) approved biologic, known as a "reference product."

A biologic that is highly similar to its reference product may have small variations in chemical structure and function, but in order to be approved by the FDA, these small variations must not have any clinically meaningful differences in purity, safety, and potency. Currently, there are 24 biosimilars approved by FDA.




Biosimilars can meet additional requirements, as outlined in the Biologics Price Competition and Innovation Act, to be considered an "interchangeable product." An interchangeable product must be therapeutically equivalent, as indicated in the latest edition of the FDA's "Lists of Licensed Biological Products with Reference Product Exclusivity and

Biosimilarity or Interchangeability Evaluations," also known within the industry as the "Purple Book."

The manufacturer of the interchangeable product must demonstrate that the biosimilar can produce the same clinical response as the reference product. If the product is administered to a patient more than once, they must demonstrate that there is no additional risk or reduced efficacy when alternating back and forth between an interchangeable product and a reference product. To date, the FDA has not approved any interchangeable products.

DC Health supports updating the Prescription Drug Price Information Act by adding "or interchangeable biological product" in places after the word "generic equivalent." However, when referencing interchangeable biologics, the Purple Book, which lists biological products licensed by FDA under the Public Health Service Act, including any approved biosimilar and interchangeable biological products, should be used instead of the "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly referred to as the "Orange Book", which is currently referenced in the legislation.

DC Health also recommends removing language requiring the Boards of Pharmacy and Medicine to maintain a link on their websites to the current list of biological products determined by the FDA to be interchangeable. By law, every pharmacy in the District of Columbia is required to maintain current drug references. DC Health recommends that the Board of Pharmacy and the Board of Medicine maintain direct links to the FDA on their respective websites. This will facilitate access to the primary source for drug references for biologics, biosimilars, and interchangeable products. Additionally, DC Health recommends removing the requirement to notify a physician when a biosimilar is dispensed to a patient. We believe a more straightforward and streamlined approach would be for prescribers to indicate if substitution is

permitted on the prescription or indicate the specific biologic, biosimilar, or interchangeable product they deem to be appropriate for their patient. This process would serve as a safeguard in ensuring that the medical practitioner and pharmacist are of one accord. If a substitution is made in accordance with the directions on the prescription, this information would be accessible through one of the following:

- an interoperable electronic medical record,
- an electronic prescribing technology,
- a pharmacist benefits managing system, or
- the patient's pharmacy record,

The FDA's high standard for approval of biosimilars means that patients and health care providers can have confidence in the safety and effectiveness of a biosimilar product. DC Health appreciates Council's proactive efforts and looks forward to working with the Mayor and Council in continuing to promote safe, cost-effective alternatives to District residents.

This concludes my testimony. I am happy to respond to any questions you may have at this time.

# ATTACHMENT E

Government of the District of Columbia
Office of the Chief Financial Officer

**Jeffrey S. DeWitt**
Chief Financial Officer

**MEMORANDUM**

| | |
|---|---|
| **TO:** | **The Honorable Phil Mendelson**<br>**Chairman, Council of the District of Columbia** |
| **FROM:** | **Jeffrey S. DeWitt**<br>**Chief Financial Officer** |
| **DATE:** | **February 24, 2020** |
| **SUBJECT:** | **Fiscal Impact Statement – Access to Biosimilars Amendment Act of 2020** |
| **REFERENCE:** | **Bill 23-430, Committee Print as provided to the Office of Revenue Analysis on February 14, 2020** |

## Conclusion

Funds are sufficient in the fiscal year 2020 through fiscal year 2023 budget and financial plan to implement the bill.

## Background

The bill allows[1] pharmacists in the District of Columbia to dispense interchangeable biological products. Biological products are viruses, therapeutic serums, toxins, antitoxins, vaccines, blood, blood component or derivatives, allergenic products, proteins, or arsphenamine or derivative of arsphenamine that are applicable to the prevention, treatment, or cure of a disease. Interchangeable biologics are biologics that can be substituted for one another without any clinically meaningful difference.

The bill also requires pharmacists, or their designee, to electronically notify[2] prescribers when an interchangeable biological product is dispensed to a patient. The notification must occur within five days after the biologic is dispensed and must include the name and manufacturer of the biological

[1] By amending The District of Columbia Prescription Drug Price Information Act, effective September 10, 1976 (D.C. Law 1-81; D.C. Official Code § 48-801.01 et seq.).
[2] Using an interoperable electronic medical records system; an electronic prescribing technology; a pharmacy benefits management system; or an electronic pharmacy record system.

product. If a pharmacist is unable to notify a prescriber electronically, they may provide notification via, fax, telephone, or other means.

