HOUSE DOCKET, NO. 1838 FILED ON: 1/17/2013

HOUSE . . . . . No. 1927

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 bill:

An Act relative to the substitution of interchangeable biosimilars.

PETITION OF:

NAME:	DISTRICT/ADDRESS:
Mark J. Cusack	*5th Norfolk*

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HOUSE . . . . . No. 1927

By Mr. Cusack of Braintree, a petition (accompanied by bill, House, No. 1927) of Mark J. Cusack relative to the substitution of interchangeable biosimilars. Public Health.

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 hereby amended by inserting after Section 12DD the following new Section:

Section 12EE. Biosimilar products.

Subsection (a). For the purposes of this Section:

"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, means:

(A) that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components; and

(B) 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.

“Interchangeable” or “Interchangeability', in reference to a biological product that is shown to meet the standards described in subsection (k)(4) of 42 U.S.C. 262, means that the biological product may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product.

“Reference product” means the single biological product licensed under subsection (a) against which a biological product is evaluated in an application submitted under subsection (k) of 42 U.S.C. 262.

“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)).

Subsection (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.

Subsection (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.

Subsection (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 Chapter. Such instruction shall be on a patient-specific basis.

Subsection (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.