



## CONNECTICUT PHARMACISTS ASSOCIATION

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### Statement

Before the General Assembly's

Committee on Public Health

Friday

February 6, 2009

### **Re: Raised Bill 757: An Act Concerning The Filling of Prescriptions For Antiepileptic Drugs**

Good morning Rep. Ritter and Sen. Harris. My name is Margherita Giuliano. I am a pharmacist and the Executive Vice President of the Connecticut Pharmacists Association. The Connecticut Pharmacists Association is a professional organization representing approximately 1,000 pharmacists in the state. I am here to oppose Raised Bill 757: **An Act Concerning the Filling of Prescriptions for Antiepileptic Drugs.**

This bill would amend current legislation to mandate that a pharmacist can not substitute a prescription for an antiepileptic drug upon initial filling or refilling to a patient for treatment of epilepsy without obtaining written permission from the prescriber. This legislation is burdensome and costly to pharmacists, patients, taxpayers, and insurance companies.

We appreciate the effort by the Epilepsy Foundation to amend the language this year to include having the ICD codes or diagnoses codes on the prescriptions. As we mentioned previously, many of the antiepileptic drugs are used for other indications besides seizures. This language change will narrow down the number of prescriptions that could be affected by this law. However, our association still opposes this legislation due to the precedent that will be set by carving out a particular therapeutic class of drugs. This legislation has passed in a few states across the country. As predicted, other brand manufacturers are introducing legislation to "carve out" entire therapeutic classes from generic substitution laws. The immunosuppressant drugs are asking to be carved out as well as drugs for Fibromyalgia.

The Food and Drug Administration (FDA) has jurisdiction to identify drugs that are determined to be generically equivalent. In 2008, the FDA stated that they are "aware that certain individuals and groups have expressed particular concern about the switching of anti-epileptic drug products. To date we have no scientific evidence that demonstrates a particular problem with this group of products. Further, there are frequently circumstances other than the switch that may cause untoward responses. We continue to follow up on such reports and interact with those concerned."

I want to stress the statement from the FDA that says they have NO SCIENTIFIC EVIDENCE. Everything we do as healthcare providers is based on best practices and evidence based medicine. To implement burdensome legislation without scientific evidence is unconscionable. We would be more than happy to work with the prescribers and the epilepsy foundation to urge the FDA to do controlled scientific studies to determine if switching manufacturers has a definitive correlation to increased seizures.

The Pharmaceutical Care Management Association published a report in October, 2008 that studied the impact of the generic carve out legislation for the therapeutic classes of brand name drugs – typically anti-epileptics, immunosuppressants, and antipsychotics – from state laws governing generic substitution. The report finds that this carved out legislation will increase prescription drug costs with no clinical benefits to the patient. If carve outs were implemented for the three therapeutic drug classes mentioned, it would cost the State of CT 444.3 million dollars in increased costs over the next 10 years. The anti-epileptic drugs alone would cost the state \$275.5 million dollars over 10 years. Can our state afford this – amongst all the cuts you are asking us to take?

Most importantly how is this going to affect the patient? The way this legislation is written patients will have to wait for an unspecified amount of time before the prescriber determines if the pharmacist can substitute or change manufacturers. And if we don't hear from the prescriber or the prescriber says no – we have to turn the patient away.

Pharmacists are allowed to use their professional judgment when it comes to generic substitution. We are the medication experts. We recognize that some of these products are considered to have a “narrow therapeutic index”. We weigh this when making generic determinations. This system has worked well for the past 15 years. To place burdensome legislation on pharmacy practice **without the scientific evidence to back it up** is costly to pharmacy, taxpayers and the patients themselves. We urge the committee to oppose this legislation.



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Food and Drug Administration  
Rockville, MD 20857

January 11, 2008

Ms. Nicole Schultz  
Iowa Pharmacy Association  
8515 Douglas Avenue, Suite 16  
Des Moines, IA 50322

Dear Ms. Schultz:

This is in reply to your correspondence dated November 6, 2007, directed to Ms. Susan Winckler requesting that the FDA provide a statement regarding generic substitution, particularly with respect to anti-epilepsy drugs. It was forwarded to the Office of Generic Drugs for a reply.

