

S T A T E O F N E W Y O R K

2855--A

2011-2012 Regular Sessions

I N S E N A T E

February 2, 2011

Introduced by Sen. KRUEGER -- read twice and ordered printed, and when printed to be committed to the Committee on Health -- recommitted to the Committee on Health in accordance with Senate Rule 6, sec. 8 -- committee discharged, bill amended, ordered reprinted as amended and recommitted to said committee

AN ACT to amend the public health law, in relation to requiring the manufacturer or labeler of each prescription drug to annually report the marketing costs of such drug to the department of health and to amend the tax law, in relation to eliminating deductibility for certain expenses incurred in the advertising of prescription drugs

THE PEOPLE OF THE STATE OF NEW YORK, REPRESENTED IN SENATE AND ASSEMBLY, DO ENACT AS FOLLOWS:

1 Section 1. Legislative intent. The legislature hereby finds and
2 declares that the price of prescription drugs in this state and across
3 the nation has been increasing at an alarming rate over the past decade.
4 Prescription drug costs are increasing at a faster rate than any other
5 component of health care and are driving the increase in overall health
6 care cost. As is apparent by the ubiquitous nature of the marketing and
7 public information campaigns relating to prescription drugs, pharmaceu-
8 tical manufacturers put a great deal of resources into marketing their
9 products. This has been especially true since the 1997 relaxation of
10 federal laws relating to prescription drug advertising. It is in the
11 interest of assisting this state in its role as a purchaser of
12 prescription drugs and administrator of prescription drug programs, to
13 enable the state to determine the scope of prescription drug marketing
14 costs and their effect on the cost, utilization and delivery of health
15 care services, and thus further the role of this state as guardian of
16 the public interest.
17 S 2. Section 206 of the public health law is amended by adding a new
18 subdivision 29 to read as follows:

EXPLANATION--Matter in *ITALICS* (underscored) is new; matter in brackets
[] is old law to be omitted.

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29. THE COMMISSIONER IS AUTHORIZED AND DIRECTED TO REQUIRE MANUFACTURERS OR LABELERS OF PRESCRIPTION DRUGS, WHICH DISPENSE SUCH DRUGS IN THIS STATE AND WHICH EMPLOY, DIRECT OR UTILIZE MARKETING REPRESENTATIVES IN THE STATE, TO REPORT THE MARKETING COSTS OF EACH OF ITS PRESCRIPTION DRUGS DISPENSED IN THIS STATE.

(A) DEFINITIONS. AS USED IN THIS SUBDIVISION, UNLESS THE CONTEXT CLEARLY INDICATES OTHERWISE, THE FOLLOWING TERMS SHALL HAVE THE FOLLOWING MEANINGS:

(I) "LABELER" MEANS ANY PERSON OR ENTITY, HAVING A LABELER CODE FROM THE FEDERAL FOOD AND DRUG ADMINISTRATION, THAT RECEIVES A PRESCRIPTION DRUG FROM THE MANUFACTURER OR A WHOLESALER OF SUCH DRUG, AND REPACKAGES SUCH DRUG TO BE DISPENSED IN THIS STATE.

(II) "MANUFACTURER" MEANS A MANUFACTURER OF PRESCRIPTION DRUGS DISPENSED IN THIS STATE, AND SHALL INCLUDE THE SUBSIDIARY OR AFFILIATE OF SUCH MANUFACTURER.

(III) "MARKETING" MEANS ADVERTISING AND PROMOTIONAL ACTIVITIES FOR PRESCRIPTION DRUGS DISPENSED IN THIS STATE INCLUDING, BUT NOT LIMITED TO, THOSE ACTIVITIES DESCRIBED IN PARAGRAPH (B) OF THIS SUBDIVISION.

(B) MANNER OF REPORTING. ON OR BEFORE JULY FIRST EACH YEAR EVERY MANUFACTURER AND LABELER SHALL FILE A REPORT WITH THE DEPARTMENT ON ITS MARKETING ACTIVITIES CONDUCTED IN THIS STATE. SUCH REPORT SHALL BE SUBMITTED IN SUCH FORM AND MANNER, AND INCLUDE THE PAYMENT OF SUCH A FEE AS SHALL BE DETERMINED BY THE COMMISSIONER. EACH SUCH REPORT SHALL INCLUDE THE VALUE, NATURE, PURPOSE AND RECIPIENT OF MARKETING EXPENSES INCLUDING, BUT NOT LIMITED TO:

