RECENT DEVELOPMENT

FUNDING THE FDA: ASSESSING THE USER FEE PROVISIONS OF THE FDA SAFETY AND INNOVATION ACT OF 2012

I. INTRODUCTION

In the weeks leading up to and immediately following the Supreme Court's controversial healthcare decision[1] this summer, Congress quietly passed a significant healthcare law with substantial bipartisan support. S. 3187, the Food and Drug Administration Safety and Innovation Act ("FDASIA"),[2] was signed into law by President Obama on July 9,[3] after clearing the Senate on a 92-4 vote on June 26.[4] The core provisions of the law's eleven titles reauthorize and expand on the user-fee schemes that provide critical funding for the Food and Drug Administration's ("FDA") drug and device review programs. The law not only reauthorizes the Prescription Drug User Fee Act ("PDUFA") for the fifth time and the Medical Device User Fee Act ("MDUFA") for the third time; it also creates two entirely new user-fee schemes: the Generic Drug User Fee Amendments ("GDUFA") and the Biosimilars User Fee Amendments ("BsUFA").[5] While this Recent Development focuses on the Act's user-fee provisions, the legislation itself extends much further, and includes, *inter alia,* provisions designed to promote continued drug and device innovation, encourage further pediatric clinical research, and address various emerging issues in the FDA's regulatory space, including drug shortages, nanotechnology, and the use of mobile and internet technology in promoting regulated products. The breadth of the law does not come as a surprise: because user fees account for more than half of the FDA's drug and device review resources and were set to expire in October of this year, reauthorization was considered "must-pass" legislation.[6] As such, the legislation served as a convenient vehicle for various other FDA-

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[1] National Fed'n of Indep. Bus. v. Sebelius, 132 S. Ct. 1161 (2012).

[2] Food and Drug Administration Safety and Innovation Act, Pub. L. No. 112-144, 126 Stat. 993 (2012).

[3] Office of the Press Secretary *Statement by the Press Secretary on H.R. 33, H.R. 2297, and S. 3187*, THE WHITE HOUSE (Jul. 9, 2012), http://www.whitehouse.gov/the-press-office/2012/07/09/statement-press-secretary-hr-33-hr-2297-and-s-3187.

[4] Brett Norman, *FDA User Fee Bill Passes Senate, 92-4*, POLITICO (June 27, 2012, 12:07 AM), http://www.politico.com/news/stories/0612/77873.html.

[5] Margaret Hamburg, *User Fees: Ensuring a Stronger and Better FDA*, FDA VOICE (June 26, 2012), http://blogs.fda.gov/fdavoice/index.php/2012/06/user-fees-ensuring-a-stronger-and-better-fda/.

[6] SUSAN THAUL ET AL., CONG. RESEARCH SERV., R42564, FDA USER FEES AND THE REGULATION OF DRUGS, BIOLOGICS, AND DEVICES: COMPARATIVE ANALYSIS OF S. 3187 AND H.R. 5651 2 (2012) ("Because revenue from [user] fees supports over 2,000 full-time equivalent FDA positions and accounts for more than half of the agency's drug and device review resources, Members of Congress have referred to the user fee reauthorizations as generally uncontroversial, must-pass legislation.").

related items on the legislative agenda, as has been the case with each previous user fee reauthorization. In the case of its non-user-fee components, the law's must-pass nature was no doubt partially responsible for the uncontroversial and bi-partisan course the law took through Congress, though the statutorily prescribed process by which the FDA solicited stakeholder input and drafted its legislative proposals surely played a crucial role, as well. Given the substantial portion of the FDA's funding on the line and the support of both the agency and the regulated parties, it is unsurprising that Congress quickly and near-unanimously passed the wide-ranging law. Nor is it surprising that the final legislation constrained user-fee programs to a more-of-the-same expansion of the existing system, one that avoided thorny-yet-important questions that continue to hover over the structure and scale of the user-fee program.

While this outcome is predictable in light of the importance of user fees and the potential disaster if reauthorization does not occur on time, the uncritical passage of FDASIA reflects a missed opportunity. Sooner or later, the FDA and the legislators who oversee and fund it will have to take real steps to address the problems that this paper and others before it have identified. Such steps are neither difficult to conceive nor should they be impossible to accomplish.

In its reauthorization of PDUFA and MDUFA and its creation of new user-fee schemes for generics and biosimilars, FDASIA sets the budgetary framework for the FDA's next five years, and dictates a great deal of what the FDA can and cannot accomplish in that period. User fees should be considered in the context of broader debates about the proper role of government in regulating private actors and the proper role of industry in funding those regulatory activities, and about the fees' impact on agency priorities and on how much control Congress can exert through the budget process. FDASIA ultimately arrived on President Obama's desk with little controversy and less fanfare because, in its key provisions on user fees, it represents no more than a logical expansion of a project that has effectively kept American drugs and devices among the safest and most effective in the world. This conservative course of action, however politically attractive, regrettably fails to address larger questions that loom over the user-fee system.

II. Historical Context

The modern era of user-fee funded FDA drug and device review (and of packaging periodic FDA reforms into user-fee legislation) began in 1992 with the passage of the Prescription Drug User Fee Act.[7] The 1992 law was passed as a result of increasing pharmaceutical-industry frustration with the timeliness and quality of FDA review of new drug applications, after it became apparent that Congress was unwilling to provide sufficient funding

[7] Prescription Drug User Fee Act of 1992, Pub. L. No. 102-571, 106 Stat. 4491.

through the appropriations process to significantly improve the agency's review capacity.[8] The legislation was the product of negotiations between the FDA under Commissioner David Kessler, the drug industry, and key players on Capitol Hill, and was "intended to bypass the anachronistic and unreliable congressional system that always underfinanced the FDA."[9] Central to the scheme was the idea that industry-funded fees would supplement—not replace—appropriations, and that the funds would represent one half of a bargain: industry would subsidize the FDA's review activities, and in exchange the agency would commit to reaching improved performance goals.[10] The 1992 law had four key elements that have informed each of its subsequent reauthorizations as well as the user-fee schemes for devices, generics, and biosimilars that have followed.

