Department of Legislative Services

Maryland General Assembly
2006 Session

FISCAL AND POLICY NOTE

House Bill 192 (Delegate Pendergrass, *et al.*)
Health and Government Operations

Health - Clinical Trials Data Bank

This bill prohibits a clinical trial sponsor from permitting any person to enroll a participant in a clinical trial in Maryland unless, not later than 21 days after a clinical trial has been opened to enrollment, the sponsor has submitted specified information to the federal Clinical Trials Data Bank. The information must include: (1) a description of the purpose of an experimental drug used in the clinical trial; (2) the eligibility criteria for clinical trial participation; (3) a description of the location of the clinical trial sites in Maryland; and (4) identification of a contact for individuals who want to enroll in the clinical trial. If a clinical trial is exempt from being listed in the data bank, the sponsor is not required to submit this information.

Fiscal Summary

State Effect: Any change in State activities would not materially affect State finances.

Local Effect: None.

Small Business Effect: None.

Analysis

Bill Summary: A clinical trial is defined as a clinical trial to test the effectiveness of drugs, including biological drug products, to treat serious or life-threatening conditions under the Food and Drug Administration's (FDA) investigational new drug regulations. It allows the Office of the Attorney General (OAG) to seek injunctive or other relief to prevent a clinical trial from being conducted. Nothing in this bill may be construed to

affect existing human subject research requirements in statute. By December 31, 2007, and annually thereafter, OAG must report to the General Assembly on the number and types of violations of the bill that occurred during the previous calendar year and the actions taken by OAG in response to the violations.

Current Law:

Clinical Trials Data Bank

The federal Food and Drug Administration Modernization Act of 1997 established the Clinical Trials Data Bank. It contains: (1) information on federal and private clinical trials for experimental treatments (drug and biological products) for patients with serious or life-threatening diseases and conditions; (2) a description of the drug's purpose; (3) patient eligibility criteria; (4) a description of the location of clinical trial sites; and (5) a point of contact for patients who want to enroll in the trial. Information in the data bank is available to the public and health care providers and researchers.

The Act requires research sponsors to submit information to the data bank about a clinical trial conducted under an investigational new drug application if it is for a drug to treat a serious or life-threatening disease or condition and it is a trial to test effectiveness. Research sponsors also may provide information on noneffectiveness trials for drugs to treat conditions that are not considered serious or life-threatening.

Federal Guidelines on Research Using Human Subjects

A person may not conduct research using human subjects unless the research is conducted according to federal regulations on the protection of human subjects. OAG may seek injunctive or other relief to prevent human subject research that violates federal regulations on the protection of human subjects. However, OAG may not duplicate federal government actions or bring an action if a federal agency has determined an investigation is not warranted.

The federal Department of Health and Human Services (HHS) requires individuals conducting research with human subjects to minimize the risks to subjects and ensure that the risks are reasonable. Prospective subjects or their legal representatives must give documented, informed consent. When appropriate, researchers must adequately provide for monitoring the data collected and protect subjects' privacy.

Each institution that proposes research to be conducted or supported by a federal agency must submit a written assurance to the agency head that the institution will comply with the requirements in the basic protection of human research subjects policy. At a

minimum, the assurances must include a statement of principles on how it protects the rights and welfare of human research subjects and the designation of an institutional review board and the board's criteria.

When research is federally regulated, the Office of Human Research Protections (OHRP) oversees and ensures compliance with federal regulations. OHRP also negotiates assurances of compliance with research institutions that propose using human research subjects.

Insurance Coverage for Clinical Trial Participants

State law requires health insurers to provide coverage for patient costs to a member in a clinical trial as a result of: (1) treatment provided for a life-threatening condition; or (2) prevention, early detection, and treatment studies on cancer.

Human Subject Research Regulated by Health Occupations Boards

Several Department of Health and Mental Hygiene (DHMH) boards have regulations specifying how research using human subjects must be conducted.

The Board of Dental Examiners requires that all proposed experimental programs be conducted in a dental school or college. Dental procedures not approved by law or regulation must first be submitted to the board and the Maryland State Dental Association for review and comment at least 180 days before the program begins.

The Board of Professional Counselors and Therapists requires that a counselor involved in research must respect the dignity, privacy, and welfare of research subjects; comply with existing federal and State laws and regulations concerning how research subjects are treated; take responsibility for the ethical treatment of research subjects; and clearly indicate to potential subjects the treatment that will be given as part of the study and obtain written permission in advance.

The Board of Examiners for Audiologists, Hearing Aid Dispensers, and Speech-Language Pathologists requires licensees to obtain informed consent before using an individual for research or as a subject of a teaching demonstration.

Background: Information regarding clinical studies sponsored by the National Institutes of Health (NIH), other federal agencies, and private industry is available through the Clinical Trials Data Bank at www.clinicaltrials.gov. Studies included in the online database are conducted in all 50 states and in more than 100 countries. The data bank was developed by NIH, through its National Library of Medicine, in collaboration with

FDA. A search of the data bank on January 23, 2005 showed 4,571 studies are being conducted in Maryland, including trials that are no longer recruiting patients.

The Pharmaceutical Research and Manufacturers of America's member companies began voluntarily posting information to the federal data bank about all new mid-to-late stage clinical trials July 1, 2005. Voluntary posting for all ongoing mid-to-late stage clinical trials began September 13, 2005. Member companies are encouraged to establish procedures for verifying compliance with this policy and making those procedures available to the public. The Executive Committee of the Pharmaceutical Research and Manufacturers Association adopted a set of principles for conduct of clinical trials and communication of clinical trial results. The principles commit to the timely communication of all meaningful results of clinical trials, whether positive or negative.

Controversy over reporting of clinical trial data heated up in 2004 when New York State Attorney General Elliot Spitzer sued GlaxoSmithKline, accusing the pharmaceutical company of concealing information that would have alerted physicians that the antidepressant Paxil could be harmful to children or adolescents. The lawsuit alleged that GlaxoSmithKline conducted at least five studies since 1998 that evaluated Paxil's use in children and adolescents but only published and disseminated one.

The lawsuit focused attention on efforts to open up the clinical trial process. Delegates to the American Medical Association 2004 annual meeting endorsed a policy that would urge HHS to establish a comprehensive registry for all clinical trials and require every trial to have a unique identifier. The International Committee of Medical Journal Editors (ICMJE) requires all clinical trials to be listed in a registry as a requirement for publication. ICMJE will consider a trial for publication only if it was registered before the first patient enrolls. This applies to trials that start recruiting on or after July 1, 2005. For ongoing trials, ICMJE will consider for publication ongoing trials that are registered before September 13, 2005 because many ongoing trials were not registered at inception.

Additional Information

Prior Introductions: Similar bills, HB 54 of 2005 and its cross file SB 681, both passed in the House and Senate after being amended by both chambers. A conference committee was unable to reach agreement over the amended bills.

Cross File: None.

Information Source(s): Department of Health and Mental Hygiene; Office of the Attorney General; "Guidance for Industry: Information Program on Clinical Trials for

Serious or Life-Threatening Diseases and Conditions," Food and Drug Administration, U.S. Department of Health and Human Services; National Institutes of Health; Pharmaceutical Research and Manufacturers of America; "Is This Clinical Trial Fully Registered?: A Statement from the International Committee of Medical Journal Editors," International Committee of Medical Journal Editors; Department of Legislative Services

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Analysis by:Lisa A. Daigle

Direct Inquiries to:
(410) 946-5510
(301) 970-5510