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I N A S S E M B L Y

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Introduced by M. of A. BURLING, FINCH, McDONOUGH, GIGLIO, JAFFEE, CASTELLI -- Multi-Sponsored by -- M. of A. CALHOUN, CROUCH, MAGEE, MONTESANO, STEVENSON, THIELE -- read once and referred to the Committee on Governmental Operations

AN ACT to amend the public health law, in relation to disclosure of certain gifts provided by drug manufacturers or wholesalers to health care providers

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

1 Section 1. Article 2 of the public health law is amended by adding a
2 new title 6 to read as follows:

3 TITLE VI

4 NEW YORK STATE PHARMACEUTICAL DRUG MANUFACTURER AND
5 WHOLESALER DISCLOSURE ACT

6 SECTION 266. LEGISLATIVE INTENT.

7 266-A. DEFINITIONS.

8 266-B. DISCLOSURE REQUIREMENTS.

9 266-C. ANNUAL CONSUMER GUIDE ON PHARMACEUTICAL DRUG MANUFACTURER
10 AND WHOLESALER GIFTS TO HEALTH CARE PROVIDERS.

11 266-D. PENALTIES.

12 266-E. RULES AND REGULATIONS.

13 S 266. LEGISLATIVE INTENT. THE LEGISLATURE FINDS THAT THE COST OF
14 PRESCRIPTION DRUGS IN THE UNITED STATES HAS GROWN DRAMATICALLY. ACCORD-
15 ING TO THE CENTERS FOR DISEASE CONTROL, SPENDING ON RETAIL PRESCRIPTION
16 DRUGS IN THE UNITED STATES MORE THAN TRIPLED FROM FIFTEEN BILLION
17 DOLLARS IN NINETEEN HUNDRED EIGHTY-TWO TO FORTY-EIGHT BILLION TWO
18 HUNDRED MILLION DOLLARS IN NINETEEN HUNDRED NINETY-TWO, THEN MORE THAN
19 TRIPLED AGAIN TO ONE HUNDRED SIXTY-TWO BILLION FOUR HUNDRED MILLION
20 DOLLARS IN TWO THOUSAND TWO. IN PER CAPITA TERMS, RETAIL PRESCRIPTION
21 DRUGS SPENDING INCREASED FROM SIXTY-FOUR DOLLARS IN NINETEEN HUNDRED

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

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1 EIGHTY-TWO TO FIVE HUNDRED SIXTY-NINE DOLLARS IN TWO THOUSAND TWO. IN
2 TWO THOUSAND FIVE, SPENDING ON PHARMACEUTICALS ROSE TO TWO HUNDRED
3 FIFTY-ONE BILLION EIGHT HUNDRED MILLION DOLLARS. WHILE THE AVAILABILITY
4 OF USEFUL NEW DRUGS TO TREAT CHRONIC CONDITIONS SUCH AS HEART DISEASE,
5 HYPERTENSION AND DEPRESSION ACCOUNTS FOR MUCH OF THE INCREASED SPENDING,
6 THERE IS WIDESPREAD CONCERN ABOUT THE IMPACT AGGRESSIVE MARKETING BY
7 DRUG MANUFACTURERS AND WHOLESALERS HAS HAD ON DRUG COSTS AND PRESCRIBING
8 PATTERNS. IN ADDITION TO THE EXPLOSIVE GROWTH IN DIRECT-TO-CONSUMER
9 ADVERTISING, THESE MARKETING EFFORTS ARE OFTEN DIRECTED AT HEALTH CARE
10 PROVIDERS AND INCLUDE GIFTS, PARAPHERNALIA, TRIPS AND TRAVEL, FOOD AND
11 ENTERTAINMENT. A COMPETITIVE MEDIA REPORTING STUDY FOUND THAT DRUG
12 COMPANIES PROVIDED SEVEN BILLION TWO HUNDRED MILLION DOLLARS WORTH OF
13 FREE SAMPLES TO PHYSICIANS' OFFICES IN NINETEEN HUNDRED NINETY-NINE.
14 THE DRUG INDUSTRY SPONSORED MORE THAN THREE HUNDRED FOURTEEN THOUSAND
15 PHYSICIAN "EVENTS" IN TWO THOUSAND ONE, RANGING FROM CATERED LUNCHEES IN
16 HOSPITAL CONFERENCE ROOMS TO WEEKEND GETAWAYS AT RESORTS, NEARLY DOUBLE
17 THE NUMBER FOUR YEARS EARLIER. DRUG COMPANIES SPENT SOME TWENTY-TWO
18 BILLION DOLLARS IN MARKETING IN TWO THOUSAND THREE. ACCORDING TO THE
19 JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION, NINETY PERCENT OF DRUG
20 COMPANY MARKETING IS DIRECTED AT PHYSICIANS. ESTEEMED MEDICAL PUBLICA-
21 TIONS SUCH AS THE JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION AND THE
22 BRITISH MEDICAL JOURNAL PRODUCED STUDIES THAT SUGGEST THESE MARKETING
23 ACTIVITIES DO INFLUENCE HEALTH CARE PROVIDERS' DECISIONS ON PRESCRIPTION
24 DRUGS, AND IN WAYS THAT ARE NOT THE BEST FOR PATIENTS OR THE HEALTH CARE
25 SYSTEM ITSELF. THE LEGISLATURE RECOGNIZES THAT DRUG MANUFACTURERS AND
26 WHOLESALERS ARE FREE TO USE ANY LEGAL SALES AND MARKETING TECHNIQUES TO
27 PROMOTE THEIR PRODUCTS. BUT THE LEGISLATURE ALSO FINDS THAT THE CONSUM-
28 ERS HAVE A RIGHT TO KNOW WHAT GIFTS, IF ANY, THEIR HEALTH CARE PROVIDERS
29 ARE RECEIVING FROM MANUFACTURERS AND WHOLESALERS, IN ORDER THAT THEY
30 MIGHT MAKE INFORMED AND COST-EFFECTIVE DECISIONS ABOUT THEIR
31 PRESCRIPTION DRUG EXPENDITURES.