**Financial Plan Impact**

Funds are sufficient in the fiscal year 2020 through fiscal year 2023 budget and financial plan to implement the bill. The Department of Health can implement the bill without additional resources. The Board of Pharmacy already enforces rules and regulation with regards to the practice of pharmacy in the District of Columbia, including the dispensing of biologics.

# ATTACHMENT F

OFFICE OF THE GENERAL COUNSEL
Council of the District of Columbia
1350 Pennsylvania Avenue NW, Suite 4
Washington, DC 20004
(202) 724-8026

**MEMORANDUM**

**TO:** **Councilmember Vincent C. Gray**

**FROM:** **Nicole L. Streeter, General Counsel** *NLS*

**DATE:** **June 20, 2020**

**RE:** **Legal sufficiency determination for Bill 23-430, the Access to Biosimilars Amendment Act of 2020**

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The measure is legally and technically sufficient for Council consideration.

The legislation amends the District of Columbia Prescription Drug Price Information Act[1] to authorize a licensed pharmacist to dispense interchangeable biological products[2] and requires the pharmacist to notify the prescribing physician when this is done.

I am available if you have any questions.

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[1] Effective September 10, 1976 (D.C. Law 1-81; D.C. Official Code § 48-801.01 *et seq.*).

[2] "Interchangeable biological product" means a biological product that is: "(A) Licensed and determined by the United States Food and Drug Administration to meet the standards for interchangeability under 42 U.S.C. § 262(k)(4); or "(B) Determined to be biosimilar or interchangeable with a reference biological product as stated in the latest edition of or supplement to the United States and Food and Drug administration's ("FDA") publication, "Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations.

# ATTACHMENT G

**Bill 23-0430**
**COMPARATIVE PRINT**
**COMMITTEE ON HEALTH**

**§ 48–804.51. Definitions**

(1A) "Biological product" shall have the same meaning as provided in 42 U.S.C. § 262.

(2A) "Interchangeable biological product" means a biological product that is:

(A) Licensed and determined by the United States Food and Drug Administration to meet the standards for interchangeability under 42 U.S.C. § 262(k)(4); or

(B) Determined to be biosimilar or interchangeable with a reference biological product as stated in the latest edition of or supplement to the United States and Food and Drug administration's ("FDA") publication, "Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations" (known as the Purple Book.)

**§ 48-803.01 Generically equivalent drug formulary; therapeutic interchange list.**

**(a)** The formulary of generically equivalent drug products for the District of Columbia shall be the chemical and generic drugs contained in the Food and Drug Administration publication, "Approved Drug Products with Therapeutic Equivalence Evaluations," including all updates issued by the Food and Drug Administration ("Orange Book").
**(b)** The Boards of Pharmacy and Medicine may jointly establish a therapeutic interchange list.
**(c)** If a therapeutic interchange list is established pursuant to subsection (b) of this section:
**(1)** The Boards of Pharmacy and Medicine shall:
**(A)** Revise or supplement the therapeutic interchange list as necessary;
**(B)** Establish procedures to allow a prescriber to consent to the substitution of therapeutically equivalent drug products without prior approval based on the therapeutic interchange list; provided, that a prescriber be allowed to limit authorization to specific conditions or patients and that no prescriber be required for any reason to consent to participation in the therapeutic interchange list; and
**(C)** Establish and maintain a database, searchable in real time, of those prescribers who have consented to use of the therapeutic interchange list, including any restrictions based on specific conditions or patients; and
**(2)** The Department of Health shall distribute the therapeutic interchange list to all pharmacies licensed in the District and shall publish it regularly in the District of Columbia Register.

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(d) The Boards of Pharmacy and Medicine shall maintain a link on their websites to the current list of biological products determined by the FDA to be interchangeable with a specific biological product."

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**D.C. Official Code § 48–803.02~~. Dispensing of generically equivalent drug products.~~ Dispensing of generically equivalent drug product or interchangeable biological product.".**

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**(a)(1)** When a pharmacist receives a prescription for a brand name drug, the pharmacist may dispense ~~a generically equivalent drug product~~ generically equivalent drug product or interchangeable biological product that is listed in the Orange Book; provided, that the pharmacist shall dispense a generically equivalent drug product or interchangeable biological product ~~generically equivalent drug product~~ if requested by the purchaser, except as provided in § 48-803.03.

**(2)** If a generic substitution is made pursuant to this subsection, the pharmacist shall dispense the ~~generically equivalent drug product~~ generically equivalent drug product or interchangeable biological product ~~-~~in stock having the lowest cost to the person purchasing the drug product.