First, the scheme had a five-year sunset provision, requiring congressional reauthorization.[11] The five-year sunset provision has been included in each subsequent authorization of user fees, and as the agency has become increasingly reliant on user fees for its day-to-day operations, this has set the stage for predictable fighting over, and passage of, major FDA legislation every five years.[12]

Second, Congress made the availability of user fees contingent on a base level of funding from the congressional appropriations process. Specifically, fees could not be assessed in a given fiscal year unless non-fee appropriations for salaries and expenses were equal to or greater than the amount of appropriations in the base year of 1992 multiplied by a statutory adjustment factor.[13] This element—the requirement that user fees supplement rather than replace congressional appropriations—is common to both PDUFA and MDUFA and is enforced through statutory "triggers." These triggers take slightly different forms under each of these schemes. Under PDUFA, the trigger is tied to the total FDA budget:

> Fees under . . . this section shall be refunded for a fiscal year beginning after fiscal year 1997 unless appropriations for salaries and expenses of the [FDA] for such fiscal year . . . are equal to or greater than the amount of appropriations for . . . the fiscal year

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[8] PETER BARTON HUTT ET AL., FOOD AND DRUG LAW: CASES AND MATERIALS 679 (3d ed. 2007).

[9] PHILIP J. HILTS, PROTECTING AMERICA'S HEALTH 278 (2003).

[10] *Id.* Performance goals principally focus on reducing the amount of time the agency takes to review and act on regulatory submissions.

[11] Prescription Drug User Fee Act of 1992, Pub. L. No. 102-571, § 105, 106 Stat. 4491, 4498.

[12] Following the 1992 passage of PDUFA I came the Food and Drug Administration Modernization Act of 1997 ("FDAMA"), Pub. L. No. 105-115, 111 Stat. 2296; the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-188, 116 Stat. 594; the Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823; and the 2012 amendments to the Act.

[13] Prescription Drug User Fee Act of 1992, Pub. L. No. 102-571, § 736(f)(1), 106 Stat. 4491, 4497. Under FDAMA and each subsequent reauthorization the base year has been 1997.

> 1997 . . . multiplied by the adjustment factor applicable to the fiscal year involved.[14]

By contrast, under MDUFA the trigger is specifically tied to congressional funding of the devices and radiological products program:

> With respect to the amount that . . . is appropriated for a fiscal year for devices and radiological products, fees may not be assessed . . . if . . . the amount so appropriated for the fiscal year . . . is more than 1 percent less than [a baseline amount] multiplied by the adjustment factor applicable to such fiscal year . . . .[15]

The new generic drug user-fee scheme created by FDASIA includes a triggering provision that essentially mimics PDUFA in conditioning the fees on a threshold appropriation to FDA as a whole.[16] The new biosimilars user fee program, interestingly, does not employ a trigger as such. Rather, the equivalent provision in BsUFA simply caps fees at a one-to-one ratio with funds appropriated for biosimilars review.[17] While the effect remains the same (making sure that user fees supplement rather than replace appropriated funds), this provision gives the agency more flexibility to reduce the biosimilars review budget without sacrificing all industry contributions.

Third, PDUFA I expressly prohibited the FDA from utilizing user-fee revenue for any purpose other than "to defray increases in the costs of . . . the review of human drug applications . . . ."[18] This limitation has been relaxed somewhat over time, such that in 2007, PDUFA IV specifically permitted the FDA to use user-fee revenue for a variety of post-market safety activities associated with a drug as well as premarket review.[19] The spirit of the limitation remains the same, however, and a version of it has been included in every reauthorization of PDUFA. Parallel limitations exist in the medical device user-fee scheme[20] and in the new user-fee schemes for generics and biosimilars established by FDASIA.[21] Unlike with drug fees, the FDA's use of medical-device user fees continues to be limited to premarket review activities.[22] As an increasing share of the FDA's total funding comes from user fees, these limitations together with the requirement discussed above that non-fee appropriations not be reduced have had the unintended

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[14] 21 U.S.C. § 379h(f)(1) (2006).

[15] 21 U.S.C. § 379j(g)(1) (2006 & Supp. V 2011). Under FDASIA, the MDUFA trigger does not substantively change except that the baseline rises to $280,587,000 from $205,720,000. FDASIA, Pub. L. No. 112-144, § 203(e), 126 Stat. 993, 1005 (2012) (to be codified at 21 U.S.C. § 379j(h)(1)(A)).

[16] FDASIA § 302 (to be codified at 21 U.S.C. § 379j–42(h)(1)).

[17] FDASIA § 402 (to be codified at 21 U.S.C. § 379j–52(b)(2)).

[18] Pub. L. No. 102-571, § 736(g)(2)(B), 106 Stat. 4491, 4497 (1992).

[19] 21 U.S.C. § 379g(6)(F) (2006 & Supp. V 2011).

[20] 21 U.S.C. § 379j(h)(2)(A)(ii) (2006).

[21] Pub. L. No. 112-144 §§ 302(i)(2)(A)(ii), 402(e)(2)(B), 126 Stat. 993, 1021, 1036 (2012).

[22] 21 U.S.C. § 379i(8) (2006 & Supp. V 2011).

but pernicious consequence of shrinking the relative funding available for non-review activities such as enforcement.[23]

Finally, a key component of the compromise that allowed PDUFA I to pass was the FDA agreeing to establish performance goals to reduce drug approval time.[24] Performance goals have been a feature of every subsequent user fee statute, and provide a yardstick for both the successes and failures of these laws as well as an indication of the scope and direction of their ambition.

III. PASSAGE

Because PDUFA IV and MDUFA III were both set to expire in September 2012, Congress and the FDA had ample time to prepare for the reauthorization effort. Indeed, the agency was expressly required by law to solicit public input on the reauthorization process and to consult with six identified stakeholder groups, including regulated industry, scientific experts, and representatives of consumer and patient advocacy groups.[25] Accordingly, the process of framing FDASIA began over two years prior to its passage, with a public meeting on April 12, 2010.[26] This public meeting was followed by at least thirty-eight separate meetings between the FDA and representatives from regulated industry, eleven meetings with stakeholder groups, and additional public meetings, just on PDUFA.[27] Additional public meetings and meetings with industry and stakeholders occurred around MDUFA reauthorization,[28] as well as the novel generic drug and biosimilars user fee acts.[29] These meetings culminated in the FDA transmitting its recommended legislative language for each of the user fee acts to Congress.[30] Senator Harkin (D-Iowa) introduced a single bill consolidating these recom-

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[23] *See infra* Part V.B.1.