The FDA has many years of experience in the review of generic drugs and assures the quality and equivalence of approved generic drug products. FDA works with pharmaceutical companies to assure that all drugs marketed in the U.S., both brand-name and generic, meet specifications for identity, strength, quality, purity and potency. In approving a generic drug product, the FDA requires that the proposed generic product is demonstrated to be equivalent to the brand-name drug in both the rate and extent of absorption. As noted in the Preface to the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") (27th Edition),

FDA classifies as therapeutically equivalent those products that meet the following criteria: (1) they are approved as safe and effective; (2) they are pharmaceutical equivalents in that they (a) contain identical amounts of the same active drug ingredient in the same dosage form and route of administration, and, (b) meet compendial or other applicable standards of strength, quality, purity, and identity; (3) they are bioequivalent; (4) they are adequately labeled; (5) they are manufactured in compliance with Current Good Manufacturing Practice regulations.

FDA considers drug products to be therapeutically equivalent if they meet the criteria outlined above, even though they may differ in certain other characteristics such as shape, scoring configuration, release mechanisms, packaging, excipients (including colors, flavors, preservatives), expiration date/time and other minor aspects of labeling (e.g., the presence of specific pharmacokinetic information) and storage conditions. When such differences are important in the care of a particular patient, it may be appropriate for the prescribing physician to require that a particular brand be dispensed as a medical necessity. With this limitation, however, FDA believes that products classified as therapeutically equivalent will produce the same clinical effect and safety profile as the prescribed product.

FDA is aware that certain individuals and groups have expressed particular concern about the switching of anti-epileptic drug products. To date, we have no scientific evidence that demonstrates a particular problem with this group of products. Further, there are frequently circumstances other than the switch that may cause untoward responses. We continue to follow-up such reports and interact with those concerned.

If FDA has determined a generic to be therapeutically equivalent to the innovator product, FDA continues to believe that:

- Additional clinical tests or examinations by the healthcare provider are not needed when a generic drug product is substituted for the brand-name product or vice-versa.
- Special precautions are not needed when a formulation or manufacturing change occurs for a drug product provided the change is approved according to applicable laws and regulations by the FDA.
- As noted in the "Orange Book," in the judgment of the FDA, products evaluated as therapeutically equivalent can be expected to have equivalent clinical effects whether the products are brand-name or generic.
- It is not necessary for the healthcare provider to approach any one therapeutic class of drug products differently from any other class when there has been a determination of therapeutic equivalence by FDA for the drug products under consideration.

We continue to monitor, take seriously, and, if indicated, investigate reports of potential inequivalence of all generic drugs. The FDA is committed to approving high-quality generic drug products that can be used with confidence by the American public.

Sincerely,



Gary Buehler, R.Ph.  
Director  
Office of Generic Drugs  
Center for Drug Evaluation and Research  
Food and Drug Administration

cc: S. Winckler  
C. Jung

## Summary

Visante was commissioned by the Pharmaceutical Care Management Association to study the impact of so called generic carve-out legislation that seeks to exempt or “carve out” certain therapeutic classes of brand name drugs—typically antiepileptics, immunosuppressants, and antipsychotics—from state laws governing generic substitution.

Well-established laws in all 50 states permit a pharmacist to make a generic substitution unless otherwise directed by a prescriber. In fact, laws in fifteen states—including health care bellwethers such as Florida, Massachusetts, New York, and Tennessee—*require* that pharmacists substitute generics for brands unless the prescriber specifically orders the brand to be dispensed. Established laws also allow a prescriber to override a generic substitution by writing “brand medically necessary” or “dispense as written” (DAW) on the prescription.

Proposed carve-out legislation would prevent a pharmacist from substituting a generic for its brand equivalent in certain drug classes unless consent is first obtained from the prescriber, even when the prescriber has given no indication that the brand is medically necessary. Some proposals go further and require pharmacists to maintain written documentation of contacts with prescribers to obtain consent. Such time-intensive requirements could cause harmful delays in the delivery of patient care and impose costly administrative burdens on prescribers and pharmacists alike.

