

1 AN ACT concerning drugs.

2 Be it enacted by the People of the State of Illinois,  
3 represented in the General Assembly:

4 Section 5. The Wholesale Drug Distribution Licensing Act  
5 is amended by changing Sections 15, 25, and 55 as follows:

6 (225 ILCS 120/15) (from Ch. 111, par. 8301-15)

7 (Section scheduled to be repealed on January 1, 2013)

8 Sec. 15. Definitions. As used in this Act:

9 "Blood" means whole blood collected from a single donor  
10 and processed either for transfusion or further  
11 manufacturing.

12 "Blood component" means that part of blood separated by  
13 physical or mechanical means.

14 "Board" means the State Board of Pharmacy of the  
15 Department of Professional Regulation.

16 "Department" means the Department of Professional  
17 Regulation.

18 "Director" means the Director of Professional Regulation.

19 "Drug sample" means a unit of a prescription drug that is  
20 not intended to be sold and is intended to promote the sale  
21 of the drug.

22 "Manufacturer" means anyone who is engaged in the  
23 manufacturing, preparing, propagating, compounding,  
24 processing, packaging, repackaging, or labeling of a  
25 prescription drug.

26 "Pedigree papers" means that term as defined in the  
27 Illinois Food, Drug and Cosmetic Act.

28 "Person" means and includes a natural person,  
29 partnership, association or corporation.

30 "Pharmacy distributor" means any pharmacy licensed in  
31 this State or hospital pharmacy that is engaged in the

1 delivery or distribution of prescription drugs either to any  
2 other pharmacy licensed in this State or to any other person  
3 or entity including, but not limited to, a wholesale drug  
4 distributor engaged in the delivery or distribution of  
5 prescription drugs who is involved in the actual,  
6 constructive, or attempted transfer of a drug in this State  
7 to other than the ultimate consumer except as otherwise  
8 provided for by law.

9 "Prescription drug" means any human drug required by  
10 federal law or regulation to be dispensed only by a  
11 prescription, including finished dosage forms and active  
12 ingredients subject to subsection (b) of Section 503 of the  
13 Federal Food, Drug and Cosmetic Act.

14 "Wholesale distribution" or "wholesale distributions"  
15 means distribution of prescription drugs to persons other  
16 than a consumer or patient, but does not include any of the  
17 following:

18 (a) Intracompany sales, defined as any transaction  
19 or transfer between any division, subsidiary, parent, or  
20 affiliated or related company under the common ownership  
21 and control of a corporate entity.

22 (b) The purchase or other acquisition by a hospital  
23 or other health care entity that is a member of a group  
24 purchasing organization of a drug for its own use from  
25 the group purchasing organization or from other hospitals  
26 or health care entities that are members of a group  
27 organization.

28 (c) The sale, purchase, or trade of a drug or an  
29 offer to sell, purchase, or trade a drug by a charitable  
30 organization described in subsection (c)(3) of Section  
31 501 of the U.S. Internal Revenue Code of 1954 to a  
32 nonprofit affiliate of the organization to the extent  
33 otherwise permitted by law.

34 (d) The sale, purchase, or trade of a drug or an

1 offer to sell, purchase, or trade a drug among hospitals  
2 or other health care entities that are under common  
3 control. For purposes of this Act, "common control"  
4 means the power to direct or cause the direction of the  
5 management and policies of a person or an organization,  
6 whether by ownership of stock, voting rights, contract,  
7 or otherwise.

8 (e) The sale, purchase, or trade of a drug or an  
9 offer to sell, purchase, or trade a drug for emergency  
10 medical reasons. For purposes of this Act, "emergency  
11 medical reasons" include transfers of prescription drugs  
12 by a retail pharmacy to another retail pharmacy to  
13 alleviate a temporary shortage.

14 (f) The sale, purchase, or trade of a drug, an  
15 offer to sell, purchase, or trade a drug, or the  
16 dispensing of a drug pursuant to a prescription.

