HR 3580

Food and Drug Administration Amendments Act of 2007

Congress: 110 (2007–2009, Ended)
Chamber: House
Policy Area: Health
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Sponsor

Name: Rep. Dingell, John D. [D-MI-15]
Party: Democratic • **State:** MI • **Chamber:** House

Cosponsors (2 total)

Cosponsor	Party / State	Role	Date Joined
Rep. Barton, Joe [R-TX-6]	R · TX		Sep 19, 2007
Rep. Pallone, Frank, Jr. [D-NJ-6]	D · NJ		Sep 19, 2007

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred To	Sep 19, 2007

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
110 HCONRES 217	Related bill	**Nov 8, 2007:** Referred to the Subcommittee on Health.
110 HR 2900	Related bill	**Jul 16, 2007:** Received in the Senate. Read twice. Placed on Senate Legislative Calendar under General Orders. Calendar No. 270.

Summary (as of Sep 27, 2007)

(This measure has not been amended since it was introduced. The summary has been expanded because action occurred on the measure.)

Food and Drug Administration Amendments Act of 2007 - **Title I: Prescription Drug User Fee Amendments of 2007** - (Sec. 101) Prescription Drug User Fee Amendments of 2007 - (Sec. 102) Amends the Federal Food, Drug, and Cosmetic Act (FFDCA) to include postmarket safety activities within the process for the review of human drug applications or supplements, including: (1) developing and using improved adverse event data collection systems and improved analytical tools to assess potential safety problems; (2) implementing and enforcing provisions relating to postapproval studies, clinical trials, labeling changes, and risk evaluation and mitigation strategies; and (3) conducting screenings of the Adverse Event Reporting System database and reporting on new safety concerns.

(Sec. 103) Reauthorizes prescription drug user fees beginning in FY2008.

Requires the Secretary of Health and Human Services (the Secretary) to provide a partial refund of an applicant's user fees if the application is withdrawn without a waiver before filing.

Sets forth special rules for positron emission tomography drugs, including subjecting an applicant in an approved human drug application for a positron emission tomography drug to one-sixth of the annual prescription drug establishment fee.

Establishes the amount of revenue that fees are to generate for FY2008-FY2012. Requires that such fees be derived equally from fees related to human drug applications and supplements, prescription drug establishments, and prescription drug products. Sets forth provisions regarding adjustments to such fees.

Authorizes appropriations for FY2008-FY2012.

Exempts approved prescription drugs or licensed biological products designated for a rare disease or condition (orphan drugs) from product and establishment fees if certain requirements are met, including the that the drug is owned or licensed and marketed by a company having gross worldwide revenues that fall below a certain amount.

(Sec. 104) Requires the Secretary to assess and collect fees for advisory review of proposed direct-to-consumer television advertisements of prescription drug products. Sets forth procedures for such review.

Subjects each person that is assessed an advisory review fee to an operating reserve fee. Establishes the amount of revenue that may be generated from such fees. Requires the Secretary to annually set the advisory review fee. Sets forth fee limits.

Terminates the advisory review program if revenue falls below a certain threshold.

Authorizes appropriations for FY2008-FY2012.

(Sec. 105) Requires the Secretary to report on the progress of the Food and Drug Administration (FDA) toward achieving goals related to expediting the drug development process and the process for the review of human drug applications.

(Sec. 106) Terminates provisions related to prescription drug users fees and advisory review fees on October 1, 2012.

Title II: Medical Device User Fee Amendments of 2007 - (Sec. 201) Medical Device User Fee Amendments of 2007 **- Subtitle A: Fees Related to Medical Devices** - (Sec. 211) Defines terms relating to fees for medical devices, including

defining "30-day notice" as a notice of a supplement to an approved application that is limited to a request to make modifications to manufacturing procedures or methods affecting the safety and effectiveness of the device.

(Sec. 212) Makes changes to medical device fees, including establishing a fee for: (1) a 30-day notice; (2) a request for classification information; and (3) periodic reporting for a class III device.

