Undermining Generic Drug Substitution: The Cost of Generic Carve-Out Legislation

A 50 State Analysis Prepared for

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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.

Introduction

Visante was commissioned by the Pharmaceutical Care Management Association to study the effect of so called generic carve-out legislation that seeks to exempt or "carve out" certain therapeutic classes of brand name drugs—typically antiepileptics, immunsuppressants, and antipsychotics—from state laws governing generic substitution. Such legislation would inhibit pharmacists from substituting FDA-approved generic drugs for a range of high-cost brand products, thereby adversely affecting the delivery of patient care. Consumers, employers, and government programs would experience substantial cost increases for prescription drugs as a result.

Generic Carve-Out Legislation Flies in the Face of Established Laws in All 50 States

All 50 states have laws that permit a pharmacist to make a generic substitution unless otherwise directed by a prescriber. 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. These laws enable prescribers to write prescriptions using the more easily remembered brand name of a medication with the knowledge that pharmacists will substitute an equivalent generic whenever appropriate.

A prescriber can prevent a generic substitution from occurring by writing "brand medically necessary" or "dispense as written" (DAW) on the prescription. Also, most states allow pharmacists to dispense the brand if specifically requested by the patient. These established legal avenues allow a patient to obtain the appropriate medication as determined by the prescriber.

Proposed carve-out measures would prevent pharmacists 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 not indicated 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. Therefore, this type of legislation is not only redundant and unnecessary, it impedes patient access to safe and affordable generic drugs.

Generic Carve-Out Legislation Contradicts FDA Policies

The FDA has repeatedly emphasized the safety and substitutability of generic drugs and encourages their use. Generic carve-out legislation runs counter to these policies.

Since Congress passed legislation creating a streamlined approval process for generic drugs in 1984, the FDA has approved thousands of generic medications, all of which are manufactured and inspected under the same strict quality guidelines as brands. Prior to 1984, all products evaluated by the FDA had to undergo extensive clinical trials even if they contained exactly the same active ingredient as an already-approved product. Congress streamlined this process by allowing the FDA to approve a generic product if it was demonstrated to be the same

medicine with the same active ingredient, strength, dosage, purity, stability, and quality as its brand counterpart.

In tracking side effects and adverse drug events, the FDA has found no difference between brands and generics. In fact, the safety record of generic drugs is impressive, with only four generics having been removed from the market for safety reasons over the past quarter century, as compared to 21 branded products over the same time period.[1] Today, the FDA actively encourages the widespread use of generic medicines by conducting consumer education campaigns featuring public service announcements, brochures, and advertisements.

FDA Holds that Generic Substitution Is Safe for All Drug Classes

According to the FDA, generics can be safely substituted for brands in all therapeutic classes. Nonetheless, proponents of generic carve-out legislation claim that generic substitution is not safe for certain drug classes.

As background, the scientific basis upon which the FDA approves generic drugs is known as bioequivalence. When two drugs are bioequivalent, they deliver the same amount of active ingredients into a patient's bloodstream over the same amount of time. Narrow therapeutic range (NTR) or narrow therapeutic index (NTI) drugs are products in which small changes in the dose and/or blood concentration could potentially result in clinically important changes in drug efficacy or safety. Usually, NTR/NTI drugs require frequent adjustments in the dose of the drug and careful patient monitoring ***irrespective*** of whether the drug is a brand or generic drug product.