17 (g) The distribution of drug samples by  
18 manufacturers' representatives or distributors'  
19 representatives.

20 (h) The sale, purchase, or trade of blood and blood  
21 components intended for transfusion.

22 "Wholesale drug distributor" means any person or entity  
23 engaged in wholesale distribution of prescription drugs,  
24 including, but not limited to, manufacturers; repackers; own  
25 label distributors; jobbers; private label distributors;  
26 brokers; warehouses, including manufacturers' and  
27 distributors' warehouses, chain drug warehouses, and  
28 wholesale drug warehouses; independent wholesale drug  
29 traders; and retail pharmacies that conduct wholesale  
30 distributions, including, but not limited to, any pharmacy  
31 distributor as defined in this Section. A wholesale drug  
32 distributor shall not include any for hire carrier or person  
33 or entity hired solely to transport prescription drugs.

34 (Source: P.A. 87-594.)

1 (225 ILCS 120/25) (from Ch. 111, par. 8301-25)

2 (Section scheduled to be repealed on January 1, 2013)

3 Sec. 25. Wholesale drug distributor licensing  
4 requirements. All wholesale distributors and pharmacy  
5 distributors, wherever located, who engage in wholesale  
6 distribution into, out of, or within the State shall be  
7 subject to the following requirements:

8 (a) No person or distribution outlet shall act as a  
9 wholesale drug distributor without first obtaining a license  
10 to do so from the Department and paying any reasonable fee  
11 required by the Department.

12 (b) The Department may grant a temporary license when a  
13 wholesale drug distributor first applies for a license to  
14 operate within this State. A temporary license shall remain  
15 valid until the Department finds that the applicant meets or  
16 fails to meet the requirements for regular licensure.  
17 Nevertheless, no temporary license shall be valid for more  
18 than 90 days from the date of issuance. Any temporary  
19 license issued under this subsection shall be renewable for a  
20 similar period of time not to exceed 90 days under policies  
21 and procedures prescribed by the Department.

22 (c) No license shall be issued or renewed for a  
23 wholesale drug distributor to operate unless the wholesale  
24 drug distributor shall operate in a manner prescribed by law  
25 and according to the rules and regulations promulgated by the  
26 Department.

27 (d) The Department may require a separate license for  
28 each facility directly or indirectly owned or operated by the  
29 same business entity within this State, or for a parent  
30 entity with divisions, subsidiaries, and affiliate companies  
31 within this State when operations are conducted at more than  
32 one location and there exists joint ownership and control  
33 among all the entities.

34 (e) As a condition for receiving and renewing any

1 wholesale drug distributor license issued under this Act,  
2 each applicant shall satisfy the Department that it has and  
3 will continuously maintain:

4 (1) acceptable storage and handling conditions plus  
5 facilities standards;

6 (2) minimum liability and other insurance as may be  
7 required under any applicable federal or State law;

8 (3) a security system that includes after hours,  
9 central alarm or comparable entry detection capability;  
10 restricted premises access; adequate outside perimeter  
11 lighting; comprehensive employment applicant screening;  
12 and safeguards against employee theft;

13 (4) an electronic, manual, or any other reasonable  
14 system of records, describing all wholesale distributor  
15 activities governed by this Act for the 2 year period  
16 following disposition of each product and reasonably  
17 accessible during regular business hours as defined by  
18 the Department's rules in any inspection authorized by  
19 the Department;

20 (5) officers, directors, managers, and other  
21 persons in charge of wholesale drug distribution,  
22 storage, and handling who must at all times demonstrate  
23 and maintain their capability of conducting business  
24 according to sound financial practices as well as State  
25 and federal law;

26 (6) complete, updated information, to be provided  
27 the Department as a condition for obtaining and renewing  
28 a license, about each wholesale distributor to be  
29 licensed under this Act, including all pertinent licensee  
30 ownership and other key personnel and facilities  
31 information deemed necessary for enforcement of this Act.  
32 Any changes in this information shall be submitted at the  
33 time of license renewal or within 45 days from the date  
34 of the change;