Based on a comprehensive literature review and analysis of sales and utilization data for drugs targeted by carve-out legislation, Visante finds that *arguments favoring carve-out legislation are not supported by expert opinion and that such legislation would substantially increase prescription drug costs with no clinical benefit to consumers.*

## Major Findings

- Generic carve-out legislation runs counter to the opinion of the Food and Drug Administration (FDA), which is that generic drugs can be expected to have the same clinical effects as their brand counterparts and encourages generic substitution across all therapeutic categories, *including* medications in the antiepileptic, immunosuppressant, and antipsychotic classes.
- Carve-out legislation would reduce the percent of prescriptions dispensed with a generic from 90 percent to an estimated 25 percent for targeted drugs, resulting in increased drug costs but no increase in quality of care.
- If generic carve-out legislation were enacted nationally in 2009 in the antiepileptic, immunosuppressant, and antipsychotic therapeutic classes, total prescription drug costs to Medicaid, commercial payors, and consumers would increase by **\$29 billion over the 2010–2019 period.**
- Nationally enacted carve-out legislation would increase drug costs to commercial payors by \$17.5 billion, Medicaid by \$6.2 billion, and consumers by \$5.3 billion over ten years.



⇒ We estimate that carve-out legislation would reduce the market share of affected generic drugs from 90 percent to 25 percent.

### Carve-Out Laws Would Raise Prescription Drug Costs for Payors and Consumers

If generic carve-out legislation were enacted nationally in 2009 in the antiepileptic, immunosuppressant, and antipsychotic therapeutic classes, total prescription drug costs to Medicaid, commercial payors, and consumers would increase by **\$29 billion over the 2010–2019 period.**

Table 1 details how nationally enacted carve-out legislation would increase drug costs to commercial payors by \$17.5 billion, Medicaid by \$6.2 billion, and consumers by \$5.3 billion over ten years.

**Table 1: Cost of Generic Carve-Outs Applied to Antiepileptics, Immunosuppressants, and Antipsychotics, 2010–2019**

(Dollar figures in billions)

Drug Category	Total	State Medicaid	Federal Medicaid	Commercial Third Party Payors and Medicare	Consumer Out-of-Pocket
Antiepileptics	\$18.20	\$1.55	\$2.16	\$11.00	\$3.49
Immunosuppressants	\$4.09	\$0.19	\$0.24	\$3.00	\$0.67
Antipsychotics	\$6.68	\$0.89	\$1.17	\$3.48	\$1.13
<b>TOTAL</b>	<b>\$29.0</b>	<b>\$2.6</b>	<b>\$3.6</b>	<b>\$17.5</b>	<b>\$5.3</b>

To be conservative, the above estimates measure only the impact of generic carve-out legislation on new generic drugs introduced during the 2010 to 2019 period. This is because the requirement that the pharmacist call the doctor for consent before dispensing a generic can be expected to have the greatest impact on the use of new generic products that have not yet established a market share. In reality, however, carve-outs could also have an impact on the use of older generic drugs, since the vast majority of prescriptions for multisource products are written using the brand name rather than the generic name.<sup>18</sup>

More detailed data is provided in the Tables 2–5, for all states and for each payor type. New York and California are the states with the greatest drug utilization and costs, and would see the greatest impact. Both states would experience increased drug costs of almost \$1 billion if carve-outs were implemented for the three drug categories analyzed.

<sup>18</sup> Steinman, M., et al., "What's in a Name? Use of Brand versus Generic Drug Names in United States Outpatient Practice," *Gen Intern Med*, 22(5): 645–648, May 2007.

**Table 3: Cost of a Generic Carve-Out Applied to Antiepileptics  
 by State, 2010–2019**

(Dollar figures in millions)

