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Written Comments of the Generic Pharmaceutical Association to the Committee on Professional Licensure Re House Bill 1635

Submitted by
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Chairman Harhart and Members of the Committee,

The Generic Pharmaceutical Association (GPhA) would like to express its opposition to HB 1635. GPhA represents the manufacturers and distributors of finished generic pharmaceutical products. Our members manufacture over 90 percent of generic pharmaceuticals dispensed in the United States. Currently, generic medicines fill 80 percent of the prescriptions in the U.S., but account for only 26 percent of the total cost of prescription drugs, providing an enormous public health benefit.

GPhA fully supports efforts to educate the public about the dangers of prescription drug abuse. Through its longstanding participation in the National Council on Patient Information and Education (NCPIE), GPhA works with a broad coalition of stakeholders in the health care system to raise awareness and address the misuse and abuse of prescription drugs. GPhA is involved in a variety of educational efforts and coalitions to combat this growing problem. HB 1635 does not address drug abuse, but market share.

Legislation has been introduced in 15 states that would require a pharmacist to obtain written consent of the prescriber in order to substitute a non-tamper resistant formulation of a product for a formulation that incorporates "tamper resistant technology" (TRF), despite FDA's determination of equivalence. Currently the only TRF products are brand products. All of these bills have failed, but some amended versions remain which eliminate the substitution language and mandate the Board of Pharmacy to create a list of TRF drugs. Legislation like HB 1635 is a strategy to protect brand market share from generic competition. This is troubling on several accounts.

First, this bill is unnecessary because doctors in the State of Pennsylvania have the authority to restrict substitution of generic drugs by writing "brand necessary" on the prescription.[1] That is, doctors can determine on a case-by-case basis if a legitimate user of the drug should receive access to the lower-cost generic.

The term "Tamper Resistant Formulation" refers to a technology designed to make a drug more difficult to abuse by making it harder to be crushed, dissolved, chewed, or cut, **but there is no empirical data that indicates TRF actually deters abuse**. In fact, addicts and abusers can easily find the means to circumvent this technology on the internet and other sources. Also, this technology does not prevent a potential overdose due to ingestion of a larger amount of this medication than typically taken.

The FDA has made no determination that a TRF product is any safer to a patient than an equivalent drug which does not have the TRF technology. In fact, FDA will **not** allow a manufacturer to indicate that a drug is TRF on its label or packaging materials. Claiming that a drug is tamper resistant is misleading to the public and promotes a false sense of security. Even a TRF drug manufacturer executive admits, *"it has not been established that this new formulation of Opana ER is less subject to misuse, abuse,*

[1] P.L. 1163 No. 259, Section 3(a)

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diversion, overdose, or addiction." Dr. Ivan Gergel, M.D., executive vice president, R&D and chief scientific officer, Endo Pharmaceuticals. [2]

The Pennsylvania Board of Pharmacy does not have resources to make scientific determinations of whether a drug contains these properties. In drug reviews, FDA evaluates double-blind, placebo-controlled studies and brings in independent experts. There are clinical end points and numerous scientific thresholds a manufacturer must meet to make claims about a drug. This legislation is asking the Pennsylvania Board of Pharmacy to assume new responsibilities with which the FDA is tasked. By mandating that the Board of Pharmacy establish a list of TRF drugs, the perception is created that TRF drugs are somehow safer for consumers than their generic equivalents, despite FDA not supporting these claims. Responsibility for making scientific determinations of safety claims is appropriately delegated to FDA, an agency equipped with the resources and authority for making such evaluations.

GPhA is also concerned about the purpose of this list. Prescribers and pharmacists have a duty to be aware of new medicines and stay abreast of trends. This list will not inform them of anything new. GPhA's concern is that once a list is created, it is only a matter of time before it becomes a barrier to generic substitution. The availability of generic medications can mean the difference between a patient taking their medication or going without critical care that they need. As noted recently by AARP, "researchers have found that patients who initiate therapy with lower-cost generic medications have higher rates of adherence, making them appealing to providers who want to ensure treatment compliance and avoid unnecessary spending." In 2009, the average price of a brand name prescription was $155 while the average price of a generic was $40. This legislation could lead to unnecessary limitations on patient access to generic medications and reduce the rate of generic substitution, thereby increasing overall prescription drug costs for patients, employers, third-party payers, state healthcare programs, and taxpayers.

In a time where employers are struggling to provide health benefits to their employees, policymakers should be focused on encouraging the use of safe and cost-effective generic medications rather than undermining them with regulations like HB 1635. GPhA respectfully requests that you oppose this legislation.

Please let us know if we can provide any additional information. Thank you for your consideration.

Sincerely,

Brynna M Clark

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[2] PR Newswire "Endo Announces FDA Approval of a New Formulation of Opana® ER Designed To Be Crush-Resistant", December 11, 2012. http://phx.corporate-ir.net/phoenix.zhtml?c=231492&p=irol-newsArticle&ID=1638555&highlight=