Proponents of generic carve-out legislation assert that the FDA's bioequivalence standard may be inadequate to ensure safe generic substitution for NTR/NTI drugs. No scientific evidence exists to support this assertion.[2,3,4] Carve-out proponents often assert differences between brands and generics by pointing out that the testing procedure used by the FDA only requires that a generic drug fall within bioequivalence limits of 80 to 125 percent across a range of tested patients. In reality, however, the 80 to 125 percent range is only a probability test, not an absolute measure of the generic's bioequivalence limits. In fact, a generic drug falling outside a comparative bioequivalence range of 3 to 4 percent from the brand will not meet the FDA's bioequivalence standard.[5] Thus, ***a generic drug, which by definition must have the same active ingredient as the brand, is almost always absorbed into a patient's bloodstream in the same concentration and over the same amount of time as its brand name counterpart.***

[1] Personal communication, Edmund Weisbart, M.D., Express Scripts, Inc, February 2007.
[2] Benet, L.Z., "Understanding Bioequivalence Testing," *Transplantation Proceedings*, 31 (Suppl 3A):7S-9S, 1999.
[3] Williams, R.L., "Therapeutic Equivalence of Generic Drugs, Response to National Association of Boards of Pharmacy," April 16, 1997, available at http://www.fda.gov/cder/news/ntiletter.htm, accessed December 12, 2007.
[4] Benet, L.Z., Goyan, J.E. "Science for Clinicians: Bioequivalence and Narrow Therapeutic Index Drugs," *Pharmacotherapy*, 1995; 15: 433–440.
[5] Benet, L.Z., "Understanding Bioequivalence Testing," *Transplantation Proceedings*, 31 (Suppl 3A):7S-9S, 1999.

No problems arising from alleged differences in bioequivalence between generic and brand name NTR/NTI drugs has ever been validated by FDA. In fact, ***FDA has repeatedly reiterated its expert opinion that generic products in all therapeutic classes—including NTR/NTI drugs—can be safely substituted for their brand name equivalents.***[6]

FDA further advises that it is "not necessary for the health care provider to approach any one therapeutic class of drug products differently from any other class when there has been a determination of therapeutic equivalence,"[7,8] as is the case for all approved generic medications. ***Any state that passes generic carve-out legislation would, in effect, be inappropriately inserting itself into what is the proper domain of the FDA—the regulation of drug safety.***

AMA Supports Generic Substitution for All Therapeutic Classes

Generic carve-out legislation also runs counter to a 2007 report adopted by the American Medical Association (AMA) that presented a comprehensive review of medical literature on the subject of generic substitution and NTI drugs. After reviewing the scientific evidence, the AMA's Council on Science and Public Health determined that a more stringent generic substitution process for NTI drugs was not necessary. Specifically, the AMA concluded that "[w]hile concerns still persist among some physicians about the therapeutic equivalence of generic NTI drugs to their brand name innovator products, scientific evidence to support these concerns either does not exist or is extremely weak."[9] The AMA further concluded that "[t]heoretical assumptions of the possibility of inequivalence are not a sufficient basis for presuming its presence and acting on that assumption" and that "[a]necdotal reports are similarly unhelpful, since one is often unable to distinguish product failure from a natural change in disease process or patient response."[10] Based on the report, AMA adopted a policy supporting generic substitution for all classes of drugs, including NTR/NTI drugs.[11]

Why Generic Carve-Out Legislation Would Increase Costs

In 2007, the average price of a brand name prescription was $120 while the average price of a generic was $34.[12] Despite these significantly lower prices, generics provide the same medication and the same clinical results as their brand equivalents. Today, generics account for 65 percent of all prescriptions filled in the United States, but comprise just 20 percent of overall prescription drug costs.[13] Each 1 percentage point increase in the market share of generics

[6] Food and Drug Administration, Letter to the Iowa Pharmacy Association, January 11, 2008.
[7] Food and Drug Administration, Letter to the National Association of Chain Drug Stores, April 16, 2007.
[8] Food and Drug Administration, Letter to the Iowa Pharmacy Association, January 11, 2008.
[9] American Medical Association, "Generic Substitution of Narrow Therapeutic Index Drugs" (A-07), available at http://www.ama-assn.org/ama/pub/category/17731.html, accessed September 2008
[10] American Medical Association, Featured Report: Generic Drugs (A-02), available at http://www.ama-assn.org/ama/pub/category/15279.html, accessed September 2008.
[11] Ibid.
[12] National Association of Chain Drug Stores, Industry Facts-at-a-Glance, available at http://www.nacds.org/wmspage.cfm?parm1=507, accessed April 2008.
[13] Generic Pharmaceutical Association, available at http://www.gphaonline.org/Content/NavigationMenu/AboutGenerics/FAQs/faqs2.htm, accessed April 2008.

results in overall drug costs decreasing by approximately 1 percentage point.[14] If generic carve-out legislation were to pass, generics would lose market share and costs would increase.

