

CRS Report for Congress

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Clinical Trials Reporting and Publication

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Summary

In 2004, concerns arose that certain antidepressants, other medicines (e.g., Vioxx), and medical devices (e.g., coronary stents), had been marketed to consumers despite unresolved safety issues. Data from clinical trials conducted both before and after a product goes to market are central to assessing its safety and effectiveness, but there is currently no centralized system for reporting results. Due to medical journal practices and drug sponsor and researcher incentives to publicize positive results, many trials with inconclusive or negative results are not publicly reported. Although Food and Drug Administration (FDA) regulations require sponsors of trials that test the effectiveness of new drugs for serious or life-threatening conditions to register with the Department of Health and Human Services (HHS) at clinicaltrials.gov, not all such trials are listed there. A voluntary registry of recent controlled trials results was created in October 2004 by the Pharmaceutical Research and Manufacturers of America (PhRMA).

Several groups have called for public access to standardized clinical trials data, including notice of trial launch and research results through a centralized system such as a registry. Proposals for registries for these purposes raise issues regarding the goals of providing public access, the appropriateness of the information and its presentation for the audience, the timing of a trial's inclusion, whether registries could compromise intellectual property rights, whether reporting should be mandatory, potential conflicts of interest, and whether medical device trials should be included.

In February 2005, Senator Christopher Dodd introduced S. 470, the Fair Access to Clinical Trials (FACT) Act. The FACT Act would expand clinicaltrials.gov to require the inclusion of trials on devices and biological products, create a database of clinical trial results, and require FDA to make public internal drug approval and safety reviews.

This report will be updated on a regular basis.

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Clinical Trials Reporting and Publication

Introduction

In 2004, Congress and others raised questions about the safety and effectiveness of several FDA-approved biomedical products on the market. These included certain antidepressants, Merck's pain relief drug, Vioxx, Boston Scientific's cardiac stents, and other drugs and medical devices. Discussion about ways to help ensure safety and effectiveness of biomedical products focused primarily on two questions: whether data from all clinical trials should be made publicly available, and whether FDA's processes for product approval and post-market surveillance and study are adequate. This report focuses on the first of these questions.¹

Clinical trials, which are the gold standard for assessing drug and device safety and effectiveness both before and after they are marketed in the United States, are scientific studies that systematically test interventions on human beings. They may include behavioral studies or other biomedical investigations, such as those that test drugs and medical devices. As described by FDA, clinical trials are generally conducted in four phases following successful animal testing.² Phase I trials study a new drug or device in a small group of people (20-80) to evaluate its safety, determine a dosage range for drugs, and identify gross side effects. Phase II trials study the product in a larger group of people (100-300) to see whether it is effective for a specific purpose and to further evaluate its safety. Phase III trials investigate the product in a large group of people (1,000-3,000), to confirm the product's effectiveness, monitor side effects, and collect information that will allow the drug, treatment or device to be used safely. Phase IV trials are usually large-scale studies, conducted after the FDA approves a product for marketing in order to demonstrate effectiveness in a broader clinical context and to watch for rare side effects that may not be identified until significant numbers of people have used the product.

The federal government has historically regulated certain aspects of some clinical trials by attaching conditions to those conducted with federal research funds, and/or by creating requirements that must be met before a drug or device can be marketed in the United States. Most federal funding occurs through the Department of Health and Human Services' (HHS) National Institutes of Health. Both pre-market approval and post-market monitoring of medical drugs and devices marketed in the U.S. are the responsibility of HHS's FDA. Each FDA center that reviews and

¹ For further information about whether FDA's processes for product approval and post-market surveillance and study are adequate, see CRS Report RL32797, *Drug Safety and Effectiveness: Issues and Action Options After FDA Approval*, by Susan Thaul.

² For further information on the role of federal agencies in evaluating biomedical products, see CRS Report RS21962, *From Bench to Bedside*, by Michele Schoonmaker.

approves biomedical products for human use — the Center for Drug Evaluation and Research, the Center for Devices and Radiological Health, and the Center for Biologics Evaluation and Research — posts summaries of safety and effectiveness data from clinical trials that support *approved* applications for new products, or new uses of approved products; FDA does not otherwise post clinical trials data.

