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No. 18

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## House Amendment to S. 3187 – The Food and Drug Administration Safety and Innovation Act

*On June 18, 2012, the Senate Health, Education, Labor and Pensions (HELP) Committee and the House Energy and Commerce Committee [released](#) a five-year Food and Drug Administration (FDA) user fee reauthorization compromise bill. On Wednesday, June 20, the House of Representatives passed S. 3187, as amended, by voice vote. Senate action is expected as early as Monday on the bill, which will arrive in the Senate in the form of a message between Houses.*

### Noteworthy

- S. 3187 reauthorizes for five years user fee programs for prescription drugs and medical devices.
- The bill also establishes new user fee programs for generic drugs and biosimilars.
- The bill contains additional FDA reforms.
- Current prescription drug and medical device user fee agreements expire on September 30, 2012.
- If Congress does not authorize new user fee agreements, the FDA must lay off staff, which would disrupt FDA's pre-market review programs.

### Background

On April 25, 2012, the Senate HELP Committee voice [voted](#) to report S. 2516, a bipartisan five-year FDA user fee reauthorization bill, to the full Senate for consideration. The legislation is titled "The Food and Drug Administration Safety and Innovation Act." On May 15, HELP Committee Chairman Harkin and Ranking Member Enzi filed an updated bill, S. 3187. The new

bill included the full text of S. 2516, as reported by the HELP Committee, and a bipartisan managers' package. On May 24, the Senate approved S. 3187 by a [vote](#) of 96 to 1.

On May 8, 2012, the House Energy and Commerce's Subcommittee on Health considered a similar, but not identical, measure. The health subcommittee unanimously [reported](#) an FDA user fee bill to the full committee by voice vote. On May 10, 2012, the Committee unanimously approved H.R. 5651, the "Food and Drug Administration Reform Act", by a [vote](#) of 46 to 0. On May 30, the House of Representatives passed H.R. 5651 by a [vote](#) of 387 to 5.

On June 18, the House of Representatives filed the compromise FDA user fee bill as an amendment to S. 3187. The House considered the bill, under suspension, on Wednesday, June 20. It passed by voice vote.

## **Bill Provisions**

### **Title I – Fees Relating to Drugs**

This title reauthorizes the Prescription Drug User Fee Act, commonly called PDUFA V. It authorizes the Secretary of Health and Human Services (HHS) to continue collecting fees from the pharmaceutical industry to support the FDA's human drug application review process.

Specifically, this title continues three types of industry fees: application fees; establishment fees; and product fees. An application fee is assessed each time a sponsor submits an application for product approval. An establishment fee is assessed for each facility that manufactures prescription drugs or devices. A product fee is assessed for each product on the market.

This title sets total PDUFA fee revenue in fiscal year 2013 at \$693 million. The bill modifies the formula used to calculate annual fee inflation adjustments to reflect FDA personnel and benefit costs.

In return, the FDA is required to do the following: (1) meet performance goals regarding the timely review of drug applications; (2) increase drug sponsor and FDA interaction during the review process; (3) improve agency engagement with patients, including those with rare diseases; (4) provide better data to improve transparency; and (5) accept an independent, third party assessment of FDA's performance in the agency's review of novel drug applications.

The PDUFA V user fee authority would sunset on October 1, 2017.

### **Title II – Fees Relating to Devices**

This title reauthorizes the Medical Device User Fee Act, commonly called MDUFA III. The new MDUFA agreement allows the Secretary of HHS to collect \$595 million in fees from the medical device industry over a five year period (fiscal years 2013 – 2017).

This title also requires: (1) the FDA to report total time to review devices; (2) the FDA offer greater sponsor interaction during a review process; and (3) an independent entity review of the

device approval and clearance process so that the FDA can implement a corrective action plan if any deficiencies are found.

The MDUFA III user fee authority would sunset on October 1, 2017.

### **Title III – Fees Relating to Generic Drugs**

This title authorizes a new Generic Drug User Fee Act (GDUFA). The proposed generic drug user fee provides additional resources to review and regulate generic pharmaceuticals. This title authorizes the Secretary of HHS to collect approximately \$299 million each year from fiscal years 2013 through 2017 (\$1.5 billion over five years). The generic drug industry agreed to this fee in return for FDA support to eliminate application backlogs and ensure that foreign generic manufacturers are subject to appropriate regulatory scrutiny.

