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FOOD AND DRUG ADMINISTRATION MODERIZATION ACT OF 1997

JHU 2141
Merck Sharp v. Johns Hopkins
IPR2024-00648

appropriate, at least 30 days prior to dissemination of the materials.

"(3) EXPEDITED WITHDRAWAL OF APPROVAL.—The Secretary may withdraw approval of a fast track product using expedited procedures (as prescribed by the Secretary in regulations which shall include an opportunity for an informal hearing) if—

"(A) the sponsor fails to conduct any required post-approval study of the fast track drug with due diligence;

"(B) a post-approval study of the fast track product fails to verify clinical benefit of the product;

"(C) other evidence demonstrates that the fast track product is not safe or effective under the conditions of use; or

"(D) the sponsor disseminates false or misleading promotional materials with respect to the product.

"(c) REVIEW OF INCOMPLETE APPLICATIONS FOR APPROVAL OF A FAST TRACK PRODUCT.—

"(1) IN GENERAL.—If the Secretary determines, after preliminary evaluation of clinical data submitted by the sponsor, that a fast track product may be effective, the Secretary shall evaluate for filing, and may commence review of portions of, an application for the approval of the product before the sponsor submits a complete application. The Secretary shall commence such review only if the applicant—

"(A) provides a schedule for submission of information necessary to make the application complete; and

"(B) pays any fee that may be required under section 736.

"(2) EXCEPTION.—Any time period for review of human drug applications that has been agreed to by the Secretary and that has been set forth in goals identified in letters of the Secretary (relating to the use of fees collected under section 736 to expedite the drug development process and the review of human drug applications) shall not apply to an application submitted under paragraph (1) until the date on which the application is complete.

"(d) AWARENESS EFFORTS.—The Secretary shall—

"(1) develop and disseminate to physicians, patient organizations, pharmaceutical and biotechnology companies, and other appropriate persons a description of the provisions of this section applicable to fast track products; and

"(2) establish a program to encourage the development of surrogate endpoints that are reasonably likely to predict clinical benefit for serious or life-threatening conditions for which there exist significant unmet medical needs.".

21 USC 356 note.

(b) GUIDANCE.—Within 1 year after the date of enactment of this Act, the Secretary of Health and Human Services shall issue guidance for fast track products (as defined in section 506(a)(1) of the Federal Food, Drug, and Cosmetic Act) that describes the policies and procedures that pertain to section 506 of such Act.

SEC. 113. INFORMATION PROGRAM ON CLINICAL TRIALS FOR SERIOUS OR LIFE-THREATENING DISEASES.

(a) IN GENERAL.—Section 402 of the Public Health Service Act (42 U.S.C. 282) is amended—

(1) by redesignating subsections (j) and (k) as subsections (k) and (l), respectively; and

(2) by inserting after subsection (i) the following:

Establishment.

"(j)(1)(A) The Secretary, acting through the Director of NIH, shall establish, maintain, and operate a data bank of information on clinical trials for drugs for serious or life-threatening diseases and conditions (in this subsection referred to as the 'data bank'). The activities of the data bank shall be integrated and coordinated with related activities of other agencies of the Department of Health and Human Services, and to the extent practicable, coordinated with other data banks containing similar information.

"(B) The Secretary shall establish the data bank after consultation with the Commissioner of Food and Drugs, the directors of the appropriate agencies of the National Institutes of Health (including the National Library of Medicine), and the Director of the Centers for Disease Control and Prevention.

"(2) In carrying out paragraph (1), the Secretary shall collect, catalog, store, and disseminate the information described in such paragraph. The Secretary shall disseminate such information through information systems, which shall include toll-free telephone communications, available to individuals with serious or life-threatening diseases and conditions, to other members of the public, to health care providers, and to researchers.