1           (7) written policies and procedures that assure  
2 reasonable wholesale distributor preparation for,  
3 protection against and handling of any facility security  
4 or operation problems, including, but not limited to,  
5 those caused by natural disaster or government emergency;  
6 inventory inaccuracies or product shipping and receiving;  
7 outdated product or other unauthorized product control;  
8 appropriate disposition of returned goods; and product  
9 recalls;

10           (8) sufficient inspection procedures for all  
11 incoming and outgoing product shipments; and

12           (8.5) pedigree papers as provided for in the  
13 Illinois Food, Drug and Cosmetic Act; and

14           (9) operations in compliance with all federal legal  
15 requirements applicable to wholesale drug distribution.

16           (f) The Department shall consider, at a minimum, the  
17 following factors in reviewing the qualifications of persons  
18 who engage in wholesale distribution of prescription drugs in  
19 this State:

20           (1) any conviction of the applicant under any  
21 federal, State, or local laws relating to drug samples,  
22 wholesale or retail drug distribution, or distribution of  
23 controlled substances;

24           (2) any felony convictions of the applicant under  
25 federal, State, or local laws;

26           (3) the applicant's past experience in the  
27 manufacture or distribution of prescription drugs,  
28 including controlled substances;

29           (4) the furnishing by the applicant of false or  
30 fraudulent material in any application made in connection  
31 with drug manufacturing or distribution;

32           (5) suspension or revocation by federal, State, or  
33 local government of any license currently or previously  
34 held by the applicant for the manufacture or distribution

1 of any drug, including controlled substances;

2 (6) compliance with licensing requirements under  
3 previously granted licenses, if any;

4 (7) compliance with requirements to maintain and  
5 make available to the Department or to federal, State, or  
6 local law enforcement officials those records required by  
7 this Act; and

8 (8) any other factors or qualifications the  
9 Department considers relevant to and consistent with the  
10 public health and safety, including whether the granting  
11 of the license would not be in the public interest.

12 (9) All requirements set forth in this subsection  
13 shall conform to wholesale drug distributor licensing  
14 guidelines formally adopted by the U.S. Food and Drug  
15 Administration (FDA). In case of conflict between any  
16 wholesale drug distributor licensing requirement imposed  
17 by the Department and any FDA wholesale drug distributor  
18 licensing guideline, the FDA guideline shall control.

19 (g) An agent or employee of any licensed wholesale drug  
20 distributor need not seek licensure under this Section and  
21 may lawfully possess pharmaceutical drugs when the agent or  
22 employee is acting in the usual course of business or  
23 employment.

24 (h) The issuance of a license under this Act shall not  
25 change or affect tax liability imposed by the State on any  
26 wholesale drug distributor.

27 (i) A license issued under this Act shall not be sold,  
28 transferred, or assigned in any manner.

29 (Source: P.A. 92-586, eff. 6-26-02.)

30 (225 ILCS 120/55) (from Ch. 111, par. 8301-55)

31 (Section scheduled to be repealed on January 1, 2013)

32 Sec. 55. Discipline; grounds.

33 (a) The Department may refuse to issue, restore, or

1 renew, or may revoke, suspend, place on probation, reprimand  
2 or take other disciplinary action as the Department may deem  
3 proper for any of the following reasons:

4 (1) Violation of this Act or its rules.

5 (2) Aiding or assisting another person in violating  
6 any provision of this Act or its rules.

7 (3) Failing, within 60 days, to respond to a  
8 written requirement made by the Department for  
9 information.

10 (4) Engaging in dishonorable, unethical, or  
11 unprofessional conduct of a character likely to deceive,  
12 defraud, or harm the public. This includes violations of  
13 "good faith" as defined by the Illinois Controlled  
14 Substances Act and applies to all prescription drugs.

15 (5) Discipline by another U.S. jurisdiction or  
16 foreign nation, if at least one of the grounds for the  
17 discipline is the same or substantially equivalent to  
18 those set forth in this Act.

