S 1082

Food and Drug Administration Revitalization Act

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Sponsor

Name: Sen. Kennedy, Edward M. [D-MA]
Party: Democratic • **State:** MA • **Chamber:** Senate

Cosponsors

No cosponsors are listed for this bill.

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Reported By	Apr 24, 2007

Subjects & Policy Tags

Policy Area:

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Related Bills

Bill	Relationship	Last Action
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 May 9, 2007)

Food and Drug Administration Revitalization Act - **Title I: Prescription Drug User Fees** - (Sec. 101) - Prescription Drug User Fee Amendments of 2007 - (Sec. 102) Amends the Federal Food, Drug, and Cosmetic Act (FFDCA) to set forth as a purpose that authorized prescription drug fees be dedicated toward expediting the drug development process, the process for the review of human drug applications, and postmarket drug safety.

Sets forth reporting requirements, including requiring the Secretary of Human Services (the Secretary) to present to Congress recommendations developed for achieving certain goals for the review process of human drug applications and for reauthorization of user fee provisions.

Makes changes to include postmarket safety activities within the process for the review of approved human drug applications or supplements, including developing and using improved adverse event data collection systems and improved analytical tools to assess potential safety problems. Removes provisions limiting the postmarket safety activities to three years after approval of a new drug.

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

Requires the Secretary to provide a partial refund of an applicant's user fees if the application is withdrawn without a waiver before filing.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 compounded positron emission tomography drugs, including allowing an applicant for an approved human drug application for a compounded positron emission tomography drug to be subject to one-fifth of the annual prescription drug establishment fee.

Establishes the amount of revenue that fees are to generate for FY2008-FY2012. Sets forth provisions regarding adjustments to such fees. Requires the Secretary to: (1) contract with an independent accounting firm to study and make recommendations on the adjustment for changes in review activities; and (2) make appropriate changes to the workload adjustment methodology in setting fees for FY2010-FY2012.

Directs the Secretary to consider only the circumstances and assets of the applicant and any affiliate when determining whether to grant a waiver or reduction of fees assessed. Excludes an entity that has a drug product that has been approved under a human drug application and introduced or delivered for introduction into interstate commerce from being considered a small business for purposes of application fee waiver rules.

(Sec. 104) Requires the Secretary to assess and collect fees for advisory review by the Secretary of direct-to-consumer television advertisement for a prescription drug product. Sets forth procedures for such review.

Subjects each person that is assessed an advisory review fee to an operating reserve fee for the first fiscal year in which an advisory review fee is assessed. Establishes the amount of revenue that may be generated from such fees.

Requires the Secretary to annually set the fee for advisory review based on the number of direct-to-consumer advertisements that the Secretary will review in the next fiscal year. Sets forth fee limits.

Requires the Secretary to establish a Direct-to-Consumer Advisory Review Operating Reserve in the Food and Drug Administration (FDA) salaries and expenses appropriation account to continue such review in the event the fees collected in any subsequent fiscal year do not generate the fee revenue amount established for that fiscal year.

Terminates such advisory review if the Secretary fails to receive a certain amount of advisory review fees and operating reserve fees.

Terminates provisions for prescription drug user fees on October 1, 2012, except certain reporting requirements.

Title II: Drug Safety - (Sec. 200) Enhancing Drug Safety and Innovation Act of 2007- **Subtitle A: Risk Evaluation and Mitigation Strategies** - (Sec. 201) Amends the FFDCA to require the Secretary to establish: (1) minimum standards for collection and transmission of postmarketing data elements from electronic health data systems; and (2) a validated and integrated postmarket risk identification and analysis system to integrate and analyze safety data from multiple sources.

Directs the Secretary to: (1) establish and maintain an active surveillance infrastructure to collect and report data for pharmaceutical postmarket risk identification and analysis, including procedures to provide for adverse event surveillance by collecting and monitoring health-related electronic data; and (2) develop, support, and participate in complementary approaches to gather and analyze such data and information to the extent the active surveillance infrastructure is not sufficient to gather data and information relevant to priority drug safety questions.

Requires the Secretary to establish collaborations with other government, academic, and private entities to provide for the risk identification and analysis of collected data and data that is publicly available or is provided to the Secretary in order to: (1) improve the quality and efficiency of postmarket drug safety risk-benefit analysis; (2) provide the Secretary with routine access to expertise to study advanced drug safety data; and (3) enhance the ability of the Secretary to make timely assessments based on drug safety data.

