



Paul R. LePage
Governor

STATE OF MAINE
DEPARTMENT OF PROFESSIONAL
AND FINANCIAL REGULATION
OFFICE OF PROFESSIONAL AND OCCUPATIONAL REGULATION
MAINE BOARD OF PHARMACY
35 STATE HOUSE STATION
AUGUSTA, MAINE
04333-0035

Anne L. Head, Esq.
Commissioner

Geraldine L. Betts
Administrator

November 12, 2013

Hon. Paul R. LePage, Governor
Office of the Governor
1 State House Station
Augusta, ME 04333-0001

Re: P.L. 2013, ch. 373

Dear Governor LePage:

The Maine Board of Pharmacy ("the Board") respectfully submits this *Statement of Concern* arising from the enactment of Public Law 2013, chapter 373, An Act to Facilitate the Personal Importation of Prescription Drugs from International Mail Order Prescription Pharmacies ("the Act"). The Board's primary purpose is to protect the public health and welfare through the regulation of the practice of pharmacy and oversight of the dispensing, delivery, or distribution of prescription drugs to Maine citizens. The Act exempts from the Board's regulatory oversight retail pharmacies located in and "licensed" by Canada, the United Kingdom of Great Britain and Northern Ireland, the Commonwealth of Australia, or New Zealand who export drugs to Maine citizens for personal use and those entities providing drugs from those pharmacies or facilitating their provision.

From our public protection perspective this exemption from regulatory oversight and compliance requirements causes great concern in an area of significant risk. We wish to bring to your attention and incorporate herein the attached National Association of Boards of Pharmacy District 2 Resolution highlighting concerns with permitting residents to obtain drugs from sources outside the United States. With no regulatory oversight of these entities and the drugs that they provide to Maine citizens, the Board will be unable to respond to complaints or to assure that standards for purity and quality of drugs have been met. Neither the Board nor Maine citizens will know

Licensing (207)624-8620
Main Receptionist (207)624-8603
Hearing Impaired/TTY MAINE RELAY 711

PRINTED ON RECYCLED PAPER
www.maine.gov/professionallicensing

Geraldine.L.Betts@maine.gov
Direct Line: (207)624-8628
Fax: (207)624-8637

OFFICE LOCATION: GARDINER ANNEX
76 NORTHERN AVENUE, GARDINER, MAINE

where the drugs received from the exempt entities were manufactured. Nor will there be anyone in Maine that can confirm that they have received the correct drug and strength. Maine citizens have initiated 131 complaints this year against pharmacists and pharmacies that the Board does regulate. Some of those complaints involved receiving the wrong drug, including situations involving patient harm. The Board reasonably believes that there will be similar complaints regarding the exempt entities, but Maine citizens will be unable to obtain assistance from the Board or its investigatory and regulatory staff. Not until after something goes wrong will our citizens discover that the Board does not have authority to address their concerns, or that the importation of their drugs may violate federal law. The Board was established to make sure that pharmacists are competent and that the drugs Maine citizens receive are safe. Sadly, some Maine citizens will not have the Board's protection. For these reasons, we respectfully issue this *Statement of Concern*.

Joseph Bruno, R.Ph., Board President

Paul Chace, R.Ph., Member, Chain Representative

Donald Watson, R.Ph., Member, Hospital Representative

Shane Savage, R.Ph., Board Complaint Officer

Kevin Holland, R.Ph., Member, Independent Representative

Joseph Pietroski, Jr., Public Member

Kirsten Martin, Public Member

Sincerely,



Geraldine L. Betts, Board Administrator

Cc: Anne L. Head, Commissioner, Department of Professional and Financial Regulation
Michael Miller, Assistant Attorney General

Enc. National Association of Boards of Pharmacy District 2 Resolution

District 2 Resolution – Permitting Residents to Obtain Drugs from Sources Outside the US

Whereas, Maine has enacted a law allowing state residents to obtain prescription drugs from sources outside the United States, and

Whereas, these drugs are not FDA-approved drugs and therefore, may not be safe and efficacious, and

Whereas, pharmacies located within the United States must be licensed by their resident Board of Pharmacy and may only dispense FDA-approved drugs, and

Whereas, NABP’s research indicates 97 percent of the internet sites do not conform with federal and state laws, often dispensing counterfeit drugs, and

Whereas, there is potential for imminent patient harm with no regulatory oversight from the United States and accountability,

Therefore, be it resolved that NABP continue its efforts in educating state policy makers and the public in the danger of obtaining prescription drugs from sources outside of the United States without federal and state oversight.

This resolution was passed at the NABP District I and II annual conference held October 17 – 19, 2013 in Bar Harbor, Maine and subject to ratification at the 110th National Association of Boards of Pharmacy annual conference in May 2014 in Phoenix, Arizona