S 3187

Food and Drug Administration Safety and Innovation Act

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Sponsor

Name: Sen. Harkin, Tom [D-IA]
Party: Democratic • **State:** IA • **Chamber:** Senate

Cosponsors (1 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Enzi, Michael B. [R-WY]	R · WY		May 15, 2012

Committee Activity

No committee referrals or activity are recorded for this bill.

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
112 HR 5651	Related bill	**Jun 4, 2012:** Received in the Senate. Read twice. Placed on Senate Legislative Calendar under General Orders. Calendar No. 420.
112 HR 5334	Related bill	**May 11, 2012:** Referred to the Subcommittee on Health.
112 S 2516	Related bill	**May 7, 2012:** Placed on Senate Legislative Calendar under General Orders. Calendar No. 389.
112 S 2289	Related bill	**Apr 17, 2012:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.
112 S 2236	Related bill	**Mar 26, 2012:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.
112 HR 4087	Related bill	**Feb 24, 2012:** Referred to the House Committee on Energy and Commerce.
112 HR 3988	Related bill	**Feb 10, 2012:** Referred to the Subcommittee on Health.

Summary (as of Jul 9, 2012)

Food and Drug Administration Safety and Innovation Act - Amends the Federal Food, Drug, and Cosmetic Act (FFDCA) to reauthorize and establish new Food and Drug Administration (FDA) prescription drug user-fee programs and revise and impose new requirements relating to: (1) prescription, pediatric, and generic drugs; (2) medical devices; (3) biosimilar biological products; (4) new infectious disease drugs; and (5) drug manufacturer reporting.

Title I: Fees Relating to Drugs - Prescription Drug User Fee Amendments of 2012 - (Sec. 103) Extends through FY2017 the authority of the Secretary of Health and Human Services (HHS) to assess and collect human drug application and supplement fees, prescription drug establishment fees, and prescription drug product fees to support the FDA drug development process and the process for the review of human drug applications. Increases for FY2013-FY2017 the level of required prescription drug user fee revenues. Provides for an inflation adjustment and a workload adjustment for FY2013 and for FY2014 and subsequent fiscal years for the required level of user fee revenue amounts.

Requires the Secretary, not later than 60 days before the start of each fiscal year, to establish, for the next fiscal year, application, product, and establishment fees based on revenue amounts established by this title.

(Sec. 104) Requires the Secretary to prepare and submit to the House Committee on Energy and Commerce and the Senate Committee on Health, Education, Labor, and Pensions (specified congressional committees) after the end of each fiscal year for which user fees are collected under this title (beginning with FY2013) a report on the progress of the FDA in achieving the goals identified in the letters sent by the Secretary to the Committees, the future plans of the FDA, and the progress of the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research in achieving such goals.

Requires such report to include, for each review division, per fiscal year, the number of: (1) original standard new drug applications and biologics license applications filed, (2) priority new drug applications and biologics license applications filed, (3) standard efficacy supplements, (4) priority efficacy supplements, (5) applications filed for review under accelerated approval, (6) applications filed for review as fast track products, (7) applications filed for orphan-designated products, and (8) breakthrough designations.

(Sec. 105) Terminates: (1) the authority of the Secretary to assess and collect prescription drug user fees on October 1, 2017, and (2) reporting requirements on January 31, 2018.

(Sec. 106) Provides that the amendments made by this title shall take effect on the later of October 1, 2012, or the enactment date of this Act, except that user fees shall be assessed for all human drug applications received on or after October 1, 2012, regardless of the enactment date of this Act.

(Sec. 107) Limits the applicability of this title to human drug applications and supplements filed before the enactment of this title.

Title II: Fees Relating to Devices - Medical Device User Fee Amendments of 2012 - (Sec. 203) Extends through FY2017 the authority of the Secretary to assess and collect fees for medical device applications and submissions. Increases for FY2013-FY2017 the level of required medical device user fee revenues. Provides for an inflation adjustment to such revenues in FY2014 and each subsequent fiscal year. Authorizes the Secretary to grant a waiver or reduction of medical device user fees if the Secretary finds that such waiver or reduction is in the interest of public health.

(Sec. 204) Requires the Secretary to prepare and submit to specified congressional committees annual reports for each fiscal year for which medical device user fees are collected on the progress of the FDA in achieving goals identified in

letters from the Secretary to such Committees. Requires publication of such reports on the FDA website.

(Sec. 205) Limits the effect of this title on medical device applications and supplements filed before the enactment of this title.

(Sec. 206) Makes the amendments made by this title effective on the later of October 1, 2012, or the enactment date of this Act.

