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House Passes FDA User Fee Bill; Congress on Track to Pass Reconciled Bill by Beginning of July

June 6, 2012

On May 30, 2012, the U.S. House of Representatives passed the Food and Drug Administration Reform Act of 2012—the chamber's FDA user fee authorization bill—by a 387–5 margin. With regard to user fees, the bill is very similar to the Food and Drug Administration Safety and Innovation Act (S. 3187), which was approved by the Senate a few days earlier, on May 24, 2012. However, there are substantive differences between the House and Senate bills with regard to provisions that address the FDA's review and oversight of drugs, medical devices and biologicals. In this newsletter, we provide an overview of some of the major aspects of both bills, and identify similarities and differences between the two pieces of legislation as the two chambers enter the reconciliation process to finalize the legislation for presentation to President Obama.

On May 30, 2012, the U.S. House of Representatives (House) easily passed the Food and Drug Administration Reform Act of 2012 (H.R. 5651), a bill that would reauthorize the Food and Drug Administration (FDA) to assess user fees to support the agency's review of marketing applications for drugs (including biologicals) and medical devices, and, for the first time, authorize the FDA to collect user fees on generic drugs and biosimilars for five years, beginning October 1, 2012. With regard to user fees, the bill is very similar to the Food and Drug Administration Safety and Innovation Act (S. 3187), which was approved by the Senate last week. (See Senate Easily Passes FDA User Fee Bill, Reconciliation with House Version Looms for more information.)

Like the Senate bill, the House legislation also includes several provisions that would modify the FDA's review and oversight of drugs, medical devices and biologicals. Though comparable in many respects, the Senate and House bills utilize different approaches to address a number of issues. This table identifies some of the major issues addressed in the two bills, and provides a high-level description of the manner in which each chamber addressed them.

Issue	Senate Bill (S. 3187)	House Bill (H.R. 5651)
Medical Devices		
Device reclassification procedures	Would allow the FDA to change a device's classification by administrative order (as opposed to regulation, as is currently required) if proposed by the Director of the Center for Devices and Radiological Health and issued by the FDA commissioner	No comparable provision
Conditioning premarket approval of a medical device on performance of post-market studies	Would allow the FDA to require, as a condition of its approval of a premarket approval application (PMA), that the applicant conduct a post-market study regarding the newly approved device	No comparable provision
Sentinel (FDA's post-market risk identification and analysis system)	Would require the FDA to extend Sentinel to include medical devices (requirement only currently applicable to drugs)	Comparable provision included in House bill
Implementation of a unique device identifier system for medical devices	▪ Would require the FDA to issue proposed regulations establishing a unique device identification system by December 31, 2012 ▪ Would also require the FDA to finalize the regulations within six months of the close of the	Would require the FDA to promulgate regulations implementing a unique device identification system within 120 days of the bill's enactment

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	comment period on the proposed rule	
Agency documentation of medical device-related decisions relating to marketing applications	▪ Would require the FDA to provide a "substantive summary of the scientific and regulatory rationale" for its decisions to deny a premarket clearance submission under section 510(k), PMA or an investigation device exemption application (IDE) ▪ Would give applicants an opportunity to request "supervisory review" of adverse decision	▪ Would require the FDA to completely document the scientific and regulatory rationale for "any significant decision" relating to a 510(k), PMA or IDE; the documentation must reference "significant controversies or differences of opinion, and the resolution of such controversies or differences of opinion ▪ Would also give applicants an opportunity to request "supervisory review" of a "significant decision"
De novo medical device classification	Would allow the FDA to classify *de novo* a new medical device without device predicates into Class I or II without first requiring a "not substantially equivalent" determination under the 510(k) clearance process	Comparable provision included in House bill
Regulation of mobile medical applications	Would prohibit the FDA from releasing final guidance on the regulation of medical mobile applications until it convenes a working group and drafts a report detailing a proposed strategy and recommendations for an "appropriate, risk-based regulatory framework" related to health information technology software	▪ Does not prohibit the FDA from releasing final guidance on the regulation of medical mobile applications ▪ Would, however, require the FDA to draft a report that identifies strategies for coordinating the regulation of health information technology (including mobile medical devices) to avoid duplication, and that provides recommendations on an appropriate regulatory framework for health information technology, including a risk-based framework
510(k) medical device modifications	▪ Would require the FDA to withdraw its draft "Guidance for Industry and Staff—510(k) Device Modifications: Deciding When to Submit a 510(k) for a Change to an Existing Device"	▪ Comparable provision included in House bill (with regard to withdrawal of draft guidance only) ▪ Would also prohibit the agency from issuing replacement draft guidance until its submission of a