Subjects each medical device establishment to a fee for each initial or annual registration beginning with its registration for FY2008, except for establishments operated by a state or federal governmental entity or an Indian tribe.

Establishes the amount of revenue that may be generated from medical device fees.

Makes changes to provisions related to qualifications for fee waivers for small businesses.

Authorizes appropriations for FY2008-FY2012.

(Sec. 213) Sets forth reporting requirements, including requiring the Secretary to report to the relevant congressional committees on the FDA's progress in achieving medical device review goals.

(Sec. 215) Authorizes additional appropriations for FY2008-FY2012 to collect, develop, review, and evaluate postmarket safety information on medical devices.

(Sec. 216) Makes amendments made by this title effective on the date of enactment of this title, except that fees shall be assessed for all premarket applications, premarket reports, supplements, and premarket notifications submissions received on or after October 1, 2007, regardless of such enactment date.

(Sec. 217) Terminates amendments made by this title on October 1, 2012.

Subtitle B: Amendments Regarding Regulation of Medical Devices - (Sec. 221) Extends the authority of accredited persons to review premarket reports for devices and make recommendations to the Secretary regarding the initial classification of devices.

(Sec. 222) Requires any establishment within a foreign country engaged in the manufacturing, propagation, compounding, or processing of a drug or device that is imported or offered for import into the United States to annually register with the Secretary.

(Sec. 223) Requires registered device producers to annually report to the Secretary with a list of new devices introduced by the registrant for commercial distribution, devices discontinued, a notice of resumption of processing of a device, and any material change in information previously submitted.

(Sec. 224) Requires registrations and listings to be submitted to the Secretary electronically unless the Secretary grants a waiver of such requirement.

(Sec. 225) Directs the Comptroller General to study the appropriate use of the process requiring registrants to report to the Secretary on the classification of a device before introduction of the device into interstate commerce.

(Sec. 226) Requires the Secretary to promulgate regulations establishing a unique identification system for medical devices.

(Sec. 227) Makes changes to reporting requirements for devices that have malfunctioned and would be likely to cause or

contribute to a death or serious injury if the malfunction were to recur.

(Sec. 228) Requires a person accredited to conduct inspections of device establishments to notify the Secretary within 30 days of any withdrawal, suspension, restriction, or expiration of certificate of conformance with the quality systems for any inspected establishment. Sets forth conditions that a device establishment must meet to be eligible for inspections by accredited persons.

(Sec. 229) Directs the Comptroller General to study and report on nosocomial infections attributed to new and reused medical devices and the causes of such infections.

Requires the Secretary, acting through the Commissioner of Food and Drugs, to determine whether: (1) the labeling requirements for indoor tanning devices provide sufficient information to consumers regarding the risks of irreversible damage to the eyes and skin, including skin cancer; (2) warning label modifications would communicate such risks more effectively; and (3) no warning would adequately communicate such risks.

Title III: Pediatric Medical Device Safety and Improvement Act of 2007- (Sec. 301) Pediatric Medical Device Safety and Improvement Act of 2007 - (Sec. 302) Requires applications for a humanitarian device exemption, an application for premarket approval of a medical device, or a product development protocol for a medical device to include, if readily available: (1) a description of any pediatric subpopulations that suffer from the disease or condition that the device is intended to treat, diagnose, or cure; and (2) the number of affected pediatric patients.

Requires the Secretary to submit to the relevant congressional committees an annual report that includes: (1) the number of devices approved in the preceding year for which there is a pediatric subpopulation that suffers from the disease; (2) the number of approved devices labeled for use in pediatric patients; (3) the number of fee-exempt devices approved; and (4) the review time for each approved device.

Authorizes the Secretary to conclude that adult data on medical devices may be used to support a determination of a reasonable assurance of effectiveness in pediatric populations if the course of the disease or condition and the effects of the device are sufficiently similar in adults and pediatric patients.