Directs the Secretary to seek recommendations from the Drug Safety and Risk Management Advisory Committee at least biannually on: (1) priority drug safety questions; and (2) mechanisms for answering such questions.

Requires the Secretary to establish and implement procedures under which the Secretary may routinely collaborate with a qualified entity to: (1) clean, classify, or aggregate data; (2) allow for prompt investigation of priority drug safety questions; (3) perform advanced research and analysis on identified drug safety risks; (4) convene an expert advisory committee to oversee the establishment of standards for the ethical and scientific uses for postmarketing data collected; and (5) focus postmarket studies and post-approval clinical trials on cases for which reports and other safety signal detection is not sufficient to resolve whether there is an elevated risk of a serious adverse event associated with the use of a drug.

Authorizes appropriations for FY2008-FY2012.

(Sec. 202) Requires a proposed risk evaluation and mitigation strategy for a new drug to include: (1) labeling for the drug for use by health care providers; and (2) a timetable for submission of assessments of the strategy. Sets forth as additional elements that a risk evaluation and mitigation strategy may include: (1) post-approval studies; (2) advertisement pre-review requirements; (3) specific disclosures in advertisements; and (4) additional elements to assure safe use. Allows an application for approval of a new drug or a license for a biological product to include a proposed risk evaluation and mitigation strategy if there is a signal of a serious risk with a drug. Authorizes the Secretary to require that the applicant submit a proposed risk evaluation and mitigation strategy if the Secretary determines that, based on such a signal, a risk evaluation and mitigation strategy is necessary to assess such signal or mitigate such risk. Sets forth a time frame for submission of such a strategy when ordered by the Secretary. Allows (or requires, if ordered by the Secretary) an applicant to submit assessments or propose modifications of such a strategy.

Establishes a Drug Safety Oversight Board to: (1) oversee disputes related to a proposed risk evaluation and mitigation

strategy, except for disputes during initial approval of a drug; and (2) provide oversight and advice to the Secretary on the management of important drug safety issues.

Sets forth civil penalties for knowingly failing in an application to comply with a requirement of an approved risk evaluation and mitigation strategy.

(Sec. 203) Deems a drug to be misbranded if it is a drug subject to an approved risk evaluation and mitigation strategy and the applicant fails to: (1) make a labeling change required by such strategy; or (2) comply with the advertising requirements of such strategy. Sets forth civil penalties for knowingly failing to comply with a requirement of such strategy.

(Sec. 204) Amends the Public Health Service Act to allow an applicant for a license for a biological product to submit to the Secretary a proposed risk evaluation and mitigation strategy.

(Sec. 205) Authorizes the Secretary to withdraw or suspend approval of a new drug application without first ordering the applicant to submit an assessment of the approved risk evaluation and mitigation strategy for the drug.

(Sec. 206) Provides that a drug that is the subject of an abbreviated new drug application (generic) shall be subject to only the following elements of an approved risk evaluation and mitigation strategy if required for the applicable listed drug: (1) labeling, as required for the applicable listed drug; (2) a Medication Guide or patient package insert; (3) pre-review of advertising; (4) specific disclosures in advertising; and (5) elements to assure safe use as necessary.

(Sec. 207) Includes within the process for review of human drug application requirements that the Secretary conduct postmarket safety activities that include reviewing, implementing, and ensuring compliance with risk evaluation and mitigation strategies.

Sets forth fee revenue amounts for FY2008-FY2012.

Requires the Secretary to submit to the relevant congressional committees a strategic plan on information technology that includes: (1) an assessment of the information technology infrastructure; (2) an assessment of the extent to which the current FDA information technology assets are sufficient to meet needs; and (3) a plan and assessment of resources needed for enhancing such assets.

(Sec. 208) Requires the holder of an approved new drug application or a biological product license to promptly notify the Secretary of new safety information that should be included in the labeling of the drug. Requires the Secretary to promptly notify the holder if the Secretary becomes aware of new safety information that should be included. Sets forth an accelerated labeling review process to resolve disagreements between the Secretary and a holder about the need for, or content of, safety labeling changes. Requires the Drug Safety Oversight Board to resolve such disputes, as necessary.

(Sec. 209) Requires the Secretary to improve the transparency of pharmaceutical data and allow patients and health care providers better access to such data by developing and maintaining an Internet website that: (1) provides comprehensive 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. 210) 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. 211) Requires the Secretary to establish the Advisory Committee on Risk Communication to advise the Commissioner on which methods to use to effectively communicate risk associated with the products regulated by the FDA.