Generic Carve-Outs Would Interfere with Medicaid and Employer-Sponsored Plans

Government programs such as Medicaid and virtually all employer-sponsored health plans actively seek to maximize the use of generic medications whenever clinically appropriate. Pharmacy benefit managers (PBMs) encourage generic drug utilization by implementing programs such as lower or waived copayments for generics, clinical step therapy protocols, as well as patient and prescriber outreach. Coupled with generic substitution laws, such programs have resulted in the typical generic substitution rate exceeding 90 percent. Generic carve-out legislation would seriously undermine the efforts of government and commercial payors to manage costs by encouraging the use of generics.

Provider Consent Requirement Would Drastically Reduce Generic Substitution

Today, prescription plan participants and their prescribers shift rapidly to generic drug alternatives when they become available. Within one month of being introduced to market, a generic drug will typically account for 90 percent of dispensed prescriptions for a given medication.[15,16] Such rapid adoption of generics is a crucial component of all payors' strategies to hold down prescription drug costs without compromising quality.

The effect of a prescriber consent requirement on generic substitution can be seen today in cases where brand drug manufacturers have engaged in a controversial practice known as "product switching." "Product switching" occurs when a brand manufacturer discontinues the marketing of or "retires" an existing brand product facing generic competition and replaces it with a new, modified version of the product. Such a modified product could be a tablet replacing a capsule of a different strength, for example. While brand manufacturers say that the new version is "new and improved," others maintain that the manufacturers are simply trying to avoid competition from generics. In at least one case, dozens of states sued, alleging that the manufacturer made trivial changes to its product simply to avoid competition.[17]

As with generic carve-out legislation, "product switching" makes it necessary for the pharmacist to contact the prescriber for approval before the generic can be dispensed in place of the brand. This is because the generic product is not identical in dosage form or strength to the original brand reference product. The impact on generic use is drastic. Based on our analysis of prescription trend data, generics typically achieve only a 25 percent market share when "product switching" has occurred. This compares to a 90 percent share in the absence of "product switching." Because carve-out legislation would impose the same onerous requirements on pharmacists, its result would be similar.

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[14] Express Scripts, "Optimizing the Copayment Differential: Impact on Generic Fill Rate," available at http://www.express-scripts.com/industryresearch/outcomes/onlinepublications/, accessed September 2008.
[15] Wosinska, M., and Huckman, R, "Generic Dispensing And Substitution In Mail And Retail Pharmacies," *Health Affairs*, July 28, 2004.
[16] Medco, "2008 Drug Trend Report," Volume 10, 2008, pp 9–11.
[17] Associated Press, "18 States Sue Abbott Laboratories for Blocking Generic Versions of Cholesterol Drug," March 18, 2008, available at http://www.iht.com/articles/ap/2008/03/18/business/NA-FIN-US-Abbott-Generics-Lawsuit.php.

⇒ **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
Immunosppressants	$4.09	$0.19	$0.24	$3.00	$0.67
Antipsychotics	$6.68	$0.89	$1.17	$3.48	$1.13
TOTAL	**$29.0**	**$2.6**	**$3.6**	**$17.5**	**$5.3**

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.[18]

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 more than $2 billion if carve-outs were implemented for the three drug categories analyzed.