(Sec. 303) Excludes a person granted a humanitarian device exemption from the prohibition against selling such a medical device for an amount that exceeds its research and development, fabrication, and distribution costs if: (1) the device is intended to treat or diagnose a disease or condition that occurs in pediatric patients; (2) the device was not approved for pediatric patients prior to enactment of this Act; (3) the number of devices distributed does not exceed an annual distribution number specified by the Secretary; and (4) the request for exemption is submitted on or before October 1, 2012.

Directs the Secretary to refer any adverse event report related to a device to the Office of Pediatric Therapeutics for review. Requires the Secretary, acting through the Office of Pediatric Therapeutics and the Center for Devices and Radiological Health, to provide for an annual review by the Pediatric Advisory Committee of all devices subject to the humanitarian device exemption to ensure that such exemption remains appropriate for the pediatric population for which it is granted.

Directs the Comptroller General to report on the impact of allowing persons granted a humanitarian device exemption to profit from such a device.

(Sec. 304) Requires the Secretary, acting through the Director of National Institutes of Health (NIH), to designate a

contact point or office to help innovators and physicians identify sources of funding available for pediatric medical device development.

Requires the Secretary, acting through the Commissioner, the Director of NIH, and the Director of the Agency for Healthcare Research and Quality, to report to the relevant congressional committees a plan for expanding pediatric medical device research and development.

(Sec. 305) Requires the Secretary to award grants or contracts for demonstration projects to promote pediatric device development.

Authorizes appropriations for FY2008-FY2012.

(Sec. 306) Includes as a duty of the Office of Pediatric Therapeutics increasing pediatric access to medical devices.

Expands the duties of the advisory committee on pediatric therapeutics to include providing advice and recommendations on matters relating to medical devices.

(Sec. 307) Allows the Secretary to require: (1) postmarket surveillance on class II or class III medical devices that are expected to have significant use in pediatric populations; (2) postmarket surveillance as a condition to approval or clearance of such devices; and (3) a prospective surveillance period of more than 36 months for such devices.

Title IV: Pediatric Research Equity Act of 2007 - (Sec. 401) Pediatric Research Equity Act of 2007 - (Sec. 402) Requires an applicant seeking to defer submission of some or all pediatric assessments of the safety and effectiveness of a new drug or biological product to submit to the Secretary a timeline for the completion of pediatric studies. Sets forth annual reporting requirements for an applicant following the approval of such a deferral.

Requires an applicant seeking a full or partial waiver of pediatric assessment submission requirements on the grounds that a pediatric formulation cannot be developed to submit to the Secretary documentation detailing why a pediatric formulation cannot be developed.

Authorizes the Secretary to require submission of a pediatric assessment if the Secretary finds that: (1) adequate pediatric labeling could confer a benefit on pediatric patients; or (2) the absence of adequate pediatric labeling could pose a risk (currently, significant risk) to pediatric patients.

Directs the Secretary to utilize an internal committee to consult with reviewing divisions on: (1) all pediatric plans and assessments prior to approval of an application or supplement for which a pediatric assessment is required; and (2) all deferral and waiver requests granted.

Requires the Secretary to track and make publicly available information related to pediatric assessments, including: (1) the number of assessments conducted; (2) the specific drugs and biological products and uses assessed; (3) the number of deferrals requested and granted; (4) the labeling changes made as a result of such assessments; and (5) the internal committee's recommendations for priority review.

Requires the Secretary to: (1) order the label of a product to include information about the results of the assessment and a statement that a pediatric assessment does or does not demonstrate that the drug is safe and effective in pediatric populations; (2) make publicly available the pharmacology reviews of pediatric assessments; (3) require the sponsors of the assessments that result in labeling changes to distribute such information to physicians and other heath care providers; and (4) ensure that all adverse event reports that have been received for a drug are referred to the Office of

Pediatric Therapeutics for review.

Requires the Secretary to contract with the Institute of Medicine to study and report to Congress regarding the pediatric studies and the labeling changes made as a result of such studies.