The GDUFA user fee authority would sunset on October 1, 2017.

### **Title IV – Fees Relating to Biosimilar Biological Products**

This title authorizes a new Biosimilars User Fee Act (BsUFA). This user fee targets products approved, under the abbreviated approval pathway, that are shown to be biosimilar to an FDA-licensed biological product.

The BsUFA creates four different types of industry fees: (1) application fee; (2) product fee; (3) establishment fee; and (4) biosimilar product development fee. Each fee calculation is based on inflation-adjusted PDUFA fee amounts in each fiscal year.

Finally, this title requires that the Secretary of HHS waive the biosimilar biological product application fee submitted by a small business. A small business is defined as an entity that employs fewer than 500 workers and does not have: (1) a drug product that has been approved under a human drug or biosimilar biological application; and (2) a drug product that has been introduced or delivered into the marketplace.

The BsUFA user fee authority would sunset on October 1, 2017.

### **Title V – Pediatric Drugs and Devices**

#### **Section 501**

This section permanently authorizes the Best Pharmaceuticals for Children Act (BPCA) and the Pediatric Research Equity Act (PREA). BPCA provides additional exclusivity for pharmaceutical companies that study their drug in children for a different use than the labeled indication (if that use is ethical and applicable). BPCA works with PREA to encourage the development of prescription drugs for children.

## **Section 502**

This section clarifies the FDA's authority to grant longer marketing exclusivity periods to drug manufacturers in return for FDA-requested pediatric use studies and reports.

## **Section 503**

This section requires the Secretary of HHS to issue guidance allowing Pediatric Review Committee evaluation of significant modifications to written requests or pediatric study plans.

## **Section 504**

This section instructs the Secretary of HHS to make public, no later than three years after enactment, the medical, statistical, and clinical pharmacology reviews of written requests made between 2002 and 2007 that resulted in a labeling change.

## **Section 505**

This section allows pediatric study deadline extensions in appropriate circumstances. Current tracking requirements are expanded to collect data about deferral extensions as well as the timeline to complete assessments. If a required pediatric study is not completed or deferred, then the Secretary of HHS must send a letter requiring a response within 45 days. Communications must be made publicly available.

## **Section 506**

This section ties submission of an initial pediatric study plan to the sponsor's end of phase 2 meeting with the FDA – unless the Secretary of HHS and the applicant agree on another date. Further, the pediatric study plan submissions process is clarified through regulation.

## **Section 507**

This section reauthorizes the Pediatric Advisory Committee and the Pediatric Subcommittee of the Oncologic Drug Advisory Committee, the Humanitarian Device Exemptions Extension, and the Program for Pediatric Study of Drugs.

## **Section 508**

This section requires a report every five years evaluating both the BPCA's and the PREA's effectiveness.

## **Section 509**

This section makes technical corrections to the statute.

## **Section 510**

This section mandates that the Secretary of HHS, no later than 18 months after the date of enactment, conduct a public meeting that brings stakeholders and the FDA together to discuss ways to encourage and accelerate pediatric rare disease therapies. The Secretary must also, within 180 days of conducting the public meeting, issue a report outlining a strategic plan to encourage and accelerate pediatric rare disease therapies and treatments.

## **Section 511**

This section requires the FDA Office of Pediatric Therapeutics to have a neonatologist on staff.

## **Title VI – Medical Device Regulatory Improvements**

### **Section 601**

This section returns the Investigational Device Exemption (IDE) approval process to the original standard outlined in statute and implementing regulations. Manufacturers need IDEs in order to conduct clinical trials on medical devices.

### **Section 602**

This section clarifies the statutory “least burdensome” standard. It forbids the FDA from asking for more than the “minimum required amount” of clinical data.

### **Section 603**

This section mandates the Secretary of HHS provide a written summary outlining the agency’s scientific and regulatory reasons for making significant decisions concerning 510(k) notifications, PMA applications, and IDE applications. After receiving a denial notification, the recipient may request a supervisory review of the decision. This request must be made no later than 30 days after receipt of the denial notice. The Secretary of HHS is mandated to follow a specific timeframe to review the decision – except in cases that require outside expert consultation.