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

(Sec. 212) 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. Allows the advisory committee review to occur within one year after approval if: (1) the clinical trial that formed the primary basis of the safety and efficacy determination was halted by a drug safety monitoring board of an Institutional Review Board before its scheduled completion due to early unanticipated therapeutic results; or (2) the Secretary determines that it would be beneficial to the public health.

(Sec. 213) Requires the Secretary to issue a report responding to the Institute of Medicine report on drug safety.

(Sec. 214) Deems drugs approved before the effective date of this Act to have an approved risk evaluation and mitigation strategy if there are restrictions on distribution or use of such a drug. Requires the Secretary to notify applicants of the date by which an assessment of an approved strategy must be submitted, which date shall be no earlier than six months after the applicant is notified, except with respect to the drug Mifeprex (mifepristone) for which such assessment must be submitted six months after the applicant is notified.

Subtitle B: Reagan-Udall Foundation for the Food and Drug Administration - (Sec. 221) 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 devices, biologics, and drugs and the safety of food, food ingredients, and cosmetics; (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. Requires the Foundation's Board of Directors to appoint an Executive Director. Directs the Commissioner to receive and assess reports submitted by the Executive Director. Sets forth reporting requirements.

(Sec. 222) 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 and ensure that there is no duplication of research efforts supported by the Foundation; (3) develop and advocate for a budget to support intramural research; (4) develop a peer review process by which intramural research can be evaluated; and (5) identify and solicit intramural research proposals from across the FDA through an advisory board composed of FDA employees.

Subtitle C: Clinical Trials - (Sec. 231) 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. Requires the Secretary to expand the data bank to require the submission of specified information for applicable drug clinical trials and applicable device clinical trials. 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 involved or device involved is cleared or approved.

Requires the Director to conduct a study to determine the best, validated methods of making the results of clinical trials publicly available after the approval of drugs.

Prohibits the submission of promotional or false or misleading clinical trial information. Sets forth civil penalties for violations.

Subtitle D: Conflicts of Interest - (Sec. 241) Requires the Secretary to recruit individuals to serve as advisory committee members. Requires the Secretary to review the individual's financial disclosure report and expertise when considering a term appointment to an advisory committee. Sets forth provisions governing the granting of waivers and financial interests of advisory committee members.

Subtitle E: Other Drug Safety Provisions - (Sec. 251) Directs the Commissioner to publish and update, quarterly, a complete list of all authorized generic drugs on the FDA's website.

(Sec. 252) Requires the Secretary to require that state-legalized medical marijuana be subject to the full regulatory requirements of the FDA.

Subtitle F: Antibiotic Access and Innovation - (Sec. 261) Makes certain antibiotic drugs eligible for market exclusivity if an application for marketing is submitted after enactment of this Act for an antibiotic drug that: (1) was approved by the Secretary before November 21, 1997; or (2) was the subject of one or more applications received by the Secretary before November 21, 1997, none of which was approved.

(Sec. 262) Requires the Commissioner of Food and Drugs to convene a public meeting regarding which serious and life-threatening infectious diseases potentially qualify for available grants and contracts or other incentives for orphan drug development.

(Sec. 263) 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. 264) 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. 265) 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.

Title III: Medical Devices - Subtitle A: Device User Fees - (Sec. 301) Medical Device User Fee Amendments of 2007 - (Sec. 302) Establishes the purpose of collecting medical device fees, including that such fees be dedicated towards expediting the process for the review of device applications and assuring the safety and effectiveness of devices.

Sets forth reporting requirements, including requiring the Secretary to report to the relevant congressional committees on the FDA's progress in achieving specified goals.

Terminates medical device user fee provisions on October 1, 2012, except certain reporting requirements.

(Sec. 303) Makes changes to medical device fees, including establishing fees for: (1) a 30-day notice for a supplement to an approved premarket application or premarket report that is limited to a request to make modifications to manufacturing procedures or methods affecting the safety and effectiveness of the device; (2) a request for classification information; (3) periodic reporting concerning a class III device; and (4) each initial or annual registration for establishments subject to a registration fee.

Establishes medical device fee amounts.

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

Authorizes appropriations.

(Sec. 305) Makes this subtitle effective on October 1, 2007.