(Sec. 403) Requires the Secretary to establish an internal committee to review written requests for pediatric studies and to provide consultation to reviewing divisions on all pediatric plans and assessments.

(Sec. 404) Requires the Comptroller General to submit a report to Congress that addresses the effectiveness of specified pediatric research provisions in ensuring that medicines used by children are tested and properly labeled.

Title V: Best Pharmaceuticals for Children Act of 2007 - (Sec. 501) Best Pharmaceuticals for Children Act of 2007 - (Sec. 502) Amends the Federal Food, Drug, and Cosmetic Act to revise provisions regarding market exclusivity for pediatric drug studies on new or already approved drugs, including to: (1) change the definition of "pediatric studies" to authorize the Secretary to include preclinical studies; (2) require the studies to be completed using appropriate formulations for each age group for which such a study is requested; and (3) prohibit the Secretary from extending the period of market exclusivity later than nine months prior to the expiration of the period.

Requires an applicant or holder that does not agree to the request for a pediatric study to submit to the Secretary the reasons such pediatric formulations cannot be developed. Requires an applicant or holder that agrees to such a request to provide the Secretary with all postmarket adverse event reports regarding the drug.

Extends to 180 days (currently, 90 days) the period the Secretary has to accept or reject reports on pediatric studies and notify the sponsor or holder.

Directs the Secretary to: (1) publish a notice identifying any drug for which a pediatric formulation was developed, studied, and found to be safe and effective in the pediatric population if the pediatric formulation is not introduced onto the market within one year after the determination regarding market exclusivity; (2) utilize the internal review committee to review all written requests for pediatric studies issued; (3) track and make publicly available information on the pediatric studies conducted; (4) order the labeling of a product to include information about the results of the study and a statement that a pediatric study does or does not demonstrate that the drug is safe and effective in pediatric populations; and (5) ensure that all adverse event reports that have been received for a drug are referred to the Office of Pediatric Therapeutics.

Sets forth actions for the Secretary to take if pediatric studies have not been completed and there is a continuing need for information relating to the use of the drug in the pediatric population.

Requires the Secretary to contract with the Institute of Medicine to study and report to Congress regarding written requests for pediatric studies made and the studies conducted.

Requires the Secretary, acting through the Director of NIH, to: (1) develop and publish a priority list of needs in pediatric therapeutics, including drugs or indications that need study; and (2) study and report to Congress on the feasibility of establishing a compilation of information on pediatric drug use.

Authorizes appropriations.

Authorizes the Foundation for the National Institutes of Health to solicit and accept gifts, grants, and other donations, establish accounts, and invest and expend funds in support of activities relating to studies on the Secretary's priority list

of needs in pediatric therapeutics and for which the Secretary determines that an assessment is required.

Amends the Best Pharmaceuticals for Children Act to require the advisory committee on pediatric therapeutics to continue to operate for five years after enactment of this Act. Requires the Pediatric Subcommittee of the Oncologic Drugs Advisory Committee to: (1) provide recommendations to the internal review committee that reviews pediatric research requests with respect to the treatment of pediatric cancer; and (2) continue to operate for five years after enactment of this Act. Sets forth reporting requirements.

Directs that the proposed rule issued by the Commissioner entitled "Toll-Free Number for Reporting Adverse Events on Labeling for Human Drug Products" take effect on January 1, 2008, unless the final rule is issued before such date.

(Sec. 503) Requires the Director of the National Institute of Child Health and Human Development to include health professionals who intend to build careers in pediatric pharmacological research within the Institute's career development activities.

Includes pediatric pharmacological research within the pediatric research loan repayment program.

Title VI: Reagan-Udall Foundation - (Sec. 601) Establishes the Reagan-Udall Foundation for the Food and Drug Administration as a nonprofit corporation to advance the mission of the FDA to modernize medical, veterinary, food, food ingredient, and cosmetic product development, accelerate innovation, and enhance product safety. Requires the Foundation to: (1) identify unmet needs in the development, manufacture, and evaluation of the safety and effectiveness of such products; (2) establish goals and priorities; (3) identify federal research and development programs and minimize duplication; (4) award grants to scientists and entities to efficiently and effectively advance such goals and priorities; and (5) provide objective clinical and scientific information to the FDA and other federal agencies.

