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

643

2009-2010 Regular Sessions

I N  A S S E M B L Y

(PREFILED)

January 7, 2009

Introduced by M. of A. JACOBS, GOTTFRIED, ORTIZ, LENTOL, BOYLAND, CLARK, MARKEY, BENEDETTO, ENGLEBRIGHT, HOYT, KAVANAGH -- Multi-Sponsored by -- M. of A. BRENNAN, COLTON, HOOPER, JOHN, LAVINE, LIFTON, LUPARDO, McENENY, MOLINARO, PERRY, PHEFFER, N. RIVERA, ROBINSON, ROSENTHAL, WEINSTEIN, WEISENBERG -- read once and referred to the Committee on Health

AN ACT to amend the public health law, in relation to requiring all clinical trials and studies on pharmaceuticals to be posted for public access; and to amend chapter 58 of the laws of 2005, amending the public health law and other laws relating to implementing the state fiscal plan for the 2005-2006 fiscal year, in relation to the effectiveness thereof

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

Section 1. Legislative intent. In an effort to promote full disclosure to patients about possible long and short term side effects of pharmaceuticals, as well as the possible interactions with other pharmaceuticals, to promote patients' involvement in health care decisions and to promote informed consultation with their physician or other health care practitioner, the legislature, in its role as purchaser of prescription drugs and administrator of prescription drug programs, hereby deems it in the public interest to require pharmaceutical companies that market their pharmaceuticals in New York state, to post the results of all clinical trials and studies regarding such pharmaceuticals on the department's website.

S 2. Section 270 of the public health law is amended by adding two new subdivisions 14 and 15 to read as follows:

14. "PHARMACEUTICAL CLINICAL TRIAL" OR "CLINICAL TRIAL" MEANS ANY MEDICAL AND SCIENTIFIC EVIDENCE RELATING TO THE SAFETY OR EFFICACY OF A DRUG, WHETHER OR NOT COMPLETED IN FULL, INCLUDING BUT NOT LIMITED TO:

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

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(I) A CLINICAL INVESTIGATION THAT INVOLVES ANY TRIAL TO TEST THE SAFETY OR EFFICACY OF A PRESCRIPTION DRUG WITH ONE OR MORE HUMAN SUBJECTS AND THAT IS INTENDED TO BE SUBMITTED TO, OR HELD FOR INSPECTION BY, THE FEDERAL FOOD AND DRUG ADMINISTRATION (FDA) AS PART OF ANY APPLICATION FOR A RESEARCH OR MARKETING PERMIT OR FOR ANY OTHER TYPE OF APPLICATION, PERMIT, PROCEDURE OR REQUIREMENT OF THE FDA, INCLUDING BUT NOT LIMITED TO AN ABBREVIATED NEW DRUG APPLICATION, AN INVESTIGATIONAL NEW DRUG APPLICATION, A NEW DRUG APPLICATION, NON-CONFIDENTIAL ADDITIONS TO THE DRUG MASTER FILE, POSTMARKETING ADVERSE EVENTS RECORDING, OR COMPLIANCE WITH THE ELECTRONIC OR PAPER COMMON TECHNICAL DOCUMENT; AND

(II) ANY PHARMACOLOGICAL STUDY SUBSEQUENT TO INITIAL APPROVAL FOR SALE BY THE FDA, INCLUDING STUDIES ASSESSING POTENTIAL OFF-LABEL APPLICATIONS, NEW THERAPIES, NEW WAYS OF USING KNOWN TREATMENTS AND COMPARATIVE DRUG TRIALS ASSESSING THE EFFICACY OR SAFETY OF A DRUG COMPARED TO OTHER THERAPIES.

15. "MANUFACTURER" MEANS A MANUFACTURER OF PRESCRIPTION DRUGS OR AN AFFILIATE OF SUCH MANUFACTURER.

S 3. The public health law is amended by adding a new section 279 to read as follows:

S 279. CLINICAL TRIAL REGISTRY. 1. THERE IS HEREBY CREATED IN THE DEPARTMENT THE NEW YORK STATE CLINICAL TRIAL REGISTRY (REFERRED TO IN THIS SECTION AS THE "REGISTRY"). THE PURPOSE OF THE REGISTRY SHALL BE TO SERVE AS A COMPREHENSIVE REPOSITORY OF INFORMATION REGARDING ALL CLINICAL TRIALS OF PRESCRIPTION DRUGS SOLD, DELIVERED, DISPENSED, OFFERED FOR SALE OR GIVEN AWAY IN THIS STATE, INCLUDING INFORMATION ABOUT THE RESULTS OF SUCH TRIALS, REGARDLESS OF OUTCOME.

2. ALL INFORMATION IN THE REGISTRY SHALL BE MADE PUBLICLY AVAILABLE, INCLUDING ON THE INTERNET. THE DEPARTMENT MAY ESTABLISH A LINK TO A WEBSITE HOSTED BY THE NATIONAL INSTITUTE OF HEALTH, AS LONG AS IT IS A FREE, NON-SUBSCRIPTION SITE THAT PROVIDES ALL OF THE INFORMATION REQUIRED IN SUBDIVISION FOUR OF THIS SECTION AND IS IN CONFORMITY WITH ANY ADDITIONAL REGULATIONS ADOPTED BY THE DEPARTMENT.