[24] *See* James L. Zelenay, Jr., *The Prescription Drug User Fee Act: Is a Faster Food and Drug Administration Always a Better Food and Drug Administration?*, 60 FOOD & DRUG L.J. 261, 278 (2005).

[25] 21 U.S.C. §§ 379h-2(d), 379j-1(b) (2006 & Supp. V 2011).

[26] Prescription Drug User Fee Act; Public Meeting, 75 Fed. Reg. 12555 (Mar. 16, 2010).

[27] *PDUFA Meetings*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm117890.htm (last updated Dec. 15, 2011).

[28] *MDUFA Meetings*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationAct MDUFMA/ucm236902.htm (last updated Mar. 15, 2012).

[29] *GDUF Negotiation Sessions*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/ForIndustry/UserFees/GenericDrugUserFees/ucm256662.htm (last updated Sept. 26, 2012); *GDUF Public Meetings and Updates*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/ForIndustry/UserFees/GenericDrugUserFees/ucm256661.htm (last updated Aug. 27, 2012); *BsUFA Authorization*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/ForIndustry/UserFees/ucm268124.htm (last updated Jul. 13, 2012).

[30] FDA transmitted final recommendations to Congress for PDUFA, GDUFA and BsUFA in January 2012. *See* Press Release, U.S. Food & Drug Admin., FDA Completes Work on Three Drug User Fee Programs (Jan. 13, 2012), *available at* http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm287723.htm. It issued a draft recommendation on MDUFA in March 2012, but did not finalize this recommendation before Congress passed

mendations as S. 2516, which was reported out of the Senate Health, Education, Labor and Pensions ("HELP") Committee on April 25, 2012.[31] Senators Harkin and Enzi (R-Wyo.) filed S. 3187 as an updated bill containing the full text of S. 2516 as well as a bipartisan managers' package on May 15.[32] This bill enjoyed enormous bipartisan support and passed the Senate 96 to 1.[33] The amended form of the bill that was approved unanimously by the House cleared the Senate again, this time by a vote of 92 to 4.[34] When the bill was signed into law by President Obama on July 9, 2012, the Obama administration heralded it as both a political and policy success.[35]

IV. Components of the Act

FDASIA has eleven titles and accomplishes a wide variety of policies, but it has six principal effects. First, in Titles I and II the law reauthorizes PDUFA and MDUFA. Second, in Titles III and IV it establishes new user-fee systems for generic drugs and biosimilar products. Third, Titles V and VIII create incentives for high-priority research in the areas of pediatric clinical science and new antibiotic development. Fourth, Titles VI, VII, and IX attempt to correct and improve on the way the FDA regulates drugs and devices. Fifth, Title X creates a new framework to prevent and address drug shortages. Lastly, Title XI instructs the FDA to take steps to deal with twenty-first century challenges including the promotion of regulated products using the internet, the advancement of regulatory science, and the emerging field of nanotechnology and nanomaterials. Other miscellaneous but important provisions of the Act include changes to the whistleblower protection accorded to the Commissioned Corps of the Public Health Service,[36] changes to the FDA's rules for reviewing some citizen petitions regarding generic and biosimilar applications,[37] changes to the FDA's conflict

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FDASIA. *See* Judith A. Johnson, Cong. Research Serv., R42508, The FDA Medical Device User Fee Program 14 (2012).

[31] *See Legislative Notice: S. 3187 – The Food and Drug Administration Safety and Innovation Act*, U.S. Senate Republican Policy Comm. (May 16, 2012), http://www.rpc.senate.gov/legislative-notices/legislative-notice-s-3187_the-food-and-drug-administration-safety-and-innovation-act.

[32] *Id.*

[33] 158 Cong. Rec. S3568 (daily ed. May 24, 2012).

[34] 158 Cong. Rec. S4611, S4626 (daily ed. June 26, 2012).

[35] *See, e.g.*, *Statement from HHS Secretary Kathleen Sebelius on the Signing of the Food and Drug Administration Safety and Innovation Act*, U.S. Dep't of Health & Human Servs. (July 9, 2012), http://www.hhs.gov/news/press/2012pres/07/20120709b.html ("This legislation, which passed both the House and Senate with overwhelming bipartisan majorities, will help speed safe and effective medical products to patients and maintain our Nation's role as a leader in biomedical innovation.").

[36] FDASIA, Pub. L. No. 112-144, § 1129, 126 Stat. 993 (2012).

[37] FDASIA § 1135.

of interest rules to improve advisory committees' access to experts,[38] and more.[39]

Needless to say, in a law of such broad scope, there are countless important and controversial provisions that an article of this scope cannot address. For purposes of this Recent Development, therefore, the focus will be on Titles I through IV of the Act, which authorize or reauthorize the user fees that have become the critical source of funding for the FDA's review activities over the past twenty years.

A. PDUFA V and MDUFA III

1. PDUFA V

Title I of the Act, also known as the Prescription Drug User Fee Amendments of 2012 or PDUFA V, is a relatively uneventful five-year reauthorization of what has become "the cornerstone of modern FDA drug review."[40] PDUFA V principally acts to increase the total revenue generable from fees (the sum of a listed base amount and annually calculated adjustments for workload and inflation). While the adjustments are calculated somewhat differently under PDUFA V than under the previous iteration, the principal change comes in the base amount, which is raised to $693,099,000[41] from $392,783,000,[42] an increase of 76%. As under the previous version, the total fee revenue is derived in equal share from three categories of fees: drug application fees, drug establishment fees, and drug product fees.[43]

In addition to setting new revenue totals for the user-fee program, the Act embraces new performance goals for the FDA.[44] Under PDUFA V, as under all previous iterations of the user fee act, the FDA's specific performance goals are not expressed in the statute. Rather, these goals are laid out by the Secretary of Health and Human Services in letters to the chairmen of the Senate HELP Committee and the House Committee on Energy and Commerce, and the Act simply directs the agency to utilize the authorized fees in accordance with the goals identified in these letters.[45] The PDUFA V per-

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[38] FDASIA § 1142.