32 S 266-A. DEFINITIONS. AS USED IN THIS TITLE, THE FOLLOWING TERMS SHALL
33 HAVE THE FOLLOWING MEANINGS:

34 1. "APPROVED CLINICAL TRIAL" MEANS A CLINICAL TRIAL THAT HAS BEEN
35 APPROVED BY THE U.S. FOOD AND DRUG ADMINISTRATION (FDA) OR HAS BEEN
36 APPROVED BY A DULY CONSTITUTED INSTITUTIONAL REVIEW BOARD (IRB) AFTER
37 REVIEWING AND EVALUATING IT IN ACCORDANCE WITH THE HUMAN SUBJECT
38 PROTECTION STANDARDS SET FORTH AT 21 C.F.R. PART 50, 45 C.F.R. PART 46,
39 OR AN EQUIVALENT SET OF STANDARDS OF ANOTHER FEDERAL AGENCY.

40 2. "BONA FIDE CLINICAL TRIAL" MEANS AN APPROVED CLINICAL TRIAL THAT
41 CONSTITUTES "RESEARCH" AS THAT TERM IS DEFINED IN 45 C.F.R. S 46.102
42 WHEN THE RESULTS OF THE RESEARCH CAN BE PUBLISHED FREELY BY THE INVESTI-
43 GATOR AND REASONABLY CAN BE CONSIDERED TO BE OF INTEREST TO SCIENTISTS
44 OR MEDICAL PRACTITIONERS WORKING IN THE PARTICULAR FIELD OF INQUIRY.

45 3. "CLINICAL TRIAL" MEANS ANY STUDY ASSESSING THE SAFETY OR EFFICACY
46 OF DRUGS ADMINISTERED ALONE OR IN COMBINATION WITH OTHER DRUGS OR OTHER
47 THERAPIES, OR ASSESSING THE RELATIVE SAFETY OR EFFICACY OF DRUGS IN
48 COMPARISON WITH OTHER DRUGS OR OTHER THERAPIES.

49 4. "DRUGS" SHALL HAVE THE SAME MEANING AS SET FORTH IN SUBDIVISION
50 SEVEN OF SECTION SIX THOUSAND EIGHT HUNDRED TWO OF THE EDUCATION LAW.

51 5. "HEALTH CARE PROVIDER" MEANS ANY PHYSICIAN OR OTHER PERSON WHO IS
52 LEGALLY AUTHORIZED TO PRESCRIBE DRUGS.

53 6. "PHARMACEUTICAL DRUG MANUFACTURER" MEANS A PERSON WHO COMPOUNDS,
54 MIXES, PREPARES, PRODUCES AND BOTTLES OR PACKS DRUGS FOR THE PURPOSE OF
55 DISTRIBUTING OR SELLING TO PHARMACIES OR TO OTHER CHANNELS OF DISTRIB-
56 UTION.