[18] 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 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
US Total	**$28,975**	**$2,628**	**$3,581**	**$17,473**	**$5,293**
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

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
US Total	**$18,204**	**$1,549**	**$2,165**	**$11,001**	**$3,489**
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 4: Cost of a Generic Carve-Out Applied to Immunosuppressants by State, 2010–2019

(Dollar figures in millions)

	Total	Medicaid (State)	Medicaid (Federal)	Commercial Third Party Payors and Medicare	Consumer Out-of-Pocket
US Total	**$4,094**	**$185**	**$242**	**$2,995**	**$672**
AK	$5.7	$0.2	$0.2	$4.6	$0.6
AL	$58.7	$2.0	$4.1	$44.2	$8.4
AR	$39.0	$1.1	$2.9	$28.7	$6.3
AZ	$88.7	$4.0	$7.8	$63.4	$13.4
CA	$504.8	$23.5	$23.5	$300.8	$157.0
CO	$57.3	$2.5	$2.5	$43.8	$8.7
CT	$45.1	$2.7	$2.7	$33.0	$6.5
DC	$25.0	$0.6	$1.5	$19.8	$3.2
DE	$8.1	$0.8	$0.8	$5.3	$1.2
FL	$252.7	$9.6	$12.7	$189.3	$41.1
GA	$111.6	$3.9	$6.6	$87.2	$13.9
HI	$10.2	$0.5	$0.6	$7.7	$1.5
IA	$43.5	$1.9	$3.0	$32.7	$5.9
ID	$8.2	$0.1	$0.2	$6.5	$1.3
IL	$194.6	$12.0	$12.0	$144.4	$26.2
IN	$71.2	$2.4	$4.0	$54.8	$10.0
KS	$40.4	$1.1	$1.6	$31.2	$6.6
KY	$49.4	$1.4	$3.3	$38.6	$6.1
LA	$37.8	$1.2	$3.3	$26.7	$6.6
MA	$131.1	$10.3	$10.3	$96.1	$14.3
MD	$83.1	$3.4	$3.4	$65.4	$10.9
ME	$9.1	$0.5	$0.9	$6.6	$1.0
MI	$132.7	$4.6	$6.4	$102.4	$19.3
MN	$83.6	$2.7	$2.7	$65.5	$12.7
MO	$93.9	$4.2	$7.0	$67.5	$15.2
MS	$15.6	$0.4	$1.3	$11.2	$2.6
MT	$9.4	$0.3	$0.5	$7.3	$1.4
NC	$139.0	$5.2	$9.2	$105.5	$19.1
ND	$12.3	$0.3	$0.6	$9.2	$2.2
NE	$21.9	$0.6	$0.8	$17.5	$2.9
NH	$8.6	$0.4	$0.4	$6.6	$1.2
NJ	$88.8	$4.5	$4.5	$64.2	$15.6
NM	$22.9	$0.3	$0.8	$17.2	$4.6
NV	$21.9	$0.6	$0.6	$17.4	$3.2
NY	$283.6	$22.4	$22.4	$205.0	$33.8
OH	$152.5	$7.0	$10.8	$115.3	$19.3
OK	$34.0	$1.1	$2.2	$25.1	$5.8
OR	$45.9	$1.3	$2.1	$36.5	$6.0
PA	$192.1	$10.0	$11.8	$143.9	$26.4
PR	$23.5	$4.2	$4.2	$9.3	$5.8
RI	$16.5	$1.1	$1.2	$12.5	$1.8
SC	$48.2	$1.7	$3.9	$35.6	$7.0
SD	$9.6	$0.3	$0.4	$7.6	$1.3
TN	$104.6	$4.4	$7.7	$77.2	$15.2
TX	$324.5	$11.6	$17.8	$245.4	$49.7
UT	$34.0	$0.7	$1.7	$27.1	$4.5
VA	$94.5	$2.6	$2.6	$73.7	$15.5
VT	$4.7	$0.2	$0.4	$3.7	$0.4
WA	$76.1	$3.2	$3.4	$58.9	$10.5
WI	$106.0	$3.4	$4.6	$82.1	$15.9
WV	$15.8	$0.6	$1.7	$11.7	$1.8
WY	$2.8	$0.1	$0.1	$2.0	$0.6