### **Section 604**

This section mandates the Secretary of HHS withdraw its 2011 “Guidance for Industry and FDA Staff – 510(k) Device Modification: Deciding When to Submit a 510(k) for a Change to an Existing Device” issued on July 27, 2011. The current FDA guidance gives insight into when the agency believes certain modifications to 510(k) devices require a new application before any newly modified devices can be legally marketed. This section prohibits the FDA from issuing any new guidance on this topic until it finalizes a report to Congress. Until the FDA issues its report and subsequent policy guidance, the agency’s 1997 guidance remains the standard.

### **Section 605**

This section mandates the Secretary of HHS create a new program assessing submitted or reported medical device recall, removal, and corrections information. The agency can use this information to identify strategies that mitigate health risks from defective or unsafe devices.

### **Section 606**

This section allows the Secretary of HHS to issue a clinical hold. This hold prohibits medical device sponsors from continuing clinical investigations of a device representing an unreasonable risk to patient safety. A device sponsor can request HHS remove a clinical hold. The sponsor must receive a decision, in writing, within 30 days.

### **Section 607**

This section grants the Secretary of HHS authority to group certain, new devices into Class I or Class II. The Secretary can do so without first issuing a formal determination that the devices are not substantially equivalent, if the devices in question meet defined risk classification criteria. This policy change streamlines the FDA's current process to classify moderate risk devices that do not have predicates.

### **Section 608**

This section allows the FDA to change a device classification through an administrative order rather than by regulation. An FDA notice of proposed reclassification must include a substantive summary of the valid scientific evidence showing (1) the benefit of the device; (2) the nature and, if known, incident of the risk of the device; and (3) why the device must be reclassified. Authority to issue an administrative order cannot be delegated below the FDA Device Center Director, who must consult with the FDA Commissioner.

### **Section 609 and Section 610**

These sections give the FDA authority to enter into agreements with foreign countries in order to harmonize medical device regulatory requirements including inspections and common international labeling symbols. These sections also provide transparency regarding the FDA's involvement in international forums.

### **Section 611 and Section 612**

These sections reauthorize 510(k) third party review accreditation as well as third party inspections of factory, warehouse, and manufacturing or processing facilities.

### **Section 613**

This section expands the current prohibition on profit exemption to encompass not only devices that have been given Humanitarian Device Exemptions, but also to include devices designed to treat or diagnose diseases and conditions that do not occur in pediatric patients. These device

exemptions occur in instances where the device's development is deemed impossible, highly impractical, or unsafe.

#### **Section 614**

This section instructs the Secretary of HHS to issue proposed regulations establishing a unique device identification system. The regulations must be made public no later than December 31, 2012, and a final regulation must be issued six months after the comment period closes.

#### **Section 615**

This section requires the Secretary of HHS include medical devices in its "Sentinel" post-market risk identification and evaluation system. When implementing this change, HHS must engage with stakeholders.

#### **Section 616**

This section clarifies the Secretary of HHS' authority to order Class II and Class III device post-market surveillance. The order can be made either at the time of approval, at clearance, or at a later time. Post-market surveillance must begin no later than 15 months after the order.

#### **Section 617**

This section clarifies the FDA policy regarding device customization for small (five or fewer per year), unique patient populations. If a device is not available in the U.S., and no other domestic device can treat the patient, then it is not forced to comply with pre-market approval requirements. This applies only if the device is intended to meet a specific, special need of a physician and if the product is custom made to meet an individual's unique physiology.

#### **Section 618**

This section instructs HHS to issue a report to Congress offering a proposed strategy and recommendations to design an appropriate regulatory framework to implement health information technology software, including mobile medical applications. HHS may convene an advisory panel on this topic.

#### **Section 619**

This section explains that notices altering regulation or policy – including notice to industry letters – are deemed guidance documents. These documents are subject to the FDA's good guidance practice rules.

#### **Section 620**

This section reauthorizes demonstration grants for non-profit consortia to promote pediatric device development.

## **Title VII – Drug Supply Chain**

### **Section 701**

This section expands the information required from registrants who manufacture, prepare, propagate, compound, or process drugs. Specifically, each registrant must provide each facility's unique identifier, point-of-contact email address, as well as specific information about each importer that takes physical possession of a drug.