Directs the FDA Commissioner to transfer specified funds to the Foundation each fiscal year, and authorizes the Foundation's Executive Director to solicit and accept funds and gifts, including from private entities, for the purposes of carrying out the Foundation's duties.

(Sec. 602) Requires the Secretary to establish an Office of the Chief Scientist to: (1) oversee, coordinate, and ensure quality and regulatory focus of FDA intramural research programs; (2) track and coordinate intramural research awards made by each FDA center or science-based office; (3) develop and advocate for a budget to support intramural research; (4) develop a peer review process by which intramural research can be evaluated; (5) identify and solicit intramural research proposals from across the FDA; and (6) develop additional postmarket safety performance measures.

(Sec. 603) Authorizes the Secretary, acting through the Commissioner, to enter into Critical Path Public-Private Partnerships with eligible entities to implement the Critical Path Initiative of the FDA by developing research, education, and outreach projects to foster medical product innovation, accelerate medical product development, manufacturing, and translational therapeutics, and enhance medical product safety.

Authorizes appropriations for FY2009-FY2012.

Title VII: Conflicts of Interest - (Sec. 701) Directs the Secretary to: (1) develop and implement strategies on effective outreach to potential members of advisory committees; and (2) review the expertise and financial disclosure report of an individual when considering an appointment to an advisory committee.

Prohibits any member of an advisory committee from participating with respect to any matter in which the member has a financial interest, unless such member is granted a waiver by the Secretary to afford the advisory committee essential

expertise. Limits the number of waivers that may be granted in FY2008 through FY2012 to a specified decreasing percentage of the number granted in 2007 and requires specified disclosures regarding the financial interests of members receiving waivers.

Title VIII: Clinical Trials Databases - (Sec. 801) Amends the Public Health Service Act to require the Secretary, acting through the Director of NIH, to expand the clinical trials registry data bank. Requires the Director to ensure that the data bank is made publicly available through the Internet. Specifies information required to be submitted for an applicable clinical trial and included in the data bank. Requires the Secretary to ensure that the data bank includes links to results information for those clinical trials that form the primary basis of an efficacy claim or are conducted after the drug or device involved is approved or cleared.

Requires the Secretary to further expand the registry and results data bank to provide more complete results information and enhance patient access to and understanding of the results of clinical trials within three years after enactment of this Act.

Prohibits the failure to submit required clinical trial information or the submission of false or misleading clinical trial information to the data bank. Sets forth civil penalties for violations.

Prohibits a state or political subdivision from establishing or continuing in effect any requirement for the registration of clinical trials or for the inclusion of information relating to the results of clinical trials in a database after the required expansion of the data bank three years after enactment of this Act.

Title IX: Enhanced Authorities Regarding Postmarket Safety of Drugs - Subtitle A: Postmarket Studies and Surveillance - (Sec. 901) Prohibits a responsible person from introducing into interstate commerce a new drug if the person is in violation of a requirement related to postapproval clinical trials or labeling changes.

Authorizes the Secretary to: (1) require a responsible person for a drug to conduct a postapproval study or clinical trial of the drug to assess a known serious risk or signals of a serious risk or to identify an unexpected serious risk; (2) require a postapproval study or clinical trial for an already approved drug only if the Secretary becomes aware of new safety information; and (3) issue an order directing a responsible person or holder of an approved application to make a labeling change to address new safety information. Sets forth procedures for dispute resolution.

Prohibits a person from introducing into interstate commerce a new drug or biological product for which a risk evaluation and mitigation strategy is required if the person fails to maintain compliance with the requirements of such strategy.

Requires a person to submit a risk evaluation and mitigation strategy as part of the application if determined necessary to ensure that the benefits of the drug involved outweigh the risks. Sets forth factors the Secretary must consider in making such a determination.