19 (6) Selling or engaging in the sale of drug samples  
20 provided at no cost by drug manufacturers.

21 (7) Conviction of the applicant or licensee, or any  
22 officer, director, manager or shareholder who owns more  
23 than 5% of stock, in State or federal court of any crime  
24 that is a felony.

25 (8) Habitual or excessive use or addiction to  
26 alcohol, narcotics, stimulants, or any other chemical  
27 agent or drug that results in the inability to function  
28 with reasonable judgment, skill, or safety.

29 (9) Violation of the Illinois Food, Drug and  
30 Cosmetic Act.

31 (b) The Department may refuse to issue, restore, or  
32 renew, or may revoke, suspend, place on probation, reprimand  
33 or take other disciplinary action as the Department may deem  
34 property including fines not to exceed \$1,500 \$1000 for any



1 of the following reasons:

2 (1) Material misstatement in furnishing information  
3 to the Department.

4 (2) Making any misrepresentation for the purpose of  
5 obtaining a license.

6 (3) A finding by the Department that the licensee,  
7 after having his or her license placed on probationary  
8 status, has violated the terms of probation.

9 (4) A finding that licensure or registration has  
10 been applied for or obtained by fraudulent means.

11 (5) Willfully making or filing false records or  
12 reports.

13 (6) A finding of a substantial discrepancy in a  
14 Department audit of a prescription drug, including a  
15 controlled substance as that term is defined in this Act  
16 or in the Illinois Controlled Substances Act.

17 (c) The Department may refuse to issue or may suspend  
18 the license or registration of any person who fails to file a  
19 return, or to pay the tax, penalty or interest shown in a  
20 filed return, or to pay any final assessment of tax, penalty  
21 or interest, as required by any tax Act administered by the  
22 Illinois Department of Revenue, until the time the  
23 requirements of the tax Act are satisfied.

24 (d) The Department shall revoke the license or  
25 certificate of registration issued under this Act or any  
26 prior Act of this State of any person who has been convicted  
27 a second time of committing any felony under the Illinois  
28 Controlled Substances Act or who has been convicted a second  
29 time of committing a Class 1 felony under Sections 8A-3 and  
30 8A-6 of the Illinois Public Aid Code. A person whose license  
31 or certificate of registration issued under this Act or any  
32 prior Act of this State is revoked under this subsection (c)  
33 shall be prohibited from engaging in the practice of pharmacy  
34 in this State.

1 (Source: P.A. 87-594.)

2 Section 10. The Illinois Food, Drug and Cosmetic Act is  
3 amended by changing Sections 2, 3, 3.7, 5, and 14 and adding  
4 Sections 2.40, 2.41, 2.42, 2.43, 2.44, 3.21a, 3.21b, 3.21c,  
5 3.21d, 3.23, 3.24, 3.25, 3.26, and 14.5 as follows:

6 (410 ILCS 620/2) (from Ch. 56 1/2, par. 502)

7 Sec. 2. In this Act unless the context otherwise  
8 requires, the words and phrases defined in the Sections  
9 following this Section and preceding Section 3 have the  
10 meanings ascribed to them in those Sections 2-1-through-2-37,  
11 have-the-meanings-set-forth-therein.

12 (Source: P.A. 84-891.)

13 (410 ILCS 620/2.40 new)

14 Sec. 2.40. Authenticate. "Authenticate" means to  
15 affirmatively verify before any distribution of a legend drug  
16 occurs that each transaction listed on the pedigree paper has  
17 occurred.

18 (410 ILCS 620/2.41 new)

19 Sec. 2.41. Contraband legend drug. "Contraband legend  
20 drug" means (i) any adulterated drug, as defined in Section  
21 14, (ii) any counterfeit drug, and (iii) any legend drug for  
22 which a pedigree paper does not exist, for which the pedigree  
23 paper in existence has been forged, counterfeited, falsely  
24 created, or that contains any altered, false, or  
25 misrepresented matter.