	Total	Medicaid (State)	Medicaid (Federal)	Commercial Third Party Payors and Medicare	Consumer Out-of-Pocket
<b>US Total</b>	<b>\$18,204</b>	<b>\$1,549</b>	<b>\$2,165</b>	<b>\$11,001</b>	<b>\$3,489</b>
AK	\$28.2	\$3.6	\$4.0	\$15.8	\$4.8
AL	\$343.5	\$21.5	\$44.9	\$210.0	\$67.1
AR	\$220.2	\$16.1	\$43.4	\$117.8	\$42.9
AZ	\$307.3	\$16.0	\$31.4	\$193.9	\$66.1
CA	\$1,538.6	\$133.2	\$133.2	\$961.2	\$311.1
CO	\$252.5	\$20.0	\$20.0	\$159.9	\$52.5
CT	\$275.5	\$17.4	\$17.4	\$181.5	\$59.2
DC	\$48.6	\$3.2	\$7.6	\$28.7	\$9.0
DE	\$63.2	\$8.0	\$8.0	\$35.6	\$11.6
FL	\$989.3	\$62.7	\$82.5	\$618.6	\$225.5
GA	\$541.2	\$40.9	\$69.9	\$329.4	\$101.1
HI	\$42.7	\$4.7	\$6.1	\$24.6	\$7.3
IA	\$172.1	\$13.7	\$22.1	\$102.7	\$33.5
ID	\$73.3	\$5.2	\$12.1	\$41.6	\$14.4
IL	\$712.9	\$71.6	\$71.6	\$427.7	\$142.0
IN	\$417.8	\$33.7	\$56.7	\$246.8	\$80.6
KS	\$187.8	\$15.4	\$22.5	\$112.0	\$37.9
KY	\$377.3	\$28.6	\$66.1	\$214.8	\$67.7
LA	\$289.2	\$18.2	\$47.9	\$165.4	\$57.6
MA	\$543.3	\$61.7	\$61.7	\$324.0	\$95.8
MD	\$329.7	\$28.2	\$28.2	\$213.9	\$59.4
ME	\$99.4	\$10.2	\$17.6	\$56.7	\$14.9
MI	\$699.7	\$41.0	\$56.8	\$462.2	\$139.7
MN	\$364.2	\$26.9	\$26.9	\$240.7	\$69.8
MO	\$483.0	\$39.7	\$66.0	\$282.9	\$94.4
MS	\$176.9	\$8.2	\$26.5	\$106.0	\$36.2
MT	\$46.6	\$3.4	\$7.4	\$26.9	\$8.8
NC	\$629.6	\$49.8	\$88.8	\$378.2	\$112.8
ND	\$48.0	\$3.4	\$6.0	\$28.8	\$9.8
NE	\$131.5	\$12.0	\$16.6	\$78.1	\$24.7
NH	\$85.8	\$8.0	\$8.0	\$54.0	\$15.8
NJ	\$451.0	\$40.0	\$40.0	\$283.9	\$87.2
NM	\$93.1	\$1.6	\$3.9	\$65.8	\$21.9
NV	\$109.6	\$7.6	\$8.5	\$69.8	\$23.8
NY	\$1,202.1	\$153.0	\$153.0	\$702.0	\$194.1
OH	\$821.8	\$87.8	\$136.0	\$455.5	\$142.5
OK	\$198.1	\$12.2	\$24.9	\$120.0	\$40.9
OR	\$163.4	\$12.2	\$19.0	\$101.2	\$30.9
PA	\$753.7	\$77.2	\$90.9	\$452.9	\$132.7
PR	\$127.5	\$20.9	\$20.9	\$62.6	\$23.0
RI	\$88.4	\$7.8	\$8.6	\$56.6	\$15.5
SC	\$260.7	\$16.3	\$37.7	\$156.5	\$50.2
SD	\$44.6	\$3.6	\$5.4	\$27.3	\$8.3
TN	\$545.2	\$44.6	\$78.4	\$318.3	\$103.8
TX	\$1,289.4	\$113.5	\$174.0	\$746.1	\$255.8
UT	\$145.1	\$8.1	\$20.5	\$89.7	\$26.8
VA	\$424.3	\$25.1	\$25.1	\$288.5	\$85.7
VT	\$47.0	\$6.3	\$9.0	\$24.7	\$7.0
WA	\$346.7	\$35.9	\$38.1	\$208.2	\$64.5
WI	\$361.5	\$27.3	\$37.2	\$228.2	\$68.8
WV	\$187.2	\$18.3	\$52.8	\$89.8	\$26.3
WY	\$24.4	\$3.0	\$3.0	\$12.9	\$5.5



**Table 2: Cost of Generic Carve-Outs Applied to Antiepileptics, Immunosuppressants, and Antipsychotics by State, 2010–2019**

(Dollar figures in millions)