Table 5: Cost of a Generic Carve-Out Applied to Antipsychotics by State, 2010–2019

(Dollar figures in millions)

	Total	Medicaid (State)	Medicaid (Federal)	Commercial Third Party Payors and Medicare	Consumer Out-of-Pocket
US Total	**$6,677**	**$894**	**$1,174**	**$3,477**	**$1,132**
AK	$13.4	$2.4	$2.6	$6.6	$1.8
AL	$91.0	$8.7	$18.2	$48.5	$15.5
AR	$77.9	$8.8	$23.7	$32.9	$12.4
AZ	$103.3	$1.6	$3.2	$79.0	$19.4
CA	$745.7	$122.1	$122.1	$378.6	$122.9
CO	$80.0	$10.2	$10.2	$44.2	$15.3
CT	$123.8	$12.8	$12.8	$73.1	$25.0
DC	$20.9	$2.6	$6.1	$9.2	$3.0
DE	$18.8	$3.2	$3.2	$9.2	$3.3
FL	$306.1	$30.2	$39.8	$168.1	$67.9
GA	$147.8	$14.7	$25.1	$83.3	$24.7
HI	$23.9	$4.0	$5.2	$11.2	$3.5
IA	$73.5	$8.3	$13.4	$38.0	$13.8
ID	$27.5	$2.8	$6.6	$13.5	$4.6
IL	$249.1	$38.1	$38.1	$128.8	$44.0
IN	$145.7	$15.8	$26.6	$78.5	$24.8
KS	$76.0	$9.0	$13.1	$39.7	$14.3
KY	$102.2	$10.7	$24.7	$50.4	$16.4
LA	$105.3	$8.8	$23.3	$50.9	$22.2
MA	$228.8	$32.4	$32.4	$126.6	$37.4
MD	$128.2	$20.9	$20.9	$67.0	$19.4
ME	$39.7	$5.4	$9.2	$19.8	$5.3
MI	$257.4	$35.2	$48.8	$132.0	$41.4
MN	$139.5	$14.7	$14.7	$81.7	$28.5
MO	$157.9	$18.6	$30.8	$78.9	$29.7
MS	$66.8	$4.3	$14.0	$36.4	$12.1
MT	$23.0	$2.2	$4.7	$12.3	$3.8
NC	$173.3	$19.9	$35.5	$90.4	$27.4
ND	$15.6	$1.3	$2.2	$8.8	$3.3
NE	$48.5	$6.4	$8.9	$24.6	$8.5
NH	$32.9	$3.9	$3.9	$19.4	$5.7
NJ	$173.5	$25.2	$25.2	$94.4	$28.9
NM	$40.1	$0.5	$1.2	$28.5	$9.9
NV	$30.5	$4.0	$4.4	$16.6	$5.5
NY	$627.0	$134.2	$134.2	$282.7	$75.8
OH	$285.9	$39.6	$61.4	$141.3	$43.6
OK	$79.4	$8.2	$16.7	$38.7	$15.7
OR	$61.7	$8.2	$12.8	$31.0	$9.7
PA	$316.4	$51.6	$60.8	$158.6	$45.5
PR	$47.1	$7.5	$7.5	$23.5	$8.6
RI	$31.0	$4.2	$4.7	$17.0	$5.1
SC	$75.8	$6.5	$15.0	$41.3	$13.0
SD	$15.8	$1.5	$2.3	$9.0	$2.9
TN	$157.4	$16.1	$28.2	$81.4	$31.8
TX	$393.4	$51.4	$78.8	$190.7	$72.6
UT	$43.6	$3.4	$8.7	$24.5	$7.0
VA	$136.0	$11.8	$11.8	$89.2	$23.2
VT	$17.5	$2.4	$3.4	$9.1	$2.6
WA	$116.8	$18.4	$19.6	$59.2	$19.6
WI	$124.7	$13.0	$17.7	$69.5	$24.4
WV	$50.3	$5.0	$14.4	$24.1	$6.8
WY	$9.1	$1.3	$1.3	$4.7	$1.8