26 (410 ILCS 620/2.42 new)

27 Sec. 2.42. Legend drug label. "Legend drug label" means  
28 any display of written, printed, or graphic matter upon the  
29 immediate container of any legend drug prior to its

1 dispensing to an individual patient pursuant to a  
2 prescription of a practitioner authorized by law to  
3 prescribe.

4 (410 ILCS 620/2.43 new)

5 Sec. 2.43. Pedigree paper. "Pedigree paper" means a  
6 document in a form approved by the Department of Public  
7 Health and containing information that records each  
8 distribution of any given legend drug, from sale by a  
9 pharmaceutical manufacturer, through acquisition and sale by  
10 any wholesaler, until final sale to a pharmacy or other  
11 person administering or dispensing the drug.

12 (410 ILCS 620/2.44 new)

13 Sec. 2.44. Prescription label. "Prescription label"  
14 means any display of written, printed, or graphic matter upon  
15 the immediate container of any legend drug dispensed pursuant  
16 to a prescription of a practitioner authorized by law to  
17 prescribe.

18 (410 ILCS 620/3) (from Ch. 56 1/2, par. 503)

19 Sec. 3. The enumerated acts in Sections 3.1 through  
20 3.21d ~~3.21~~ and the causing thereof are prohibited in this  
21 State.

22 (Source: P.A. 84-891.)

23 (410 ILCS 620/3.7) (from Ch. 56 1/2, par. 503.7)

24 Sec. 3.7. The purchase or sale of prescription drugs for  
25 wholesale distribution except in accordance with the  
26 Wholesale Drug Distribution Licensing Act. ~~The-giving-of-a~~  
27 guaranty-or-undertaking-which-is-false,-except--by--a--person  
28 who--relied--on--a-guaranty-or-undertaking-to-the-same-effect  
29 signed-by-and-containing-the-name-and-address-of--the--person  
30 residing--in--the--State-of-Illinois-from-whom-he-received-in

1 ~~good-faith-the-food, drug, device or cosmetic.~~

2 (Source: Laws 1967, p. 959.)

3 (410 ILCS 620/3.21a new)

4 Sec. 3.21a. Removing a pharmacy's dispensing label from  
5 a dispensed prescription drug with the intent to further  
6 distribute the prescription drug.

7 (410 ILCS 620/3.21b new)

8 Sec. 3.21b. Distributing a prescription drug that was  
9 previously dispensed by a licensed pharmacy, unless such  
10 distribution was authorized by the Pharmacy Practice Act of  
11 1987.

12 (410 ILCS 620/3.21c new)

13 Sec. 3.21c. Failure to obtain or pass on a pedigree  
14 paper.

15 (410 ILCS 620/3.21d new)

16 Sec. 3.21d. The receipt of a prescription drug pursuant  
17 to a wholesale distribution without first receiving a  
18 pedigree paper that was attested to as accurate and complete  
19 by the wholesale distributor.

20 (410 ILCS 620/3.23 new)

21 Sec. 3.23. Criminal acts involving contraband or  
22 adulterated drugs.

23 (a) A person, other than a manufacturer, engaged in the  
24 wholesale distribution of legend drugs who fails to deliver  
25 to another person complete and accurate pedigree papers  
26 concerning a legend drug or contraband legend drug prior to  
27 transferring the legend drug or contraband legend drug to  
28 another person commits a Class 3 felony.

29 (b) A person engaged in the wholesale distribution of

1 legend drugs who fails to acquire complete and accurate  
2 pedigree papers concerning a legend drug or contraband legend  
3 drug prior to obtaining the legend drug or contraband legend  
4 drug from another person commits a Class 3 felony.

5 (c) A person who knowingly destroys, alters, conceals,  
6 or fails to maintain complete and accurate pedigree papers  
7 concerning any legend drug or contraband legend drug in his  
8 or her possession commits a Class 3 felony.