(I) ALL EXPENSES ASSOCIATED WITH ADVERTISING, MARKETING AND DIRECT PROMOTION OF PRESCRIPTION DRUGS THROUGH RADIO, TELEVISION, MAGAZINES, NEWSPAPERS, DIRECT MAIL AND TELEPHONE COMMUNICATIONS AS THEY PERTAIN TO RESIDENTS OF THIS STATE;

(II) WITH REGARD TO ALL PROVIDERS OF HEALTHCARE SERVICES REGULATED BY THE DEPARTMENT UNDER THE PROVISIONS OF ARTICLE TWENTY-EIGHT, THIRTY-SIX OR FORTY-FOUR OF THIS CHAPTER, INCLUDING HEALTH MAINTENANCE ORGANIZATIONS ESTABLISHED PURSUANT TO ARTICLE FORTY-THREE OF THE INSURANCE LAW, THE FOLLOWING INFORMATION:

(A) ALL EXPENSES ASSOCIATED WITH EDUCATIONAL OR INFORMATIONAL PROGRAMS, MATERIALS AND SEMINARS, AND REMUNERATION FOR PROMOTING OR PARTICIPATING IN EDUCATIONAL OR INFORMATIONAL SESSIONS, REGARDLESS OF WHETHER THE MANUFACTURER OR LABELER PROVIDES THE EDUCATIONAL OR INFORMATIONAL SESSIONS OR MATERIALS,

(B) ALL EXPENSES ASSOCIATED WITH FOOD, ENTERTAINMENT AND GIFTS VALUED AT MORE THAN SEVENTY-FIVE DOLLARS, AND ANYTHING PROVIDED TO A HEALTH CARE PROFESSIONAL FOR LESS THAN MARKET VALUE,

(C) ALL EXPENSES ASSOCIATED WITH TRIPS AND TRAVEL, AND

(D) ALL EXPENSES ASSOCIATED WITH PRODUCT SAMPLES, EXCEPT FOR SAMPLES THAT WILL BE DISTRIBUTED FREE OF CHARGE TO PATIENTS; AND

(III) THE AGGREGATE COST OF ALL EMPLOYEES AND CONTRACTORS OF THE MANUFACTURER OR LABELER WHO DIRECTLY OR INDIRECTLY ENGAGE IN THE ADVERTISING OR PROMOTIONAL ACTIVITIES LISTED IN SUBPARAGRAPHS (I) AND (II) OF THIS PARAGRAPH, INCLUDING ALL FORMS OF PAYMENT TO SUCH EMPLOYEES AND CONTRACTORS. THE COST REPORTED PURSUANT TO THIS SUBPARAGRAPH SHALL REFLECT ONLY THAT PORTION OF PAYMENT TO EMPLOYEES AND CONTRACTORS THAT PERTAINS TO ACTIVITIES WITHIN THIS STATE OR TO RECIPIENTS OF THE ADVERTISING OR PROMOTIONAL ACTIVITIES WHO ARE RESIDENTS OF OR ARE EMPLOYED IN THIS STATE.

(C) EXCEPTIONS. THE FOLLOWING MARKETING EXPENSES SHALL NOT BE SUBJECT TO THE REPORTING REQUIREMENTS OF THIS SUBDIVISION:

1 (I) EXPENSES OF SEVENTY-FIVE DOLLARS OR LESS;

2 (II) REASONABLE COMPENSATION AND REIMBURSEMENT FOR EXPENSES IN
3 CONNECTION WITH A BONA FIDE CLINICAL TRIAL OF A NEW VACCINE, THERAPY OR
4 TREATMENT; AND

5 (III) SCHOLARSHIPS AND REIMBURSEMENT OF EXPENSES FOR ATTENDING A
6 SIGNIFICANT EDUCATIONAL, SCIENTIFIC OR POLICY-MAKING CONFERENCE OR SEMI-
7 NAR OF A NATIONAL, REGIONAL OR SPECIALTY MEDICAL OR OTHER PROFESSIONAL
8 ASSOCIATION IF THE RECIPIENT OF THE SCHOLARSHIP IS CHOSEN BY THE ASSOCI-
9 ATION SPONSORING THE CONFERENCE OR SEMINAR.