Appendix: Methodology

Data used for this analysis were obtained for the years 2006 and 2007 from four national PBMs representing more than 165 million covered lives. These data were augmented with market research data on prescription drug sales and utilization obtained from commercial sources. Prescription and dollar volume data at the pharmacy level were obtained for brand and generic drugs within three therapeutic categories (antiepileptics, immunosuppressants, and antipsychotics). Data collected for each drug included the total number of prescriptions, units dispensed, and total prescription costs segmented by payor: Medicaid, commercial third party payors (including Medicare), and consumer out-of-pocket. A number of economic projections were then applied to these data on a drug-by-drug basis in order to develop baseline 10-year expenditure projections for each therapeutic class.

First, increases in drug prices and utilization were projected based on historical trends. Prescription utilization was projected to increase at 2.9 percent per year during the 2008–2019 period based on a linear projection of overall prescription utilization trends during the 2000–2006 period. Brand name prescription prices were projected to increase at 5.8 percent per year during the 2008–2019 period based on a linear projection of price trends during the 2000–2007 period.[19] Finally, generic drug prices were projected to increase at 1 percent per year based on trends during the 2000–2007 period.[20]

Next, drug expenditure data were adjusted downward to reflect manufacturer rebates. Manufacturer rebates were projected to reduce brand drug prices within the commercial sector by 15 percent, consistent with Medicaid's statutory manufacturer rebate formula that is linked to "best prices" in the commercial sector.[21] Manufacturer rebates for brand and generic products in the Medicaid sector were projected to reduce prices consistent with recent trends reported for state Medicaid programs.[22,23,24]

Next, expenditure data were adjusted to reflect the impact of expected new brand product approvals during the 2008–2019 period. Data from the Pharmaceutical Research and Manufacturers of America (PhRMA) were used to determine the number of new drugs in development in each therapeutic category. [25] Based on PhRMA estimates that an average of one in five new drugs entering clinical trials will be approved by the FDA, the number of new drugs in each category was estimated (see Table A.1). The market entry of these products was projected based on average development times as reported by PhRMA.

It should be noted that PhRMA pipeline data suggest that the number of new chemical entities (NCEs) expected to be introduced in the studied therapeutic categories will be significantly greater during the 2008–2019 period than during the previous decade. From 1998 to 2007, three new antipsychotics, one new immunosuppressant, and two new seizure drugs entered

[19] U.S. General Accounting Office, Prescription Drug PriceTrends, GAO Report 07-1201R, September 7, 2007.
[20] Ibid.
[21] Congressional Budget Office, "Prescription Drug Pricing in the Private Sector," January 2007.
[22] Wisconsin Legislative Fiscal Bureau, Fiscal Effect of Senate Bill 71: Epilepsy Drugs, February 18, 2008.
[23] Kansas Health Policy Authority, Report on Prescription Drug Generic Rebate and Dispensing Cost Study, November 30, 2006.
[24] Congressional Budget Office, "Prices for Brand-Name Drugs Under Selected Federal Programs," June 2005.
[25] PhRMA Medicines in Development, www.phrma.org/medicines_in_development/, accessed June 2008.

the market. By assuming a greater number of new brand product introductions, the potential impact of generic carve-out legislation was lessened, since new brands will capture market share from existing brands and thereby reduce the market for generic versions of these existing brands. Also, new brand products will not likely face generic competition during the 2008–2019 estimation period.

