

HOUSE No. 2153

By Mr. Koutoujian of Waltham, petition of Peter J. Koutoujian relative to the wholesale distribution of prescription medications. Public Health.

The Commonwealth of Massachusetts

In the Year Two Thousand and Seven.

AN ACT REGARDING WHOLESALE LICENSURE AND PRESCRIPTION MEDICATION INTEGRITY.

Be it enacted by the Senate and House of Representatives in General Court assembled, and by the authority of the same, as follows:

1 SECTION 1. Section 36A of Chapter 112 of the General Laws of
2 the Official 2004 Edition is hereby amended by adding the following
3 subsections:—

4 Section 1. For the purposes of this section the following words
5 shall have the following meanings:—

6 “Authentication”, to affirmatively verify before any wholesale
7 distribution of a prescription drug occurs that each transaction listed
8 on the pedigree has occurred.

9 “Authorized distributor of record”, a wholesale distributor with
10 whom a manufacturer has established an ongoing relationship to dis-
11 tribute the manufacturer’s prescription drug. An ongoing relation-
12 ship is deemed to exist between such wholesale distributor and a
13 manufacturer when the wholesale distributor, including any affili-
14 ated group of the wholesale distributor, as defined in Section 1504 of
15 the Internal Revenue Code, complies with any one of the
16 following:—

17 (1) the wholesale distributor has a written agreement currently in
18 effect with the manufacturer evidencing such ongoing relationship;
19 and/or

20 (2) the wholesale distributor is listed on the manufacturer’s cur-
21 rent list of authorized distributors of record, which is updated by the
22 manufacturer on no less than a monthly basis.

23 “Drop shipment”, the sale of a prescription drug to a wholesale
24 distributor by the manufacturer of the prescription drug, that

25 manufacturer's third party logistics provider, or that manufacturer's
26 exclusive distributor, whereby the wholesale distributor or chain
27 pharmacy warehouse takes title but not physical possession of such
28 prescription drug and the wholesale distributor invoices the phar-
29 macy or chain pharmacy warehouse, and the pharmacy or chain
30 pharmacy warehouse receives delivery of the prescription drug
31 directly from the manufacturer, or that manufacturer's third party
32 logistics provider, or that manufacturer's exclusive distributor.

33 "Chain pharmacy warehouse", a physical location for prescription
34 drugs that acts as a central warehouse and performs intracompany
35 sales or transfers of such drugs to a group of chain pharmacies that
36 have the same common ownership and control.

37 "Co-licensed product", a prescription drug in which 2 or more
38 parties have the right to engage in the manufacturing and/or mar-
39 keting of such drug.

40 "Facility", a facility of a wholesale distributor where prescription
41 drugs are stored, handled, repackaged, or offered for sale.

42 "Manufacturer's exclusive distributor", anyone who contracts
43 with a manufacturer to provide or coordinate warehousing, distribu-
44 tion, or other services on behalf of a manufacturer and who takes
45 title to that manufacturer's prescription drug, but who does not have
46 general responsibility to direct the sale or disposition of the manu-
47 facturer's prescription drug. Such manufacturer's exclusive distrib-
48 utor must be licensed as a wholesale distributor under this Act.

49 "Normal distribution channel", a chain of custody for a prescrip-
50 tion drug that goes from a manufacturer of the prescription drug, or
51 from that manufacturer to that manufacturer's co-licensed partner, or
52 from that manufacturer to that manufacturer's third-party logistics
53 provider, or from that manufacturer to that manufacturer's exclusive
54 distributor to:—

55 (1) a pharmacy to a patient or other designated persons authorized
56 by law to dispense or administer such drug to a patient;

57 (2) a wholesale distributor to a pharmacy to a patient or other des-
58 igned persons authorized by law to dispense or administer such
59 drug to a patient; or

60 (3) a wholesale distributor to a chain pharmacy warehouse to that
61 chain pharmacy warehouse's intracompany pharmacy to a patient or
62 other designated persons authorized by law to dispense or administer
63 such drug to a patient; or

64 (4) an authorized distributor of record to a specialty wholesale
65 distributor to a specialty pharmacy to a patient or other designated
66 persons authorized by law to dispense or administer such drug to a
67 patient.

68 “Pedigree”, a document or electronic file containing information
69 that records each distribution of any given prescription drug within
70 the distribution channel.

