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

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2009-2010 Regular Sessions

I N A S S E M B L Y

March 6, 2009

Introduced by M. of A. BURLING, FINCH, ALFANO, McDONOUGH, GIGLIO, WALKER, JAFFEE -- Multi-Sponsored by -- M. of A. BARRA, CALHOUN, CROUCH, ERRIGO, MAGEE, 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:

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

TITLE VI

NEW YORK STATE PHARMACEUTICAL DRUG MANUFACTURER AND WHOLESALER DISCLOSURE ACT

SECTION 266. LEGISLATIVE INTENT.
266-A. DEFINITIONS.
266-B. DISCLOSURE REQUIREMENTS.
266-C. ANNUAL CONSUMER GUIDE ON PHARMACEUTICAL DRUG MANUFACTURER AND WHOLESALER GIFTS TO HEALTH CARE PROVIDERS.
266-D. PENALTIES.
266-E. RULES AND REGULATIONS.

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

LBD06145-01-9

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

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

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

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

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

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

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

6. "PHARMACEUTICAL DRUG MANUFACTURER" MEANS A PERSON WHO COMPOUNDS, MIXES, PREPARES, PRODUCES AND BOTTLES OR PACKS DRUGS FOR THE PURPOSE OF DISTRIBUTING OR SELLING TO PHARMACIES OR TO OTHER CHANNELS OF DISTRIBUTION.

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

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

9. "UNRESTRICTED GRANT" MEANS ANY GIFT, PAYMENT, SUBSIDY, OR OTHER ECONOMIC BENEFIT TO AN EDUCATIONAL INSTITUTION, PROFESSIONAL ASSOCIATION, HEALTH CARE FACILITY, OR GOVERNMENTAL ENTITY WHICH DOES NOT IMPOSE ANY RESTRICTIONS ON THE USE OF THE GRANT, SUCH AS FAVORABLE TREATMENT OF A CERTAIN PRODUCT OR AN ABILITY OF THE MARKETER TO CONTROL OR INFLUENCE THE PLANNING, CONTENT, OR EXECUTION OF THE EDUCATION ACTIVITY.

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

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

3. SUCH ANNUAL REPORT SHALL CONTAIN: (A) THE NAME, ADDRESS AND TELEPHONE NUMBER OF THE PHARMACEUTICAL DRUG MANUFACTURER OR WHOLESALER; (B) AN ITEMIZED LIST CONTAINING A DESCRIPTION OF EACH GIFT FALLING UNDER SUBDIVISION ONE OF THIS SECTION AND THE NAME, ADDRESS AND TELEPHONE NUMBER OF THE HEALTH CARE PROVIDER WHO RECEIVED EACH GIFT; (C) THE MONETARY VALUE OF EACH GIFT; AND (D) SUCH OTHER INFORMATION AS DEEMED NECESSARY BY THE COMMISSIONER FOR COMPLIANCE WITH THIS ARTICLE.

4. THE FOLLOWING SHALL BE EXEMPT FROM DISCLOSURE:

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

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

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

(D) UNRESTRICTED GRANTS FOR CONTINUING MEDICAL EDUCATION PROGRAMS;

(E) PRESCRIPTION DRUG REBATES AND DISCOUNTS; AND

(F) FREE SAMPLES OF DRUGS.

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

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

THE GUIDE SHALL BE TRANSMITTED TO THE OFFICE FOR THE AGING FOR DISTRIBUTION AT EVERY OFFICE FOR THE AGING IN THE STATE, TO EVERY COUNTY OFFICE FOR THE AGING IN THE STATE AND TO THE COMMISSIONER OF EDUCATION FOR DISTRIBUTION TO EVERY PUBLIC LIBRARY IN THE STATE WHERE COPIES OF THE GUIDE SHALL BE MADE AVAILABLE FREE OF CHARGE TO THE PUBLIC. THE COMMISSIONER SHALL ALSO POST THE GUIDE ON THE DEPARTMENT'S INTERNET WEBSITE.

S 266-D. PENALTIES. 1. THE COMMISSIONER MAY IMPOSE A CIVIL PENALTY FOR FAILURE TO FILE A TIMELY REPORT AS REQUIRED BY SECTION TWO HUNDRED SIXTY-SIX-B OF THIS TITLE IN AN AMOUNT UP TO FIFTY DOLLARS A DAY UNTIL SUCH REPORT IS FILED OR THREE THOUSAND DOLLARS, WHICHEVER IS LESS.

2. ANY PERSON WHO VIOLATES ANY OTHER PROVISION OF THIS TITLE SHALL BE SUBJECT TO A CIVIL PENALTY IN AN AMOUNT NOT TO EXCEED THREE THOUSAND DOLLARS FOR EACH VIOLATION. THE COMMISSIONER IS AUTHORIZED TO ASSESS THE CIVIL PENALTY UNDER THIS SECTION PURSUANT TO SECTION TWELVE OF THIS CHAPTER.

S 266-E. RULES AND REGULATIONS. THE COMMISSIONER IS AUTHORIZED TO PROMULGATE RULES AND REGULATIONS AS DEEMED NECESSARY TO CARRY OUT AND ENFORCE THE PROVISIONS OF THIS TITLE.

S 2. This act shall take effect on the first of January next succeeding the date on which it shall have become a law.