Table A.1: Estimated Number of New Chemical Entities (NCEs) Approved by Therapeutic Class, 2009–2019

Therapeutic Category	Number of NCEs in Pipeline	Projected Number of NCE Approvals 2009-2019
Antiepileptics	19	4
Immunosupressants	11	2
Antipsychotics	33	7

Based on historical claims data for drugs in the same therapeutic classes, it was projected that NCE approvals would be priced at an average of its leading three branded oral solid competitors. Likewise, based on historical trends, it was projected that once an NCE enters a therapeutic category, it captures an average 11 percent market share from each drug in the category, both brand and generic.

Next, the impact of product line extensions for brand drugs was considered. Public information available from pharmaceutical manufacturers on potential product extensions and patent applications for extended release formulations were used to project launches of sustained release (SR) and extended release (XR) product line extensions. Two such product line extensions were projected for the antiepileptic category, one for the immunosuppressant category, and two for the antipsychotic category, as summarized in Table A.2.

Based on analysis of historical PBM claims data in the studied categories, line extension (SR/XR) dosage forms were projected to be priced at the same level as the original brand for an equivalent days supply. Historical trends also showed that SR/XR line extensions typically captured a 50 percent share of the original brand prior to its patent expiration. These findings were then applied to expenditure projections for corresponding drugs in the three therapeutic categories. As was the case with new product introductions, brand product line extensions reduce the potential cost of generic carve-out legislation by reducing the potential market for generic drugs.

Next, the anticipated availability of new generic drugs in each therapeutic category was considered. The projected years of availability for new generics were obtained from the *Express Scripts 2007 Drug Trend Report*, published in April 2008, as well as structured interviews with industry experts. To be conservative, new generic drugs were assumed to become available starting in January of the year *following* the estimated year of availability.

Table A.2: Generic Introductions and Product Line Extensions by Therapeutic Class

	Estimated Generic Entry*	Estimated SR/XR Line Extension
Antiepileptics		
Depakote	2008	
Keppra	2008	2008
Lamictal	2008	2008
Topamax	2009	
Gabitril	2012	
Lyrica	2017	
Immunosuppressants		
Myfortic	2009	
CellCept	2009	
Prograf	2009	2009
Rapamune	2014	
Antipsychotics		
Zyprexa	2011	
Seroquel	2011	2007
Geodon	2012	2011
Abilify	2015	

** To be conservative, the impact of new generics was modeled starting the year following their estimated year of entry.*

Based on an analysis of generic carve-out legislation conducted by the State of Wisconsin,[26] the price of generic drugs in the examined categories was projected to average 40 percent of the brand name product's price. This value was consistent with the price of generics currently available in the examined categories.

With baseline drug-by-drug trends in each therapeutic category projected as outlined above, the impact of generic carve-out legislation on these trends was modeled. We estimated the ten-year cost of generic carve-out legislation being passed in 2009 and taking effect in 2010.

To be conservative, the impact of generic carve-out legislation was only applied to new generic drugs introduced during the 2010 to 2019 period. 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 introductions because these products have not yet established any market share. In reality, however, carve-outs could also have an impact on the use of older

[26] Wisconsin Legislative Fiscal Bureau, Fiscal Effect of Senate Bill 71: Epilepsy Drugs, Feb 18, 2008.

generic drugs, since the vast majority of prescriptions for multisource products are written using the trade (brand) name rather than the chemical (generic) name.[27]

In the absence of generic carve-outs, new generic entries were projected to capture 90 percent of the market previously held by their respective brand equivalents. This projection was based on the average generic dispensing rate observed in 2006 and 2007 in the studied drug categories.

With generic carve-outs, new generic entries were projected to capture only 25 percent of their respective markets. This assumption is based on analysis of PBM claims data for situations where brand drugs have competed with non-AB-rated generics (e.g., Neurontin, Tricor, Verelan). In these situations, the pharmacist would need to telephone the prescriber for approval in order to substitute the generic, making the situation analogous to what would occur if proposed generic carve-out legislation were enacted.

[27] 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.