71 “Prescription drug”, any drug (including any biological product,
72 except for blood and blood components intended for transfusion or
73 biological products that are also medical devices) required by Fed-
74 eral law (including Federal regulation) to be dispensed only by a
75 prescription, including finished dosage forms and bulk drug sub-
76 stances subject to Section 503(b) of the Federal Food, Drug and
77 Cosmetic Act (“FFDCA”).

78 “Repackage”, repackaging or otherwise changing the container,
79 wrapper, or labeling to further the distribution of a prescription drug
80 excluding that completed by the pharmacists responsible for dis-
81 pensing product to the patient.

82 “Repackager”, a person who repackages.

83 “Specialty wholesale distributor”, anyone who exclusively dis-
84 tributes a prescription drug to a specific group of specialty pharma-
85 cies or licensed practitioners and who has certified to the Board of
86 Pharmacy that the distribution of such products will only occur in
87 the limited situations described herein. Such specialty wholesale dis-
88 tributors shall be separately licensed and designated as specialty
89 wholesale distributors by the Board of Pharmacy or shall be
90 inspected and accredited as a specialty wholesale distributor by a
91 nationally recognized accreditation program approved by the
92 licensing agency.

93 “Third party logistics provider”, anyone who contracts with a pre-
94 scription drug manufacturer to provide or coordinate warehousing,
95 distribution, or other services on behalf of a manufacturer, but does
96 not take title to the prescription drug or have general responsibility
97 to direct the prescription drug’s sale or disposition. Such third party
98 logistics provider must be licensed as a wholesale distributor under
99 this Act.

100 “Wholesale distributor”, anyone engaged in the wholesale distrib-
101 ution of prescription drugs, including, but not limited to, repack-
102 agers; own-label distributors; private-label distributors; jobbers;

103 brokers; warehouses, including manufacturers' and distributors'
104 warehouses; manufacturer's exclusive distributors; and authorized
105 distributors of record; drug wholesalers or distributors; independent
106 wholesale drug traders; specialty wholesale distributors; third party
107 logistics providers; and retail pharmacies that conduct wholesale dis-
108 tribution; and chain pharmacy warehouses that conduct wholesale
109 distribution.

110 "Wholesale distribution", distribution of prescription drugs to per-
111 sons other than a consumer or patient, but does not include:—

112 (1) Intracompany sales of prescription drugs, meaning any trans-
113 action or transfer between any division, subsidiary, parent or affili-
114 ated or related company under common ownership and control of a
115 corporate entity, or any transaction or transfer between co-licensees
116 of a co-licensed product.

117 (2) The sale, purchase, distribution, trade, or transfer of a pre-
118 scription drug or offer to sell, purchase, distribute, trade, or transfer
119 a prescription drug for emergency medical reasons.

120 (3) The distribution of prescription drug samples by manufac-
121 turers' representatives.

122 (4) Drug returns, when conducted by a hospital, health care entity,
123 or charitable institution in accordance with 21 C.F.R. § 203.23.

124 (5) The sale of minimal quantities of prescription drugs by retail
125 pharmacies to licensed practitioners for office use.

126 (6) The sale, purchase, or trade of a drug, an offer to sell, pur-
127 chase, or trade a drug, or the dispensing of a drug pursuant to a pre-
128 scription.

129 (7) The sale, transfer, merger or consolidation of all or part of the
130 business of a pharmacy or pharmacies from or with another phar-
131 macy or pharmacies, whether accomplished as a purchase and sale
132 of stock or business assets.

133 (8) The sale, purchase, distribution, trade, or transfer of a pre-
134 scription drug from one authorized distributor of record to one addi-
135 tional authorized distributor of record when the manufacturer has
136 stated in writing to the receiving authorized distributor of record that
137 the manufacturer is unable to supply such prescription drug and the
138 supplying authorized distributor of record states in writing that the
139 prescription drug being supplied had until that time been exclusively
140 in the normal distribution channel.

141 (9) Drop shipments of a prescription drug from the manufacturer
142 of such prescription drug, or that manufacturer's co-licensed partner,
143 or that manufacturer's third party logistics provider or that manufac-
144 turer's exclusive distributor, to a pharmacy, or chain pharmacy ware-
145 house.

146 (10) The delivery of, or offer to deliver, a prescription drug by a
147 common carrier solely in the common carrier's usual course of busi-
148 ness of transporting prescription drugs, and such common carrier
149 does not store, warehouse, or take legal ownership of the prescrip-
150 tion drug.