1 7. "PHARMACEUTICAL DRUG WHOLESALER" MEANS A PERSON WHOSE PRIMARY BUSI-
2 NESS PURPOSE IS TO BOTTLE, PACK OR PURCHASE DRUGS FOR THE PURPOSE OF
3 SELLING OR RESELLING TO PHARMACIES OR TO OTHER CHANNELS AS PROVIDED IN
4 THIS TITLE.

5 8. "PHARMACY" SHALL HAVE THE SAME MEANING AS SET FORTH IN SUBDIVISION
6 ONE OF SECTION SIX THOUSAND EIGHT HUNDRED TWO OF THE EDUCATION LAW.

7 9. "UNRESTRICTED GRANT" MEANS ANY GIFT, PAYMENT, SUBSIDY, OR OTHER
8 ECONOMIC BENEFIT TO AN EDUCATIONAL INSTITUTION, PROFESSIONAL ASSOCI-
9 ATION, HEALTH CARE FACILITY, OR GOVERNMENTAL ENTITY WHICH DOES NOT
10 IMPOSE ANY RESTRICTIONS ON THE USE OF THE GRANT, SUCH AS FAVORABLE
11 TREATMENT OF A CERTAIN PRODUCT OR AN ABILITY OF THE MARKETER TO CONTROL
12 OR INFLUENCE THE PLANNING, CONTENT, OR EXECUTION OF THE EDUCATION ACTIV-
13 ITY.

14 S 266-B. DISCLOSURE REQUIREMENTS. 1. ANY PHARMACEUTICAL DRUG MANUFAC-
15 Turer OR PHARMACEUTICAL DRUG WHOLESALER, INCLUDING ANY EMPLOYEE OR AGENT
16 OF SUCH MANUFACTURER OR WHOLESALER, THAT MAKES ANY GIFT WHETHER IN THE
17 FORM OF MONEY, SERVICE, LOAN, TRAVEL, ENTERTAINMENT, HOSPITALITY, THING
18 OR PROMISE, OR IN ANY OTHER FORM, TO A HEALTH CARE PROVIDER SHALL REPORT
19 THE GIFT TO THE COMMISSIONER IN THE MANNER SET FORTH IN SUBDIVISION TWO
20 OF THIS SECTION.

21 2. ANY PHARMACEUTICAL DRUG MANUFACTURER OR PHARMACEUTICAL DRUG WHOLE-
22 SALER WHO MAKES AT LEAST ONE GIFT UNDER SUBDIVISION ONE OF THIS SECTION
23 SHALL FILE WITH THE COMMISSIONER AN ANNUAL REPORT, DUE NO LATER THAN
24 JUNE FIRST OF EACH YEAR, BEGINNING IN TWO THOUSAND THIRTEEN, OF ALL
25 GIFTS MADE BY THE MANUFACTURER OR WHOLESALER TO HEALTH CARE PROVIDERS.

26 3. SUCH ANNUAL REPORT SHALL CONTAIN: (A) THE NAME, ADDRESS AND TELE-
27 PHONE NUMBER OF THE PHARMACEUTICAL DRUG MANUFACTURER OR WHOLESALER; (B)
28 AN ITEMIZED LIST CONTAINING A DESCRIPTION OF EACH GIFT FALLING UNDER
29 SUBDIVISION ONE OF THIS SECTION AND THE NAME, ADDRESS AND TELEPHONE
30 NUMBER OF THE HEALTH CARE PROVIDER WHO RECEIVED EACH GIFT; (C) THE MONE-
31 TARY VALUE OF EACH GIFT; AND (D) SUCH OTHER INFORMATION AS DEEMED NECES-
32 SARY BY THE COMMISSIONER FOR COMPLIANCE WITH THIS ARTICLE.