(Sec. 207) Terminates the medical device user fee program on October 1, 2017, and the reporting requirements on January 31, 2018.

Sec. 208) Authorizes the Secretary to appoint employees to positions in the FDA to perform, administer, or support activities related to the review of medical device applications and to meet performance objectives, without regard to requirements governing appointments in the competitive service. Terminates this authority three years after enactment of this Act.

Title III: Fees Relating to Generic Drugs - Generic Drug User Fee Amendments of 2012 - (Sec. 302) Directs the Secretary, beginning in FY2013, to assess and collect the following fees related to generic drugs: (1) a one-time backlog fee for abbreviated new drug applications pending on October 1, 2012; (2) a drug master file fee; (3) an abbreviated new drug application and prior approval supplement filing fee, as well as an additional fee for certain active pharmaceutical ingredient information; and (4) a generic drug facility fee and active pharmaceutical ingredient facility fee. Provides that submission of an application for a positron emission tomography drug or active pharmaceutical ingredient for such a drug shall not require the payment of any fee. Terminates such authority on October 1, 2017.

(Sec. 303) Requires the Secretary to prepare and submit to specified congressional committees annual reports for each fiscal year for which generic drug fees are collected on the progress of the FDA in achieving goals identified in letters from the Secretary to such Committees and on the implementation of the authority for such fees and the use of such fees by the FDA in each fiscal year. Requires publication of such reports on the FDA website.

Sec. 304) Terminates: (1) the authority to assess and collect generic drug user fees on October 1, 2012, and (2) the reporting requirements with respect to the generic drug user fee program on January 31, 2018.

Sec. 305) Makes the amendments made by this title effective on the later of October 1, 2012, or the enactment date of this title.

(Sec. 306) Deems as misbranded a drug or active pharmaceutical ingredient manufactured, prepared, propagated, compounded, or processed in a facility for which fees have not been paid or for which identifying information has not been provided.

(Sec. 307) Authorizes the Secretary to appoint employees to positions in the FDA to perform, administer or support activities related to human generic drug activities, without regard to requirements governing appointments in the competitive service. Terminates this authority three years after enactment of this Act.

Sec. 308) Requires the Secretary, beginning in FY2013 and ending after FY2017, to report to specified congressional committees on all applications for approval of a generic drug, amendments to such applications, and prior approval supplements with respect to such applications filed in the previous fiscal year.

Title IV: Fees Relating to Biosimilar Biological Products - Biosimilar User Fee Act of 2012 - (Sec. 402) Directs the

Secretary, beginning FY2013, to assess and collect the following fees related to biosimilar biological products: (1) biosimilar program development fees, encompassing an initial biosimilar biological development fee, an annual biosimilar biological product development fee, and a reactivation fee; (2) a biosimilar biological product application and supplement fee; (3) a biosimilar biological product establishment fee; and (4) a biosimilar biological product fee. Waives such fees for the first biosimilar biological product application of a small business. Terminates such authority on October 1, 2017.

(Sec. 403) Requires the Secretary to prepare and submit to specified congressional committees annual reports for each fiscal year for which biosimilar user fees are collected on the progress of the FDA in achieving goals identified in letters from the Secretary to such Committees, the implementation of the authority for such fees, and the use of such fees by the FDA in each fiscal year. Requires publication of such reports on the FDA website.

(Sec. 404) Terminates: (1) the authority to assess and collect biosimilar drug user fees on October 1, 2012, and (2) the reporting requirements with respect to the biosimilar drug user fee program on January 31, 2018.

(Sec. 405) Makes the amendments made by this title effective on the later of October 1, 2012, or the enactment date of this title.

Sec. 408) Requires the Secretary to report to specified congressional committees within 120 days after the end of each fiscal year for which biosimilar biological product fees are collected (beginning in FY2014) on: (1) the number of applications for approval of a biological license, and (2) the percentage of applications approved by the Secretary.

Title V: Pediatric Drugs and Devices - (Sec. 501) Makes permanent the: (1) the Best Pharmaceuticals for Children Act granting extended market exclusivity for new and already-marketed drugs for the pediatric population, and (2) the Pediatric Research Equity Act of 2003 relating to research into pediatric uses for drugs and biological products.

(Sec. 502) Provides that exclusivity for the completion of a pediatric study or studies shall be granted only for those that are the subject of a written request.

