



GENERIC PHARMACEUTICAL ASSOCIATION

Written Comments of the Generic Pharmaceutical Association to the Joint General Law Committee Re House Bill 5484

Submitted by
Bryinna Clark, Sr. Director State Affairs

Co-chairs Doyle, and Baram, Vice Chairs Fonfara, and Kiner, Ranking Members Carter, and Witkos, and honorable members of the Joint General Law committee, the Generic Pharmaceutical Association (GPhA) would like to express its opposition to HB 5484. GPhA represents the manufacturers and distributors of finished dose generic pharmaceuticals, manufacturers and distributors of bulk pharmaceutical chemicals, and suppliers of other goods and services to the generic industry. Generic pharmaceuticals fill 80 percent of the prescriptions dispensed in the U.S. but account for only 27 percent of total drug spending. GPhA's members provide more than 90 percent of the generic medicines dispensed in the U.S.

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 (NCPPIE), the American Medicine Chest Challenge, and other organization, GPhA is actively involved in a broad coalition of health care stakeholders to raise awareness of the misuse and abuse of prescription medications. We believe that HB 5484 will have the unintended consequence of limiting patient access to these important medications while not preventing drug abuse.

HB 5484 prohibits pharmacists and insurance companies from substituting generic drugs for tamper-resistant formulation brand name drugs without the consent of the prescribing health care provider. This is completely unnecessary as prescribers already have the ability to block generic substitution in Connecticut by writing "BRAND MEDICALLY NECESSARY" on the prescription form. This check insures the prescriber determines which drug is appropriate during the patient's appointment. It is pharmacy practice to dispense the prescription indicated on the form.

Tamper Resistant Formulation is a claim made by brand manufactures that their drug is more difficult to crush, dissolve, chew, or cut. TRF technology also comes with new patents which is a brand ploy to block generic entry to the marketplace. There is no empirical data that indicates TRF actually deters abuse and the FDA has not recognized any opioid products as being tamper resistant. In fact, addicts and abusers can find the means to circumvent this technology on the internet. It is important to note that TRF **does not** prevent overdoses due to ingestion of larger doses than prescribed, **which the FDA cites as "the most common form of abuse" in its January 2013 Guidance on Abuse Deterrent Opioids.**

Currently the only products claiming to incorporate tamper resistant properties are expensive brand products The FDA has made no determination that a product claiming to be a TRF is any safer to a patient than an equivalent drug which does not have the so-called TRF technology. Claiming that a drug is tamper resistant without the FDA's input is misleading to the public and promotes a false sense of security. Even a drug manufacturer executive of a so-called TRF product admits, *"it has not been established that this new formulation of Opana ER is less subject to misuse, abuse, diversion, overdose, or addiction."* Dr.



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Ivan Gergel, M.D., executive vice president, R&D and chief scientific officer, Endo Pharmaceuticals.¹ The result of HB 5484 would be the protection of brand drug market share from generic competition.

The overwhelming majority of patients receiving opioid-based medicines use them properly to fight pain and live more productive lives. Many insurers limit the number of brand name drugs they cover. Effectively forcing a patient to use another branded medicine may put them over their limit, and in the untenable situation of having to choose between which medications they can afford. 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.”

HB 5484 also has the potential to cost the state of Connecticut millions of dollars. A 2011 fiscal note accompanying TRF legislation in Tennessee showed a significant budget impact to TennCare, the state’s Medicaid program. The fiscal note estimated that TRF legislation like this would increase state expenditures by \$11,873,100 as a result of preventing access to lower cost generic versions of opioids. The availability of generic medications can mean the difference between a patient taking their medication or going without critical care that they need

GPhA does *not* oppose tamper resistant technology. GPhA does object to brand-sponsored ploys to manipulate state laws to protect monopoly markets at the expense of state Medicaid budgets. GPhA also believes that the FDA is the only regulatory body with the ability to determine interchangeability and that states should wait for guidance from them. In a time where employers are struggling to provide health benefits to their employees, policymakers should be focused on safe and cost-effective generic medications rather than pursuing well-intentioned, but counterproductive policies like that in HB 5484. 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
Senior Director of State Affairs
Generic Pharmaceutical Association