[39] For a detailed section-by-section summary and analysis of the law's provisions, see *Food and Drug Administration Safety and Innovation Act*, HYMAN, PHELPS & MCNAMARA, P.C. (July 11, 2012), http://www.hpm.com/pdf/blog/FDASIA-HP&MSummary&Analysis.pdf.

[40] *Prescription Drug User Fee Act (PDUFA): Adding Resources and Improving Performance in FDA Review of New Drug Applications*, U.S. FOOD & DRUG ADMIN. (Nov. 11, 2005), http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm119253.htm.

[41] FDASIA § 103(2)(A)(ii) (to be codified at 21 U.S.C. § 379h(b)(1)(a)).

[42] 21 U.S.C. § 379h(b)(1)(A) (2006 & Supp. V 2011).

[43] 21 U.S.C. § 379h(b)(2).

[44] *See* FDASIA, Pub. L. No. 112-144, § 101(b), 126 Stat. 993, 996 (2012).

[45] This incorporation of the goals by reference dates to PDUFA I, when the FDA insisted that they be "set forth in a separate letter" rather than be included in the legislation. HUTT ET AL., *supra* note 8, at 679.

formance goals include a variety of changes, including minor changes in review goals from PDUFA IV (e.g., new molecular entity ("NME") NDAs are now subject to slightly more relaxed goals than non-NME NDAs: ninety percent reviewed within twelve months versus ten months[46]) as well as goals relating to enhancing regulatory science, such as increased use of meta-analysis methodologies and biomarkers and pharmacogenomics.[47]

2. MDUFA III

Title II of the Act is the Medical Device User Fee Amendments of 2012 ("MDUFA III"). As with PDUFA, the most important change under MDUFA III is an increase in the total amount of fees available. The total appropriations under MDUFA III are significantly greater than under MDUFA II, jumping from $67,118,000 in FY 2012[48] to $97,722,301 in FY 2013 and eventually $130,184,348 in FY 2017.[49] MDUFA III also expands the categories of medical device establishments that are subject to registration fees. Whereas previously only (1) manufacturers, (2) single-use device reprocessors, and (3) specification developers were "establishment[s] subject to a registration fee,"[50] MDUFA III broadens the category to include any establishment that "is engaged in the manufacture, preparation, propagation, compounding, or processing of a device."[51] The estimated result of this change will be to increase the number of fee-paying establishments from 16,000 to 22,000.[52]

Like PDUFA, MDUFA incorporates performance goals laid out in letters to Congressional leaders from the Secretary of Health and Human Services.[53] Under the MDUFA III performance goals the agency commits to providing "substantive interaction" with applicants within established time goals for progressively greater percentages of medical device submissions over the Act's five-year lifespan.[54] The MDUFA performance goals also include implementing final guidance on what factors the FDA considers when making benefit-risk determinations in medical device premarket review, providing greater clarity for device sponsors.[55]

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[46] *PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2013 Through 2017*, U.S. Food & Drug Admin. 1–2, http://www.fda.gov/downloads/forindustry/userfees/prescriptiondruguserfee/ucm270412.pdf (last visited Dec. 20, 2012).

[47] *Id.* at 21–22.

[48] 21 U.S.C. § 379j(h)(3)(E) (2006 & Supp. V 2011).

[49] FDASIA § 203(b)(3) (to be codified at 21 U.S.C. § 379j(b)(2)).

[50] 21 U.S.C. § 379i(13)(A)-(C) (2010).

[51] FDASIA § 202(3) (to be codified at 21 U.S.C. § 379i(13)).

[52] *Food and Drug Administration Safety and Innovation Act*, *supra* note 39.

[53] FDASIA, Pub. L. No. 112-144, § 201(b), 126 Stat. 993, 1002 (2012).

[54] *MDUFA Performance Goals and Procedures*, U.S. Food & Drug Admin. 6–10 (Apr. 18, 2012), http://www.fda.gov/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/ucm295454.pdf.

[55] *Id.* at 6.

B. GDUFA and BsUFA

Among the greatest impacts of FDASIA is that it established entirely new user-fee schemes for two categories of FDA-regulated products: generic drugs and "biosimilars" or biological products shown to be interchangeable with an existing, licensed "reference product." In structure, both schemes are similar to the existing drug and device user-fee acts (including in that both systems incorporate performance goals set forth by the Secretary by reference), and both programs will result in substantial new revenue streams for the agency.

1. GDUFA—The Generic Drug User Fee Amendments of 2012

Under GDUFA (Title III of FDASIA), generic drug manufacturers will be responsible for paying four types of user fees: a one-time backlog fee for abbreviated new drug applications ("ANDAs") that applies to all sponsors of pending ANDAs as of October 1, 2012;[56] an additional one-time "drug master file fee" applicable to each person who owns a generic drug master file ("DMF") referenced in a generic drug submission;[57] a traditional application fee for each ANDA and prior approval supplement filing;[58] and an annual facility fee for any facility that produces finished dosage forms of generic drugs or active pharmaceutical ingredients.[59] All told, GDUFA will generate $299,000,000 in fees for FDA in 2013,[60] and more in each subsequent year depending on statutory inflation-based adjustments to this base amount.[61] After 2013 (and the one-time backlog fee), 70% of fees under GDUFA will come from the facilities fees, with 24% coming from application fees, and the remaining 6% coming from the one-time DMF fees.[62] As with PDUFA, GDUFA will allow the agency to expend user-fee revenue not just on reviewing submissions, but also on post-market safety activities.[63] For example, GDUFA funds can be used for inspections of facilities associated with generic drugs and for the development and implantation of adverse-event reporting systems.[64]

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[56] FDASIA, Pub. L. No. 112-144, § 302, 126 Stat. 993, 1011 (2012) (to be codified at 21 U.S.C. § 379j–42(a)(1)).