3. THE MANUFACTURER OF EVERY PHARMACEUTICAL DRUG MARKETED OR OFFERED FOR SALE IN NEW YORK STATE SHALL SUBMIT ALL MEDICAL AND SCIENTIFIC EVIDENCE AND INFORMATION FROM CLINICAL TRIALS REGARDING THE PRESCRIPTION DRUG TO THE NEW YORK STATE CLINICAL TRIAL REGISTRY. TO THE EXTENT THAT DISCLOSURE IS PERMITTED UNDER FEDERAL LAW, THE REGISTRY SHALL INCLUDE, BUT NOT BE LIMITED TO, THE FOLLOWING INFORMATION:

(A) NAME OF ALL MANUFACTURERS, FUNDERS AND CLINICAL TRIAL SPONSORS, INCLUDING THE NAME AND CONTACT INFORMATION, AS WELL AS THE INSTITUTIONAL AFFILIATION OF ALL SPONSORS, CO-SPONSORS AND ADMINISTRATORS;

(B) SUMMARY OF THE PURPOSE OF THE CLINICAL TRIAL, INCLUDING THE NAME OF THE DRUG BEING TESTED AND ITS ACTIVE INGREDIENTS, OVERALL DESIGN OF THE STUDY, INCLUDING STATISTICAL METHOD TO BE EMPLOYED, STATUS/PHASE TYPE OF THE TRIAL, INCLUSION AND EXCLUSION CRITERIA, TREATMENT METHODS USED, ALL HYPOTHESES TESTED BY THE TRIAL, THE MEDICAL CONDITION OR CONDITIONS BEING STUDIED AND OUTCOMES THAT WERE EVALUATED;

(C) START AND END DATE OF TRIAL;

(D) INFORMATION PERTAINING TO THE RESULTS OF THE CLINICAL TRIAL, INCLUDING, BUT NOT LIMITED TO, POTENTIAL OR ACTUAL ADVERSE EFFECTS OF THE DRUG OR BIOLOGICAL PRODUCT ASSOCIATED WITH THE CLINICAL TRIAL, INCLUDING THE FREQUENCY, SEVERITY, AND NATURE OF ADVERSE EVENTS FOR ANY TRIAL PARTICIPANT, AND THE NUMBERS OF PARTICIPANTS WHO DISCONTINUED PARTICIPATION IN THE TRIAL AND THE REASONS FOR DISCONTINUANCE; AND

(E) ANY OTHER INFORMATION DETERMINED BY THE COMMISSIONER TO BE RELEVANT TO ENSURE THE SAFETY OF PRESCRIPTION DRUGS PURCHASED BY THE STATE OR WITH STATE FUNDS.

4. THE COMMISSIONER SHALL:

(A) COLLECT AND HAVE POSTED SUCH RESULTS, DATING BACK TO ALL CLINICAL TRIALS COMPLETED OR TERMINATED ON AND AFTER JANUARY FIRST, NINETEEN HUNDRED NINETY, INCLUDING ANY CLINICAL TRIALS COMPLETED AFTER A PRESCRIPTION DRUG HAS BEEN APPROVED FOR SALE BY THE FEDERAL FOOD AND DRUG ADMINISTRATION (FDA) OR ITS SUCCESSOR AGENCY;

(B) MONITOR SUCH WEBSITE FOR COMPLIANCE WITH THE REQUIREMENTS OF SUBDIVISION THREE OF THIS SECTION; AND

(C) ENSURE PUBLIC ACCESS THROUGH PUBLIC SERVICE ANNOUNCEMENTS.

5. NO PHARMACEUTICAL DRUG MAY BE SOLD OR OFFERED FOR SALE IN THIS STATE UNLESS THE MANUFACTURER OF THE PRESCRIPTION DRUG HAS COMPLIED WITH THIS SECTION. THIS SUBDIVISION SHALL NOT APPLY TO ANY PRESCRIPTION DRUG THAT HAS BEEN SOLD IN THIS STATE PRIOR TO ONE YEAR AFTER THE EFFECTIVE DATE OF THIS SECTION. DISCLOSURE SHALL OCCUR IN THE FOLLOWING INSTANCES:

(A) NEW DRUG APPLICATIONS, WITHIN SIXTY DAYS OF APPROVAL BY THE FDA OR WITHIN NINETY DAYS OF THE EFFECTIVE DATE OF THIS SECTION, WHICHEVER IS LATER;

(B) A DRUG THAT HAS BEEN APPROVED FOR SALE BY THE FDA, WITHIN NINETY DAYS AFTER THE COMPLETION OR TERMINATION OF THE CLINICAL TRIAL; OR WITHIN NINETY DAYS OF THE EFFECTIVE DATE OF THIS SECTION, WHICHEVER IS LATER;

(C) DISCONTINUED TRIALS, SUCH AS THOSE STOPPED FOR SAFETY REASONS, INFORMATION SHALL BE POSTED WITHIN THIRTY DAYS OF THE TERMINATION OF THE TRIAL OR WITHIN NINETY DAYS OF THE EFFECTIVE DATE OF THIS SECTION, WHICHEVER IS EARLIER.