(Sec. 503) Requires the Secretary, not later than one year after enactment of this Act, to issue internal standard operating procedures for the review of any significant modifications to initial pediatric study plans, agreed initial pediatric study plans, and written requests for studies under the FFDCA. Requires such procedures to be made publicly available on the FDA website.
(Sec. 504) Requires the Secretary, not later than three years after enactment of this Act, to make publicly available the medical, statistical, and clinical pharmacology reviews of, and corresponding written requests issued to an applicant, sponsor, or holder for, pediatric studies submitted between January 4, 2002, and September 27, 2007, under the FFDCA for which six months of market exclusivity was granted and that resulted in a labeling change.

(Sec. 505) Grants the Secretary authority to extend a deadline for a pediatric drug study under specified circumstances.

(Sec. 506) Requires an applicant for approval of a pediatric drug to submit to the Secretary an initial pediatric study plan prior to the submission of drug safety assessments.

(Sec. 507) Amends the Best Pharmaceuticals for Children Act to reauthorize: (1) the Pediatric Advisory Committee, and (2) the Pediatric Subcommittee of the Oncologic Drug Advisory Committee.

Amends the FFDCA to extend through FY2017 the authorization of appropriations for the humanitarian device exemption.

Amends the Public Health Service Act to extend through FY2017 the authorization of appropriations for the pediatric

study of drugs program.

(Sec. 508) Requires the Secretary to report to specified congressional committees within four years after enactment of this Act and every five years thereafter on the effectiveness of the pediatric study of drugs and research into pediatric uses for drugs and biological products under the FFDCA, and make such report publicly available on the FDA website. Sets forth the required content of such report.

(Sec. 510) Requires the Secretary to: (1) hold at least one public meeting within 18 months after enactment of this Act to discuss ways to encourage and accelerate the development of new therapies for pediatric rare diseases; and (2) issue a report that includes a strategic plan for developing treatments for such diseases.

(Sec. 511) Amends the Best Pharmaceuticals for Children Act to require the staff of the Office of Pediatric Therapeutics in the FDA to include individuals with expertise in pediatric epidemiology and neonatology.

Title VI: Medical Device Regulatory Improvements - (Sec. 601) Prohibits the Secretary from disapproving an application for approval of a medical device for investigational use on the basis that: (1) the investigation may not support a substantial equivalence or de novo classification determination or approval of the device; (2) the investigation may not meet a requirement, including a data requirement, relating to the approval or clearance of a device; or (3) an additional or different investigation may be necessary to support clearance or approval of the device.

(Sec. 602) Defines "necessary" for purposes of information required for the premarket approval regulatory process to mean the minimum required information that would support a determination by the Secretary that a medical device application provides reasonable assurance of the effectiveness of the device (least burdensome standard).

(Sec. 603) Requires the Secretary to provide a substantive summary of the scientific and regulatory rationale for any significant decision of the Center for Devices and Radiological Health regarding medical devices. Authorizes supervisory review of a significant decision.

(Sec. 604) Requires the Secretary to: (1) submit to specified congressional committees a report on when a premarket notification should be submitted for a modification or change to a legally marketed medical device; (2) withdraw certain draft guidance relating to changes to an existing device; (3) suspend issuance of any draft guidance or proposed regulation that addresses when to submit a premarket notification for changes and modifications made to a manufacturer's previously cleared device until receipt of the Secretary's report by the appropriate congressional committees; and (4) suspend any final guidance or regulation for one year after the receipt of such report.

(Sec. 605) Requires the Secretary to: (1) establish a program to assess information relating to recalls of medical devices, and (2) document the basis for termination by the FDA of a device recall.

(Sec. 606) Authorizes the Secretary to prohibit the sponsor of an investigation of the effectiveness of a medical device from conducting such investigation (clinical hold) if the Secretary makes a determination that the device represents an unreasonable risk to the safety of the persons who are the subjects of the clinical investigation.

(Sec. 607) Authorizes the Secretary to: (1) classify certain new medical devices without first issuing a determination that such devices are not substantially equivalent to existing devices; and (2) change the classification of a medical device, based upon new information about such device, by administrative order instead of by regulation.

(Sec. 609) Authorizes the Secretary, with respect to medical devices, to enter into arrangements with nations regarding methods and approaches to harmonizing regulatory requirements for activities, including inspections and common

international labeling symbols.

(Sec. 611) Extends until October 1, 2017, authority for programs for third-party review and inspection of medical devices.

(Sec. 613) Expands the exemption from the prohibition on profit for medical devices that have been granted humanitarian device exemptions to include devices intended for use in adults if such a device is intended for the treatment or diagnosis of a disease or condition that does not occur in pediatric patients, or that occurs in such numbers that the device's development is impossible, highly impracticable, or unsafe.