Requires a proposed risk evaluation and management strategy to include a timetable for assessment of the strategy. Allows the Secretary to require such a strategy to include additional elements, including: (1) distribution to each patient of a Medication Guide and a patient package insert; (2) a communication plan to health care providers; and (3) assurances of safe use.

Establishes the Drug Safety Oversight Board.

Authorizes the Secretary to: (1) require the submission of any television advertisement for a drug for review before dissemination; (2) make recommendations with respect to information included in the label of the drug or on statements

for inclusion in advertisements but not require changes in such advertisements; and (3) require inclusion in advertisements of certain disclosures about a serious risk listed in the labeling of the drug.

(Sec. 902) Deems to be misbranded a drug: (1) subject to an approved risk evaluation and mitigation strategy if the responsible person fails to comply with the strategy's requirements; or (2) if the responsible person is in violation of a requirement relating to postmarket studies and clinical trials or labeling.

(Sec. 903) Authorizes the Secretary to withdraw or suspend the approval of a new drug application without first ordering the applicant to submit an assessment of the approved risk evaluation and mitigation strategy.

(Sec. 904) Directs the Commissioner to report to Congress on how best to communicate to the public the risks and benefits of new drugs and the role of the risk evaluation and mitigation strategy in assessing such risks and benefits.

(Sec. 905) Requires the Secretary to develop validated methods for the establishment of a postmarket risk identification and analysis system. Directs the Secretary to establish and maintain procedures: (1) for risk identification and analysis based on electronic health data; (2) for the reporting of data on all serious adverse drug experiences; (3) to provide for active adverse event surveillance using federal and private health-related electronic data and other data as the Secretary deems necessary; (4) to identify certain trends and patterns with respect to data accessed by the system; and (5) to provide regular reports to the Secretary regarding adverse events.

Requires the Comptroller General to evaluate data privacy, confidentiality, and security issues relating to accessing, transmitting, and maintaining data for the active postmarket risk identification and analysis system under this Act and make recommendations to relevant congressional committees regarding the need for any additional legislative or regulatory actions to ensure privacy, confidentiality, and security.

(Sec. 906) Deems a drug or device to be misbranded if published direct-to-consumer advertisements do not include a specified statement related to reporting negative side effects.

(Sec. 908) Authorizes appropriations for FY2008-FY2012.

(Sec. 909) Deems drugs approved before the effective date of this Act to have an approved risk evaluation and mitigation strategy if there are in place elements to assure safe use of such drug.

Subtitle B: Other Provisions to Ensure Drug Safety and Surveillance (Sec. 911) Requires the Secretary to issue guidance for the conduct of clinical trials with respect to antibiotic drugs.

(Sec. 912) Prohibits the introduction into interstate commerce of any food to which has been added an approved drug, a licensed biological product, or certain other drugs or biological products unless: (1) such drug or biological product was marketed in food prior to approval, licensure, or clinical investigation; (2) the Secretary has issued a regulation approving the use of such drug or biological product in the food; (3) the use of the drug or the biological product is to enhance the safety of the food and not to have independent biological or therapeutic effects on humans and the use is in conformity with specified regulations; or (4) the drug is a new animal drug whose use is not unsafe.

(Sec. 913) Requires the Secretary to: (1) develop standards to secure the drug supply chain against counterfeit, diverted, subpotent, substandard, adulterated, misbranded, or expired drugs; (2) prioritize and develop standards for the identification, validation, authentication, tracking, and tracing of prescription drugs; (3) develop a standardized numerical identifier for prescription drugs; and (4) expand and enhance resources and facilities for enforcement of this Act to secure the drug supply chain.

(Sec. 914) Prohibits the Secretary from delaying approval of a pending application on the basis of a citizen petition unless the Secretary determines that a delay is necessary to protect the public health.

