



MEMORANDUM IN OPPOSITION

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90 State Street • Suite 825
Albany, NY 12207-1717
518.462.2293
Fax: 518.462.2150
www.nyhpa.org

Re: S.2590 (Hannon)/A.6574 (Aubry) – AN ACT to amend the public health law and education law, in relation to requiring notification of and the informed consent of the prescriber and the patient prior to the substitution of a prescribed anti-epileptic drug.

This legislation, S.2590/A.6574, proposes to exempt anti-epileptic drugs from New York’s successful generic substitution law by requiring a pharmacist to secure additional approvals from prescribers and patients prior to making an appropriate therapeutic substitution. This proposal undermines public confidence in FDA approved generics, which, in turn, will lead to higher pharmacy costs without a demonstrable commensurate improvement in outcomes. The New York Health Plan Association (HPA) strongly opposes this legislation.

Continually rising prescription drug costs have contributed significantly to increasing health insurance premiums over the past decade. Health plans and pharmacy benefit managers have utilized a variety of innovative tools to help dampen the impact of drug costs in premiums. Increasing appropriate utilization of generic drugs is at the foundation of every plan’s pharmacy benefit design.

The FDA is unequivocal on the safety and efficacy of generic drugs. When approving generic drugs, the FDA requires many rigorous tests and procedures to assure that the generic is interchangeable with the brand-name drug under all approved indications and conditions for use. According to the FDA, “to date, there are no documented examples of a generic product manufactured to meet its approved specifications that could not be used interchangeably with the corresponding brand-name drug.” This includes anti-epilepsy agents, obviating the need for this proposal.

This legislation takes New York in the wrong direction by establishing a unique and additional step in making a therapeutic interchange for a single therapeutic class. The result will be higher costs for employers purchasing health care and increased out-of-pocket costs for patients. Likewise, taxpayers will be asked to cover the additional costs this proposal will generate in public programs such as Medicaid, Child Health Plus and Family Health Plus.

Moreover, if such a change can be made to this therapeutic class, it will establish a precedent for carving out other therapeutic classes from New York’s generic drug law. The result will be a substantial reduction in prescribed generics that will increase overall pharmacy costs and force premium payers to make serious decisions about keeping a pharmacy benefit, which is an optional coverage.

New York’s carefully crafted generic drug law provides that if an attending physician believes a generic or therapeutic substitution would not be in the best interest of the patient, the prescription can specify “dispense as written” (“DAW”). This is not a new protocol and prescribers in this state are well versed in New York’s generic substitution law in which the prescriber is the ultimate authority in determining his/her patient’s pharmacological regimen. By not marking the prescription DAW, prescribers have already expressed permission to substitute an available generic. The additional administrative layer envisioned under this proposal only serves certain pharmaceutical manufacturers who will enjoy greater utilization of their high cost branded agents while undermining the generic drug law to the detriment of all New Yorkers.

New York's landmark generic drug bill has saved New Yorkers billions of dollars. Over the decades since its enactment, there is no evidence that the law needs to be changed to address manufacturers' concerns that FDA approved generics for epilepsy - or any other condition - are not meeting equivalent therapeutic results.

For all these reasons and more, HPA opposes S.2590/A.6574.

The New York Health Plan Association represents 25 managed care health plans that provide comprehensive health care services to nearly 7 million New Yorkers.