(Sec. 614) Requires the Secretary to: (1) issue proposed regulations establishing a unique medical identification system by December 31, 2012, and to finalize such proposed regulations within six months after the close of the comment period; and (2) implement the final regulations with respect to devices that are implantable, life-saving, and life sustaining not later than two years after the regulations are finalized, taking into account patient access to medical devices and therapies.

(Sec. 615) Requires the Secretary to include medical devices in the postmarket risk identification and evaluation system (Sentinel) and to engage outside stakeholders in the development of the system.

(Sec. 616) Authorizes the Secretary to order postmarket surveillance for specified medical devices either at the time of their approval or clearance or at any time thereafter. Requires device manufacturers to start surveillance not later than 15 months after the date the Secretary issues an order.

(Sec. 617) Exempts from premarket approval requirements medical devices for small or unique populations that are created or modified to comply with the order of an individual physician or dentist and that are designed to treat a unique pathology or physiological condition that no other device is domestically available to treat.

(Sec. 618) Requires the Secretary to post on the websites of the FDA, the Federal Communications Commission (FCC), and the Office of the National Coordinator for Health Information Technology within 18 months after enactment of this Act a report that contains a proposed strategy and recommendations on an appropriate, risk-based regulatory framework pertaining to health information technology, including mobile medical applications, that promotes innovation, protects patient safety, and avoids regulatory duplication.

(Sec. 619) Classifies notices that set forth changes in interpretations of a regulation or FDA policy, including a notice to industry advisory letter, as a guidance document subject to FDA's good guidance practice rules.

(Sec. 620) Reauthorizes through FY2017 the grant program for promoting pediatric medical device development by non-profit consortia. Requires the Secretary to issue a proposed rule to implement the requirement for including information on pediatric uses of medical devices in applications and to issue a final rule implementing such requirement by December 31, 2013.

Title VII: Drug Supply Chain - (Sec. 701) Imposes new or expanded FDA registration requirements for domestic and foreign drug establishments.

(Sec. 703) Expands drug product listing information to include information on drug excipient establishments, including all establishments used in the production of such excipient, a unique facility identifier of such establishment, and a point-of-contact e-mail address for each excipient manufacturer.

(Sec. 704) Requires the Secretary, after specifying a unique facility identifier system, to maintain an electronic database

to enable FDA personnel to identify and inform risk-based inspections.

(Sec. 705) Requires the Secretary to: (1) conduct risk-based inspections of registered drug establishments, including biennial inspections for medical devices; and (2) post on the FDA website, beginning in 2014, a report on the number of domestic and foreign establishments registered in the previous fiscal year, the number of inspections of such establishments, and the percentage of the FDA budget used to fund such inspections.

(Sec. 706) Requires the owner or operator of an establishment that is engaged in the manufacture, preparation, propagation, compounding, or processing of a drug to provide the FDA with records or other information in advance of an inspection.

(Sec. 707) Deems a drug adulterated if the owner or operator of a factory, warehouse, or establishment in which such drug was manufactured, processed, packed, or held delays, denies, or limits inspection or refuses to permit entry or inspection. Requires the Secretary to issue guidance within one year after enactment of this Act on what would constitute delaying, denying, or limiting inspection.

(Sec. 708) Authorizes the FDA to destroy counterfeit or adulterated imported drug products that have minor monetary value or that have a reasonable probability of causing serious adverse health consequences or death. Requires the FDA to issue regulations providing for notice and an opportunity to appear before the FDA and produce testimony prior to the destruction of a drug.

(Sec. 709) Authorizes the FDA to detain, for a reasonable period, drugs found during inspection to be adulterated or misbranded. Requires the FDA to issue implementing regulations for such detention authority.

(Sec. 710) Exempts the FDA from freedom of information disclosure requirements with respect to information about drugs obtained from a foreign government if: (1) the information alerts the FDA to a potential need for a safety investigation; (2) the information is provided to the FDA voluntarily on the condition that it is not be released to the public; and (3) the information is covered by, and subject to, a written agreement between the FDA and the foreign government.

(Sec. 711) Defines "current good manufacturing practice" to include the implementation of oversight and control over the manufacture of drugs to ensure quality, including managing the risk of, and establishing the safety of, raw materials, materials used in the manufacturing of drugs, and finished drug products.

(Sec. 712) Authorizes the Secretary to enter into arrangements and agreements with a foreign government to recognize the inspection of importers in order to facilitate risk-based inspections.

(Sec. 713) Authorizes the FDA to require importers of drugs to provide certain information to allow the FDA to assess the risk of importing such drugs.

(Sec. 714) Requires the registration of commercial drug importers with the FDA. Requires the Secretary to promulgate regulations to establish good importer practices that specify the measures an importer shall take to ensure that imported drugs are in compliance with this Act and the Public Health Service Act.

