HOUSE DOCKET, NO. 3790 FILED ON: 7/17/2013

HOUSE . . . . . No. 3667

The Commonwealth of Massachusetts

PRESENTED BY:

Mark J. Cusack

To the Honorable Senate and House of Representatives of the Commonwealth of Massachusetts in General Court assembled:

The undersigned legislators and/or citizens respectfully petition for the passage of the accompanying:

An Act relative to the substitution of interchangeable biosimilars.

PETITION OF:

NAME:	DISTRICT/ADDRESS:
Mark J. Cusack	*5th Norfolk*
Steven M. Walsh	*11th Essex*
Jennifer E. Benson	*37th Middlesex*

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By Mr. Cusack of Braintree, a petition (subject to Joint Rule 12) of Mark J. Cusack, Steven M. Walsh and Jennifer E. Benson relative to the substitution of interchangeable biosimilars. Health Care Financing.

The Commonwealth of Massachusetts

In the Year Two Thousand Thirteen

An Act relative to the substitution of interchangeable biosimilars.

Be it enacted by the Senate and House of Representatives in General Court assembled, and by the authority of the same, as follows:

Chapter 112 of the General Laws is here by amended by inserting after Section 12DD the following new Section:

Section 12D ½ . Biosimilar products.

(a). As used in this section, the following words shall have the following meanings:

"Biological product", means a virus, therapeutic serum, toxin, antitoxin, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide), or analogous product, 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

"Biosimilar" or "Biosimilarity‘', in reference to a biological product that is the subject of an application under subsection (k) of 42 U.S.C. 262,

"Department", the department of public health.

"Interchangeable biological product", a prescription biological product that has been determined by the United States Food and Drug Administration to be interchangeable with the

prescribed brand name biological product pursuant to Section 351 of the Public Health Service Act (42 U.S.C. 262).

"Practitioner", a physician, dentist, veterinarian, podiatrist, scientific investigator or other person registered to distribute, dispense, conduct research with respect to, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research in the commonwealth.

"Prescription", with respect to a biological product, means an order for a product that is subject to Section 503(b) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 353(b)).

(b). A biosimilar product determined to be interchangeable by the United States Food and Drug Administration (FDA) shall be available for substitution in the Commonwealth, in accordance with the provisions of this Act, Chapter 94 of the General Laws and any other applicable laws.

(c). Except as provided in subsection (d), a pharmacist filling a prescription for a biological product prescribed by its trade or brand name may substitute any biosimilar product that the FDA has determined to be interchangeable with the prescribed product.

(d). The pharmacist shall not substitute a biosimilar product that is interchangeable with the prescribed product if the prescriber instructs otherwise, either orally or in writing, pursuant to this section. Such instruction shall be on a patient-specific basis.

(e). No additional restrictions, limitations or requirements shall be imposed related to biological product substitution unless such restrictions, limitations or requirements also apply in the case of all other drug product substitution

(f). Within a reasonable time following the substitution, the dispensing pharmacist or the pharmacist's designee shall notify the prescribing practitioner of the substitution. Said notification shall not be required until full interoperability of electronic health records systems is reached, pursuant to section 7 of chapter 118I as inserted by section 134 of chapter 224 of the

acts of 2012. Entry of the substitution in the patient's electronic health record shall constitute notification

(g). Within a reasonable time following the substitution, the dispensing pharmacist or the pharmacist's designee shall notify the patient, or the patients authorized representative, of the substitution. Such notification may be written or oral and may be conveyed by telephone, facsimile, electronic transmission, a notation in the patients record system shared with the prescriber, or other means consistent with prevailing pharmacy practice in accordance with section 12D of Chapter 112 of Massachusetts General Law

(h). Upon full interoperability of electronic health records systems, pursuant to section 7 of chapter 118I as inserted by section 134 of Chapter 224 of the Acts of 2012, the dispensing pharmacist, the prescribing provider and administering practitioner shall retain a record for no less than one year from the date of the last entry in the profile record, of any interchangeable biological product dispensed on the patient's electronic health record. Entry in the electronic health record shall constitute retention of record. Nothing in this subsection shall limit the application of the Professional Standards for Registered Pharmacists, Pharmacies and Pharmacy Departments as promulgated by the board of registration in pharmacy.