151 (11) The sale or transfer from a retail pharmacy or chain phar-
152 macy warehouse of expired, damaged, returned, or recalled prescrip-
153 tion drugs to the original manufacturer or to a third party returns
154 processor.

1 SECTION 2. Wholesale Drug Distributor Licensing Require-
2 ment/Minimum Requirements for Licensure.

3 (a) Every wholesale distributor who engages in the wholesale dis-
4 tribution of prescription drugs must be licensed by the State
5 licensing authority in the State in which it resides, and every non-
6 resident wholesale distributor must be licensed in a State if it ships
7 prescription drugs into that State, in accordance with this Act before
8 engaging in wholesale distributions of wholesale prescription drugs.
9 The State licensing authority shall exempt manufacturers from any
10 licensing and other requirements of this section, to the extent not
11 required by Federal law or regulation, unless particular requirements
12 are deemed necessary and appropriate following rulemaking.

13 (b) The State licensing authority shall require the following min-
14 imum information from each wholesale distributor applying to get a
15 license under paragraph (a):—

16 (1) The name, full business address, and telephone number of the
17 licensee.

18 (2) All trade or business names used by the licensee.

19 (3) Addresses, telephone numbers, and the names of contact per-
20 sons for all facilities used by the licensee for the storage, handling,
21 and distribution of prescription drugs.

22 (4) The type of ownership or operation (i.e., partnership, corpora-
23 tion, or sole proprietorship).

24 (5) The name(s) of the owner and/or operator of the licensee,
25 including:—

26 (A) If a person, the name of the person;

27 (B) If a partnership, the name of each partner, and the name of the
28 partnership;

29 (C) If a corporation, the name and title of each corporate officer
30 and director, the corporate names, and the name of the State of incor-
31 poration; and

32 (D) If a sole proprietorship, the full name of the sole proprietor
33 and the name of the business entity.

34 (6) A list of all licenses and permits issued to the applicant by any
35 other State that authorizes the applicant to purchase or possess pre-
36 scription drugs.

37 (7) Designated Representative - The name of the applicant's des-
38 ignated representative for the facility, together with the personal
39 information statement and fingerprints, required pursuant to subpara-
40 graph (8) for such person.

41 (8) Personal Information Statement - Each person required by
42 subparagraph (7) to provide a personal information statement and
43 fingerprints shall provide the following information to the State:—

44 (A) The person's places of residence for the past 7 years;

45 (B) The person's date and place of birth;

46 (C) The person's occupations, positions of employment, and
47 offices held during the past 7 years;

48 (D) The principal business and address of any business, corpora-
49 tion, or other organization in which each such office of the person
50 was held or in which each such occupation or position of employ-
51 ment was carried on;

52 (E) Whether the person has been, during the past 7 years, the sub-
53 ject of any proceeding for the revocation of any license or any crim-
54 inal violation and, if so, the nature of the proceeding and the
55 disposition of the proceeding;

56 (F) Whether, during the past 7 years, the person has been
57 enjoined, either temporarily or permanently, by a court of competent
58 jurisdiction from violating any Federal or State law regulating the
59 possession, control, or distribution of prescription drugs or criminal
60 violations, together with details concerning any such event;

61 (G) A description of any involvement by the person with any
62 business, including any investments, other than the ownership of

63 stock in a publicly traded company or mutual fund, during the past 7
64 years, which manufactured, administered, prescribed, distributed, or
65 stored pharmaceutical products and any lawsuits in which such busi-
66 nesses were named as a party;

67 (H) A description of any misdemeanor or felony criminal offense
68 of which the person, as an adult, was found guilty, regardless of
69 whether adjudication of guilt was withheld or whether the person
70 pled guilty or nolo contendere. If the person indicates that a criminal
71 conviction is under appeal and submits a copy of the notice of appeal
72 of that criminal offense, the applicant must, within 15 days after the
73 disposition of the appeal, submit to the State a copy of the final
74 written order of disposition; and

75 (I) A photograph of the person taken in the previous 30 days.

76 (c) The information required pursuant to paragraph (b) shall be
77 provided under oath.