33 4. THE FOLLOWING SHALL BE EXEMPT FROM DISCLOSURE:

34 (A) THE PAYMENT OF REASONABLE COMPENSATION AND REIMBURSEMENT OF
35 EXPENSES IN CONNECTION WITH BONA FIDE CLINICAL TRIALS;

36 (B) ANY GIFT THE VALUE OF WHICH IS LESS THAN SEVENTY-FIVE DOLLARS;

37 (C) SCHOLARSHIP OR OTHER SUPPORT FOR MEDICAL STUDENTS, RESIDENTS AND
38 FELLOWS TO ATTEND A SIGNIFICANT EDUCATIONAL, SCIENTIFIC, OR POLICY-MAK-
39 ING CONFERENCE OF A NATIONAL, REGIONAL, OR SPECIALTY MEDICAL OR OTHER
40 PROFESSIONAL ASSOCIATION IF THE RECIPIENT OF THE SCHOLARSHIP OR OTHER
41 SUPPORT IS SELECTED BY THE ASSOCIATION;

42 (D) UNRESTRICTED GRANTS FOR CONTINUING MEDICAL EDUCATION PROGRAMS;

43 (E) PRESCRIPTION DRUG REBATES AND DISCOUNTS; AND

44 (F) FREE SAMPLES OF DRUGS.

45 S 266-C. ANNUAL CONSUMER GUIDE ON PHARMACEUTICAL DRUG MANUFACTURER AND
46 WHOLESALER GIFTS TO HEALTH CARE PROVIDERS. 1. NO LATER THAN SEPTEMBER
47 FIRST OF EACH YEAR, BEGINNING IN TWO THOUSAND THIRTEEN, THE COMMISSIONER
48 SHALL PUBLISH AND MAKE AVAILABLE, FREE OF CHARGE TO THE PUBLIC, A
49 CONSUMER GUIDE ON GIFTS PROVIDED BY PHARMACEUTICAL DRUG MANUFACTURERS
50 AND WHOLESALERS TO HEALTH CARE PROVIDERS. SUCH GUIDE SHALL CONTAIN ALL
51 OF THE INFORMATION PROVIDED IN THE ANNUAL REPORT REQUIRED BY SECTION TWO
52 HUNDRED SIXTY-SIX-B OF THIS TITLE AND THE INFORMATION SHALL BE WRITTEN
53 IN PLAIN LANGUAGE IN A CLEAR AND UNDERSTANDABLE FORMAT.

54 2. THE COMMISSIONER SHALL PROVIDE FOR THE ADEQUATE DISTRIBUTION AND
55 AVAILABILITY OF THE CONSUMER GUIDE ON PHARMACEUTICAL DRUG MANUFACTURER
56 AND WHOLESALER GIFTS TO HEALTH CARE PROVIDERS. APPROPRIATE COPIES OF

1 THE GUIDE SHALL BE TRANSMITTED TO THE OFFICE FOR THE AGING FOR DISTRIB-
2 UTION AT EVERY OFFICE FOR THE AGING IN THE STATE, TO EVERY COUNTY OFFICE
3 FOR THE AGING IN THE STATE AND TO THE COMMISSIONER OF EDUCATION FOR
4 DISTRIBUTION TO EVERY PUBLIC LIBRARY IN THE STATE WHERE COPIES OF THE
5 GUIDE SHALL BE MADE AVAILABLE FREE OF CHARGE TO THE PUBLIC. THE COMMIS-
6 SIONER SHALL ALSO POST THE GUIDE ON THE DEPARTMENT'S INTERNET WEBSITE.
7 S 266-D. PENALTIES. 1. THE COMMISSIONER MAY IMPOSE A CIVIL PENALTY
8 FOR FAILURE TO FILE A TIMELY REPORT AS REQUIRED BY SECTION TWO HUNDRED
9 SIXTY-SIX-B OF THIS TITLE IN AN AMOUNT UP TO FIFTY DOLLARS A DAY UNTIL
10 SUCH REPORT IS FILED OR THREE THOUSAND DOLLARS, WHICHEVER IS LESS.
11 2. ANY PERSON WHO VIOLATES ANY OTHER PROVISION OF THIS TITLE SHALL BE
12 SUBJECT TO A CIVIL PENALTY IN AN AMOUNT NOT TO EXCEED THREE THOUSAND
13 DOLLARS FOR EACH VIOLATION. THE COMMISSIONER IS AUTHORIZED TO ASSESS THE
14 CIVIL PENALTY UNDER THIS SECTION PURSUANT TO SECTION TWELVE OF THIS
15 CHAPTER.
16 S 266-E. RULES AND REGULATIONS. THE COMMISSIONER IS AUTHORIZED TO
17 PROMULGATE RULES AND REGULATIONS AS DEEMED NECESSARY TO CARRY OUT AND
18 ENFORCE THE PROVISIONS OF THIS TITLE.
19 S 2. This act shall take effect on the first of January next succeed-
20 ing the date on which it shall have become a law.