### **Section 702**

This section requires foreign facilities that manufacture, prepare, propagate, compound, or process drugs to register. The section does so by deeming drugs from an unregistered facility as misbranded. The section also updates registration requirements – mandating a unique facility identifier and point-of-contact email address, as well as similar information on each drug importer and the importer's facilities.

### **Section 703**

This section expands the manufacturer product listing requirement to include information on drug recipient establishments. Manufacturers must provide additional information including a unique facility identifier and point-of-contact email address in its product listing.

### **Section 704**

This section mandates the Secretary of HHS set up a unique facility identifier system. It also requires the Secretary maintain an electronic database. Finally, the Secretary must guarantee the accuracy and coordination of FDA databases in an effort to identify and inform risk-based inspections.

### **Section 705**

This section directs the Secretary of HHS to carry out drug facility inspections according to a risk-based schedule. The Secretary is not authorized to distinguish between prescription and nonprescription drug products.

### **Section 706**

This section instructs manufacturers to submit certain inspection records (at the Secretary of HHS' request) in a timely and reasonable manner. The submissions are done at the manufacturer's expense. The Secretary must clearly describe what records and information the agency is requesting and provide the manufacturer a confirmation receipt.

### **Section 707**

This section authorizes the Secretary of Homeland Security, at the specific request of the Secretary of HHS, to bar a drug from entering the United States if the product is manufactured in

a facility that is deemed to have delayed, limited, or denied an inspection. This section mandates the Secretary of HHS, no later than 1 year after the date of enactment, issue guidance defining the circumstances that would constitute delaying, denying, limiting, or refusing an inspection.

### **Section 708**

This section allows the FDA to destroy counterfeit or adulterated imported drug products, valued at \$2,500 or less, after adequate notice.

### **Section 709**

This section provides FDA administrative authority to detain drugs found during an inspection that the inspecting officer has reason to believe are either adulterated or misbranded.

### **Section 710**

This section protects drug-related information, acquired by the Secretary of HHS from disclosure under the Freedom of Information Act, when a federal, state, local, or foreign government agency requests the information remain confidential. In certain cases, however, the Secretary can reveal drug-related trade secret information via written agreement with a foreign government. The Secretary can do so as long as he or she certifies that the foreign government is able to protect full trade secret disclosure.

### **Section 711**

This section clarifies criteria to determining a drug has been adulterated. The section says that “current good manufacturing practices” must include manufacturing quality controls and assure raw material safety.

### **Section 712**

This section allows the FDA to take trusted foreign government inspections into account when conducting a risk-based assessment of an establishment.

### **Section 713**

This section allows the Secretary of HHS to require electronic submission of certain information by a drug importer as a condition to grant entry. This data includes regulatory status, facility information (unique identifier), and inspection and compliance information.

### **Section 714**

This section requires all commercial drug importers to register with the FDA. It also allows the Secretary of HHS to set up a good importer program allowing expedited product entry into the United States.

## **Section 715**

This section authorizes the Secretary of HHS to require establishments that manufacture, prepare, propagate, compound, or process drugs – as well as wholesale distributors – to notify the agency if: (1) it is known that use of such drug in the United States may result in serious injury or death; (2) there is a significant known loss or theft of a drug; (3) the drug has been or is currently being counterfeited and is in commerce in the United States or is reasonably expected to be introduced into commerce in the United States; and (4) such drug has been or is being imported or offered for import into the United States.

## **Section 716**

This section increases the penalty and fine for any person who knowingly and intentionally contaminates a drug when doing so has a reasonable expectation to cause serious, adverse health consequences or death. The penalty is not more than 20 years imprisonment, a fine not to exceed \$1 million, or both.

## **Section 717**

This section raises the penalty and fine for any individual who knowingly and intentionally commits certain prohibited acts related to the forging or counterfeiting of drug products. This includes the selling and dispensing of drug products. The penalty is not more than 20 years imprisonment, a fine not to exceed \$4 million, or both. This section also amends the federal criminal code to establish criminal penalties of a fine, imprisonment for not more than 20 years or both for trafficking or attempting to traffic counterfeit drugs. Finally, it directs the United States Sentencing Commission to review and, if appropriate, amend its guidelines and policy statements to reflect congressional intent to increase criminal penalties.