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	▪ Would also provide affected stakeholders the opportunity to comment before revised guidance on this issue is finalized	report on the applicability of 510(k) requirements for device modifications, and would prohibit finalization of replacement guidance until one year after issuance of the report ▪ Would also re-establish the effectiveness of the FDA's 1997 guidance "Deciding When to Submit a 510(k) for a Change to an Existing Device" until revised FDA guidance is issued (the FDA's draft guidance had proposed to replace the 1997 guidance as the FDA's "current thinking")
FDA oversight of laboratory-developed tests	No comparable provision	Would require the FDA to give congressional committees 60 days' notice of the FDA's intent to issue draft or final guidance on the regulation of laboratory-developed tests, as well as the anticipated contents of such guidance
Drugs		
Registration of domestic and foreign drug establishments	Would expand the information required for registration to include the drug establishment's "unique facility identifier" and a point of contact's e-mail address	Would require drug establishments to include the unique facility identifier only
Implementation of unique facility identifier system	Would authorize the FDA to "specify the unique facility identifier system"	Would require the FDA to (within two years of the bill's enactment) issue guidance specifying a unique facility identifier system
Identifying drug establishments for inspection	▪ Would require the FDA to identify drug establishment for inspections using a risk-based system ▪ Relevant factors in assessing risk include compliance history of the establishment and the record, and history and nature of recalls linked to the establishment	Comparable provision included in House bill

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	(among others)	
Effect of interference with inspection of drug establishment	No comparable provision	▪ Would identify as "adulterated" any drug that has been manufactured, processed, packed or held in a factory, warehouse or establishment, if an agent of such location delays, denies or limits, or refuses to permit an FDA inspection ▪ Would also require the FDA to (within one year) issue guidance that defines the circumstances under which an individual would be considered to be delaying, denying, limiting or refusing to permit an inspection
Notice requirement for lost, stolen or counterfeit drugs	Would require two types of entities (a drug establishment or wholesale drug distributor) to notify the FDA in the event of "substantial loss or theft" of a drug, or if a drug has been or is being counterfeited and is in commerce in the United States or being offered for import into the United States	Would require several types of entities (establishments, commercial importers, wholesale distributors or any person who distributes drugs, except those who distribute exclusively for retail sale) to notify the FDA if they know (1) the use of such drug in the United States may cause "serious injury or death," (2) of a "significant loss or known theft" of a drug intended for use in the United States or (3) that a drug has been or is being counterfeited, and the product is in commerce or may reasonably be expected to be introduced into commerce, or the 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
Disposition of adulterated, misbranded or counterfeit drugs offered for import	No comparable provision	Would permit the FDA to destroy, without opportunity for export, any drug refused admission into the United States that has a "reasonable probability of causing serious adverse health consequences or death" or is valued at $2,000 or less
Penalty for drug adulteration	Enhances penalty for "knowingly and intentionally" adulterating a drug in a manner that has a reasonable probability of causing adverse health	Comparable provision included in House bill

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	consequences or death to up to 20 years imprisonment and/or $1 million in fines (current maximum penalty for first violation is three years imprisonment and/or $10,000 if committed with the intent to defraud or mislead)	
Penalties for drug counterfeiting	▪ Enhances penalty for an "individual" who "knowingly and intentionally" counterfeits drugs to up to 20 years' imprisonment and/or $4 million in fines for a first offense; for subsequent offenses, penalties up to 20 years' imprisonment and/or $8 million in fines (current maximum penalty for first violation is three years imprisonment and/or $10,000 if committed with the intent to defraud or mislead) ▪ Sets penalty for counterfeiting by a "person other than an individual" to up to $10 million for a first offense, and fines up to $20 million for subsequent offenses	▪ Enhances penalty for a "person" who knows or has reason to know that they are holding, selling or dispensing a counterfeit drug; potential penalties include fines or imprisonment up to 20 years ▪ If use of a counterfeit drug is the proximate cause of a consumer's death, maximum penalty is life in prison
Registration of commercial importers	No comparable provision	▪ Would require a "commercial importer" to register with the FDA and to submit the unique facility identifier associated with applicant's principal place of business ▪ Would prohibit importation of drugs by unregistered commercial importers ▪ Would deem a drug imported or offered for import by an unregistered commercial importer to be misbranded
Documentation for admissibility of imports	▪ Would permit the FDA to require, as a condition of granting admission to an imported drug or a drug offered for import, that the importer electronically submit certain documentation or information	Comparable provision in House bill (except the House bill does not require electronic submission of information, and does not provide a deadline for finalization of the associated regulations)