The FDA Modernization Act of 1997 (FDAMA, P.L. 105-115, Section 113) required the Secretary of HHS to establish a clinical trials registry, intending the availability of information to increase the access of individuals to cutting-edge medical care available only through research protocols. Sponsors of trials testing the effectiveness of life-threatening disease or condition treatments (drugs, but not devices) that are being conducted to obtain FDA approval for marketing,³ under an expanded use protocol⁴ of an investigational new drug application to FDA, or on Group C⁵ cancer drugs are required to register. In addition, any trial (drug, device, or other) that has been approved by a human subject review board (or equivalent) and conforms to the regulations of the appropriate national or international health authority may also be included. In response to FDAMA, the National Library of Medicine (NLM) established a clinical trials registry and made it available to the public in 2000 [<http://www.clinicaltrials.gov>]. It was later reported that an FDA analysis found that in 2002 only 48% of trials of cancer drugs had been registered, and a preliminary review indicated the listing rate for drugs for some other serious diseases is in the single digits. Some companies reportedly have listed no studies; some trials are listed without identifying the sponsoring company or the drug being tested.⁶ In March 2002, FDA issued a guidance document, instructing industry how and when to participate in the registry [<http://www.fda.gov/cder/guidance/4856fnl.htm>].

Despite the centrality of clinical trials in assessing biomedical products' safety, particularly Phase III and IV studies, a presentation of all results related to a product can be difficult to find. Researchers have traditionally reported pre- and post- market

³ Pursuant to 21 U.S.C. § 355(i).

⁴ An expanded use protocol is one that allows for widespread patient access to an investigational new drug not yet approved for marketing, when the drug has shown promise for treating a serious or life-threatening condition, there is no comparable or satisfactory alternative therapy, and the sponsor is actively pursuing permission to market the drug (21 U.S.C. § 360bbb(c)).

⁵ Group C “was established by agreement between FDA and the National Cancer Institute (NCI). The Group C program is a means for the distribution of investigational agents to oncologists for the treatment of cancer under protocols outside the controlled clinical trial. Group C drugs are generally Phase 3 study drugs that have shown evidence of relative and reproducible efficacy in a specific tumor type. They can generally be administered by properly trained physicians without the need for specialized supportive care facilities. Group C drugs are distributed only by the National Institutes of Health under NCI protocols.” *Information Sheets: Guidance for Institutional Review Boards and Clinical Investigators, 1998 Update, Drugs and Biologics*, FDA, at [<http://www.fda.gov/oc/ohrt/irbs/drugsbiologics.html>].

⁶ Shankar Vedantam, “Drugmakers Prefer Silence on Test Data,” *Washington Post*, July 6, 2004, p. A 1.

trial results in peer-reviewed medical journals, which have historically tended to favor publication of clinical trials demonstrating successful intervention; the results of negative or inconclusive trials often go unpublished.⁷ Other venues for the dissemination of research results are industry, government, or university press releases and presentations at medical conferences. Researchers — who may be affiliated with a product's manufacturer, a university, the government, or an association established to find better treatments for a particular disease — may have various motives for publishing or not publishing results. Some observers have expressed concern that a lack of transparency, particularly for negative data, could adversely affect medical decision-making.⁸

Clinical trials reporting can mean public access to results after a trial's conclusion, to a proposed plan before a trial is begun, or both. There is no centralized system for either type of reporting, so different trials may have the same title, one trial may be reported in several places under different titles, and many trials are never reported. Recent discussions of clinical trials reporting have largely focused on post-market trials concerning drugs' and devices' long-term effects, and their safety and effectiveness in specific sub-populations such as children or persons with heart conditions.

Recent Events

In 2004, a number of national and international groups recommended that clinical trial reporting be centralized, standardized, and/or include both positive and negative results. In April 2004, the World Health Organization (WHO), which supports and funds much of the international research on marginalized populations, announced a system designed to facilitate the sharing of research. The system will assign standardized numbers to each randomized controlled trial the WHO ethics review board approves. A London-based company will maintain a no-charge, online register of these numbered trials at [<http://www.controlled-trials.com>] to identify and track them throughout their life cycle. The system is designed to avoid the problem of publication bias by posting information on trial starts and their results.