(Sec. 715) Requires a manufacturer, commercial importer, wholesale distributor, or other non-retail distributor (regulated person) to notify the FDA if such regulated person knows: (1) that the use of any drug in the United States may result in serious injury or death; (2) of a significant loss or known theft of such drug intended for use in the United States; or (3) that such drug has been or is being counterfeited and the counterfeit product is in commerce in the the United States, or such drug has been or is being imported into the United States or may reasonably be expected to be offered for import

into the United States.

(Sec. 716) Increases criminal penalties for knowingly and intentionally adulterating a drug if such adulteration creates a reasonable probability of causing serious adverse health consequences or death to humans or animals.

(Sec. 717) Amends the federal criminal code to extend the penalties for trafficking in counterfeit goods and services to trafficking in counterfeit drugs (drugs that use a counterfeit mark on or in connection with a drug).

Directs the U.S. Sentencing Commission to review, and if appropriate, amend its guidelines and policy statements to include persons convicted of trafficking in counterfeit drugs.

(Sec. 718) Grants extraterritorial jurisdiction over any violation of the FFDCA for any article regulated by such Act if such article was intended for import into the United States or if any act in furtherance of the violation was committed in the United States.

Title VIII: Generating Antibiotic Incentives Now - (Sec. 801) Extends by five years the exclusivity period for qualified infectious disease products. Defines "qualified infectious disease product" as an antibacterial or antifungal drug for human use intended to treat serious or life-threatening infections, including those caused by: (1) an antibacterial or antifungal resistant pathogen, including novel or emerging infectious pathogens; or (2) qualifying pathogens designated by the Secretary. Requires the Secretary to establish and maintain a list of qualifying pathogens and make public the methodology for developing such list.

(Sec. 802) Makes qualified infectious disease products eligible for priority and fast track review.

(Sec. 804) Requires the Secretary to review and, as appropriate, revise guidance documents for the conduct of clinical trials for antibacterial and antifungal drugs. Allows the sponsor of a qualified infectious disease product to request the Secretary to provide written recommendations for nonclinical and clinical investigations the Secretary deems necessary for obtaining approval of such products.

(Sec. 805) Requires the Secretary to report to specified congressional committees within five years after enactment of this Act on qualified infectious disease products, including the number of initial designations of drugs as qualified infectious disease products, the number of approvals of such products, and whether such products address the need for antibacterial and antifungal drugs to treat serious and life-threatening infections.

(Sec. 806) Requires the Secretary to publish draft guidance by June 30, 2013,and final guidance by December 31, 2014, that: (1) specifies how preclinical and clinical data can be utilized to inform an efficient and streamlined pathogen-focused antibacterial drug development program that meets FDA approval standards, and (2) provides advice on approaches for the development of antibacterial drugs that target a more limited spectrum of pathogens.

Title IX: Drug Approval and Patient Access - (Sec. 901) Expresses the sense of Congress that the FDA should apply accelerated approval and fast track provisions to expedite the development and availability of treatments for serious or life-threatening diseases or conditions while maintaining safety and effectiveness standards for such treatments.

(Sec. 902) Requires the Secretary, at the request of a sponsor of a drug, to expedite the development and review of such drug if the drug treats a serious or life-threatening disease or condition and the drug demonstrates substantial improvement over existing therapies (breakthrough therapy).

(Sec. 903) Provides for consultation with stakeholders and external experts on rare diseases, targeted therapies, and

genetic targeting of treatments.

(Sec. 904) Requires the Architectural and Transportation Barriers Compliance Board to convene a stakeholder working group to develop best practices on access to information on prescription drug container labels for blind or visually-impaired individuals.

(Sec. 905) Requires the Secretary to implement a structured risk-benefit assessment framework in the revised drug approval process of this Act.

(Sec. 906) Extends through FY2017 the authorization of appropriations for grants and contracts for the development of drugs for rare diseases and conditions (orphan drugs).

(Sec. 907) Requires publication on the FDA website and transmittal to Congress of a report examining the extent to which current requirements for clinical trial participation and the inclusion of safety and effectiveness data by demographic subgroups, including sex, age, race, and ethnicity, are included in applications submitted to the FDA.

(Sec. 908) Directs the Secretary to: (1) award a priority review voucher (providing for FDA review within six months) to a sponsor of a rare pediatric disease product application, and (2) establish a user fee program for such sponsors.

Requires the Comptroller General to study and report on the effectiveness of awarding rare pediatric disease priority vouchers.

Title X: Drug Shortages - (Sec. 1001) Revises requirements for notifying the Secretary of drug shortages.