"(3) The data bank shall include the following:

"(A) A registry of clinical trials (whether federally or privately funded) of experimental treatments for serious or life-threatening diseases and conditions under regulations promulgated pursuant to section 505(i) of the Federal Food, Drug, and Cosmetic Act, which provides a description of the purpose of each experimental drug, either with the consent of the protocol sponsor, or when a trial to test effectiveness begins. Information provided shall consist of eligibility criteria for participation in the clinical trials, a description of the location of trial sites, and a point of contact for those wanting to enroll in the trial, and shall be in a form that can be readily understood by members of the public. Such information shall be forwarded to the data bank by the sponsor of the trial not later than 21 days after the approval of the protocol.

"(B) Information pertaining to experimental treatments for serious or life-threatening diseases and conditions that may be available—

"(i) under a treatment investigational new drug application that has been submitted to the Secretary under section 561(c) of the Federal Food, Drug, and Cosmetic Act; or

"(ii) as a Group C cancer drug (as defined by the National Cancer Institute).

The data bank may also include information pertaining to the results of clinical trials of such treatments, with the consent of the sponsor, including information concerning potential toxicities or adverse effects associated with the use or administration of such experimental treatments.

"(4) The data bank shall not include information relating to an investigation if the sponsor has provided a detailed certification to the Secretary that disclosure of such information would substantially interfere with the timely enrollment of subjects in the investigation, unless the Secretary, after the receipt of the certification, provides the sponsor with a detailed written determination that

such disclosure would not substantially interfere with such enrollment.

Appropriation authorization.

"(5) For the purpose of carrying out this subsection, there are authorized to be appropriated such sums as may be necessary. Fees collected under section 736 of the Federal Food, Drug, and Cosmetic Act shall not be used in carrying out this subsection.".

42 USC 282 note.

(b) COLLABORATION AND REPORT.—

(1) IN GENERAL.—The Secretary of Health and Human Services, the Director of the National Institutes of Health, and the Commissioner of Food and Drugs shall collaborate to determine the feasibility of including device investigations within the scope of the data bank under section 402(j) of the Public Health Service Act.

(2) REPORT.—Not later than two years after the date of enactment of this section, the Secretary of Health and Human Services shall prepare and submit to the Committee on Labor and Human Resources of the Senate and the Committee on Commerce of the House of Representatives a report—

(A) of the public health need, if any, for inclusion of device investigations within the scope of the data bank under section 402(j) of the Public Health Service Act;

(B) on the adverse impact, if any, on device innovation and research in the United States if information relating to such device investigations is required to be publicly disclosed; and

(C) on such other issues relating to such section 402(j) as the Secretary determines to be appropriate.

SEC. 114. HEALTH CARE ECONOMIC INFORMATION.

(a) IN GENERAL.—Section 502(a) (21 U.S.C. 352(a)) is amended by adding at the end the following: "Health care economic information provided to a formulary committee, or other similar entity, in the course of the committee or the entity carrying out its responsibilities for the selection of drugs for managed care or other similar organizations, shall not be considered to be false or misleading under this paragraph if the health care economic information directly relates to an indication approved under section 505 or under section 351(a) of the Public Health Service Act for such drug and is based on competent and reliable scientific evidence. The requirements set forth in section 505(a) or in section 351(a) of the Public Health Service Act shall not apply to health care economic information provided to such a committee or entity in accordance with this paragraph. Information that is relevant to the substantiation of the health care economic information presented pursuant to this paragraph shall be made available to the Secretary upon request. In this paragraph, the term 'health care economic information' means any analysis that identifies, measures, or compares the economic consequences, including the costs of the represented health outcomes, of the use of a drug to the use of another drug, to another health care intervention, or to no intervention.".

21 USC 352 note.

(b) STUDY AND REPORT.—The Comptroller General of the United States shall conduct a study of the implementation of the provisions added by the amendment made by subsection (a). Not later than 4 years and 6 months after the date of enactment of this Act, the Comptroller General of the United States shall prepare and submit to Congress a report containing the findings of the study.