**(b)** When a pharmacist receives a prescription for a ~~drug by generic name~~ drug by generic name or interchangeable biological product, the pharmacist shall dispense the listed product in stock that has the lowest cost to the person purchasing the drug product.

**(c)** Repealed.

**D.C. Official Code § 48-803.03(2). Dispensing of substitute drug products — conditions.**

**(2)** ~~Generically equivalent drug product~~ Generically equivalent drug product or interchangeable biological product pursuant to § 48-803.02 if:

**(A)** The prescriber writes on a prescription order, signed by the prescriber, in the prescriber's own handwriting "dispense as written" or "D.A.W." or a similar notation; provided, that checking or initialing a box preprinted or stamped on a prescription form shall not constitute an acceptable notation; or

**(B)** The prescriber, by telephone, expressly indicates that the prescription is to be dispensed as communicated and this indication is noted in the pharmacist's own handwriting in the manner provided in subparagraph (A) of this paragraph;

**D.C. Official Code § 48–803.03a. Dispensing of substitute drug products by pharmacists — notification of substitution.**

**(a)** An individual shall be notified of a ~~drug substitution~~ drug substitution, including an interchangeable biological product and provided the right to refuse the substitution prior to purchase of the substitute drug product.

**D.C. Official Code § 48–803.04. Dispensation of equivalent products by pharmacists — Recording and labeling required.**

When a drug is ~~substituted under this subchapter~~ substituted under this title, including the substitution of an interchangeable biological product, the pharmacist shall record on the prescription form the drug substituted by name and manufacturer, and retain the form for inspection by District officials. The pharmacist shall also label the prescription container with the name of the drug substituted, unless the prescribing physician writes "do not label," or words of similar import, on the prescription, or, in communicating the prescription by telephone, orders that the container not be so labelled.

**D.C. Official Code § 48–803.05. Dispensation of equivalent products by pharmacists — Consideration as practice of medicine or evidence of negligence; failure of physician to specify specific brand.**

**(a)** The substitution of drugs by a licensed pharmacist ~~under this subchapter~~ under this title, including the substitution of an interchangeable biological product shall not constitute the practice of medicine. Nothing in this subchapter shall be construed as authorizing a pharmacist to prescribe any drug or medication.
**(b)** Substitution of drugs made in accordance with § 48-803.02 shall not constitute evidence of negligence or improper pharmacy practice if the substitution was made within reasonable and prudent pharmacy practice or if the prescribed and substituted drugs were ~~generically equivalent drug products drugs [sic]~~ generically equivalent drugs products or an interchangeable biological product as determined under this chapter.

**The District of Columbia Prescription Drug Price Information Act**

Sec. 306. Pharmacist notification to prescriber of substitution of interchangeable biological product.

(a) Within 5 business days after dispensing a biological product to a patient, the dispensing pharmacist or the pharmacist's designee shall communicate to the prescriber the specific biological product dispensed, including the name and manufacturer of the biological product; except, that this communication shall not be required if the FDA has not approved an interchangeable biological product for the biological product prescribed to the patient or a refill prescription is not changed from the biological product dispensed on the most recent filling of the prescription.

(b)(1) Except as provided under subsection (c) of this section, the communication required under subsection (a) of this section shall be provided by making an entry that is electronically accessible to the health care provider through:

(A) An interoperable electronic medical records system;

(B) An electronic prescribing technology; or

(C) A pharmacy benefits management system.

(2) Making an entry through a mechanism listed in paragraph (1) of this subsection is presumed to provide the communication to the prescriber required under subsection (a) of this section.

(c) If the mechanisms listed in subsection (b)(1) of this section are unavailable, the communication required under subsection (a) of this section may be provided by facsimile, telephone, electronic transmission, or other means.

(d) The requirements under subsections (a) through (c) above shall not apply to dispensing pharmacists or their designees at a health maintenance organization that operates as a group model for services furnished through internal pharmacy operations for members and patients of the health maintenance organization.

# ATTACHMENT H

**Committee Print**
**Bill 23-430, Access to Biosimilars Amendment Act of 2020**
**Committee on Health**
**July 1, 2020**

A BILL

_____

IN THE COUNCIL OF THE DISTRICT OF COLUMBIA

_____

To amend the District of Columbia Prescription Drug Price Information Act to authorize licensed pharmacists to dispense interchangeable biological products, and to require notifications to physicians when interchangeable biological products are dispensed with certain exceptions.

BE IT ENACTED BY THE COUNCIL OF THE DISTRICT OF COLUMBIA, That this act may be cited as the "Access to Biosimilars Amendment Act of 2020".