In June 2004, the American Medical Association (AMA) recommended that HHS create a comprehensive, centralized clinical trials registry. The AMA further called on all institutional review boards to make registration in this database a condition of their approval of the bioethical aspects of clinical trials.⁹ Noting the

⁷ "Pressure Mounts for Clinical Trial Registry," *Medicine & Health*, vol. 58, no. 24 (June 21, 2004), pp. 2-3.

⁸ Robert Steinbrook, "Public Registration of Clinical Trials," *JAMA*, vol. 351, no. 4 (July 22, 2004), p. 315.

⁹ Joseph M. Heyman, "AMA Encouraged by Early Signs of Industry Support for National Clinical Trials Registry," *American Medical Association*, press release, June 18, 2004, at [<http://www.ama-assn.org/ama/pub/category/13909.html>].

AMA's position, Senators Tim Johnson and Christopher Dodd called for a national clinical drug trial registry in a July 8, 2004 letter to the heads of NIH and FDA.¹⁰

In July 2004, the FDA announced that clinical trial sponsors could use a standard format, the Study Data Tabulation Model (SDTM) developed by the nonprofit organization Clinical Data Interchange Standards Consortium (CDISC), to submit data to the agency [<http://www.cdisc.org/index.html>]. According to the FDA, providing a consistent framework and format for clinical trial information is expected to enhance data integration opportunities and thereby reduce data management barriers for sharing the latest clinical trial data.¹¹

In September 2004, the International Committee of Medical Journal Editors (ICMJE), which comprises the editors of 12 major journals, including the *New England Journal of Medicine*, *The Lancet*, and the *Journal of the American Medical Association*, announced a new clinical trials publication policy. The policy requires, for publication of clinical trial results, that a sponsor have posted its trial in a public registry before enrolling patients.¹² The policy is expected to go into effect on July 1, 2005. The ICMJE said it did not advocate any particular registry, but cited clinicaltrials.gov as the only database currently meeting its requirements.

In an effort that dovetails with the ICMJE policy, NIH announced that as of May 2, 2005, it would request that investigators with manuscripts that are accepted for publication, and that are the result of research supported in whole or in part with direct costs from NIH, submit them voluntarily to NLM's PubMed Central.¹³ This effort would only enable free access to results published elsewhere and would not facilitate access to previously undisclosed results. The NIH announcement was preceded by a July 2004 House Committee recommendation that NIH provide free public access to the complete text of articles and supplemental materials generated by NIH-funded research.¹⁴

¹⁰ "Senators Call for National Registry of Clinical Drug Trials," Senator Tim Johnson, press release, July 8, 2004, at [<http://johnson.senate.gov/~johnson/releases/200407/2004708B20.html>].

¹¹ "FDA Announces Standard Format That Drug Sponsors Can Use to Submit Human Drug Clinical Trial Data," *FDA News*, July 21, 2004, at [<http://www.fda.gov/bbs/topics/news/2004/NEW01095.html>].

¹² Catherine De Angelis et al., "Clinical Trial Registration: A Statement from the International Committee of Medical Journal Editors," *New England Journal of Medicine*, vol. 351, no. 12 (Sept. 16, 2004), p. 1250, at [<http://content.nejm.org/cgi/content/full/351/12/1250>].

¹³ National Institutes of Health, "Policy on Enhancing Public Access to Archived Publications Resulting from NIH-Funded Research," NOT-OD-05-022, Feb. 2, 2005, at [<http://grants2.nih.gov/grants/guide/notice-files/NOT-OD-05-022.html>].

¹⁴ U.S. Congress, House Committee on Appropriations, *Departments of Labor, Health and Human Services, and Education and Related Agencies Appropriations Bill, 2005*, report to accompany H.R. 5006, 108th Cong., 2nd sess., H.Rept. 108-636 (Washington, GPO, 2004).

The pharmaceutical industry's reaction to clinical trials reporting has been mixed, although as litigation and FDA and congressional interest have increased, some individual manufacturers and groups have volunteered to make some of their clinical trials data public. How the industry defines the types of trials to include (e.g., hypothesis-testing or late-phase only) could affect a registry's utility. Initially skeptical, PhRMA introduced its own clinical trials database in October 2004 at [<http://www.clinicalstudyresults.org>]. Companies that market drugs in the United States can voluntarily post the positive and negative results of controlled trials (mainly Phase III and IV studies) completed after October 2002 on the PhRMA database. As of March 22, 2005, 19 companies had posted results for 47 drugs. According to FDA, more than 10,000 drugs are approved for marketing in the United States. In January 2005, PhRMA additionally called for its members to voluntarily post all hypothesis-testing clinical trials on NLM's registry, clinicaltrials.gov.