	Total	State Medicaid	Federal Medicaid	Commercial Third Party Payors and Medicare	Consumer Out-of-Pocket
<b>US Total</b>	<b>\$28,975</b>	<b>\$2,628</b>	<b>\$3,581</b>	<b>\$17,473</b>	<b>\$5,293</b>
AK	\$47.2	\$6.2	\$6.8	\$27.0	\$7.2
AL	\$493.2	\$32.2	\$67.3	\$302.8	\$91.0
AR	\$337.0	\$26.0	\$70.0	\$179.5	\$61.6
AZ	\$499.3	\$21.6	\$42.4	\$336.3	\$98.9
CA	\$2,789.1	\$278.8	\$278.8	\$1,640.5	\$591.0
CO	\$389.8	\$32.7	\$32.7	\$247.9	\$76.4
CT	\$444.3	\$33.0	\$33.0	\$287.6	\$90.7
DC	\$94.6	\$6.5	\$15.1	\$57.8	\$15.2
DE	\$90.1	\$11.9	\$11.9	\$50.1	\$16.1
FL	\$1,548.0	\$102.5	\$135.0	\$976.0	\$334.5
GA	\$800.6	\$59.4	\$101.6	\$499.9	\$139.8
HI	\$76.8	\$9.2	\$11.9	\$43.4	\$12.3
IA	\$289.1	\$23.9	\$38.5	\$173.4	\$53.2
ID	\$109.0	\$8.2	\$18.9	\$61.6	\$20.3
IL	\$1,156.6	\$121.7	\$121.7	\$701.0	\$212.2
IN	\$634.8	\$52.0	\$87.3	\$380.1	\$115.4
KS	\$304.3	\$25.4	\$37.2	\$182.9	\$58.7
KY	\$528.9	\$40.7	\$94.0	\$303.9	\$90.2
LA	\$432.3	\$28.3	\$74.5	\$243.1	\$86.4
MA	\$903.1	\$104.4	\$104.4	\$546.8	\$147.6
MD	\$541.0	\$52.5	\$52.5	\$346.4	\$89.7
ME	\$148.1	\$16.1	\$27.8	\$83.0	\$21.2
MI	\$1,089.7	\$80.7	\$111.9	\$696.6	\$200.5
MN	\$587.2	\$44.2	\$44.2	\$387.8	\$110.9
MO	\$734.8	\$62.5	\$103.8	\$429.3	\$139.2
MS	\$259.3	\$13.0	\$41.8	\$153.5	\$50.9
MT	\$79.0	\$5.8	\$12.7	\$46.5	\$14.0
NC	\$941.9	\$74.9	\$133.5	\$574.1	\$159.3
ND	\$75.9	\$5.0	\$8.8	\$46.8	\$15.3
NE	\$201.9	\$19.1	\$26.3	\$120.3	\$36.2
NH	\$127.3	\$12.3	\$12.3	\$80.0	\$22.7
NJ	\$713.4	\$69.7	\$69.7	\$442.4	\$131.7
NM	\$156.1	\$2.4	\$5.8	\$111.5	\$36.5
NV	\$162.1	\$12.2	\$13.5	\$103.8	\$32.5
NY	\$2,112.7	\$309.6	\$309.6	\$1,189.7	\$303.8
OH	\$1,260.1	\$134.4	\$208.3	\$712.1	\$205.4
OK	\$311.5	\$21.5	\$43.8	\$183.8	\$62.4
OR	\$270.9	\$21.8	\$33.8	\$168.7	\$46.6
PA	\$1,262.3	\$138.8	\$163.5	\$755.4	\$204.6
PR	\$198.1	\$32.6	\$32.6	\$95.4	\$37.4
RI	\$135.9	\$13.0	\$14.4	\$86.1	\$22.4
SC	\$384.7	\$24.5	\$56.6	\$233.4	\$70.1
SD	\$70.0	\$5.4	\$8.1	\$43.9	\$12.6
TN	\$807.1	\$65.1	\$114.3	\$476.9	\$150.8
TX	\$2,007.4	\$176.5	\$270.6	\$1,182.2	\$378.1
UT	\$222.7	\$12.2	\$30.9	\$141.2	\$38.3
VA	\$654.7	\$39.5	\$39.5	\$451.4	\$124.4
VT	\$69.2	\$8.9	\$12.8	\$37.5	\$10.0
WA	\$539.7	\$57.5	\$61.1	\$326.3	\$94.7
WI	\$592.2	\$43.8	\$59.5	\$379.9	\$109.0
WV	\$253.3	\$23.9	\$68.9	\$125.6	\$34.9
WY	\$36.4	\$4.5	\$4.5	\$19.6	\$7.9