9 (d) A person engaged in the wholesale distribution of  
10 legend drugs who is in possession of pedigree papers  
11 concerning legend drugs or contraband legend drugs and who  
12 fails to authenticate the matters contained in the pedigree  
13 papers and who nevertheless attempts to further distribute  
14 legend drugs or contraband legend drug commits a Class 3  
15 felony.

16 (e) A person in possession of pedigree papers concerning  
17 legend drugs or contraband legend drugs who falsely swears or  
18 certifies that he or she has authenticated the matters  
19 contained in the pedigree papers commits a Class 3 felony.

20 (f) A person who knowingly forges, counterfeits, or  
21 falsely creates any pedigree paper; who falsely represents  
22 any factual matter contained on any pedigree paper; or who  
23 knowingly omits to record material information required to be  
24 recorded in a pedigree paper, commits a Class 1 felony.

25 (g) A person who knowingly purchases or receives from a  
26 person not authorized to distribute legend drugs under this  
27 Act a legend drug in a wholesale distribution transaction  
28 commits a Class 1 felony.

29 (h) A person who knowingly sells or transfers to a  
30 person not authorized to purchase or possess legend drug,  
31 under the law of the jurisdiction in which the person  
32 receives the drug, a legend drug in a wholesale distribution  
33 transaction commits a Class 1 felony.

34 (i) A person who is knowingly in actual or constructive

1 possession of any amount of contraband legend drugs, who  
2 knowingly sells or delivers, or who possesses with intent to  
3 sell or deliver any amount of contraband legend drugs,  
4 commits a Class 1 felony.

5 (j) A person who knowingly forges, counterfeits, or  
6 falsely creates any prescription label or legend drug label,  
7 or who falsely represents any factual matter contained on any  
8 prescription label or legend drug label, commits a Class X  
9 felony.

10 (410 ILCS 620/3.24 new)

11 Sec. 3.24. Trafficking in contraband legend drugs.

12 (a) A person who knowingly sells, purchases,  
13 manufactures, delivers, or brings into this State, or who is  
14 knowingly in actual or constructive possession of any amount  
15 of contraband legend drugs valued at \$25,000 or more commits  
16 a Class X felony. Upon conviction, each defendant shall be  
17 ordered to pay a mandatory fine according to the following  
18 schedule:

19 (1) If the value of contraband legend drugs  
20 involved is \$25,000 or more, but less than \$100,000, the  
21 defendant shall pay a mandatory fine of \$25,000. If the  
22 defendant is a corporation or other person that is not a  
23 natural person, it shall pay a mandatory fine of \$75,000.

24 (2) If the value of contraband legend drugs  
25 involved is \$100,000 or more, but less than \$250,000, the  
26 defendant shall pay a mandatory fine of \$100,000. If the  
27 defendant is a corporation or other person that is not a  
28 natural person, it shall pay a mandatory fine of  
29 \$300,000.

30 (3) If the value of contraband legend drugs  
31 involved is \$250,000 or more, the defendant shall pay a  
32 mandatory fine of \$200,000. If the defendant is a  
33 corporation or other person that is not a natural person,

1 it shall pay a mandatory fine of \$600,000.

2 (b) As used in this Section, "value" means the market  
3 value of the property at the time and place of the offense  
4 or, if the market value cannot be satisfactorily ascertained,  
5 the cost of replacement of the property within a reasonable  
6 time after the offense.

7 (c) Amounts of value of separate contraband legend drugs  
8 involved in distinct transactions for the distribution of the  
9 contraband legend drugs committed pursuant to one scheme or  
10 course of conduct, whether involving the same person or  
11 several persons, may be aggregated in determining the  
12 punishment of the offense.

13 (410 ILCS 620/3.25 new)

14 Sec. 3.25. Sale or purchase of contraband legend drugs  
15 resulting in great bodily harm. A person who knowingly sells,  
16 purchases, manufactures, delivers, or brings into this State,  
17 or who is knowingly in actual or constructive possession of  
18 any amount of contraband legend drugs, and whose acts in  
19 violation of this Section result in great bodily harm to a  
20 person, commits a Class X felony.