78 (d) The State shall not issue a wholesale distributor license to an
79 applicant, unless the State:—

80 (1) Conducts a physical inspection of the facility at the address
81 provided by the applicant as required in Section 2(b)(1); and

82 (2) Determines that the designated representative meets the
83 following qualifications:—

84 (A) Is at least 21 years of age;

85 (B) Has been employed full time for at least 3 years in a phar-
86 macy or with a wholesale distributor in a capacity related to the dis-
87 pensing and distribution of, and recordkeeping relating to,
88 prescription drugs;

89 (C) Is employed by the applicant full time in a managerial level
90 position;

91 (D) Is actively involved in and aware of the actual daily operation
92 of the wholesale distributor;

93 (E) Is physically present at the facility of the applicant during reg-
94 ular business hours, except when the absence of the designated rep-
95 resentative is authorized, including but not limited to, sick leave and
96 vacation leave;

97 (F) Is serving in the capacity of a designated representative for
98 only one applicant at a time, except where more than one licensed
99 wholesale distributor is co-located in the same facility and such
100 wholesale distributors are members of an affiliated group, as defined
101 in Section 1504 of the Internal Revenue Code;

102 (G) Does not have any convictions under any Federal, State, or
103 local laws relating to wholesale or retail prescription drug distribu-
104 tion or distribution of controlled substances; and

105 (H) Does not have any felony convictions under Federal, State, or
106 local laws.

107 (e) The State shall submit the fingerprints provided by a person
108 with a license application for a statewide criminal record check and
109 for forwarding to the Federal Bureau of Investigation for a national
110 criminal record check of the person.

111 (f) Bond Requirement - The State licensing authority shall require
112 every wholesale distributor applying for a license to submit a bond
113 of at least \$100,000, or other equivalent means of security accept-
114 able to the State, such as an irrevocable letter of credit or a deposit in
115 a trust account or financial institution, payable to a fund established
116 by the State pursuant to paragraph (g). The purpose of the bond is to
117 secure payment of any fines or penalties imposed by the State and
118 any fees and costs incurred by the State regarding that license, which
119 are authorized under State law and which the licensee fails to pay 30
120 days after the fines, penalties, or costs become final. The State may
121 make a claim against such bond or security until 1 year after the
122 licensee's license ceases to be valid. The bond shall cover all facili-
123 ties operated by the applicant in the state.

124 (g) The State licensing authority shall establish a fund, separate
125 from its other accounts, in which to deposit the wholesale distributor
126 bonds.

127 (h) If a wholesale distributor distributes prescription drugs from
128 more than one facility, the wholesale distributor shall obtain a
129 license for each facility.

130 (i) Every calendar year, the State licensing authority shall send to
131 each wholesale distributor licensed under this Section 2 a form set-
132 ting forth the information that the wholesale distributor provided
133 pursuant to paragraph (b) of this Section. Within 30 days of
134 receiving such form, the wholesale distributor must identify and
135 state under oath to the State licensing authority all changes or cor-
136 rections to the information that was provided pursuant to paragraph
137 (b). Changes in, or corrections to, any information in paragraph (b)
138 shall be submitted to the State licensing authority as required by
139 such authority. The State licensing authority may suspend or revoke
140 the license of a wholesale distributor if such authority determines

141 that the wholesale distributor no longer qualifies for the license
142 issued under this Section 2.

143 (j) The designated representative identified pursuant to paragraph
144 (b)(7) of this Section 2 must receive and complete continuing
145 training in applicable Federal and State laws governing wholesale
146 distribution of prescription drugs.

147 (k) Information provided under this Section 2 shall not be dis-
148 closed to any person or entity other than a State licensing authority,
149 government board, or government agency provided such licensing
150 authority, government board, or agency needs such information for
151 licensing or monitoring purposes.

1 SECTION 3. Restrictions on Transactions.

2 (a) Purchases and Receipts from Pharmacies. A wholesale distrib-
3 utor shall receive prescription drug returns or exchanges from a
4 pharmacy or chain pharmacy warehouse pursuant to the terms and
5 conditions of the agreement between the wholesale distributor and
6 the pharmacy and/or chain pharmacy warehouse, including the
7 returns of expired, damaged, and recalled pharmaceutical product to
8 either the original manufacturer or a third party returns processor,
9 and such returns or exchanges shall not be subject to the pedigree
10 requirement of Section 4 of this Act. Wholesale distributors shall be
11 held accountable for policing their returns process and insuring that
12 the aspects of this operation are secure and do not permit the entry of
13 adulterated and counterfeit product.

14 (b) Sale, Distribution, or Transfer to an Unlicensed Person - A
15 manufacturer or wholesale distributor shall furnish prescription
16 drugs only to a person licensed by the appropriate State licensing
17 authorities. Before furnishing prescription drugs to a person not
18 known to the manufacturer or wholesale distributor, the manufac-
19 turer or wholesale distributor shall affirmatively verify that the
20 person is legally authorized to receive the prescription drugs by con-
21 tacting the appropriate State licensing authorities.