¹PR 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=>

**TENNESSEE GENERAL ASSEMBLY
FISCAL REVIEW COMMITTEE**



FISCAL NOTE

SB 993 - HB 1818

April 1, 2011

SUMMARY OF BILL: Prohibits a drug that is not a tamper-resistant opioid from being considered therapeutically equivalent to a tamper resistant opioid and prohibits such substitution. Prohibits health benefit plans from excluding or limiting the benefits for a brand name tamper resistant opioid unless the exclusion or limitation is the same as or less restrictive than an exclusion or limitation that applies to benefits for other prescription drugs under the plan. Coverage of a brand name tamper resistant opioid is not subject to prior authorization if there is not a generic tamper resistant opioid available on the market and shall not be contingent on the previous use of a drug product that is not a tamper resistant opioid. The provisions of the bill will become effective January 1, 2012.

ESTIMATED FISCAL IMPACT:

Increase State Expenditures - \$11,873,100

Increase Local Expenditures – Exceeds \$100,000*

Increase Federal Expenditures - \$22,896,400

Potential Impact on Health Insurance Premiums (required by Tenn. Code Ann. § 3-2-111): Such legislation will result in an increase in the cost of health insurance premiums for benefit plans that currently offer this drugs under limitations and other approval processes. It is estimated to exceed \$100,000.

Assumptions:

- According to the Department of Commerce and Insurance, any costs incurred to review and approve additional forms, policies, certificates, and contracts to ensure compliance will not be significant and can be accommodated within existing resources without an increase appropriation or a reduced reversion.
- The bill will prohibit any health benefits plan from placing prior authorization criteria, quantity limits, or therapeutic duplication edits on these products.
- According to TennCare, these drugs would also bypass the program's monthly prescription limits because there are other drugs that are not subject to the limitation. There will be an increase in the brand drugs over the lower-priced generic and the total number of prescriptions for each enrollee.

- TennCare assumes there will be a five percent increase in utilization due to limits being removed. TennCare based its estimated impact on two drugs, Embeda and Oxycontin. TennCare receives approximately 2,352 prescription requests for Embeda each year and approves 114 of those, resulting in 2,238 denials filled by a generic. Five percent growth will result in 2,350, of which 3.5 percent, or 82, will be new prescriptions and 2,268 will be existing prescriptions at the additional costs.
- The price of Embeda is \$434 and the price of the generic is \$39. The increase in expenditures for Embeda will be \$931,448 [(82 x \$434) + (2,268 x \$395)].
- TennCare receives approximately 59,856 prescription requests for Oxycontin each year and approves 8,779 of those, resulting in 51,077 denials filled by a generic. Five percent growth will result in 53,631, of which 10.8 percent, or 5,792, will be new prescriptions and 47,839 will be existing prescriptions at the additional costs.
- The price of Oxycontin is \$662 and the price of the generic is \$39. The increase in expenditures for Oxycontin will be \$33,638,001 [(5,792 x \$662) + (47,839 x \$623)].
- The total increase to the TennCare program will be \$34,569,449 (\$931,448 + \$33,638,001) of which, \$11,673,066 will be state funds at a rate of 33.767 percent and \$22,896,383 will be federal funds at a match rate of 66.233 percent.
- According to the Department of Finance and Administration, prior authorization and quantity limitations that generally apply yield a reduction in benefit payments of approximately \$200,000 a year to the state sponsored public sector plans.
- It is assumed that local governments that do not currently opt into the state sponsored plans but provide health insurance benefits to employees will also see an increase in expenditures estimated to exceed \$100,000.
- Private health insurance impact: Most health benefit plans offer some type of limitations or private approval for drugs to keep costs down. If these limitations and processes are prohibited, the costs to the plans will increase and will be shifted to enrollees through increased premiums. This increase in estimated to exceed \$100,000.

*Article II, Section 24 of the Tennessee Constitution provides that: *No law of general application shall impose increased expenditure requirements on cities or counties unless the General Assembly shall provide that the state share in the cost.*

CERTIFICATION:

The information contained herein is true and correct to the best of my knowledge.



James W. White, Executive Director

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