10 (D) DEPARTMENT REPORTS. ANNUALLY ON OR BEFORE NOVEMBER THIRTIETH, THE
11 DEPARTMENT SHALL SUBMIT A REPORT, PROVIDING INFORMATION IN AGGREGATE
12 FORM, ON PRESCRIPTION DRUG MARKETING EXPENSES TO THE GOVERNOR, TEMPORARY
13 PRESIDENT OF THE SENATE AND SPEAKER OF THE ASSEMBLY. ON OR BEFORE JANU-
14 ARY FIRST, TWO THOUSAND THIRTEEN AND EVERY TWO YEARS THEREAFTER, THE
15 DEPARTMENT SHALL PROVIDE A REPORT TO THE GOVERNOR, TEMPORARY PRESIDENT
16 OF THE SENATE AND SPEAKER OF THE ASSEMBLY, PROVIDING INFORMATION IN
17 AGGREGATE FORM, CONTAINING AN ANALYSIS OF THE DATA SUBMITTED TO THE
18 DEPARTMENT, INCLUDING THE SCOPE OF PRESCRIPTION DRUG MARKETING ACTIV-
19 ITIES AND EXPENSES AND THEIR EFFECT ON THE COST, UTILIZATION AND DELIV-
20 ERY OF HEALTH CARE SERVICES AND ANY RECOMMENDATIONS WITH REGARD TO
21 MARKETING ACTIVITIES OF PRESCRIPTION DRUG MANUFACTURERS AND LABELERS.

22 (E) CONFIDENTIALITY; PUBLIC INFORMATION. NOTWITHSTANDING ANY PROVISION
23 OF LAW TO THE CONTRARY, ALL INFORMATION SUBMITTED TO THE DEPARTMENT
24 PURSUANT TO THIS SUBDIVISION SHALL BE CONFIDENTIAL AND NOT A PUBLIC
25 RECORD AS DEFINED IN SECTION EIGHTY-SIX OF THE PUBLIC OFFICERS LAW. DATA
26 COMPILED IN AGGREGATE FORM BY THE DEPARTMENT FOR THE PURPOSES OF REPORT-
27 ING REQUIRED BY THIS SUBDIVISION SHALL BE A PUBLIC RECORD AS DEFINED IN
28 SECTION EIGHTY-SIX OF THE PUBLIC OFFICERS LAW, AS LONG AS IT DOES NOT
29 REVEAL TRADE INFORMATION THAT IS PROTECTED BY STATE OR FEDERAL LAW.

30 (F) VIOLATIONS. ANY PERSON WHO VIOLATES ANY PROVISION OF THIS SUBDIVI-
31 SION SHALL BE LIABLE TO THE PEOPLE OF THE STATE FOR A CIVIL PENALTY OF
32 TEN THOUSAND DOLLARS, PLUS COURT COSTS AND ATTORNEYS' FEES, WHICH SHALL
33 BE ENFORCED PURSUANT TO TITLE TWO OF THIS ARTICLE.

34 (G) RULES. ANY AND ALL RULES AND REGULATIONS NECESSARY TO IMPLEMENT
35 THE PROVISIONS OF THIS SUBDIVISION SHALL BE PROMULGATED BY THE COMMIS-
36 SIONER.

37 S 3. Paragraph (b) of subdivision 9 of section 208 of the tax law is
38 amended by adding a new subparagraph 21 to read as follows:

39 (21) EXPENSES INCURRED BY A MANUFACTURER OR DISTRIBUTOR OF A DRUG, THE
40 DISPENSING OF WHICH TO A CONSUMER WITHOUT A PRESCRIPTION IS PROHIBITED
41 BY EITHER FEDERAL OR STATE LAW, FOR THE ADVERTISING OF SUCH DRUG TO
42 CONSUMERS.

43 S 4. Subsection (b) of section 612 of the tax law is amended by adding
44 a new paragraph 40 to read as follows:

45 (40) EXPENSES INCURRED BY A MANUFACTURER OR DISTRIBUTOR OF A DRUG, THE
46 DISPENSING OF WHICH TO A CONSUMER WITHOUT A PRESCRIPTION IS PROHIBITED
47 BY EITHER FEDERAL OR STATE LAW, FOR THE ADVERTISING OF SUCH DRUG TO
48 CONSUMERS.

49 S 5. This act shall take effect on the one hundred eightieth day after
50 it shall have become a law; provided that effective immediately, any
51 rules and regulations necessary to implement the provisions of this act
52 on its effective date are authorized to be made on or before such effec-
53 tive date and provided further that the provisions of sections three and
54 four of this act shall take effect immediately and shall apply to taxa-
55 ble years beginning on or after January first of the year in which it
56 shall have become a law.