Subtitle B: Amendments Regarding Regulation of Medical Devices - (Sec. 311) Requires a person accredited to conduct inspections of establishments that manufacture, prepare, propagate, compound, or process class II or class III devices to notify the Secretary of any withdrawal, suspension, restriction, or expiration of certificate of conformance with the quality systems for any device establishment that such person inspects within 30 days after such action. Allows an accredited person to conduct audits to establish conformance with the quality systems. Sets forth conditions that a device establishment must meet to be eligible for inspections by accredited persons. Deems a device establishment to have clearance to participate in the program and to use an accredited person for inspections unless the Secretary denies such clearance or requests certain compliance data or information concerning the relationship between the owner of the establishment and the accredited person. Sets forth conditions under which the Secretary may deny clearance.

(Sec. 312) Extends the authority of accredited persons to review pre-market reports for devices and make recommendations to the Secretary regarding the initial classification of devices.

(Sec. 313) Requires every person who owns or operates any establishment in any state engaged in the manufacture, preparation, propagation, compounding, or processing of a device to register with the Secretary. Requires any such establishment within a foreign country to register electronically with the Secretary.

(Sec. 314) Requires a registered person to report to the Secretary with regard to devices once each year.

(Sec. 315) Requires electronic registration for device establishments, unless the Secretary grants a waiver.

Title IV: Pediatric Medical Products - Subtitle A: Best Pharmaceuticals for Children - Best Pharmaceuticals for Children Amendments of 2007 - (Sec. 402) Amends the Federal Food, Drug, and Cosmetic Act to make changes to provisions in regard to market exclusivity for pediatric drug studies on new drugs or already approved drugs, including to: (1) require that the studies are completed using appropriate formulations for each age group for which the study is requested; (2) require that appropriate labeling changes are made as determined appropriate by the Secretary within a time frame requested by the Secretary; and (3) prohibit the Secretary from extending market exclusivity if the determination of eligibility for such market exclusivity is made less than nine months prior to its expiration.

Requires an applicant or holder who does not agree with a request to conduct pediatric studies on the grounds that it is not possible to develop the appropriate pediatric formulation to submit to the Secretary the reasons such pediatric formulation 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 that are available prior to submission of reports on such studies.

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 formulation is not introduced onto the market within one year after the Secretary's determination regarding market exclusivity; and (2) create an internal review committee to review all written requests issued and all reports submitted. Requires the committee to be responsible for tracking and making available to the public: (1) the number of pediatric studies conducted; (2) the specific drugs and uses studied; (3) the types of studies conducted, the number of pediatric patients studied, and the number of centers and countries involved; (4) the number of pediatric formulations developed and the number not developed and the reasons formulations were not developed; (5) the labeling changes made as a result of studies; (6) an annual summary of labeling changes made as a result of studies conducted for distribution; and (7) information regarding reports submitted after enactment of this Act.

Reduces market exclusivity for pediatric studies from six months to three months for drugs for which combined annual gross sales exceed $1 billion.

Requires the Secretary to: (1) order the labeling of a drug to include information about the result of a pediatric study whether it does or does not demonstrate that the drug is safe and effective, including whether such study results are inconclusive; (2) ensure that all adverse event reports that have been received are referred to the Office of Pediatric Therapeutics for review.

(Sec. 403) Reauthorizes the Secretary, acting through the Director of NIH, to: (1) develop, publish, and revise every three years a priority list of needs in pediatric therapeutics; and (2) report to Congress on the feasibility of establishing a compilation of information on pediatric drug use. Requires the Director to submit proposed pediatric study requests for consideration by the Commissioner.

(Sec. 404) Requires the Comptroller General to submit a report to Congress that addresses the effectiveness of providing market exclusivity for pediatric studies in ensuring that medicines used by children are tested and properly labeled.

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

(Sec. 405) 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.

(Sec. 406) 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 pediatric studies of drugs for which the Secretary determines that there is a continuing need for information relating to the use of the drug in a pediatric population.

(Sec, 407) Requires the advisory committee on pediatric therapeutics to continue to operate for five years after enactment of this Act.

(Sec. 408) 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.

(Sec. 409) 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 the final rule is issued before such date.

Subtitle B: Pediatric Research Improvement - Pediatric Research Improvement Act - (Sec. 412) Requires an applicant seeking a waiver from requirements to submit pediatric assessments for new drugs and biological products to submit to the Secretary documentation detailing why a pediatric formulation cannot be developed.