## **Section 718**

This section makes extraterritorial violations of the Federal Food, Drug and Cosmetic Act subject to enforcement in the United States if either the article related to the violation was intended for import into the United States, or an act in furtherance of the violation was committed in the United States.

## **Title VIII – Generating Antibiotic Incentives Now**

### **Section 801**

This section offers incentives to develop new qualified infectious disease products (QIDPs). This section provides an additional five year market exclusivity period – in addition to other exclusivity periods for which the product might qualify. It also clearly defines QIDPs as antibacterial or antifungal drugs intended to treat serious or life-threatening infections.

### **Section 802**

This section makes QIDPs eligible for priority review.

### **Section 803**

This section makes QIDPs eligible for fast track review.

### **Section 804**

This section mandates that the Secretary of HHS review and, when needed, update clinical trial guidance documents for antibacterial and antifungal drug products. This section also allows the Secretary, upon written request by a sponsor-seeking QIDP approval, to provide clinical trial recommendations.

### **Section 805**

This section requires the Secretary of HHS submit a report to Congress within 5 years reassessing the QIDP incentives.

### **Section 806**

This section mandates the FDA issue guidance facilitating antibacterial drug development for serious or life-threatening bacterial infections, particularly in areas of unmet need.

## **Title IX – Drug Approval and Patient Access**

### **Section 901**

This section contains a sense of Congress that the FDA should help expedite the availability of drugs intended to treat serious or life-threatening diseases and conditions while maintaining safety and effectiveness standards. This section also requires the Secretary of HHS facilitate development and expedite review of “fast-track” products. These are drugs demonstrating potential to meet an unmet need for a serious or life-threatening medical condition.

### **Section 902**

This section requires the Secretary of HHS expedite the development and review of “breakthrough therapy” drugs. In order to be classified as a breakthrough therapy, a drug must treat a serious or life-threatening disease, and preliminary clinical evidence must show that that the drug is a significant improvement over existing therapies.

### **Section 903**

This section mandates the Secretary of HHS to offer consultation opportunities with stakeholder groups from the rare disease community. The Secretary must maintain a list of outside scientific and medical experts to consult on rare disease projects.

## **Section 904**

This section instructs the Architectural and Transportation Barriers Compliance Board to convene a stakeholder working group. This group must develop best practices to help people who are blind or visually impaired access information about prescription drug labels.

## **Section 905**

This section directs the Secretary of HHS to include risk-benefit analysis into its regulatory decision making process.

## **Section 906**

This section reauthorizes the Orphan Product Grants Program through 2017. This program encourages the development of drug, device, biologic, and medical food products to treat rare diseases or conditions.

## **Section 907**

This section instructs the Secretary of HHS to post, on the FDA website, a report to Congress examining the extent to which current clinical trial participation requirements include safety and effectiveness data by demographic subgroups. These subgroups include sex, age, race and ethnicity.

## **Section 908**

This section creates a demonstration project offering priority review vouchers to companies that develop drugs for pediatric rare diseases. The company can redeem a voucher for a subsequent application or the voucher can be transferred to another company. This section also requires the GAO conduct a study analyzing the effectiveness of the voucher program no later than one year after the FDA issues its third priority review voucher.

## **Title X – Drug Shortages**

### **Section 1001**

This section modifies current reporting requirements for manufacturers who produce life-supporting, life-sustaining prescription drugs. These are drugs intended to prevent or treat debilitating diseases and conditions. This section also authorizes the Secretary of HHS to expedite (1) establishment inspections and (2) review of supplements and applications that could mitigate or prevent a drug shortage. Finally, this section allows the Secretary of HHS to apply this standard, by regulation, to biological products. In doing so, however, the Secretary must consider if the vaccine notification requirement could also be met through the CDC vaccine shortage notification program.

**Section 1002**

This section requires the Secretary of HHS issue an annual drug shortages report. The report must include data outlining: (1) the number of notifications submitted; (2) the communication between FDA field investigators and staff at the Center for Drug Evaluation and Research; (3) the actions taken by the Secretary of HHS to prevent or mitigate drug shortages; and (4) the coordination between FDA and the Drug Enforcement Administration (DEA) to prevent or alleviate drug shortages.