[57] *Id.* § 302, 126 Stat. at 1011–12 (to be codified at 21 U.S.C. § 379j–42(a)(2)). A DMF is a discretionary submission to the FDA that may be used in support of a subsequent ANDA. *See Drug Master Files: Guidelines*, U.S. Food & Drug Admin., http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm122886.htm (last updated Oct. 11, 2011).

[58] FDASIA § 302, 126 Stat. at 1013–14 (to be codified at 21 U.S.C. § 379j–42(a)(3)).

[59] *Id.* § 302, 126 Stat. at 1014–15 (to be codified at 21 U.S.C. § 379j–42(a)(4)).

[60] *Id.* § 302, 126 Stat. at 1015 (to be codified at 21 U.S.C. § 379j–42(b)(1)).

[61] *Id.* (to be codified at 21 U.S.C. § 379j–42(b)(1)(B)).

[62] *Id.* § 302, 126 Stat. at 1016 (to be codified at 21 U.S.C. § 379j–42(b)(2)(A)–(D)).

[63] *Id.* § 302, 126 Stat. at 1010 (to be codified at 21 U.S.C. § 379j–41(8)).

[64] *Id.*

2. BsUFA—The Biosimilars User Fee Amendments of 2012

BsUFA, found in title IV of the Act, creates a user-fee scheme for a category of regulated products that is itself novel. So-called "biosimilar biological products" are a regulatory category created by the Biologics Price Competition and Innovation Act ("BCPI Act"), passed as part of the President Obama's landmark healthcare law, the Affordable Care Act.[65] The BCPI Act created a new regulatory pathway for biological products that are demonstrated to be "biosimilar" or "interchangeable" with an existing FDA-licensed biological product.[66] Though the term "generic" refers only to small-molecule drugs under the Federal Food, Drug, and Cosmetic Act ("FDCA"), it is not far off to think of biosimilars as being something like generic versions of biologic products.

The structure of BsUFA largely parallels that of PDUFA, which applies to standard biologic products as well as small-molecule drugs.[67] Thus the application, product, and establishment fees under BsUFA will be familiar. The major departure from PDUFA is the creation of additional "Biological Product Development" ("BPD") fees (payable both per submission and annually) for products in development.[68] These fees would apply to any person who submits to the FDA either a meeting request or clinical protocol for an investigatory new drug ("IND") protocol relating to the development of a new biosimilar product.[69] As with PDUFA and GDUFA, fees collected through BsUFA can be expended on either activities associated with the review of biosimilar product applications or on postmarket safety activities related to products approved under a biosimilar biological product application.[70]

Unlike the other user-fee programs, BsUFA does not set its own fees. Instead, the fee amounts under BsUFA are pegged to those under PDUFA, limited in that the total fees charged each year cannot exceed the resource costs allocated to review of biosimilar product applications.[71] Also unique to BsUFA is the lack of an appropriations "trigger." As noted *supra*, the biosimilars scheme imposes a statutory cap on fees tied to appropriations, but does not condition the collection of fees on some threshold appropriations number.[72]

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[65] Patient Protection and Affordable Care Act, Pub. L. No. 111-148 §§ 7001–03, 124 Stat. 119, 804–21 (2010) (codified in scattered sections of the U.S.C.).

[66] *Biosimilars*, U.S. Food & Drug Admin., http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/default.htm (last updated July 10, 2012).

[67] *See* 21 U.S.C. § 379g(1)(A)–(B) (2006 & Supp. V 2011).

[68] FDASIA § 402, 126 Stat. at 1029–32 (to be codified at 21 U.S.C. § 379j-52(a)(1)).

[69] *Id.* § 402, 126 Stat. at 1029–30 (to be codified at 21 U.S.C. § 379j-52(a)(1)(A)).

[70] *Id.* § 402, 126 Stat. at 1034–35 (to be codified at 21 U.S.C. § 379j-51(13)(A)–(F)).

[71] *Id.* § 402, 126 Stat. at 1028–29 (to be codified at 21 U.S.C. § 379j-52(b)(1)–(2)).

[72] *See supra* text accompanying note 17.

V. Significance and Limitations

On the day the Senate passed FDASIA, FDA Commissioner Margaret Hamburg applauded the Act's passage in a blog post on FDA's website entitled "User Fees: Ensuring a Stronger and Better FDA."[73] While it is true that user fees have played an important role in increasing the speed of FDA review and have provided a consistent and growing budget for the agency largely independent of the appropriations process, the user-fee system is by no means perfect. Some complaints—for example, that user fees create over-reliance on the very industry the FDA is supposed to be regulating—are old, and whatever their merits, the continued reauthorizations of the user-fee statutes at least reflect a legislative determination that these concerns are outweighed by the benefits of the system. Other concerns, however, particularly concerns related to the unintended consequences on the FDA's non-review activities of an increasingly fee-funded budget, are comparatively newer, and must eventually be addressed. FDASIA's various user-fee provisions fail to address these concerns, even as they otherwise seem to be forward looking. FDASIA accomplishes its primary objective: it expands the user-fee program by simultaneously broadening the categories of fee-eligible activities and increasing the total authorized fee revenues in each category, and it does so in a way that basically satisfies FDA, regulated industry, and other stakeholders. But FDASIA, like so much must-pass legislation, is ultimately too conservative.

In addition to affecting agency priority-setting and creating the risk of real or perceived bias, user fees have a particularly urgent relevance today in light of Congress's efforts at deficit reduction. Because user fees are both contingent on base amounts of budget appropriations and earmarked for specific uses, they raise challenging statutory questions when Congress, in the exercise of its budget authority, implements broad budget reduction or sequestration.

A. Why User Fees Matter

User fees are a vital part of the FDA's mission today. They accounted for thirty-five percent of the agency's total budget in FY 2012[74] and under President Obama's FY 2013 proposed budget over $1.9 billion in fees would account for forty-four percent of the agency's budget and pay for over 4,700 full-time equivalent employees.[75] For the drug and device review programs, user fees play a particularly vital role: in 2012 user fees funded over fifty-

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[73] Hamburg, *supra* note 5.