(Sec. 915) Requires the Secretary to improve the transparency of information about drugs and allow patients and health care providers better access to such information by developing and maintaining a website that: (1) provides links to drug safety information for approved prescription drugs; and (2) improves communication of drug safety information to patients and providers.

Requires the Advisory Committee on Risk Communication to: (1) regularly perform a comprehensive review and evaluation of the types of risk communication information provided on such website; and (2) recommend ways for the FDA to work with outside entities to help facilitate the dispensing of risk communication information to patients and providers.

(Sec. 916) Requires that certain information related to a new drug application be published on the FDA's website, including: (1) documents generated by the FDA related to review of an application; and (2) a summary review of conclusions from all reviewing disciplines about the drug. Provides that a scientific review of an application is considered the work of the reviewer. Prohibits the altering of such work by management or the reviewer once it is final.

(Sec. 917) Requires the Secretary to establish the Advisory Committee on Risk Communication to advise the Commissioner on methods to effectively communicate risks associated with the products regulated by the FDA.

Directs the Secretary to partner with professional medical societies, medical schools, academic medical centers, and other stakeholders to develop robust and multifaceted systems for communication to health care providers about emerging postmarket drug risks.

(Sec. 918) Requires the Secretary to refer a drug of which no active ingredient has been approved in any other application to an FDA advisory committee for review prior to approval or provide a summary of the reasons why the Secretary did not refer the drug.

(Sec. 919) Requires the Secretary to issue a report responding to the Institute of Medicine report on drug safety.

(Sec. 920) Directs the Commissioner to publish and update, quarterly, a complete list of all authorized generic drugs on the FDA's website.

(Sec. 921) Requires the Secretary to: (1) conduct regular, biweekly screening of the Adverse Event Reporting System database and post a report on the Adverse Event Reporting System website of any new safety information or any potential signal of a serious risk identified by the System within the last quarter; (2) report to Congress on FDA processes and procedures to address ongoing postmarket safety issues identified by the Office of Surveillance and Epidemiology and on how such recommendations are handled within the FDA; and (3) review annually the entire backlog of postmarket safety commitments to determine which commitments require revision or should be eliminated, report to Congress on such determinations, and assign start dates and estimated completion dates for such commitments.

Title X: Food Safety - (Sec. 1002) Requires the Secretary to establish: (1) ingredient standards and definitions with respect to pet food; (2) processing standards for pet food; and (3) updated standards for pet food labeling that include nutritional and ingredient information.

Requires the Secretary to establish an early warning and surveillance system to identify adulteration of the pet food supply and outbreaks of illness associated with pet food.

(Sec. 1003) Requires the Secretary, during an ongoing recall of human or pet food regulated by the Secretary, to: (1) work with companies, professional associations, and other organizations to collect and aggregate pertinent information; (2) use existing networks of communication to enhance the quality and speed of communication with the public; and (3) post information regarding recalled human and pet foods on the FDA's website in a single location.

(Sec. 1004) Requires the Secretary to work with states in undertaking activities that assist in improving the safety of food, including fresh and processed produce.

(Sec. 1005) Requires the Secretary to: (1) establish a Reportable Food Registry to which instances of reportable food may be submitted by the FDA; and (2) issue an alert or a notification using information from the Registry as the Secretary deems necessary to protect the public health.

Requires a responsible party who determines that an article of food is a reportable food to: (1) submit a report to the FDA within 24 hours; and (2) investigate the cause of the adulteration if the adulteration may have originated with the responsible party.

Requires the Secretary to immediately notify the Secretary of Homeland Security if the Secretary believes food reported to the Registry may have been deliberately adulterated.

(Sec. 1006) Authorizes the Secretary to enhance, as necessary, the inspection regime of the FDA for aquaculture and seafood, consistent with U.S. obligations under international agreements and U.S. law.

(Sec. 1007) Requires the Commissioner to produce a report on any environmental risks associated with genetically engineered seafood products.