**Section 1003**

This section instructs the Secretary of HHS establish a task force designed to enhance the Agency's response to drug shortages. This section also requires the Secretary create and implement a strategic plan to address drug shortages.

**Section 1004**

This section mandates FDA maintain a drug shortage list. This list can provide patients, providers, and the general public with specific information designed to prevent, mitigate, and manage drug shortages.

**Section 1005**

This section requires the DEA give timely approval or denial determinations when manufacturers request controlled substance quota increases. These determinations are important when an increase could mitigate or prevent a drug shortage.

**Section 1006**

This section instructs the DEA issue an annual report outlining the agency's efforts to prevent or mitigate drug shortages. The agency's progress must be based on the specific metrics determined by Congress.

**Section 1007**

This section allows hospitals, within the same health system, to repackage drugs into smaller units in order to alleviate drug shortages.

**Section 1008**

This section authorizes GAO to conduct a study examining the causes of drug shortages. The GAO must issue recommendations on ways to prevent or alleviate a drug shortage. The report should provide critical data looking at regulatory impact, manufacturing challenges, and other challenges that contribute to drug shortages.

## **Title XI – Other Provisions**

### **Section 1101**

This section reauthorizes a sponsor's ability to obtain separate approval and exclusivity for drugs containing a single enantiomer, when the racemic drug has already been approved. The racemic drug and enantiomer are identical, but opposite, molecules.

### **Section 1102**

This section reauthorizes the Critical Path Public-Private Partnerships through fiscal year 2017. The partnership enables industry, the FDA, and academia to work on emerging challenges for medical product development such as biomarkers.

### **Section 1111 through Section 1113**

These sections streamline and modernize regulation of core medical gases. These gases include oxygen, nitrogen, nitrous oxide, carbon dioxide, helium, carbon monoxide, and medical air.

### **Section 1121**

This section directs the Secretary of HHS to issue guidance explaining FDA policy when promoting FDA-regulated medical products using the internet. This includes social media outlets.

### **Section 1122**

This section instructs the Secretary of HHS to issue a report to Congress outlining federal initiatives to combat prescription drug abuse and misuse. The report must include recommendations identifying opportunities to better utilize federal data sources, distribute best practices, and develop education tools.

### **Section 1123**

This section requires the FDA work collaboratively with peer regulators to reduce pre-market approval study duplication. This section does not change pre-market standards to review medical products. It directs the FDA to accept data from clinical investigations conducted outside the U.S. if the applicant demonstrates that the data is adequate to meet U.S. standards. The FDA must provide notice to the sponsor if the data is not adequate to support a U.S. application.

### **Section 1124**

This section directs the FDA establish a comprehensive strategy and implementation plan to advance regulatory science. The FDA must, from fiscal years 2013 to 2017, biannually report on regulatory science goals.

**Section 1125**

This section instructs the FDA to issue a report outlining a comprehensive information technology strategy plan. This plan must be consistent with GAO recommendations. GAO must also report on the FDA's progress in meeting goals outlined in the plan.

**Section 1126**

This section requires the Secretary of HHS intensify current activities that enhance the scientific knowledge of nanomaterials.

**Section 1127**

This section directs the GAO issue a study regarding problems posed by online pharmacy websites that violate state or federal law.

**Section 1128**

This section requires the FDA submit a report to Congress outlining the opportunities and resources the agency makes available to small businesses.

**Section 1129**

This section extends certain whistleblower protections to the Commissioned Corps of the Public Health Service Act.

**Section 1130**

This section codifies the compliance date of the FDA regulation titled "Labeling and Effectiveness Testing; Sunscreen Drug Products for Over-the-Counter Human Use".

**Section 1131**

This section mandates the Secretary of HHS submit to Congress an integrated management strategy. This management strategy must be based on GAO recommendations. It also must identify goals for the FDA Center for Drug Evaluation and Research; Center for Biologics Evaluation and Research; and Center for Devices and Radiological Health.

**Section 1132**

This section makes minor changes to the Risk Evaluation and Mitigation Strategy (REMS) system. Certain drugs must have REMS to ensure that the benefit of the drug outweighs the risk. The provision allows sponsors and the FDA to make minor modifications to the REMS without needing to undergo a full reassessment of the REMS.

