THE REPUBLICAN STUDY COMMITTEE
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Legislative Bulletin……..June 20, 2012

Contents:

House Amendments to S. 3187— Food and Drug Administration Safety and Innovation Act of 2012 *(Harkin, D-IA)*

Order of Business: The bill is scheduled to be considered on Wednesday, June 20, 2012, under a motion to suspend the rules requiring two-thirds majority vote for passage.

Summary: The amendments to S. 3187 make significant reforms to the drug and medical device review process as well as other changes within the U.S. Food and Drug Administration (FDA). Principally, the bill reauthorizes two existing user-fee drug and medical device review programs scheduled to expire on September 30, 2012, and creates two new user-fee drug review programs. Other reforms include the establishment of a new fee program related to rare pediatric diseases, the permanent reauthorization of FDA programs that evaluate the use of drugs by children, as well as other non-fee related activities to modify how the FDA regulates drugs and devices. The bill also provides the FDA with additional regulatory authority to address the safety of the nation's drug supply chain as well as systems to prevent future drug shortages.

(S. 3187) passed the U.S. Senate on May 24, 2012 by a vote of 96-1. The House passed its FDA Reform bill (H.R. 5651) on May 30, 2012 by a vote of 387-5.[1]

Additional Information: The RSC Legislative Bulletin on the House-passed H.R. 5651 can be found here. A summary of the major changes to it are described below:

Medical Device Regulatory Reforms

- Permits the Secretary of Health and Human Services (HHS), but presumably responsibility delegated to the FDA Commissioner,[2] to change the classification of a medical device by administrative action instead of by the current regulatory action. This process will now require the FDA to convene an advisory panel to

[1] Also, on May 10, 2012, the House Energy and Commerce Committee reported H.R. 5651 favorably by a vote of 46-0.
[2] Wherever "Secretary" is used, it is presumed that the HHS Secretary delegates authority to the FDA Commissioner.

recommend or not recommend the classification change. Under current law, the convening of an advisory panel is discretionary;
- Requires the Secretary to issue proposed regulations which establish a unique medical device identification system by December 31, 2012 which takes into account patient safety and access to medical devices and therapies. This section also requires this regulation to be finalized within six months of the close of the comment period, and for the system to be implemented within two years. The 2007 FDA Reauthorization established this identification requirement upon the FDA, but the FDA has not yet promulgated the regulation;

Drug Supply Chain Reforms

- Expands the required product listing information that drug manufacturers must illustrate in their annual FDA notifications to include drug excipients. Drug excipient are drug's non-active ingredients;
- Permits the FDA to share certain confidential drug information with trusted foreign countries. The House provision permitted the FDA to share information with foreign state and local governments;
- Permits the FDA to take into account the drug facility inspections of domestic drug facilities by trusted foreign governments. Under current law, the FDA is required to inspect domestic drug facilities every two years. This provision allows the FDA to rely on the inspections of these domestic facilities by trusted foreign governments in determining whether to inspect certain domestic drug facilities;
- Increases the federal penalties and prison times of up to 20 years imprisonment and fines of up to $4 million (or both) for persons who knowingly and intentionally commit acts related to trafficking in counterfeit drugs. This provision is similar to the provisions adopted in H.R. 3668, which passed the House by voice vote on Monday, June 18, 2012;

Antibiotics Incentives

- Provides an additional five years of market exclusivity to manufacturers that develop new qualified infectious disease products (QIDPs). This section defines QIDPs as antibacterial or antifungal drugs intended to treat serious or life-threatening infections. The House version of this provision required a manufacturer to prove that the new antibiotic had an impact that cured a specific pathogen. The new provision now requires only that the manufacturer show that the antibiotic treats a serious or life-threatening infection.

Drug Approval and Patient Access

- Requires the development of best practices to assist the visually-impaired or blind obtain prescription drug label information as well as a Government Accountability Office (GAO) study on utilization of such best practices;
- Requires the Secretary to publish on the FDA's website a report examining the extent that 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. This report will be provided to Congress;

Drug Shortages

- Modifies existing FDA reporting requirements for drug manufacturers who produce drugs that are life-supporting, life-sustaining, used to prevent or treat debilitating diseases or conditions, as well as drugs used in emergency medical care or surgery. It also authorizes the Secretary to expedite drug establishment inspections for supplements and drug applications that could help mitigate or prevent a drug shortage. This section does not apply to biologic. However, the Secretary has the regulatory authority to promulgate regulations that include biologics in this reporting requirement;
- Requires the Secretary to create a task force to enhance the Secretary's response to shortages, and create a strategic plan to address stated aspects of shortages;