Requires an applicant to annually submit to the Secretary: (1) information detailing the progress made in conducting pediatric studies; or (2) if no progress has been made, evidence and documentation that such studies will be conducted with due diligence and at the earliest possible time. Requires such information to promptly be made publicly available.

(Sec. 413) Requires an applicant seeking a waiver from a requirement to submit a pediatric assessment for an already marketed drug or biological product to submit to the Secretary documentation detailing why a pediatric formula cannot be developed. Requires the the applicant's submission to promptly be made available to the public if such a waiver is granted.

(Sec. 414) Requires the Secretary to create an internal committee to review pediatric assessment requests, pediatric assessments conducted, and deferral and waiver requests from such requirements. Makes the committee responsible for tracking and making public in an easily accessible manner information related to such pediatric assessments, including: (1) the number of assessments conducted and the drugs and drug uses assessed; (2) the number of pediatric formulations developed and the number not developed and the reasons formulations were not developed; and (3) the labeling changes made as a result of assessments.

Deems any supplement to a new drug applicant or license for a biological product proposing a labeling change as a result of any pediatric assessments to be a priority supplement.

Provides for referral to the Pediatric Advisory Committee for disputes on labeling changes. Requires the Secretary to: (1) order the labeling of a product to include information about the results of the assessment and a statement of the Secretary's determination that a pediatric assessment does or does not demonstrate that the drug is safe and effective; and (2) make publicly available the medical, statistical, and clinical pharmacology reviews of such pediatric assessments; and (3) ensure that all adverse event reports that have been received for the drug are referred to the Office of Pediatric Therapeutics for review.

(Sec 415) Considers a drug to represent a meaningful therapeutic benefit over existing therapies if the Secretary determines (currently, estimates) that the drug or biological product if approved could (currently, would) represent a significant improvement in the treatment, diagnosis, or prevention of a disease.

(Sec. 416) Requires the Secretary to contract with the Institute of Medicine to study and report to Congress regarding the pediatric studies of new drugs or biological products conducted pursuant to the FFDCA since 1997.

Requires the Comptroller General to submit to Congress a report that addresses the effectiveness of such studies in ensuring that medicines used by children are tested and properly labeled.

Subtitle C: Pediatric Medical Devices - Pediatric Medical Device Safety and Improvement Act of 2007 - (Sec. 422) 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. 423) Excludes a medical device distributed pursuant to the humanitarian device exemption from the prohibition that no device be sold for an amount that exceeds the cost of the device, if: (1) the device is intended for the treatment or diagnosis of 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.

Requires the Secretary to refer any adverse event report related to a device to the Office of Pediatric Therapeutics for review.

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

(Sec. 424) Requires the Secretary, acting through the Director of NIH, to designate a contact point or office to help innovators and physicians identify sources of funding available for pediatric medical device development.

(Sec. 425) Requires the Secretary to award grants for demonstration projects to promote pediatric device development.

(Sec. 426) Includes as a duty of the Office of Pediatric Therapeutics increasing pediatric access to medical devices. Requires the Office to report to the relevant congressional committees a plan for expanding pediatric medical device research and development. Expands the duties of the advisory committee on pediatric therapeutics to include providing advice and recommendations on matters relating to medical devices.

(Sec. 427) 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) a postmarket surveillance as a condition of approval of an application or a product development protocol or as a condition to clearance of a premarket notification for such pediatric devices; and (3) a prospective surveillance period of more than 36 months for such pediatric devices as necessary to assess the impact of the device on growth and development or the effects of growth, development, activity level, or other factors on the safety of the device.

Title V: Other Provisions - (Sec. 501) Amends the FFDCA to require the Secretary, through the Commissioner of Food and Drugs, 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. 504) Expresses the sense of the Senate that legislation should be enacted to provide the FDA with the authority and flexibility to approve biopharmaceuticals subject to an abbreviated approval pathway.

(Sec. 505) Requires the Secretary to: (1) award a transferable, priority review voucher to the sponsor of a tropical disease product upon approval by the Secretary of such product; and (2) establish a priority review user fee program.

(Sec. 506) Prohibits the Secretary from delaying approval of a new drug application while a petition is reviewed or considered, unless such a delay is necessary to protect the public health. Requires the Secretary to take final agency action on a petition not later than 180 days after submission, unless such a delay is necessary. Requires petitions to be signed and to contain specified verifications.

Sets forth reporting requirements.