[74] Susan Thaul et al., Cong. Research Serv., R42564, FDA User Fees and the Regulation of Drugs, Biologics, and Devices: Comparative Analysis of S. 3187 and H.R. 5651 4 (2012).

[75] Dep't of Health and Human Servs., Fiscal Year 2013 Food and Drug Administration Justification of Estimates for Appropriations Committees 4 (2012), *available*

one percent of the Human Drug Program[76] and about fourteen percent of the Devices and Radiological Health program.[77] Under President Obama's budget for 2013, those numbers would rise to sixty-two percent[78] and seventeen percent[79] respectively—increases caused by a combination of greater fee revenue and decreased budget allocations in both categories. These funds are earmarked for the "process for the review" of drug and device applications. To understand why this is and what this means requires a short digression into how drugs and devices reach the market in the United States.

A legally marketed drug in the United States is subject to regulation by the FDA for its entire lifecycle, from the investigatory phases of research until after it has been paid for and used by the end user. Any given drug must survive at least three phases of regulatory submissions: an investigatory new drug ("IND") application before it undergoes clinical trials, a new drug application ("NDA") before it can be marketed, and ongoing submissions once the drug is on the market to demonstrate to the FDA that production, distribution, and use comply with applicable laws and regulations. With the caveat that this is a radical oversimplification, this set of regulatory hurdles applies to essentially all drugs, with additional steps before a drug can go over-the-counter or generic.[80] By contrast, only a relatively small subset of new medical devices—about one third—have to undergo any premarket approval process. This happens for various reasons, some political and some historic, but on a basic level it is because most medical devices are simply not dangerous enough to merit an expensive premarket review process.[81] Indeed, under the FDCA medical devices are classified based on their level of risk. All of the lowest-risk, class I devices and some of the medium-risk class II devices are exempt from premarket review. The remaining products are subjected to one of two premarket review regimes: a premarket approval application ("PMA") process that, like the NDA process, requires submission of clinical data to prove safety and efficacy, or a 510(k) premarket notification, in which the device sponsor need only demonstrate "substantial equivalence" with a previously approved "predicate device" to receive FDA "clearance."[82]

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at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/BudgetReports/UCM291555.pdf.

[76] *Id.* at 163.

[77] *Id.* at 289.

[78] *Id.* at 163.

[79] *Id.* at 289.

[80] For a more thorough treatment of drug regulation, see generally SUSAN THAUL, CONG. RESEARCH SERV., R41983, HOW FDA APPROVES DRUGS AND REGULATES THEIR SAFETY AND EFFECTIVENESS (2012).

[81] For example, there is no need to engage in a costly premarket review for a simple and harmless device like a rolled cotton "saliva absorber." *Product Classification*, U.S. FOOD & DRUG ADMIN., http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=1047 (last updated Oct. 19, 2012).

[82] For a more thorough introduction to the regulation of medical devices, see generally JUDITH A. JOHNSON, CONG. RESEARCH SERV., R42130, FDA REGULATION OF MEDICAL DEVICES (2011).

Regardless of whether FDA is receiving an IND, an NDA, a 510(k) or a PMA, there are several things that will generally be true. First, a thorough review of the submission requires both substantial time and a high level of scientific expertise and experience. Second, the sponsor of the drug or device has already expended tremendous resources to get their product to that state of development. Finally, every day that FDA spends reviewing the submission has a real cost for a variety of parties: sponsors both lose money on sunk costs like salaries and overhead and watch their patent exclusivity period tick away; more importantly, patients who could be helped by the drug or device go without that care. For these reasons, as long as we have had a premarket approval system there has been concern with unnecessary delay by regulators, a phenomenon commonly referred to as "drug lag."

The notion that the United States actually suffers or suffered a drug lag has long been the subject of debate, focused mostly on the question of the appropriate balance between speed and safety.[83] But whereas regulators, industry and consumer advocates may disagree about how quickly new drugs should be allowed to come to market, they all agree that a fully funded, fully staffed FDA is a necessary prerequisite to a successful review program, no matter what metric (e.g., speed, post-approval safety) one uses to measure success. As has already been briefly discussed above, it was the consensus between industry and regulators that the FDA's resources had become woefully inadequate that finally prompted both parties to accept a user-fee structure. Since 1992, neither government nor industry has ever seriously considered going back.

It is no wonder that they have not: as Congress has piled additional responsibilities onto the agency and life-sciences industries have developed ever more complex, cutting-edge drugs and devices, new congressional appropriations have not been forthcoming. User fees have been the singular predictable source of new funds for an agency that, today, regulates twenty-five cents out of every dollar spent in the United States.[84] What is more, user fees appear to have worked, at least with respect to addressing the drug lag: median approval time for new drugs was ten months in FY 2011, down from nineteen months in FY 1993.[85] In a way, it no longer matters from a

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[83] *See generally* Leonard G. Schifrin, *Lessons from the Drug Lag: A Retrospective Analysis of the 1962 Drug Regulations*, 5 HARV. J. L. & PUB. POL'Y 91 (1982). Several FDA commissioners have questioned the severity of the so-called "drug lag" and characterized the issue as being more complex than the simple question of whether new drugs are available in the United States as quickly as in other nations. *See, e.g.*, Donald Kennedy, *A Calm Look at "Drug Lag*," 239 J. AM. MED. ASS'N 423 (1978); David A. Kessler, *Remarks by the Commissioner of Food and Drugs*, 51 FOOD & DRUG L.J. 207, 208–15 (1996). Other commentators have characterized the drug lag as an instance of regulatory failure. *See, e.g.*, Frederick Beckner, III, Note, *The FDA's War on Drugs*, 82 GEO. L.J. 529, 530–31 (1993).

[84] John P. Swann, *FDA's Origin*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/AboutFDA/WhatWeDo/History/Origin/ucm124403.htm (last updated June 18, 2009).