Legislation Introduced in the 109th Congress

In February 2005, Senator Christopher Dodd introduced S. 470, the Fair Access to Clinical Trials (FACT) Act. He and Representative Edward Markey introduced similar legislation (S. 2933 and H.R. 5252) in the 108th Congress. The FACT Act would create a publicly accessible data bank that consists of an expanded clinicaltrials.gov registry and a new database of clinical trial results for drugs, biological products, and devices, as well as results from some other types of trials. For trials included in the registry and/or the database, the FACT Act would create the requirement that the HHS Secretary assign a unique identifier that is consistent to the extent possible with internationally recognized identifiers. The Act would also require FDA to make public its internal drug approval and safety reviews. At the present time, the FDA releases this information only if it relates to an approval, so applications for new drugs or for label changes that are not approved are not made public by FDA.

Regarding the registry portion of the data bank (clinicaltrials.gov), the FACT Act would maintain the current requirement that only trials aimed at treating life-threatening conditions need register. However, the Act would expand the registry by requiring the inclusion of not only drug trials, but also of trials of devices and biological products. The registry would contain information aimed at enabling potential research subjects to locate and decide whether to participate in clinical trials: trial descriptions, location, recruitment and contact information, administrative data, and funding sources.

The FACT Act would require that a results database be constructed to help ensure that the trial results, whether negative or positive, would be reported. Therefore, some information would be entered at the trial's inception (title, product tested, description, purpose, projected end date), and a summary of results would be added after the trial's end.

The registry and database would have the following characteristics:

Public Access. Both the registry and database would be publicly accessible. *Current law: The registry, clinicaltrials.gov, is publicly accessible (42 U.S.C. § 282 (j)(2)).*

Types of Trials. The bill defines a clinical trial as a research study in human volunteers to answer specific health questions, including treatment trials, prevention trials, diagnostic trials, screening trials, and quality-of-life trials. Clinical trials with all three of the following characteristics would have to be included in the registry:

- conducted on drugs, devices, or biological products (except for Phase I studies);
- aimed at testing a treatment for a life-threatening disease or condition; and
- conducted in the United States, or conducted abroad if federally funded or used in requesting FDA approval.

The registry may also include certain Phase I trials and trials of other health-related interventions with the consent of the responsible person.

In the results database, clinical trials with all three of the following characteristics would have to be included:

- conducted on drugs, devices, or biological products, or required by the HHS Secretary to be included in the interest of public health;
- completed after the enactment of the FACT Act, or required by the HHS Secretary to be included in the interest of public health; and
- conducted in the United States, or conducted abroad if federally funded or used in requesting FDA approval.

Even if not required by the HHS Secretary, those who have conducted clinical trials that do not involve drugs, biological products, or devices (such as those comparing surgical procedures, for example), and also those completed before the bill's enactment may voluntarily include their studies in the results database. *Current law: Only trials that meet all three of the following criteria must be included in the registry, clinicaltrials.gov: (1) The trial is testing a drug; (2) The trial is being conducted to obtain FDA approval for marketing, is conducted pursuant to an expanded use protocol of investigational new drug application to FDA, or is conducted on a Group C cancer drug; and (3) The trial tests treatments of serious or life-threatening conditions. Other trials that have been approved by a human subject review board (or equivalent) and conform to the regulations of the appropriate national or international health authority may also be included.*

Types of Information Posted for Each Trial. The registry would include information describing the trial's title, procedures (including safeguards), purpose, outcome measures, recruitment and contact information (including eligibility and exclusion criteria), administrative data (including funding source), and also list the trial's location. The database would include a synopsis of the study and safety data, and a summary of results presented in a standard format. *Current law: The registry, clinicaltrials.gov, includes research subject eligibility criteria, trial site location*

descriptions, and points of contact for those wanting to enroll, presented in a form that can be readily understood by members of the public.

