

508 North Third Street, Harrisburg, PA 17101-1199 phone: 717-234-6151 fax: 717-236-1618 website: www.PApharmacists.com

September 17, 2012

The Honorable Julie Harhart Pennsylvania House of Representatives 313 Main Capitol Building PO Box 202183 Harrisburg, PA 17120

Dear Representative Harhart:

On behalf of the more than 2,000 members of the Pennsylvania Pharmacists Association (PPA), we are requesting your opposition to HB 1635, legislation that would place extraordinary substitution restrictions on opioid medications that go above and beyond current FDA regulations. Although this bill is presented as an attempt to address concerns about diversion regarding the abuse of opioid analgesics, it actually causes more problems. We are opposed to this bill for three reasons: the proposed legislation would increase costs for patients, state prescription programs and insurance companies, delay patient care and is unnecessary.

Pharmacists currently may only substitute medications that are A rated therapeutically equivalent according to FDA standards. Medications would only have this ranking if they have the same bioequivalence. Generic medications with this ranking are lower in cost then brand name medications. HB 1635 would place a financial burden on patients since their only option would be to take the more expensive brand medication. State programs such as PACE, Medicaid and PEBTF companies would see an increase in cost since they would have to cover brand medications. These programs and other insurance companies are able to save money by dispensing generic medication equivalents. With this proposed bill, pharmaceutical manufacturers are trying to protect the market share of their brand medications. The proposed bill would go above and beyond the Food and Drug Administration (FDA) Therapeutic Equivalence Evaluations system for generic substitution, placing extraordinary restrictions on opioid medications.

A delay in patient's care could be experienced since the proposed legislation sets up unnecessary obstacles that would have to be overcome before pharmacists would be able to dispense the medication. If insurance companies do not cover brand medications or cover at a higher copay, the patient, unless they are willing and able to pay the higher amount, would have to wait until the pharmacist calls the prescriber for permission to substitute. On weekends or in the evenings, when the prescriber is not available, patients' may not receive their medications on the same day.

Although tamper-resistant technologies are intended to prevent opioid abuse since the technology prevents the medication from being crushed, chewed, dissolved, or cut, this does not prevent a potential overdose due to ingestion of a larger amount of medication then prescribed from occurring. No Empirical Data exists to support the claim that tamper resistant technology actually does deter the abuse of opioid medications.

We feel that this proposed legislation does not ultimately benefit the public health due to both the increase in costs for patients and insurance companies and the potential delay in the patients' treatment. Please let me know if you have any other questions or would like to discuss this further.

Sincerely,

Patricia A. Epple, CAE CEO

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Don L. Smith Government Relations Manager

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