[85] SUSAN THAUL, CONG. RESEARCH SERV., R42366, PRESCRIPTION DRUG USER FEE ACT (PDUFA): ISSUES FOR REAUTHORIZATION (PDUFA V) IN 2012 6 (2012). *But see* Zelenay, *supra* note 24 (questioning the normative desirability of reduced drug approval times).

reauthorization perspective whether or not user fees have done anything to alleviate the drug lag, since it is beyond dispute that if Congress allowed fees to expire (taking with them the 3,569 FTE employees funded by user fees in FY 2012[86]), the agency's review activities would screech to a halt.

B. The Problems with User Fees

The central problem with the user-fee system, aside from doubts about its actual effectiveness, arises from the fact that, boiled down, it consists of having industry provide the operating funds the FDA needs to do its day-to-day work, with strings attached. This problem has two principal aspects, though these are necessarily interrelated. First, the character of the strings, combined with budget politics, has the dangerous effect of creating an agency of "haves and have-nots," wherein some centers and programs receive both user fees and the lion's share of appropriations, while others end up struggling to carry out their work, which is often vital to the FDA's mission of protecting the public health. Second, because the amount of fees the agency collects and the range of activities for which it collects them has grown steadily over the last two decades and appears likely to continue in that direction, the user-fee program creates at least the appearance that the FDA is beholden to the parties it is supposed to regulate. At best, this problem simply undermines public confidence in the FDA and FDA-approved products. Though there is little evidence to suggest the worst case scenario—that FDA reviewers feel pressured to approve individual drugs to maintain critical industry support for fees—it is evident that, at the very least, the user-fee system has allowed industry to have a key role in setting agency priorities, both through its participation in setting user-fee performance goals and in its ability to dictate the regulatory and legislative agenda every five years when user-fee-reauthorization legislation comes up.

1. User Fees Effectively De-Fund Important FDA Activities

From the first iteration of PDUFA, there has always been a concern that the statute's triggers would create an incentive during tight budgets to shift funds away from non-user-fee divisions of the agency in order to satisfy the triggers for fees, and accordingly create an agency of "haves and have-nots."[87] While this particular version of the fear has not yet played out (due to Congress's willingness to appropriate at least the bare minimum to satisfy the user-fee triggers),[88] the user-fee scheme has in fact had a "pernicious

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[86] DEP'T OF HEALTH AND HUMAN SERVS., *supra* note 75, at 98.
[87] Zelenay, *supra* note 24, at 292–93.
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FDA meets this trigger consistently, even though for most years since FY 1997 FDA did not receive increases to cover the cost of pay increases and inflation for its core programs—which was the original intent of the trigger. FDA meets this trigger pri-

impact" on the budget at FDA, creating both rich and poor centers and "rich and poor functions" within centers.[89] User fees do so through the requirements that fees be additive rather than substitutive and that they be earmarked only for review activities. Because some user-fee triggers require inflation-indexed increases in appropriations for review activities each year, these activities are inevitably first in line for whatever appropriations Congress is making to the FDA. This alone would result in an imbalance over time, but on top of that, the costs of non-review activities have risen predictably as the complexity and scope of the agency's work has continued to grow. What is more, the mere cost of doing business as a government agency has increased radically since the beginning of the user-fee program, as unfunded mandates have "cascade[d] down on the FDA from all sides of the political spectrum."[90] These include both added FDA-specific tasks laid out in over 100 statutes enacted since the late 1980s[91] and significant additional administrative responsibilities imposed by statutes and executive orders of general applicability, such as the Freedom of Information Act[92] and executive orders and statutes requiring agencies to conduct cost-benefit analysis, environmental-impact analysis, small-business-impact analysis, and more for every new regulation.[93]

The result of user fees has thus been to increase resources for new drug review while effectively shrinking the share of the FDA's total budget for activities not funded by user fees. As the Institute of Medicine ("IOM") noted in its 2007 report on the user-fee system:

> Although PDUFA has facilitated substantial expansion of [Center for Drug Evaluation and Research ("CDER")] staff, especially in the Office of New Drugs (OND), growth has been largely to shorten review times and improve related processes, including interactions with industry representatives and the development of guidances, rather than strategic with respect to the full breadth of functions and disciplines needed to operate the largest center of a world-class regulatory agency. . . . These restrictions have contributed to a troubling resource imbalance between OND and other CDER units (e.g., postmarketing safety activities, compliance).[94]

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marily because FDA has received appropriation increases earmarked for specific initiatives since 1997 (e.g., food safety, counter-terrorism, etc.).

PDUFA IV 5-Year Financial Plan (2009): Assumptions, U.S. Food & Drug Admin., http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm153481.htm (last updated June 18, 2009).

[89] Peter Barton Hutt, *Recent Development: The State of Science at the Food and Drug Administration*, 60 Admin. L. Rev. 431, 454 (2008).

[90] *Id.* at 441.

[91] *Id.* at 436–38 tbl. I.

[92] 5 U.S.C. § 552 (2006).

[93] Hutt, *supra* note 89, at 438–41.

[94] Inst. of Med. of the Nat'l Acads., The Future of Drug Safety: Promoting and Protecting the Health of the Public 194–95 (2007).

The Institute of Medicine report concluded that the "limitations or 'strings' that direct how CDER can use PDUFA funds" was, for this reason, the "most troubling aspect of the arrangement."[95] While there have been positive steps to address these strings, most notably the expansion of the definition of the process of review to encompass substantial preclinical-, clinical-, and postmarket-regulatory activity,[96] these are not enough: they do not apply to the medical device user fee act, for example, and they fail to provide funding for other vital postmarket activities, such as regulation of drug advertising.[97] In the end, notwithstanding the attempt to resolve the have-and-have-not problem through some relaxation of the use restrictions, the result of the string-and-trigger system has been FDA's transformation into "an agency with expanded responsibilities, stagnant resources, and the consequent inability to implement or enforce its statutory mandate."[98]

As it happens, the terms of the new biosimilars user-fee scheme present an interesting possible approach to alleviating some of these concerns. As noted above, the biosimilars scheme does away with a traditional trigger in favor of tying a limit on user fees to the amount of money appropriated for biosimilars review.[99] This approach gives the Congress and the agency the flexibility to adjust the funding of different programs as budgetary realities and regulatory priorities demand without risking the substantial negative impacts of violating a statutory trigger, while maintaining the assurance that fees not replace appropriations. There would doubtless be strong opposition from industry to shifting other user-fee schemes to this model, since implicit in the current user-fee compromise is the idea that fees are only "worth it" to industry if they are part of a funding program that can actually keep review times low. Nonetheless, the switch to an appropriations-tied cap on fees would presumably still be less objectionable than a scheme imposing user fees without any triggers or limits. As an intermediate position between the current system and that more drastic result, the biosimilars model should at least be part of the larger conversation about FDA funding reform.