Timing. Information would have to be submitted to the registry no later than 21 days after the trial is opened for enrollment. Information would have to be submitted to the results database both at the outset (*initial information* — including the trial’s title, description, purpose, funding source, etc.) and conclusion of the study (*results* — including a description of outcome measures, a summary of results, safety data, FDA actions, etc.).

The date by which the initial information would have to be submitted to the results database might vary, depending on whether the trial is federally funded, whether it is governed by FDA regulations, and whether it tests drugs, biological products, or devices. For federally funded clinical trials, initial information would have to be submitted to the database before the HHS Secretary could approve or fund the project. For non-federally funded clinical trials that are subject to FDA regulation (such as, for example, privately funded drug trials), initial information would have to be submitted to the database at a time determined by the HHS Secretary’s modification of regulations governing the protection of human subjects and institutional review board (IRB) review.¹⁵ For two types of trials for which submissions would generally be voluntary — non-federally funded trials that do not involve drugs, biological products or devices (for example, clinical trials comparing surgical techniques), and trials completed prior to the enactment of the FACT Act — in the event that the HHS Secretary made submission of initial information mandatory, the Secretary would determine the required submission date. For non-federally funded clinical trials that involve drugs, biological products, or devices but are not subject to FDA regulation (such as, for example, FDA-approved drugs trials that the drug’s sponsor does not know about),¹⁶ the timing of the initial submission is unspecified.

The results would have to be submitted to the database within one year of the earlier of the actual or estimated completion of a trial, unless one of the following apply: (1) the HHS Secretary grants an extension to accommodate publication in a peer-reviewed journal; (2) the study is not federally funded and does not involve drugs, biological products or devices; or (3) the study is completed prior to the enactment of the FACT Act. In the first case, the length of the extension would determine the submission date, and in the second and third cases, if the HHS Secretary made submission of results mandatory, the Secretary would determine the submission date.

¹⁵ An institutional review board (IRB) is a group formally designated by an institution (such as a hospital or university) to review, to approve the initiation of, and to conduct periodic review of biomedical research involving human subjects to ensure the protection of their rights and welfare. IRB review is required by federal regulations for clinical trials regulated by FDA, and for those funded by most federal agencies (21 C.F.R. § 56.102(g)).

¹⁶ FDA requirements apply to those responsible for creating and distributing the drug (such as, for example, sponsors, manufacturers, and distributors), not to others. *See, e.g.*, 21 C.F.R. § 310.305, regarding adverse event reporting requirements.

Current law: Information must be submitted to the registry, clinicaltrials.gov, not later than 21 days after the trial is opened for enrollment (42 U.S.C. § 282(j)(3)).

Audits and Corrections. To encourage compliance, the HHS Secretary could conduct audits of any information submitted to the registry or database, and following prior notification of the responsible party, modify it if it is factually inaccurate, false, or misleading. *Current law: The Secretary does not have the authority to audit or correct entries in the registry, clinicaltrials.gov.*

Sanctions. In a trial with a non-federal funding source (which would include a trial that is partially federally funded), if the responsible person (usually the sponsor) fails to comply with the bill's requirements, the person may be fined \$10,000 per day until the proper submissions are filed. For trials solely supported with federal funding, a principal investigator who fails to send trial results to the database will be ineligible to receive federal grants, contracts and cooperative agreements until the required submissions are made. *Current law: No specific enforcement mechanism or penalties exist for failing to register in clinicaltrials.gov. General mechanisms for enforcing compliance with FDA requirements may be applicable, but have not been applied by FDA.*

Cost Recovery. Non-profit sponsors would be able to recover the costs of IRB review and submissions made to the registry and database direct expenses in their federally funded clinical trials. *Current law: No costs associated with the review of human research protocols by an Institutional Review Board (IRB) may be charged as direct costs for NIH-funded research involving human participants, unless such costs are not included in the institution's facilities and administrative rate,¹⁷ implying that a non-profit without a standing IRB may be able to recover the costs of IRB review and regulatory compliance as a direct expense.*

Reports. The HHS Secretary would be directed to commission a report from the Institute of Medicine (IOM) to determine the extent to which the bill impacted the public health. The Secretary would also be required to make a report to the appropriate committees of Congress on the status of the implementation of regulations regarding the registry and database. *Current law: No such reports are required.*