Additional Reforms

- Requires the FDA to either accept foreign clinical data or notify the drug or device applicant of the FDA's rationale for its decision that the data are not adequate to support approval, licensure, or clearance under applicable FDA standards;
- Requires the GAO to examine problems posed by online pharmacy websites that violate state or federal law;
- Extends the tentative approval time period of generic drug applications for those generic drug manufacturers who challenge a brand manufacturer's patent as being invalid from current law 30 months to 40 months (with a gradual phase down back to the 30 months while the FDA eliminates the backlog of pending generic applications). According to the House Energy and Commerce Committee, the FDA average response time for tentative generic approvals is 32 months. The original House version included a 45 month extension. Upon tentative approval of such generic applications, these applications receive 180 days market exclusivity vis-à-vis other generic competition;
- Requires the FDA to take a final agency action on certain citizen petitions regarding generic drug and biosimilar applications within 150 days. These petitions request the FDA to delay approval of generic applications based on scientific or medical questions. The FDA is required under current law to take final agency action on these petitions with regard to generic drugs within 180 days. Reducing the amount of time the FDA is required to take action has the effect of reducing federal spending on medications provided for in Medicare, Medicaid, and other federal health programs because less expensive generic drugs (and now biosimilars) will reach the market quicker. **Note**—some conservative groups issued letters asking House and Senate negotiators to additionally include a Senate offset CBO scored as reducing the deficit by over $750 million. It involved the Risk Evaluation Mitigation Strategies (REMS). This REMS

provision is **not** *included* in this bill. Some controversy surrounded this provision since it could have lead to the FDA forcing drug sales between brand and generic manufacturers;

- Requires the FDA to hold public meetings on the scheduling of hydrocodone. Senate efforts had attempted to classify hydrocodone as a Schedule II drug, which has a high potential for abuse that may lead to severe psychological or physical dependence;
- Amends the Controlled Substances Act to designate certain synthetic substances as Schedule I drugs, which are drugs that have a high potential for abuse, have no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use of the drug or other substance under medical supervision. This provision is similar to the House-passed H.R. 1254 that passed the House by a vote of 317-98.

Committee Action: No Committee activity has occurred on the bill. However, the House Energy and Commerce Committee reported out the House version (H.R. 5651) by a unanimous 46-0 vote. Also, the Committee report cites many hearings pertaining to FDA reforms and user fee programs dating back to the beginning of the 112th Congress.

Administration Position: As of press time, no Statement of Administration Policy (SAP) has been released. However, the Administration did release a SAP on May 17, 2012 in "strong support" of the original Senate's version of this legislation (S. 3187).

Cost to Taxpayers: The Congressional Budget Office (CBO) released a cost estimate on the House Amendments to S. 3187 on June 19, 2012 showing that the amended bill reduces direct spending by $307 million and increases revenues by $4 million resulting in deficit reduction of $311 million over ten years.

Does the Bill Expand the Size and Scope of the Federal Government?: The bill creates two new user-fee programs and one priority review voucher demonstration project within the FDA. It also permanently reauthorizes two pediatric programs and increases the FDA's regulatory authority to address the safety of our nation's drug supply chain and prevent future drug shortages. Additionally, it increases criminal imprisonment terms and monetary fines for those who knowingly hold, sell, or dispense of counterfeit or adulterated drugs. However, it reduces direct spending by $307 million over ten years.

Does the Bill Contain Any New State-Government, Local-Government, or Private-Sector Mandates?: Yes. The May 29, 2012 CBO estimate that the bill contains several private sector mandates with the most costly requiring manufacturers of branded drugs, generic drugs, biosimilar products, and medical devices to pay fees to the FDA. Note—the respective manufacturing industries negotiated with the FDA the terms of these user fees and have agreed to pay these user-fees in exchange for the timely review by the FDA of drug and medical device applications. CBO also highlights other private sector mandates including preventing manufacturers of generic or biosimilar versions of branded drugs from entering the market during periods of branded drug exclusivity;

expanded requirements relating to pediatric drug approval; expanded registration requirements on certain drug manufacturers; authorizing the HHS Secretary to destroy certain imported drugs; and notification requirements on manufacturers pertaining to drug supply interruptions or potential drug shortages.

Does the Bill Comply with House Rules Regarding Earmarks/Limited Tax Benefits/Limited Tariff Benefits?: The Committee Report for the House version (H.R. 5651) states that the bill does not contain any congressional earmarks, limited tax benefits, or limited tariff benefits as defined in clause 9(e), 9(f), or 9(g) of Rule XXI.

Constitutional Authority: The Constitutional Authority Statement accompanying the House bill (H.R. 5651) on introduction states, "Congress has the power to enact this legislation pursuant to the following: Article I, Section 8, Clause 3 of the United States Constitution [the Commerce Clause]."

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