22 (c) Prescription drugs furnished by a manufacturer or wholesale
23 distributor shall be delivered only to the premises listed on the
24 license; provided that the manufacturer or wholesale distributor may
25 furnish prescription drugs to an authorized person or agent of that
26 person at the premises of the manufacturer or wholesale distributor
27 if:—

28 (1) The identity and authorization of the recipient is properly
29 established; and

30 (2) This method of receipt is employed only to meet the imme-
31 diate needs of a particular patient of the authorized person.

32 (d) Prescription drugs may be furnished to a hospital pharmacy
33 receiving area provided that a pharmacist or authorized receiving
34 personnel signs, at the time of delivery, a receipt showing the type
35 and quantity of the prescription drug so received. Any discrepancy
36 between receipt and the type and quantity of the prescription drug
37 actually received shall be reported to the delivering manufacturer or
38 wholesale distributor by the next business day after the delivery to
39 the pharmacy receiving area.

40 (e) A manufacturer or wholesale distributor shall not accept pay-
41 ment for, or allow the use of, a person or entity's credit to establish
42 an account for the purchase of prescription drugs from any person
43 other than the owner(s) of record, the chief executive officer, or the
44 chief financial officer listed on the license of a person or entity
45 legally authorized to receive prescription drugs. Any account estab-
46 lished for the purchase of prescription drugs must bear the name of
47 the licensee.

1 SECTION 4. Pedigree.

2 (a) In General. Each person who is engaged in wholesale distribu-
3 tion of prescription drugs, (including repackagers, but excluding the
4 original manufacturer of the finished form of the prescription drug)
5 that leave the normal distribution channel shall before each whole-
6 sale distribution of such drug provide a pedigree to the person who
7 receives such drug.

8 (1) A retail pharmacy or chain pharmacy warehouse shall comply
9 with the requirements of this section only if the pharmacy or chain
10 pharmacy warehouse engages in wholesale distribution of prescrip-
11 tion drugs.

12 (2) The Board of Pharmacy shall determine by July 1, 2007, a
13 mandated implementation date for electronic pedigree. Such a deter-
14 mination shall be based on consultation with manufacturers, distrib-
15 utors, and pharmacies responsible for the sale and distribution of
16 prescription drug products in the State. The implementation date for
17 the mandated electronic pedigree will be no sooner than July 1,
18 2008.

19 (b) Authentication. Each person who is engaged in the wholesale
20 distribution of a prescription drug (including repackagers, but
21 excluding the original manufacturer of the finished form of the pre-
22 scription drug), who is provided a pedigree for a prescription drug
23 and attempts to further distribute that prescription drug, shall affir-
24 matively verify before any distribution of a prescription drug occurs
25 that each transaction listed on the pedigree has occurred.

26 (c) Contents. The pedigree shall:—

27 (1) Include all necessary identifying information concerning each
28 sale in the chain of distribution of the product from the manufacturer
29 through acquisition and sale by any wholesale distributor or repack-
30 ager, until final sale to a pharmacy or other person dispensing or
31 administering the drug. At minimum, the necessary chain of distrib-
32 ution information shall include:—

33 (A) Name, address, telephone number, and if available, the e-mail
34 address, of each owner of the prescription drug, and each wholesale
35 distributor of the prescription drug;

36 (B) Name and address of each location from which the product
37 was shipped, if different from the owner's;

38 (C) Transaction dates; and

39 (D) Certification that each recipient has authenticated the pedi-
40 gree.

41 (2) At minimum, the pedigree shall also include the:—

42 (A) Name of the prescription drug;

43 (B) Dosage form and strength of the prescription drug;

44 (C) Size of the container;

45 (D) Number of containers;

46 (E) Lot number of the prescription drug; and

47 (F) Name of the manufacturer of the finished dosage form.

48 (d) Maintenance Provisions. Each pedigree or electronic file shall
49 be:—

50 (1) Maintained by the purchaser and the wholesale distributor for
51 3 years from the date of sale or transfer; and

52 (2) Available for inspection or use within 5 business days upon a
53 request of an authorized officer of the law.

54 (e) Implementation — The state licensing authority administering
55 this Act shall adopt rules and a form relating to the requirements of
56 this paragraph no later than [90] days after the effective date of this
57 Act.