(Sec. 1008) Expresses the sense of Congress that: (1) it is vital for Congress to provide the FDA with additional resources, authorities, and direction to ensure the safety of the U.S. food supply; (2) the Secretary should make it a priority to enter into agreements with U.S. trading partners with respect to food safety; and (3) Congress should work to develop a comprehensive response to the issue of food safety.

(Sec. 1009) Sets forth reporting requirements with respect to food products regulated by the FDA.

(Sec. 1010) Requires the Commissioner to annually submit to Congress and publish on the FDA's website a report concerning the results of the FDA's pesticide residue monitoring program.

Title XI: Other Provisions - Subtitle A: In General (Sec. 1101) Requires the Secretary, through the Commissioner, to establish and make publicly available clear written policies to govern the timely submission, review, clearance, and disclaimer requirements for publication of articles by an FDA officer or employee.

(Sec. 1102) Requires the Secretary to: (1) award a transferable, priority review voucher to the sponsor of a tropical disease product application upon approval by the Secretary of such application; and (2) establish a priority review user fee program.

(Sec. 1103) Requires the Secretary to enter into a contract with the Institute of Medicine to conduct a study to assess the overall safety and quality of genetic tests and prepare a report that includes recommendations to improve federal oversight and regulation of genetic tests.

Subtitle B: Antibiotic Access and Innovation (Sec. 1111) Requires the Secretary, through the Commissioner, to

identify and periodically update clinically susceptible concentrations (specific values that characterize bacteria as clinically susceptible, intermediate, or resistant to the drug tested).

(Sec. 1112) Directs the Commissioner to convene a public meeting regarding which serious and life threatening infectious diseases potentially qualify for available grants and contracts under the Orphan Drug Act or other incentives for development.

Amends the Orphan Drug Act to reauthorize appropriations for grants and contracts to defray the costs of: (1) qualified testing expenses incurred in connection with the development of drugs for rare diseases and conditions, (2) developing medical devices for rare diseases or conditions, and (3) developing medical foods for rare diseases or conditions.

(Sec. 1113) Allows an applicant for a non-racemic drug containing as an active ingredient a single enantiomer that is contained in a racemic drug approved in another application to elect to have the single enantiomer considered the same active ingredient as that contained in the approved racemic drug under certain circumstances.

(Sec. 1114) Direct the Comptroller General to submit a report to the relevant congressional committees that examines whether and how this subtitle has: (1) encouraged the development of new antibiotics and other drugs; and (2) prevented or delayed timely generic entry into the market.

Actions Timeline

- **Sep 27, 2007:** Signed by President.
- **Sep 27, 2007:** Became Public Law No: 110-85.
- **Sep 26, 2007:** Presented to President.
- **Sep 21, 2007:** Message on Senate action sent to the House.
- **Sep 20, 2007:** Passed/agreed to in Senate: Passed Senate without amendment by Unanimous Consent.(consideration: CR S11831-11841)
- **Sep 20, 2007:** Passed Senate without amendment by Unanimous Consent. (consideration: CR S11831-11841)
- **Sep 20, 2007:** Cleared for White House.
- **Sep 19, 2007:** Introduced in House
- **Sep 19, 2007:** Referred to the House Committee on Energy and Commerce.
- **Sep 19, 2007:** Mr. Dingell moved to suspend the rules and pass the bill.
- **Sep 19, 2007:** Considered under suspension of the rules. (consideration: CR H10551-10599)
- **Sep 19, 2007:** DEBATE - The House proceeded with forty minutes of debate on H.R. 3580.
- **Sep 19, 2007:** Passed/agreed to in House: On motion to suspend the rules and pass the bill Agreed to by the Yeas and Nays: (2/3 required): 405 - 7 (Roll no. 885).(text: CR H10551-10594)
- **Sep 19, 2007:** On motion to suspend the rules and pass the bill Agreed to by the Yeas and Nays: (2/3 required): 405 - 7 (Roll no. 885). (text: CR H10551-10594)
- **Sep 19, 2007:** Motion to reconsider laid on the table Agreed to without objection.
- **Sep 19, 2007:** Received in the Senate, read twice.

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