6. MANUFACTURERS MAY APPLY TO THE COMMISSIONER FOR AN EXTENSION OF SIX MONTHS IF THEY CAN DOCUMENT THAT THE CLINICAL TRIAL WILL BE PUBLISHED IN A PEER-REVIEWED MEDICAL JOURNAL AND THAT PUBLICATION ON THE CLINICAL TRIAL REGISTRY WILL VIOLATE THE TERMS OF SUCH PUBLICATION. THE COMMISSIONER SHALL USE HIS OR HER DISCRETION TO APPROVE OR DENY THIS APPLICATION; HOWEVER, IN THE EVENT OF INFORMATION VITAL TO THE PUBLIC SAFETY, THE APPLICATION SHALL BE DENIED. EXTENSIONS SHALL BE RESTRICTED TO ONE FOR EACH CLINICAL TRIAL.

7. NOTWITHSTANDING SECTION TWELVE OF THIS CHAPTER, THE ATTORNEY GENERAL SHALL HAVE THE AUTHORITY TO BRING AN ACTION TO ENFORCE COMPLIANCE WITH THIS SECTION WITHOUT REFERRAL BY THE COMMISSIONER.

8. THE COMMISSIONER MAY GRANT A WAIVER TO PERMIT SALE OR OFFERING FOR SALE OF A PRESCRIPTION DRUG, WHERE THE MANUFACTURER OF THE PRESCRIPTION DRUG HAS NOT COMPLIED WITH THIS SECTION. A WAIVER UNDER THIS SUBDIVISION SHALL BE BASED ON A FINDING BY THE COMMISSIONER THAT SPECIAL CIRCUMSTANCES REQUIRE THE WAIVER IN ORDER TO PROTECT THE HEALTH OF A PATIENT OR PATIENTS. THE WAIVER MAY BE SOUGHT BY A HEALTH CARE PRACTITIONER SEEKING TO PRESCRIBE THE PRESCRIPTION DRUG OR A PATIENT TO WHOM A HEALTH CARE PRACTITIONER HAS PRESCRIBED THE PRESCRIPTION DRUG. THE COMMISSIONER SHALL APPROPRIATELY LIMIT THE EXTENT OF THE WAIVER AS TO TIME, CIRCUMSTANCES, CLASS OF HEALTH CARE PRACTITIONERS OR PATIENTS, OR INDIVIDUAL HEALTH CARE PRACTITIONER OR PATIENT. THE WAIVER SHALL BE IN WRITING, SHALL SPECIFICALLY STATE THE FINDINGS ON WHICH IT IS BASED, AND SHALL BE A PUBLIC DOCUMENT, PROVIDED THAT ANY DISCLOSURE OF THE DOCUMENT SHALL INCLUDE APPROPRIATE REDACTION OF INDIVIDUAL PATIENT IDENTIFYING INFORMATION AND TRADE SECRET INFORMATION THAT WOULD BE EXEMPT FROM DISCLOSURE UNDER THE FEDERAL OR STATE FREEDOM OF INFORMATION LAW.

9. THE COMMISSIONER SHALL PROMULGATE RULES AND REGULATIONS TO PREVENT THE DISCLOSURE OF ANY TRADE SECRETS RESULTING FROM THE OPERATION OF THE CLINICAL TRIAL REGISTRY.

S 4. Reporting requirements. The commissioner of health shall make an annual report to the legislature of his or her findings and recommendations concerning the effectiveness, impact and benefits derived from the posting of pharmaceutical clinical trials and studies as provided for in this act. Such report shall be delivered on or before the first day of March and shall contain evaluations of the policies and any legislation deemed necessary and proper.

S 5. Subdivision 1 of section 79 of part C of chapter 58 of the laws of 2005, amending the public health law and other laws relating to implementing the state fiscal plan for the 2005-2006 fiscal year, is amended to read as follows:

1. sections ten through fifteen of this act shall expire and be deemed repealed on and after June 15, 2012; PROVIDED, HOWEVER, THAT SECTION 270 OF THE PUBLIC HEALTH LAW, AS ADDED BY SECTION TEN OF THIS ACT, SHALL NOT EXPIRE OR BE DEEMED REPEALED;

S 6. This act shall take effect immediately; provided, however, that the amendments to article 2-A of the public health law made by section three of this act shall survive the repeal of such article, as provided in section 79 of part C of chapter 58 of the laws of 2005, as amended. Effective immediately, the addition, amendment and/or repeal of any rule or regulation necessary for the implementation of this act on its effective date are authorized and directed to be made and completed on or before such effective date.