SENATE DOCKET, NO. 1945 FILED ON: 11/25/2013

SENATE . . . . . No. 1965

The Commonwealth of Massachusetts

PRESENTED BY:

John F. Keenan

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 to reduce prescription drug tampering and abuse.

PETITION OF:

NAME:	DISTRICT/ADDRESS:
John F. Keenan	*Norfolk and Plymouth*
Jennifer L. Flanagan	*Worcester and Middlesex*
Elizabeth A. Malia	*11th Suffolk*
Bruce E. Tarr	*First Essex and Middlesex*
James B. Eldridge	*Middlesex and Worcester*
Carolyn C. Dykema	*8th Middlesex*
William Smitty Pignatelli	*4th Berkshire*
Daniel A. Wolf	*Cape and Islands*
Richard T. Moore	*Worcester and Norfolk*
Randy Hunt	*5th Barnstable*
Benjamin B. Downing	*Berkshire, Hampshire, Franklin and Hampden*
Linda Dorcena Forry	*First Suffolk*
Katherine M. Clark	*Fifth Middlesex*
Diana DiZoglio	*14th Essex*
Walter F. Timilty	*7th Norfolk*
William C. Galvin	*6th Norfolk*
James J. O'Day	*14th Worcester*

Nick Collins	*4th Suffolk*
Gale D. Candaras	*First Hampden and Hampshire*
Colleen M. Garry	*36th Middlesex*
Kenneth J. Donnelly	*Fourth Middlesex*
James M. Cantwell	*4th Plymouth*
Geoff Diehl	*7th Plymouth*
Brian M. Ashe	*2nd Hampden*
Claire D. Cronin	*11th Plymouth*
Carole Fiola	*6th Bristol*

SENATE DOCKET, NO. 1945 FILED ON: 11/25/2013

SENATE . . . . . No. 1965

By Mr. Keenan, a petition (subject to Joint Rule 12) of John F. Keenan, Jennifer L. Flanagan, Elizabeth A. Malia, Bruce E. Tarr and other members of the General Court for legislation to reduce prescription drug tampering and abuse. Mental Health and Substance Abuse.

The Commonwealth of Massachusetts

In the Year Two Thousand Thirteen

An Act to reduce prescription drug tampering and abuse.

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

SECTION 1. Section 13 of Chapter 17 of the General Laws, as appearing in the 2012 Official Edition, is hereby amended by inserting after the third paragraph the following 2 new paragraphs:-

"The commission shall also prepare a drug formulary of tamper resistant interchangeable opioid drug products, which shall be adopted by regulations of the department, and which shall list commercially available tamper resistant products that serve as equivalent alternatives to non-tamper resistant opioid products. Said formulary shall include formulations of opioid drugs of schedules II through V that are pharmaceutically and therapeutically equivalent and interchangeable, and that also incorporate tamper-resistant technology satisfying at least two of the following qualities:

(i) Physical and chemical barriers that can prevent chewing, crushing, cutting, grating, grinding, melting or other physical manipulations that enable abuse, and resist extraction of the opioid by common solvents such as water, alcohol or other organic solvents;

(ii) Agonist/antagonist combinations that interfere with, reduce or defeat the euphoria associated with abuse;

(iii) Aversion qualities that produce an unpleasant effect if the dosage form is manipulated or altered;

(iv) Delivery systems that, pursuant to United States Food and Drug Administration guidance, offer resistance to abuse;

(v) Prodrug techniques that limit opioid activity until transformed in the gastrointestinal tract; or

(vi) Other techniques as may be identified or recommended by the Food and Drug Administration that offer significant abuse deterrence.

In preparing a formulary of tamper resistant interchangeable opioid drug products, the commission shall consider information contained in drug applications approved by the United States Food and Drug Administration, and other regulatory and guidance documents distributed by said administration; provided further, that the commission may exclude any drug product that incorporates tamper-resistant technology if the commission deems said technology to be ineffective against or inconsistent with common forms of abuse of the drug product; and provided further, that a determination of interchangeability between two drug products shall not require that both products incorporate the same methods of tamper-resistance. Inclusion of a drug on this formulary shall not be construed to authorize labeling or marketing claims of abuse deterrence potential, unless such claims are authorized by the Food and Drug Administration."

SECTION 2. Said section 13 is hereby further amended by striking from lines 29, 34, and 39 the word "formulary" and inserting in place thereof, in each instance, the word:- "formularies"

SECTION 3. Section 18 of Chapter 94C of the General Laws, as appearing in the 2012 Official Edition, is hereby amended by inserting after subsection (e) the following new subsection:-

"(f) A prescription shall not be issued or filled for any opioid product or substance contained in schedule II or III that is formulated as a non-tamper resistant opioid drug, as defined in section 12D of chapter 112 of the General Laws, unless the drug formulary commission has determined, pursuant to section 13 of chapter 17 of the General Laws, that no tamper resistant interchangeable opioid drug product is available as a substitute for the indicated product or substance."

SECTION 4. Section 12D of Chapter 112 of the General Laws, as appearing in the 2012 Official Edition, is hereby amended by inserting after the definition of "Practitioner" the following two new definitions:-

"Non-tamper resistant opioid drug", any opioid drug product that is approved for medical use but that does not meet the requirements for listing as a tamper resistant interchangeable opioid drug product.

"Tamper resistant interchangeable opioid drug product", an opioid drug that is rated by the U.S. Food and Drug Administration as pharmaceutically and therapeutically equivalent to the prescribed product or substance, and that also incorporates tamper-resistant technology and has

been identified as such by the drug formulary commission in accordance with section 13 of chapter 17 of the General Laws."

SECTION 5. Said section 12D is hereby further amended by inserting after the word "practitioner" in line 32 the following new paragraph:-

"Notwithstanding the substitution requirements of this section, or any brand name or "no substitution" indication by the practitioner, the pharmacist shall not, in any case, dispense an opioid drug of schedule II or schedule III that is formulated as a non-tamper resistant opioid drug product, unless the drug formulary commission has determined that no tamper resistant interchangeable opioid drug product is available as a substitute for the indicated product or substance.

SECTION 6. Chapter 176O of the General Laws, as appearing in the 2012 Official Edition, is hereby amended by inserting after Section 16 the following new section:

Section 16A. A carrier may not exclude or deny reimbursement for tamper resistant opioid drug products dispensed in accordance with section 12D of chapter 112 of the General Laws solely due to the cost of said tamper resistant products; provided however that this section shall not be construed to prohibit a carrier from applying prior authorization requirements and utilization reviews for opioid drug products when such measures, and any service denials made pursuant thereto, are established in consideration of a drug's potential for abuse and addiction and are applied equally to tamper resistant and non-tamper resistant products.