(Sec. 1002) Requires the Secretary to submit an annual report to specified congressional committees on drug shortages that includes: (1) a specification of the number of manufacturers that submitted a drug shortage notification and the number of drug shortages occurring during the calendar year, (2) a list of major actions taken by the Secretary to prevent or mitigate drug shortages, and (3) a description of the coordination between the FDA and the Drug Enforcement Administration (DEA) to prevent or alleviate drug shortages.

(Sec. 1003) Requires the Secretary to establish a task force to develop and implement a strategic plan for enhancing the Secretary's response to preventing and mitigating drug shortages.

(Sec. 1004) Requires the Secretary to maintain an up-to-date list of drugs determined to be in shortage, including the name of each drug in shortage, the name of each manufacturer of a drug in shortage, the reason for the shortage, and the estimated duration of the shortage.

(Sec. 1005) Amends the Controlled Substances Act to require the Attorney General to review requests to increase quotas of controlled substances and make a determination within 30 days if a request pertains to a drug in shortage.

(Sec. 1006) Requires the Attorney General to submit an annual report to the House Committee on Energy and Commerce and the Senate Committee on the Judiciary on drug shortages that identifies requests by manufacturers pertaining to controlled substances in shortage, describes the coordination between the DEA and the FDA on efforts to prevent or alleviate drug shortages, and identifies drugs containing a controlled substance determined by the Secretary to be in shortage.

(Sec. 1007) Allows a hospital that is owned and operated by the same entity and that shares access to databases with drug order information for its patients to repackage a drug in shortage (i.e., divide its volume into smaller amounts) and

transfer it to another hospital within the same health system without incurring otherwise applicable FDA registration requirements.

(Sec. 1008) Requires the Comptroller General to study and report on the cause of drug shortages and formulate recommendations to prevent or alleviate such shortages.

Title XI: Other Provisions - Subtitle A: Reauthorizations - (Sec. 1101) Extends until October 1, 2017, the deadline for applications for elections relating to marketing exclusivity for certain drugs containing single enantiomers.

(Sec. 1102) Extends through FY2017 the authorization of appropriations for Critical Path Public-Private Partnerships to implement the FDA's Critical Path Initiative.

Subtitle B: Medical Gas Product Regulation - (Sec. 1111) Provides for expanded FDA regulation of medical gases. Defines: (1) "medical gas" as a drug that is manufactured or stored in a liquefied, non liquefied, or cryogenic state and administered as a gas; and (2) "designated medical gas" as oxygen, nitrogen, nitrous oxide, carbon dioxide, helium, carbon monoxide, medical air, and other medical gas designated by the Secretary that meets specified standards.

(Sec. 1112) Requires the Secretary, after obtaining input from medical gas manufacturers and the public, to: (1) determine whether any changes to federal drug regulations are necessary for medical gases; and (2) issue final regulations on medical gases, within 48 months after enactment of this Act, if changes are deemed necessary.

Subtitle C: Miscellaneous Provisions - (Sec. 1121) Requires the Secretary, within two years after enactment of this Act, to issue guidance regarding the promotion, using the Internet (including social media), of medical products that are regulated by the FDA.

(Sec. 1122) Requires the Secretary to: (1) review current federal initiatives and identify gaps and opportunities with respect to ensuring the safe use of prescription drugs with the potential for abuse and the treatment of prescription drug dependence, (2) post a report on the HHS website of the findings of such review, and (3) promulgate guidance on the development of abuse-deterrent drug products.

(Sec. 1123) Requires the Secretary to: (1) work with other regulatory authorities and international organizations to foster and encourage uniform, scientifically driven clinical trial standards for medical products around the world; and (2) accept data from clinical investigations conducted outside of the United States, including in the European Union, in determining whether to approve, license, or clear a drug or device for which an application has been submitted.

(Sec. 1124) Requires the Secretary to develop a strategy and implementation plan for advancing regulatory science for medical products to promote public health and advance innovation in regulatory decisionmaking.

(Sec. 1125) Requires the Secretary to report to Congress on: (1) the development and implementation of a comprehensive information technology strategic plan to align the information technology systems modernization projects with FDA strategic goals, (2) efforts to finalize and approve a comprehensive inventory of FDA information technology systems, (3) the ways in which the FDA uses the strategic plan to guide and coordinate its modernization projects and activities, and (4) the extent to which the FDA has fulfilled or is implementing recommendations of the Government Accountability Office (GAO) with respect to the FDA and information technology. Requires GAO to report on the strategic plan by January 1, 2016.