21 (410 ILCS 620/3.26 new)

22 Sec. 3.26. Sale or purchase of contraband legend drugs  
23 resulting in death. A person who knowingly manufactures,  
24 sells, purchases, delivers, or brings into this State, or who  
25 is knowingly in actual or constructive possession of any  
26 amount of contraband legend drugs, and whose acts in  
27 violation of this Section result in the death of a person,  
28 commits a Class X felony.

29 (410 ILCS 620/5) (from Ch. 56 1/2, par. 505)

30 Sec. 5. (a) A person who violates any of the provisions  
31 of this Act, other than Sections 3.22, 3.23, 3.24, 3.25,

1 3.26, and 6, is guilty of a Class C misdemeanor; but if the  
2 violation is committed after a conviction of such person  
3 under this Section has become final, the person shall be  
4 guilty of a Class A misdemeanor. A person who violates the  
5 provisions of Section 6 of this Act is guilty of a Class A  
6 misdemeanor; but if the violation is committed after a  
7 conviction of such person under this Section has become  
8 final, the person shall be guilty of a Class 4 felony.

9 (b) No person is subject to the penalties of subsection  
10 (a) of this Section for (1) violating Section 3.1 or 3.3 if  
11 he establishes a guaranty or undertaking signed by and  
12 containing the name and address of the person residing in the  
13 State of Illinois from whom he received the article in good  
14 faith, to the effect that the article is not adulterated or  
15 misbranded within the meaning of this Act, designating this  
16 Act; or (2) for having violated clause (2) of Section 3.16 if  
17 such person acted in good faith and had no reason to believe  
18 that the use of the punch, die, plate, stone or other thing  
19 involved would result in a drug being a counterfeit drug, or  
20 for having violated clause (3) of Section 3.16 if the person  
21 doing the act or causing it to be done acted in good faith  
22 and had no reason to believe that the drug was a counterfeit  
23 drug.

24 (c) No publisher, radio-broadcast licensee, agency or  
25 medium for the dissemination of an advertisement, except the  
26 manufacturer, packer, distributor or seller of the article to  
27 which a false advertisement relates is liable under this  
28 Section for the dissemination of such false advertisement  
29 unless he has refused on the request of the Director to  
30 furnish the Director the name and post office address of the  
31 manufacturer, packer, distributor, seller or advertising  
32 agency residing in the State of Illinois who causes him to  
33 disseminate such advertisement.

34 (d) No person shall be subject to the penalties of



1 subsection (a) of this Section for a violation of Section 3  
2 involving misbranded food if the violation exists solely  
3 because the food is misbranded under subsection (c) of  
4 Section 11 because of its advertising, and no person shall be  
5 subject to the penalties of subsection (a) of this Section  
6 for such a violation unless the violation is committed with  
7 the intent to defraud or mislead.

8 (Source: P.A. 86-704; 87-754.)

9 (410 ILCS 620/14) (from Ch. 56 1/2, par. 514)

10 Sec. 14. A drug or device is adulterated: (a) (1) If it  
11 consists in whole or in part of any filthy, putrid or  
12 decomposed substance; or (2) (A) if it has been produced,  
13 prepared, packed or held under unsanitary conditions whereby  
14 it may have been contaminated with filth or whereby it may  
15 have been rendered injurious to health; or (B) if it is a  
16 drug and the methods used in, or the facilities or controls  
17 used for, its manufacture, processing, packing or holding do  
18 not conform to or are not operated or administered in  
19 conformity with current good manufacturing practice to assure  
20 that such drug meets the requirements of the Act as to safety  
21 and has the identity and strength and meets the quality and  
22 purity characteristics which it purports or is represented to  
23 possess; or (3) if it is a drug and its container is  
24 composed, in whole or in part, of any poisonous or  
25 deleterious substance which may render the contents injurious  
26 to health; or (4) if (A) it is a drug and it bears or  
27 contains, for purposes of coloring only, a color additive  
28 which is unsafe within the meaning of Section 706 of the  
29 Federal Act or (B) it is a color additive, the intended use  
30 of which in or on drugs or devices is for purposes of  
31 coloring only and is unsafe within the meaning of Section 706  
32 of the Federal Act; or (5) if it is a new animal drug which  
33 is unsafe within the meaning of Section 512 of the Federal

1 Act; or (6) if it is an animal feed bearing or containing a  
2 new animal drug, and such animal feed is unsafe within the  
3 meaning of Section 512 of the Federal Act.