1 SECTION 5. Enforcement. Order to Cease Distribution of a Drug
2 (a) Order to Cease Distribution of a Prescription Drug – If the
3 State finds that there is a reasonable probability that:—
4 (1) A wholesale distributor, other than a manufacturer, has:—
5 (A) Violated a provision in this Act, or
6 (B) Falsified a pedigree, or sold, distributed, transferred, manu-
7 factured, repackaged, handled, or held a counterfeit prescription
8 drug intended for human use,
9 (2) The prescription drug at issue as a result of a violation in para-
10 graph (1) could cause serious, adverse health consequences or death,
11 and
12 (3) Other procedures would result in unreasonable delay, the State
13 shall issue an order requiring the appropriate person (including the
14 distributors, or retailers of the drug) to immediately cease distribu-
15 tion of the drug within that state.
16 (b) An order under paragraph (a) shall provide the person subject
17 to the order with an opportunity for an informal hearing, to be held
18 not later than 10 days after the date of the issuance of the order, on
19 the actions required by the order. If, after providing an opportunity
20 for such a hearing, the State determines that inadequate grounds
21 exist to support the actions required by the order, the State shall
22 vacate the order.

1 SECTION 6. Prohibited Acts.
2 It is unlawful for a person to perform or cause the performance of
3 or aid and abet any of the following acts in this State:—
4 (a) Failure to obtain a license in accordance with this Act, or
5 operating without a valid license when a license is required by this
6 Act;
7 (b) If the requirements of Section 3(a) are applicable and are not
8 met, the purchasing or otherwise receiving a prescription drug from
9 a pharmacy;
10 (c) If a state license is required pursuant to Section 3(b) of this
11 Act, the sale, distribution, or transfer of a prescription drug to a
12 person that is not authorized under the law of the jurisdiction in
13 which the person receives the prescription drug to receive the pre-
14 scription drug;
15 (d) Failure to deliver prescription drugs to specified premises, as
16 required by Section 3(c) of this Act;

17 (e) Accepting payment or credit for the sale of prescription drugs
18 in violation of Section 3(e) of this Act;

19 (f) Failure to maintain or provide pedigrees as required by this
20 Act;

21 (g) Failure to obtain, pass, or authenticate a pedigree, as required
22 by this Act;

23 (h) Providing the State or any of its representatives or any federal
24 official with false or fraudulent records or making false or fraudulent
25 statements regarding any matter within the provisions of this Act;

26 (i) Obtaining or attempting to obtain a prescription drug by fraud,
27 deceit, misrepresentation or engaging in misrepresentation or fraud
28 in the distribution of a prescription drug;

29 (j) Except for the wholesale distribution by manufacturers of a
30 prescription drug that has been delivered into commerce pursuant to
31 an application approved under Federal law by the Food and Drug
32 Administration, the manufacture, repacking, sale, transfer, delivery,
33 holding, or offering for sale any prescription drug that is adulterated,
34 misbranded, counterfeit, suspected of being counterfeit, or has other-
35 wise been rendered unfit for distribution;

36 (k) Except for the wholesale distribution by manufacturers of a
37 prescription drug that has been delivered into commerce pursuant to
38 an application approved under Federal law by the Food and Drug
39 Administration, the adulteration, misbranding, or counterfeiting of
40 any prescription drug;”

41 (l) The receipt of any prescription drug that is adulterated, mis-
42 branded, stolen, obtained by fraud or deceit, counterfeit, or sus-
43 pected of being counterfeit, and the delivery or proffered delivery of
44 such drug for pay or otherwise; and

45 (m) The alteration, mutilation, destruction, obliteration, or
46 removal of the whole or any part of the labeling of a prescription
47 drug or the commission of any other act with respect to a prescrip-
48 tion drug that results in the prescription drug being misbranded.

49 (n) The aforesaid “prohibited acts” do not include a prescription
50 drug manufacturer, or agent of a prescription drug manufacturer,
51 obtaining or attempting to obtain a prescription drug for the sole pur-
52 pose of testing the prescription drug for authenticity.

1 SECTION 7. Penalties.

2 (a) Unknowing Violations. If a person engages in the wholesale
3 distribution of prescription drugs in violation of this Act, the person
4 may be imprisoned for not more than 15 years, and fined not more
5 than \$50,000, or both.

6 (b) Knowing Violations. If a person knowingly engages in whole-
7 sale distribution of prescription drugs in violation of this Act, the
8 person shall be imprisoned for any term of years, or fined not more
9 than \$500,000, or both.