(Sec. 1126) Requires the Secretary to expand activities related to nanomaterials included in FDA-regulated products and to address the potential toxicology of such nanomaterials, the potential benefit of new therapies derived from

nanotechnology, the effects of such nanomaterials on biological systems, and the interaction of such nanomaterials with biological systems.

(Sec. 1127) Requires the Comptroller General to report on problems posed by pharmacy Internet websites that violate federal or state law.

(Sec. 1128) Requires the FDA to report to Congress within one year after enactment of this Act on its small business initiatives and programs.

(Sec. 1129) Extends whistleblower protections to officers of the Commissioned Corps of the Public Health Service.

(Sec. 1130) Requires sunscreen drug products subject to a specified FDA final rule to comply with such rule by December 17, 2012 (by December 17, 2013, for products with annual sales of less than $25,000).

(Sec. 1131) Requires the Secretary to submit to Congress within one year after enactment of this Act a strategic integrated management plan for the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, and the Center for Devices and Radiological Health.

(Sec. 1132) Revises the risk evaluation and mitigation strategy system.

(Sec. 1133) Extends from 30 to 40 months, effective between the enactment date of this Act and September 30, 2015, the period during which a generic drug applicant may obtain tentative FDA approval without forfeiting its 180-day exclusivity period. Reduces such period to 36 months beginning on October 1, 2015, and ending on September 30, 2016.

(Sec. 1134) Requires the Secretary to issue a final, substantive determination on any petition filed by a generic drug applicant for determining whether a drug was withdrawn for a safety or effectiveness reason no later than 270 days after the filing of any such petition.

(Sec. 1135) Revises rules relating to review of citizen petitions regarding generic and biosimilar applications. Reduces the period in which the FDA is required to act on such petitions from 180 to 150 days after submission.

(Sec. 1136) Requires electronic submission of drug, generic drug, biologic, and biosimilar applications beginning not earlier than 24 months after issuance of a final FDA guidance developed after a public notice and comment period.

(Sec. 1137) Requires the Secretary to develop and implement strategies to solicit the views of patients during the medical product development process.

(Sec. 1138) Requires the Commissioner of Food and Drugs to: (1) review and modify, as necessary, the FDA's communication plan to inform and educate health care providers and patients on the benefits and risk of medical products, with particular focus on underrepresented subpopulations, including racial subgroups; (2) issue such communication plan within one year after enactment of this Act; and (3) post such plan on the website of the FDA's Office of Minority Health.

(Sec. 1139) Requires the Secretary to hold a public meeting within 60 days after enactment of this Act to solicit advice and recommendations from a variety of stakeholders with respect to the scheduling of drug products containing hydrocodone, combined with other analgesics or as an antitussive.

(Sec. 1140) Directs the Comptroller General to conduct a study and report on the benefits and efficiencies of electronic patient labeling of prescription drugs.

(Sec. 1141) Authorizes the Secretary to facilitate the development of recommendations on interoperability standards to inform and facilitate the exchange of prescription drug information across state lines by states receiving grant funds under the Harold Rogers Prescription Drug Monitoring Programs and the Controlled Substance Monitoring Program. Requires the Secretary to report to Congress on enhancing the interoperability of state prescription drug monitoring programs with other technologies and databases used for detecting and reducing fraud, diversion, and drug abuse.

(Sec. 1142) Revises requirements relating to the disclosure of conflicts of interest by individuals recruited to serve on FDA advisory committees.

(Sec. 1143) Prohibits the FDA from issuing any draft or final guidance on the regulation of laboratory-developed tests under the FFDCA without, at least 60 days prior to such issuance: (1) notifying specified congressional committees of its intent to issue guidance; and (2) including in such notification the anticipated details of such action. Terminates such prohibition five years after enactment of this Act.

Subtitle D: Synthetic Drugs - Synthetic Drug Abuse Prevention Act of 2012 - (Sec. 1152) - Amends the Controlled Substances Act to add as a Schedule I controlled substance: (1) any material, compound, mixture, or preparation which contains specified cannabimimetic agents (or the salts, isomers, or salts of isomers thereof); and (2) specified additional hallucinogenic substances.

(Sec. 1153) Extends the period for which the Attorney General may temporarily include a substance in Schedule I to avoid an imminent hazard to public safety to two years with a one-year extension (currently, one year with a six-month extension).