Requires the Office of the Inspector General of the Department of Health and Human Services (HHS) to evaluate evidence of FDA compliance with the requirement that the consideration by the Secretary of petitions that do not raise public health concerns remain separate and apart from the review and approval of a new drug application.

(Sec. 507) Requires the Commissioner to annually submit to Congress and the public on the FDA's Internet website a report concerning the results of the FDA's pesticide residue monitoring program.

(Sec. 508) Amends the Head Start Act to require a Head Start agency to obtain written parental consent before administration of any nonemergency intrusive physical examination of a child in connection with participation in a Head Start program.

(Sec. 509) Requires the FDA to report on the question of whether substances used to preserve the appearance of fresh meat may create any health risks or mislead consumers.

(Sec. 510) 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.

(Sec. 511) Expresses the sense of the Senate that the FDA should enter into a contract with the Institute of Medicine for a study concerning measures that may be taken to improve the likelihood that FDA-approved drugs that are safe and effective in treating children with orphan diseases (rare genetic diseases) are made available and affordable for pediatric indications.

(Sec. 512) Requires the Secretary, after the close of a fiscal year in which color certification fees are collected, to submit to Congress: (1) a performance report on the number of batches of color additives approved, the average turn around time for approval, and quantifiable goals for improving laboratory efficiencies; and (2) a financial report for the color certification program.

(Sec. 513) Prohibits any food product from being imported into the United States that is the product of a registered foreign food facility that refuses to permit U.S. inspectors, upon request, to inspect such facility or that unduly delays access to U.S. inspectors.

(Sec. 514) Provides that the certification requirement before implementation of the prescription drug importation provisions under this Act shall not apply to requirements for counterfeit-resistant technologies.

(Sec. 515) 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. 516) Expresses the sense of the Senate that the U.S. Trade Representative should: (1) use all available tools to address violations and other concerns with intellectual property; and (2) develop and submit to Congress a strategic plan to address the problem of countries infringing upon American pharmaceutical intellectual property rights and engaging in price manipulation.

(Sec. 517) Requires the Commissioner of Food and Drugs to produce a report on any environmental risks associated with genetically engineered seafood products.

(Sec. 518) Requires the Secretary to submit to the relevant congressional committees a report on the differences between taxonomies of certain species of lobster.

(Sec. 519) Establishes civil penalties for dissemination of false or misleading direct-to-consumer advertisements for a prescription drug.

(Sec. 520) Requires the Secretary, acting through the Commissioner, 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) modifying the warning label required on tanning beds would communicate such risks more effectively; and (3) there is no warning that would be capable of adequately communicating such risks. Requires the Secretary, in making such determinations, to: (1) conduct appropriate consumer testing using the best available methods for determining consumer understanding of label warnings; and (2) hold public hearings and solicit comments from the public.

Title VI: Food Safety - (Sec. 602) Requires the Secretary to establish: (1) processing and ingredient standards with respect to pet food, animal waste, and ingredient definitions; and (2) update standards pet food labeling that includes 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. 603) Requires the Secretary, during an ongoing recall of human or pet food, 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 products on the FDA's website in a consolidated, searchable form that is easily accessed and understood by the public.

(Sec. 604) Requires the Secretary to work with states in undertaking activities that assist in improving the safety of fresh and processed produce.

(Sec. 605) Requires the Secretary to establish an Adulterated Food Registry to which instances of reportable adulterated food may be submitted by the FDA. Requires the Secretary to issue an alert if the Registry shows that a food: (1) has been associated with repeated and separate outbreaks of illness or has been repeatedly determined to be adulterated; or (2) is a reportable adulterated food. Allows such an alert to apply to a particular food or to food from a particular producer, manufacturer, shipper, growing area, or country.

Requires a responsible party or importer who determines that an article of food it produced, processed, manufactured,

distributed, or otherwise handled is a reportable adulterated food to provide notification to other parties linked in the supply chain and to submit a report to the FDA.

Requires the Secretary to immediately notify the Secretary of Homeland Security if the Secretary suspects such food may have been deliberately adulterated.

(Sec. 606) Expresses the sense of the Senate 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) the Senate should work to develop a comprehensive response to the issue of food safety.

(Sec. 607) Sets forth reporting requirements with respect to food products regulated by the FDA.

(Sec. 609) Authorizes appropriations.