Sec. 2. The District of Columbia Prescription Drug Price Information Act, effective September 10, 1976 (D.C. Law 1-81; D.C. Official Code § 48-801.01 *et seq.*), is amended as follows:

(a) Section 2 (D.C. Official Code § 48-804.51) is amended by adding new paragraphs (1A) and (2A) to read as follows:

"(1A) "Biological product" shall have the same meaning as provided in 42 U.S.C. § 262.

"(2A) "Interchangeable biological product" means a biological product that is:

"(A) Licensed and determined by the United States Food and Drug Administration to meet the standards for interchangeability under 42 U.S.C. § 262(k)(4); or

"(B) Determined to be biosimilar or interchangeable with a reference biological product as stated in the latest edition of or supplement to the United States and Food and Drug administration's ("FDA") publication, "Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations" (known as the Purple Book)."

(b) Section 301 (D.C. Official Code § 48-803.01) is amended by adding a new subsection (d) to read as follows:

"(d) The Boards of Pharmacy and Medicine shall maintain a link on their websites to the current list of biological products determined by the FDA to be interchangeable with a specific biological product.".

(c) Section 302 (D.C. Official Code § 48-803.02) is amended as follows:

(1) The section heading is amended to read as follows:

"Sec. 302. Dispensing of generically equivalent drug product or interchangeable biological product.".

(2) Subsection (a) is amended by striking the phrase "generically equivalent drug product" wherever it appears and inserting the phrase "generically equivalent drug product or interchangeable biological product" in its place.

(3) Subsection (b) is amended by striking the phrase "drug by generic name" and inserting the phrase "drug by generic name or interchangeable biological product" in its place.

(d) Section 303(2) (D.C. Official Code § 48-803.03(2)) is amended by striking the phrase "generically equivalent drug product" and inserting the phrase "generically equivalent drug product or interchangeable biological product" in its place.

(e) Section 303a(a) (D.C. Official Code § 48-803.03a(a)) is amended by striking the phrase “drug substitution” and inserting the phrase “drug substitution, including an interchangeable biological product,” in its place.

(f) Section 304 (D.C. Official Code § 48-803.04) is amended by striking the phrase “substituted under this title,” and inserting the phrase “substituted under this title, including the substitution of an interchangeable biological product,” in its place.

(g) Section 305 (D.C. Official Code § 48-803.05) is amended as follows:

(1) Subsection (a) is amended by striking the phrase “under this title” and inserting the phrase “under this title, including the substitution of an interchangeable biological product” in its place.

(2) Subsection (b) is amended by striking the phrase “generically equivalent drug products drugs” and inserting the phrase “generically equivalent drugs products or an interchangeable biological product” in its place.

(h) A new section 306 is added to read as follows:

“Sec. 306. Pharmacist notification to prescriber of substitution of interchangeable biological product.

“(a) Within 5 business days after dispensing a biological product to a patient, the dispensing pharmacist or the pharmacist’s designee shall communicate to the prescriber the specific biological product dispensed, including the name and manufacturer of the biological product; except, that this communication shall not be required if the FDA has not approved an interchangeable biological product for the biological product prescribed to the patient or a refill prescription is not changed from the biological product dispensed on the most recent filling of the prescription.

"(b)(1) Except as provided under subsection (c) of this section, the communication required under subsection (a) of this section shall be provided by making an entry that is electronically accessible to the health care provider through:

"(A) An interoperable electronic medical records system;

"(B) An electronic prescribing technology; or

"(C) A pharmacy benefits management system.

"(2) Making an entry through a mechanism listed in paragraph (1) of this subsection is presumed to provide the communication to the prescriber required under subsection (a) of this section.

"(c) If the mechanisms listed in subsection (b)(1) of this section are unavailable, the communication required under subsection (a) of this section may be provided by facsimile, telephone, electronic transmission, or other means.

"(d) The requirements under subsections (a) through (c) above shall not apply to dispensing pharmacists or their designees at a health maintenance organization that operates as a group model for services furnished through internal pharmacy operations for members and patients of the health maintenance organization.".

Sec. 3. Fiscal impact statement.

The Council adopts the fiscal impact statement in the committee report as the fiscal impact statement required by section 4a of the General Legislative Procedures Act of 1975, approved October 16, 2006 (120 Stat. 2038; D.C. Official Code § 1-301.47a).

Sec. 4. Effective date.

This act shall take effect following approval by the Mayor (or in the event of veto by the

Mayor, action by the Council to override the veto), a 30-day period of congressional review as provided in section 602(c)(l) of the District of Columbia Home Rule Act, approved December 24, 1973 (87 Stat. 813; D.C. Official Code § 1-206.02(c)(l)), and publication in the District of Columbia Register.