Actions Timeline

- **Jul 9, 2012:** Signed by President.
- **Jul 9, 2012:** Became Public Law No: 112-144.
- **Jun 28, 2012:** Presented to President.
- **Jun 27, 2012:** Message on Senate action sent to the House.
- **Jun 26, 2012:** Considered by Senate. (consideration: CR S4602-4606, S4610-4627)
- **Jun 26, 2012:** Motion by Senator Reid to concur in the House amendment to the bill (S. 3187) with an amendment (SA 2461) withdrawn in Senate by Unanimous Consent. (consideration: CR S4602, S4626; text: CR S4602)
- **Jun 26, 2012:** Resolving differences -- Senate actions: Senate agreed to House amendment to the bill (S. 3187) by Yea-Nay Vote. 92 - 4. Record Vote Number: 168.(consideration: CR S4626)
- **Jun 26, 2012:** Senate agreed to House amendment to the bill (S. 3187) by Yea-Nay Vote. 92 - 4. Record Vote Number: 168. (consideration: CR S4626)
- **Jun 25, 2012:** Cloture on the motion to concur in the House amendment invoked in Senate by Yea-Nay Vote. 89 - 3. Record Vote Number: 166. (consideration: CR S4449; text: CR S4449)
- **Jun 25, 2012:** Motion by Senator Reid to refer to Senate Committee on Health, Education, Labor, and Pensions with instructions to report back forthwith with the following amendment (SA 2463) fell when cloture on the motion to concur in the House amendment to the bill (S. 3187) was invoked in Senate.
- **Jun 21, 2012:** Measure laid before Senate by unanimous consent. (consideration: CR S4409-4410)
- **Jun 21, 2012:** Motion to concur in the House amendment made in Senate.
- **Jun 21, 2012:** Cloture motion on the motion to concur in the House amendment presented in Senate. (consideration: CR S4410; text: CR S4410)
- **Jun 21, 2012:** Motion to concur in the House amendment with an amendment (SA 2461) made in Senate. (consideration: CR S4410)
- **Jun 21, 2012:** Motion by Senator Reid to refer to Senate Committee on Health, Education, Labor, and Pensions with instructions to report back forthwith with the following amendment (SA 2463) made in Senate. (consideration: CR S4410)
- **Jun 20, 2012:** Mr. Upton moved to suspend the rules and pass the bill, as amended.
- **Jun 20, 2012:** Considered under suspension of the rules. (consideration: CR H3825-3868)
- **Jun 20, 2012:** DEBATE - The House proceeded with forty minutes of debate on S. 3187.
- **Jun 20, 2012:** Passed/agreed to in House: On motion to suspend the rules and pass the bill, as amended Agreed to by voice vote.(text: CR H3825-3861)
- **Jun 20, 2012:** On motion to suspend the rules and pass the bill, as amended Agreed to by voice vote. (text: CR H3825-3861)
- **Jun 20, 2012:** Motion to reconsider laid on the table Agreed to without objection.
- **Jun 20, 2012:** Message on House action received in Senate and at desk: House amendment to Senate bill.
- **May 25, 2012:** Received in the House.
- **May 25, 2012:** Held at the desk.
- **May 24, 2012:** Considered by Senate. (consideration: CR S3536-3609)
- **May 24, 2012:** Passed/agreed to in Senate: Passed Senate with amendments by Yea-Nay Vote. 96 - 1. Record Vote Number: 111.(text: CR S3568-3608)
- **May 24, 2012:** Passed Senate with amendments by Yea-Nay Vote. 96 - 1. Record Vote Number: 111. (text: CR S3568-3608)
- **May 24, 2012:** Message on Senate action sent to the House.
- **May 23, 2012:** Motion to proceed to consideration of measure made in Senate. (consideration: CR S3459-3479)
- **May 23, 2012:** Motion to proceed to consideration of measure agreed to in Senate by Unanimous Consent. (consideration: CR S3479)
- **May 23, 2012:** Measure laid before Senate by motion. (consideration: CR S3479-3509)
- **May 22, 2012:** Motion to proceed to consideration of measure made in Senate. (consideration: CR S3389-3400, S3400-3420)
- **May 21, 2012:** Motion to proceed to consideration of measure made in Senate. (consideration: CR S3295-3307)
- **May 21, 2012:** Cloture motion on the motion to proceed to the measure withdrawn by unanimous consent in Senate. (consideration: CR S3316)

May 17, 2012: Motion to proceed to consideration of measure made in Senate. (consideration: CR S3243-3248, S3252-3271)

- **May 17, 2012:** Cloture motion on the motion to proceed to the measure presented in Senate. (consideration: CR S3252; text: CR S3252)
- **May 16, 2012:** Read the second time. Placed on Senate Legislative Calendar under General Orders. Calendar No. 400.
- **May 15, 2012:** Introduced in Senate
- **May 15, 2012:** Introduced in the Senate. Read the first time. Placed on Senate Legislative Calendar under Read the First Time.