Title VII: Domestic Pet Turtle Market Access - Domestic Pet Turtle Market Access Act of 2007 - (Sec. 703) Prohibits the Food and Drug Administration (FDA) from restricting the sale by a turtle farmer, wholesaler, or other commercial retail seller of a turtle that is less than 10.2 centimeters in diameter as a pet if: (1) the state or territory in which such farmer is located has developed a regulatory process by which pet turtle farmers are required to have a state license; (2) such state or territory requires certification of sanitization that requires each turtle to be sanitized or treated for diseases and is dependent upon using proven non-antibiotic methods to make the turtle salmonella-free; and (3) the turtle farmer or commercial retail seller makes certain disclosures to a buyer. Sets forth required disclosures, which include: (1) information regarding the possibility that salmonella can re-colonize in turtles, the dangers that could result if the turtle is not properly handled and safely maintained, the proper handling of the turtle, and the proven methods of treatment that keep the turtle safe from salmonella; (2) a detailed explanation of how to properly treat the turtle to keep it safe from salmonella and how the buyer can continue to purchase the tools, treatments, or any other required item to continually treat the turtle; and (3) a statement that buyers of pet turtles should not abandon turtles, but should instead return them to a commercial retail pet seller or other organization that would accept turtles no longer wanted as pets.

(Sec. 704) Authorizes the Commissioner of Food and Drugs to restrict the sale of a turtle only if the Secretary determines that the actual implementation of state health protections are insufficient to protect consumers against infectious diseases acquired from such turtle at the time of sale.

Title VIII: Importation of Prescription Drugs - Pharmaceutical Market Access and Drug Safety Act of 2007 - (Sec. 804) Amends the FFDCA to revise provisions governing the importation of prescription drugs. Waives the limitation on importation of prescription drugs that have been exported from the United States.

Prohibits the importation of a qualifying drug unless such drug is imported by: (1) a registered importer; or (2) an individual for personal use. Defines "qualifying drug" as a drug for which there is a corresponding U.S. label drug.

Includes among registration conditions for importers and exporters: (1) the drug to be imported or exported was manufactured in an approved facility and manufactured for sale in the United States or a permitted country; (2) a chain of custody exists for such drug; (3) the exporter or importer allows onsite inspections by the Secretary; (4) there is proper labeling of the shipment; (5) importers provide prior notice of all shipments; and (6) importers and exporters pay a registration fee and an inspection fee.

Requires the Secretary to inspect places of business, verify chain of custody, review records, monitor shipment labels,

inspect facilities, and check for compliance with registration conditions.

Sets forth provisions governing the importation of qualifying drugs that are different from U.S. label drugs, including standards for judging such differences, labeling requirements, and bioequivalence.

Establishes conditions for individual importation of a qualifying drug, including requiring a valid prescription and a quantity not exceeding a 90-day supply.

Prohibits manufacturers from: (1) discriminating against registered exporters or importers; (2) causing there to be a difference in a prescription drug distributed in the United States and one distributed in a permitted country; (3) engaging in actions to restrict, prohibit, or delay the importation of a qualifying drug; or (4) engaging in any action that the Federal Trade Commission (FTC) determines discriminates against a person engaged in the importation of a qualifying drug. Allows states to bring actions for violations.

States that the resale in the United States of prescription drugs that were properly sold abroad is not patent infringement.

Gives priority in the registration of exporters to significant Canadian exporters. Allows the Secretary to limit the number of registered exporters and importers.

Requires the Secretary to educate consumers regarding prescription drug importation.

(Sec. 805) Requires the Secretary of Homeland Security to deliver violative shipments to the Secretary. Requires the Secretary to destroy such shipments under certain circumstances.

(Sec. 806) Requires the Secretary to establish alternative requirements to identify the chain of custody of a drug from the manufacturer throughout the wholesale distribution to a pharmacist who intends to sell the drug at retail if the Secretary determines that such requirements: (1) will identify such chain of custody or the identity of the discrete package from which the drug is dispensed with equal or greater certainty than current requirements; and (2) are economically and technically feasible.

Directs the Secretary to require the use of standardized anti-counterfeiting and track-and-track technologies on prescription drugs at the case and pallet level. Sets forth additional counterfeiting technologies to be incorporated into prescription drug packaging.

(Sec. 807) Prohibits any person from dispensing a prescription drug pursuant to a sale if: (1) any part of the sales transaction for the drug is conducted through an Internet site; (2) the person dispenses the drug to the purchaser by mailing or shipping the drug to the purchaser; and (3) such site fails to meet specified requirements regarding inclusion of a page (and links thereto) providing the identities and licensing information of the seller, pharmacists, or medical consultants.