4 (b) If it purports to be or is represented as a drug the  
5 name of which is recognized in an official compendium, and  
6 its strength differs from or its quality or purity falls  
7 below the standard set forth in such compendium. Such  
8 determination as to strength, quality or purity shall be made  
9 in accordance with the tests or methods of assay set forth in  
10 such compendium or in the absence of or inadequacy of such  
11 tests or methods of assay, those prescribed under authority  
12 of the Federal Act. No drug defined in an official compendium  
13 is adulterated under this subsection because it differs from  
14 the standard of strength, quality or purity therefor set  
15 forth in such compendium, if its difference in strength,  
16 quality or purity from such standard is plainly stated on its  
17 label. When a drug is recognized in both the United States  
18 Pharmacopoeia - National Formulary and the Homeopathic  
19 Pharmacopoeia of the United States it shall be subject to the  
20 requirements of the United States Pharmacopoeia - National  
21 Formulary unless it is labeled and offered for sale as a  
22 homeopathic drug, in which case it shall be subject to the  
23 provisions of the Homeopathic Pharmacopoeia of the United  
24 States and not to those of the United States Pharmacopoeia -  
25 National Formulary.

26 (c) If it is not subject to the provisions of subsection  
27 (b) of this Section and its strength differs from or its  
28 purity or quality falls below that which it purports or is  
29 represented to possess.

30 (d) If it is a drug and any substance has been (1) mixed  
31 or packed therewith so as to reduce its quality or strength;  
32 or (2) substituted wholly or in part therefor.

33 (e) If it is, or purports to be or is represented as, a  
34 device which is subject to a performance standard established

1 under Section 514 of the Federal Act, unless such device is  
2 in all respects in conformity with such standard.

3 (f) If it is a device and the methods used in, or the  
4 facilities or controls used for, its manufacture, packing,  
5 storage, or installations are not in conformity with  
6 applicable requirements under Section 520(b)(1) of the  
7 Federal Act or an applicable condition as prescribed by an  
8 order under Section 520(b)(2) of the Federal Act.

9 (g) If it is a device for which an exemption has been  
10 granted under Section 520(g) of the Federal Act for  
11 investigational use and the person who was granted such  
12 exemption fails to comply with a requirement prescribed by or  
13 under such Section.

14 (h) If it is a legend drug for which the required  
15 pedigree paper is nonexistent, fraudulent, or incomplete  
16 under the requirements of this Act or the applicable rules,  
17 or that has been purchased, held, sold, or distributed at any  
18 time by a person not authorized under federal or state law to  
19 do so.

20 (Source: P.A. 84-891.)

21 (410 ILCS 620/14.5 new)

22 Sec. 14.5. Pedigree papers; requirements. A legend drug's  
23 pedigree paper must at least contain the following  
24 information: (i) the amount of the legend drug, (ii) its  
25 dosage form and strength, (iii) its lot numbers, (iv) the  
26 name and address of each owner of the legend drug and his or  
27 her signature, (v) its shipping information, including the  
28 name and address of each person certifying delivery or  
29 receipt of the legend drug, (vi) a certification that the  
30 recipient has authenticated the pedigree papers, and (vii)  
31 the name, address, telephone number, and, if available,  
32 e-mail contact information of each wholesaler involved in the  
33 chain of the legend drug's custody.

1           Section 99. Effective date. This Act takes effect on  
2    January 1, 2006.