Issues

Issues surrounding the possibility of clinical trials reporting and publication have focused on a range of topics:

Goals. Proponents of public access to clinical trials data cite the need to provide information to members of the general public, health care workers, and researchers, both to help inform treatment decisions and to help eliminate abuses. Industry advocates have also cited the potential benefits of public awareness of the

¹⁷ NIH Policy on Direct Cost Charges for IRB Review (NOT-OD-03-042), May 22, 2003, at [http://www.niams.nih.gov/rtac/funding/grants/notice/not_od_03_042.pdf].

resources necessary to get a drug approved, and the elimination of duplicated failed efforts. PhRMA cites making clinical trial results for U.S.-marketed pharmaceuticals more transparent, and providing information to practicing physicians and their patients. The FACT Act's stated purpose is to create a publicly accessible clinical trial registry (accessible to patients and health care practitioners seeking information related to ongoing clinical trials for serious or life-threatening diseases and conditions) and a results database (accessible to the scientific community, health care practitioners, and members of the public); and to foster transparency and accountability in health-related intervention research and development.

Appropriateness/Presentation. Some have questioned whether registration and publication of clinical trials and their results are the best mechanism for ensuring patient safety, both because the language may be too technical for lay audiences, and because numerous trials may need to be viewed together in order to draw meaningful conclusions — an analysis that would be difficult for many doctors as well. (A single clinical trial may generate thousands of pages of documentation.) These questions have led some to focus on how information might be presented in an audience-appropriate way. PhRMA's registry contains a link to drug labels, a bibliography, and a summary of results in a format developed by industry consensus.¹⁸ The FACT Act registry would include, among other things, recruitment information and trial descriptions; the database would include, among other things, the trial result summaries, adverse event reports, and FDA actions.

Timing. Some have argued that only clinical study results are important to judging effectiveness, so publication of a trial's inception is not necessary. Others have argued that some registration at inception is necessary to avoid abuse, and is helpful for connecting potential subjects with various trials. FDAMA requires that notice of a qualifying trial be submitted to clinicaltrials.gov no later than 21 days after the trial is open for enrollment. PhRMA's database only accepts results from completed trials. The FACT Act would require registration at a trial's inception (before human subjects testing could have begun), and posting of results within one year of the earlier of the trial's actual or projected completion date.

Intellectual Property. Some have expressed concern that publication of information about clinical trials will lead to problems in protecting both trade secrets and copyright. Others maintain that the information needed to protect public safety is not the type protected by trade secret or copyright law. PhRMA's registry is voluntary, giving companies control over what information is released. Although the FACT Act would require reporting, it would allow manufacturers to strip their submissions of trade secret information.

Voluntary or Mandatory/Penalties. Concerns about the potential regulatory burden on smaller drug and device manufacturers, as well as about the potential for intellectual property problems, have led some to call for voluntary registration and publication. The desire to protect public safety and to reduce abuse has led others to back mandatory reporting. PhRMA's registry is voluntary. The

¹⁸ Structure and Content of Clinical Study Reports; Guideline Approved by the International Conference on Harmonization; July 1996, at [<http://www.fda.gov/cder/guidance/iche3.pdf>].

reporting proposed in the FACT Act would be mandatory (with limited exceptions for trials not conducted on drugs, devices, or biological products and those completed before the bill's enactment) and would carry penalties for noncompliance.

Conflicts of Interest. Some commentators have focused on the need for public disclosure of financial and other arrangements between researchers and sponsors in order to demonstrate potential conflicts of interest that may affect clinical trial design, interpretation of data, and presentation of results. The PhRMA database does not include information about funding relationships, though products there are identifiable by company, which may also be the trial funding source. The FACT Act would require the disclosure of funding source(s), among other things.

Devices. Some have questioned whether information about clinical trials related to medical devices should be included in the registry. The medical device advocacy group, Avamed, points out that FDA regulation of devices is different from its regulation of drugs. Devices are often approved based on analytical comparisons to existing products rather than on the conduct of new clinical trials. Devices as compared to drugs often tend to present a lower risk to patients, tend to be manufactured by smaller companies, tend to have a short market life due to frequent, incremental refinements rather than major breakthroughs, and tend to require more financial incentives to test. PhRMA's database contains only information related to drug trials; those proposed in the FACT Act would require information about device trials.