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	▪ Would require the FDA to specify, by regulation, the information it will require, including (potentially) the regulatory status of the drug, unique facility identifier and indication of compliance with good manufacturing practices, among other information ▪ Would require the FDA to issue a final rule describing the required documentation within 18 months of the bill's enactment	
"Track and trace" provisions	▪ Would give the FDA authority to establish a uniform, comprehensive, national system to ensure the safety of the pharmaceutical supply chain ▪ Sponsoring Senators have stated this provision is intended to serve "as a placeholder" while discussions continue on what would be the best structure for a national drug pedigree system to "trace back" a drug's chain of distribution without "preempting" more stringent state pedigree laws (*e.g.*, California)	No comparable provision
Enhanced market exclusivity for qualifying anti-infective drugs	▪ Would extend market exclusivity for a "qualified infectious disease product" by five years beyond that which the applicant is currently entitled under the Federal Food, Drug, and Cosmetic Act ▪ Would define "qualified infectious disease product" as an antibacterial or antifungal drug for human use intended to treat "serious or life-threatening infections" ▪ Designation as "qualified infectious disease product" may be made at any time before submission of a marketing application	▪ Comparable extension of market exclusivity provision included in House bill ▪ However, would expand scope by defining "qualified infectious disease product" as an antibacterial or antifungal drug for human use that treats or prevents "an infection caused by a qualifying pathogen" ▪ Designation as "qualified infectious disease product" may be made at any time prior to submission of a marketing application, but no later than 45 days after submission of the application

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Expedited approval of drugs for serious or life-threatening diseases or conditions	▪ Would allow the FDA to, at the sponsor's request, "facilitate the development and expedite the review" of a drug that is intended (either alone or in combination with another drug) for the treatment of a serious or life-threatening disease or condition, and that demonstrates the potential to address unmet medical needs for the disease or condition ▪ Current law only allows fast-tracking for serious or life-threatening conditions (not diseases), and does not provide that fast-track drug products may be used in combination with other drugs	Comparable provision included in House bill
Drug shortage: Manufacturer notification to the FDA	Would require manufacturers of certain drugs (*e.g.*, drugs that are life-supporting, life-sustaining, intended for use in the prevention of a debilitating disease or condition, a sterile injectable product, or used in emergency medical care or during surgery (excluding products that are radiopharmaceuticals, human tissue replaced by a recombinant product, a product derived from human plasma or any other product designated by the FDA)) to notify the FDA at least six months before taking action that would result in the permanent discontinuance of the manufacture of the drug or could lead to a meaningful interruption in the overall drug supply	Comparable provision included in House bill
Drug shortage: FDA consideration of enforcement action	Would affirmatively require the FDA to consider, before the issuance of an enforcement action, the effect of such action on the availability of certain drugs (*e.g.*, drugs that are life-supporting, life-sustaining, intended for use in the treatment of a debilitating disease or condition, a sterile injectable product, or used in emergency medical care or during surgery (excluding products that are radiopharmaceuticals, human tissue	No comparable provision

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	replaced by a recombinant product, a product derived from human plasma or any other product designated by the FDA))	
Extension of period before forfeiting the 180-day marketing exclusivity period associated with an abbreviated new drug application (ANDA)	No comparable provision	Would give the first applicant to file a paragraph (iv) certification in connection with a generic drug marketing application up to 45 months from the date of filing the application to obtain tentative approval from the FDA before forfeiting the 180-day exclusivity period (current deadline to receive approval is 30 months from date of filing)
Miscellaneous Provisions		
Internet promotion of FDA-regulated products	Would require the FDA (within two years of enactment of the bill) to issue guidance to industry describing its policy on the promotion of FDA-regulated products on the internet	No comparable provision
Impact of Risk Evaluation and Mitigation Strategies (REMS) on generic drug/biosimilar manufacturers	Would mandate that the element to assure safe use in a REMS may not be used by brand name drug manufacturers to prohibit access to a drug or biological by a generic drug or biosimilar product developer	No comparable provision
Deadline for agency action on citizen petition or petition for stay of agency action on a section 505(b)(2) application[1], an ANDA or a biosimilar application	No comparable provision	Would require the FDA to take final action within 150 days of receiving a citizen petition or a petition for stay of action on a 505(b)(2), ANDA or biosimilar application
Public participation in agency activities	Would require the FDA to develop and implement strategies to solicit the views and perspectives of patients during product development and regulatory discussions	No comparable provision.

[1] A 505(b)(2) application is a new drug application that contains full reports of investigations of safety and effectiveness, but in which some of the investigations relied upon for approval are those not conducted by or for the applicant and for which the applicant has not obtained a right of reference. *21 U.S.C. §355(b)(2).*

The House and the Senate hope to reconcile the differences between the two bills by the first week of July 2012.

Implications

For the second time in a week, a chamber of Congress has nearly unanimously passed important bipartisan legislation that will keep the FDA adequately funded to continue to review marketing applications of FDA-regulated products through FY 2017. Although substantial differences exist between the two bills on the "FDA reform" aspects of the legislation—most notably, the Senate's inclusion of drug "track and trace" language and changes to medical device regulation—Congress appears on course to meet its goal of passing a final bill by July 4, 2012, nearly three months before the FDA's current user fee authorization is set to expire. The final reconciliation process will have important implications for clients and stakeholders as the changes to the FDA's review and oversight functions, and the new requirements for medical product developers, manufacturers and distributors, will substantially impact industry and consumers of medical products.

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