

House Bill 681

By: Representatives Byrd of the 20th, Lunsford of the 110th, Shipp of the 58th, Hill of the 21st,
Cheokas of the 134th, and others

A BILL TO BE ENTITLED

AN ACT

1 To amend Article 5 of Chapter 4 of Title 26 of the Official Code of Georgia Annotated,
2 relating to prescription drugs, so as to change certain provisions relating to the substitution
3 of generic drugs; to provide legislative findings; to eliminate redundant language relating to
4 the practice of medicine; to prohibit the substitution of anti-epileptic drugs except under
5 certain conditions; to provide for related matters; to repeal conflicting laws; and for other
6 purposes.

7 BE IT ENACTED BY THE GENERAL ASSEMBLY OF GEORGIA:

8 **SECTION 1.**

9 The General Assembly finds that epileptic children and adults are entering clinics and
10 emergency rooms with life-threatening seizures due to the undisclosed substitution of generic
11 drugs for their prescribed drugs. While the Food and Drug Administration is investigating
12 whether an extended release generic drug provides less active drug effects than the
13 comparable brand name, leading to increased risk of severe and life-threatening seizures,
14 Georgia continues to authorize the substitution of generic drugs without patient or physician
15 consent. This undisclosed generic drug substitution has resulted in medical complications,
16 severe injuries, seizure-related automobile accidents, and even death of epileptic patients,
17 including many epileptic children. Experts in epilepsy and its treatment have routinely
18 advised against switching among different versions of the same drug without physician
19 guidance, monitoring, and oversight. The General Assembly further finds that the potential
20 for increased profits to pharmacies or cost savings to medical insurance companies resulting
21 from the use of generic drugs does not outweigh the substantial risk of permitting drug
22 substitution without informed consent. No one should have to risk a seizure because of a
23 flawed formulation of their medication.

24 **SECTION 2.**

25 Article 5 of Chapter 4 of Title 26 of the Official Code of Georgia Annotated, relating to
26 prescription drugs, is amended by revising Code Section 26-4-81, relating to substitution of
27 generic drugs for brand name drugs, as follows:

28 "26-4-81.

29 (a) In accordance with this Code section and except as otherwise provided in Code Section
30 26-4-81.1, a pharmacist may substitute a drug with the same generic name in the same
31 strength, quantity, dose, and dosage form as the prescribed brand name drug product which
32 is, in the pharmacist's reasonable professional opinion, pharmaceutically equivalent.

33 (b) If a practitioner of the healing arts prescribes a drug by its generic name, the
34 pharmacist shall dispense the lowest retail priced drug product which is in stock and which
35 is, in the pharmacist's reasonable professional opinion, pharmaceutically equivalent.

36 (c) Substitutions as provided for in subsections (a) and (b) of this Code section are
37 authorized for the express purpose of making available to the consumer the lowest retail
38 priced drug product which is in stock and which is, in the pharmacist's reasonable
39 professional opinion, both therapeutically equivalent and pharmaceutically equivalent.

40 (d) Whenever a substitution is made, the pharmacist shall record on the original
41 prescription the fact that there has been a substitution and the identity of the dispensed drug
42 product and its manufacturer. Such prescription shall be made available for inspection by
43 the board or its representative in accordance with the rules of the board.

44 (e) The substitution of any drug by a registered pharmacist pursuant to this Code section
45 does not constitute the practice of medicine.

46 (f) A patient for whom a prescription drug order is intended may instruct a pharmacist not
47 to substitute a generic name drug in lieu of a brand name drug.

48 (g) A practitioner of the healing arts may instruct the pharmacist not to substitute a generic
49 name drug in lieu of a brand name drug by including the words 'brand necessary' in the
50 body of the prescription. When a prescription is a hard copy prescription drug order, such
51 indication of brand necessary must be in the practitioner's own handwriting and shall not
52 be printed, applied by rubber stamp, or any such similar means.

53 ~~(h) The substitution of any drug by a registered pharmacist pursuant to this Code section~~
54 ~~does not constitute the practice of medicine."~~

55 **SECTION 3.**

56 Said article is further amended by adding a new Code section to read as follows:

57 "26-4-81.1.

58 (a) As used in this Code section, the term:

59 (1) 'Anti-epileptic drug' means:

60 (A) Any drug prescribed for the treatment of epilepsy; and

61 (B) A drug used to treat or prevent seizures.

62 (2) 'Epilepsy' means a neurological condition characterized by recurrent seizures.

63 (3) 'Interchange' means the substitution of one version of a drug for another, including
64 a generic version for the prescribed brand version, a brand version for the prescribed
65 generic version, a generic version by one manufacturer for a generic version by another
66 manufacturer, a different formulation of the prescribed version, and a different drug for
67 the product prescribed.

68 (4) 'Seizure' means an acute clinical change secondary to a brief disturbance in the
69 electrical activity of the brain.

70 (b) A pharmacist shall not interchange an anti-epileptic drug or formulation of an
71 anti-epileptic drug without prior approval from the prescribing physician."

72 **SECTION 4.**

73 All laws and parts of laws in conflict with this Act are repealed.