**Section 1133**

This section extends the generic forfeitures timeline. Current law states that a generic manufacturer who is the “first filer” to challenge a brand manufacturer’s patent must forfeit its 180 day exclusivity period if the FDA fails to grant approval within 30 months. Data shows the FDA average time to approve generic applications is approximately 32 months. This provision temporarily increases the FDA approval time frame to 40 months. The 40 month period is phased back down to 30 months only after the FDA eliminates its backlog of pending generic drug user fee applications.

**Section 1134**

Current law allows the FDA to deny a generic application if the drug referenced in the application has been withdrawn for safety or effectiveness reasons. Federal regulations do allow a company to petition the FDA requesting a determination whether a reference drug was withdrawn for safety or effectiveness reasons. There is, however, no set timeframe for the FDA to respond to the petition. This section requires the FDA respond within 270 days to reference listed drug petitions.

**Section 1135**

This section creates new rules regarding citizen petitions. The section speeds the FDA response to citizen petitions that raise scientific or medical questions about generic and biosimilar applications. Today the FDA can take final agency action on generic drug petitions within 180 days. This section requires the FDA take final agency action on generic and biosimilar drug petitions within 150 days. This change accounts for most of the projected savings in the bill.

**Section 1136**

This section mandates electronic submission of drug, generic drug, biologic, and biosimilar new drug applications after the Secretary of HHS issues a final guidance.

**Section 1137**

This section directs the Secretary of HHS to develop and implement strategies soliciting patient views and perspectives during the medical product development process as well as during regulatory discussions.

**Section 1138**

This section requires the FDA develop a communication plan to inform and educate health care providers and patients about the benefits and the risks of certain medical products. The education plan must focus on underrepresented subpopulations, including racial subgroups.

### **Section 1139**

This section instructs the FDA to hold a public meeting regarding the scheduling of drug products containing hydrocodone.

### **Section 1140**

This section directs GAO to conduct a study regarding electronic prescription drug labeling.

### **Section 1141**

This section allows the Secretary of HHS to facilitate exchange of prescription drug information across state lines. This section requires a report on these interoperability standards as well as how health care providers may use the prescription drug monitoring programs to prevent abuse and misuse.

### **Section 1142**

This section changes FDA conflict of interest rules. Congress established conflict of interest rules in the 2007 PDUFA reauthorization. These rules increased advisory committee vacancy rates, especially for committees studying rare diseases. By eliminating the cap on the number of conflict of interest waivers the Secretary of HHS can grant, FDA advisory committees will have greater access to scientific experts. This section retains disclosure provisions outlined in current law, makes annual waiver reporting requirements public, and mandates the agency produce a guidance document should a proposed committee member appear to have a conflict of interest.

### **Section 1143**

This section mandates the FDA notify both the Senate HELP Committee and the House Energy and Commerce Committee 60 days before the agency plans to issue guidance on the regulation of laboratory developed tests. This regulatory notification requirement expires in 5 years.

### **Section 1151 – Section 1153**

These sections amend the Controlled Substances Act and designate certain synthetic substances as schedule I drugs.

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## **Administration Position**

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On May 17, 2011, the Obama Administration [issued](#) a Statement of Administration Policy in support of S. 3187.

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## **Cost**

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The Congressional Budget Office (CBO) released a [cost estimate](#) of S. 2516, the bill reported by the Senate HELP Committee, on May 7, 2012. CBO estimates that enacting S. 2516 would:

- Reduce direct spending, on net, by \$71 million over the 2013-2017 period and by \$358 million over the 2013-2022 period.
- Increase federal revenues, on net, by \$5 million over the 2013-2022 period.

CBO released an updated [cost estimate](#) for S. 3187, the Senate-passed bill, on May 24, 2012. CBO estimated that enacting S. 3187 would:

- Reduce direct spending, on net, by \$71 million over the 2013-2017 period and by \$358 million over the 2013-2022 period.
- Increase federal revenues, on net, by \$5 million over the 2013-2022 period.

Finally, CBO released its [cost estimate](#) of S. 3187, the House-Senate compromise bill. CBO estimates that enacting S. 3187, as amended, would:

- Reduce direct spending, on net, by \$113 million over the 2013-2017 period and by \$311 million over the 2013-2022 period.
- Increase federal revenues, on net, by \$4 million over the 2013-2022 period.