Prohibits a person from selling or dispensing a prescription drug if: (1) the purchaser communicated with the person through the Internet; (2) the purchaser did not have a valid prescription when the communication began; (3) the person provided for the involvement of a practitioner; (4) the practitioner issued a prescription for the drug that was purchased; (5) the person knew that no qualifying medical relationship existed (defines "qualifying medical relationship" as requiring an in-person medical evaluation); and (6) the person received payment.

Allows states to bring civil actions against a person for violations of this Act.

Prevents Internet providers from being held liable for dispensing or selling prescription drugs on account of another person's activities.

Includes the dispensing or selling of a prescription drug in violation of this Act as a prohibited act under the FFDCA.

Requires the Secretary to award a grant or contract to the National Clearinghouse on Internet Prescribing to identify and report Internet sites that violate federal or state laws concerning the dispensing of drugs.

(Sec. 808) Prohibits the introduction of restricted transactions with unregistered foreign pharmacies into a payment system or the completion of such transactions using a payment system.

Requires the Board of Governors of the Federal Reserve System to promulgate regulations requiring designated payment systems to establish policies and procedures that are reasonably designed to prevent the introduction of a restricted transaction into a payment system.

(Sec. 809) Amends the Controlled Substances Import and Export Act to allow a U.S. resident entering the United States with a controlled substance for which the individual does not have a valid prescription to import not more than ten dosage units combined of all such controlled substances.

(Sec. 811) Directs that this title only becomes effective if the Secretary certifies to Congress that its implementation will: (1) pose no additional risk to the public's health and safety; and (2) result in a significant reduction in the cost of covered products to the American consumer.

Actions Timeline

- **May 10, 2007:** Received in the House.
- **May 10, 2007:** Message on Senate action sent to the House.
- **May 10, 2007:** Held at the desk.
- **May 9, 2007:** Considered by Senate. (consideration: CR S5759-5824)
- **May 9, 2007:** The committee substitute as amended agreed to by Unanimous Consent.
- **May 9, 2007:** Cloture motion on the bill withdrawn by unanimous consent in Senate.
- **May 9, 2007:** Passed/agreed to in Senate: Passed Senate with an amendment and an amendment to the Title by Yea-Nay Vote. 93 - 1. Record Vote Number: 157.(text: CR S5773-5822)
- **May 9, 2007:** Passed Senate with an amendment and an amendment to the Title by Yea-Nay Vote. 93 - 1. Record Vote Number: 157. (text: CR S5773-5822)
- **May 8, 2007:** Considered by Senate. (consideration: CR S5682-5686, S5689-5707)
- **May 7, 2007:** Considered by Senate. (consideration: CR S5634-5651)
- **May 7, 2007:** Cloture on the committee substitute amendment as modified invoked in Senate by Yea-Nay Vote. 82 - 8. Record Vote Number: 152. (consideration: CR S5641-5642; text: CR S5641)
- **May 3, 2007:** Considered by Senate. (consideration: CR S5526-5558)
- **May 3, 2007:** Cloture motion on the committee substitute amendment as modified presented in Senate. (consideration: CR S5556-5557)
- **May 3, 2007:** Cloture motion on the measure presented in Senate. (consideration: CR S5557)
- **May 2, 2007:** Considered by Senate. (consideration: CR S5444-5485, S5486-5492)
- **May 1, 2007:** Considered by Senate. (consideration: CR S5325-5329, S5332-5362, S5367, S5368-5371, S5372-5379, S5380-5385, S5387-5388)
- **May 1, 2007:** The committee reported substitute amendment was modified by Unanimous Consent. (text as modified: CR S5333-5361)
- **Apr 30, 2007:** Measure laid before Senate by unanimous consent. (consideration: CR S5270-5303; text of measure as reported in Senate: CR S5270-5294)
- **Apr 24, 2007:** Committee on Health, Education, Labor, and Pensions. Reported by Senator Kennedy with an amendment in the nature of a substitute and an amendment to the title. Without written report.
- **Apr 24, 2007:** Placed on Senate Legislative Calendar under General Orders. Calendar No. 120.
- **Apr 18, 2007:** Committee on Health, Education, Labor, and Pensions. Ordered to be reported with an amendment in the nature of a substitute favorably.
- **Apr 10, 2007:** Introduced in Senate
- **Apr 10, 2007:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.