2. *User Fees Make FDA Too Dependent On the Industry It Is Supposed to Regulate*

The expansion of user fees has been, in some ways, a response to the concerns just discussed: after all, if the fear is that user-fee funded programs will flourish while those relying on budget appropriations wither, one logical solution is simply to fund everything we consider important through user fees. While we have not embraced this theory fully (more on that in Section VI, *infra*), the expansion of user fees has been noteworthy, as FDASIA itself

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[95] *Id.* at 197.
[96] THAUL, *supra* note 85, at 4.
[97] Zelenay, *supra* note 24, at 311–12.
[98] Hutt, *supra* note 89, at 432.
[99] *See supra* text accompanying note 17.

well illustrates. Programs that many feared would become have-nots in the early days of PDUFA, like device review and food safety, are now more or less supported by their own user-fee schemes.[100] This expansion of user fees has occurred in tandem with a general stagnation in appropriations,[101] perhaps itself attributable in part to the vicious circle wherein user fees create the appearance of adequate funding, making it easier for Congress to resist increasing appropriations beyond the bare minimum inflation adjustments required by the user-fee triggers. As one former FDA Chief Counsel put it, the existence of user fees has "shielded the serious deterioration of FDA science from public view."[102]

The point is that over the last two decades the FDA's budget has become increasingly dependent on user fees, as the gap between what the agency needs to do its job and what Congress is willing to pay has grown ever wider. This state of affairs has been a source of alarm for many, who see it as a principle drawback of the user-fee system. Thus, in the Institute of Medicine's 2007 report on drug safety at the FDA, it noted its concern that user fees had "increase[ed] the agency's dependence on industry funding for its drug review activities, severely skewing CDER's focus to facilitating review and approval perhaps at the expense of other center activities, and creating an environment of intense pressures on its reviewers."[103] The report further expressed its concern that, "[i]n the negotiations between FDA and

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[100] MDUFA has already been discussed at length. A full discussion of the user fee scheme for food is beyond the scope of this paper, but food user fees are particularly controversial in the wake of the Food Safety Modernization Act ("FSMA"), Pub. L. No. 111-353, 124 Stat. 3885 (2011). The law's estimated cost of nearly $1.5 billion dwarfs the approximately $100 million increase FDA has received from Congress for food programs since the law was passed. Helena Bottemiller, *Taylor: Sequestration Would Be "Huge Blow" to Food Safety Progress*, Food Safety News (Sept. 12, 2012), http://www.foodsafetynews.com/2012/09/taylor-budget-sequestration-would-be-huge-blow-to-food-safety. In response, President Obama's FY 2013 budget called for over $228 million in user fees for the foods program, up from under $17 million in FY 2012. Dep't of Health and Human Servs., Fiscal Year 2013 Food and Drug Administration Justification of Estimates for Appropriations Committees 101 (2012), *available at* http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/BudgetReports/UCM291555.pdf. The bulk of this increase, nearly $190 million, would come from Food Establishment Registration Fees, a controversial fee category *not* authorized by the FSMA, which authorizes fees only for certain reinspections, recalls, and importation activities. The food industry has continued to resist the expansion of user fees, and has urged Congress to provide the agency with sufficient funding through the appropriations process. *See* Helena Bottemiller, *Food Industry Continues to Oppose Fees to Fund FDA*, Food Safety News (Feb. 28, 2012), http://www.foodsafetynews.com/2012/02/food-industry-continues-to-argue-against-fees-to-fund-fda/#.UEwv-kKu18w.

[101] Almost 35% of the FDA's enacted FY 2012 budget of around $3.8 billion came from user fees, with the balance coming from appropriations. By comparison, only 26% of the FY 2011 budget of just over $3.3 billion came from user fees. Dep't of Health and Human Servs., *supra* note 75, at 4. Eight years before that, the FDA's total budget for FY 2003 was around $1.6 billion, of which user fees accounted for less than 15%. U.S. Food & Drug Admin., FY 2005 Budget Proposal, *available at* http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/BudgetReports/2005FDABudgetSummary/ucm117038.htm (last updated Mar. 25, 2009).

[102] Hutt, *supra* note 89, at 453.

[103] Inst. of Med. of the Nat'l Acads., *supra* note 94, at 71.

the industry, Congress has given the industry a considerable role in influencing what the user fees will fund, thus limiting regulatory discretion and independence."[104] The appearance of agency capture is reinforced by the history of industry-friendly changes accomplished during reauthorizations. Industry has both a large statutory role in setting performance goals and the implicit power to shape their nature and scope,[105] as is evident in twenty years of performance goals whose undeniable primary focus has been on increasing the FDA's speed of review (as opposed to some other metric more directly tied to public health outcomes).[106] The perception of industry influence is visible elsewhere as well. Consider perhaps the most symbolically important example of industry's perceived ability to dictate terms to the FDA: during the first reauthorization of PDUFA, despite the agency's expressed preference that the reauthorization occur in a "clean bill" simply reauthorizing the program,[107] industry and members on the hill used the opportunity to push through a broad reform package, what became the Food and Drug Administration Modernization Act of 1997.[108] Among the many changes introduced in this package was the addition to the statute of a new FDA mission statement. This mission statement, enshrined at FDCA Section 1003(b)[109] departed from the agency's historical understanding of itself as first and foremost a law enforcement and public health agency[110] and made clear that this public protection goal was now secondary:

> The Administration shall–
> (1) promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner;
> (2) with respect to such products, protect the public health . . . .[111]

The imposition of this business- and innovation-promoting objective over the public protection mission has apparently never been entirely accepted by the agency itself, which still explains on its website's "What We Do" page that:

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[104] INST. OF MED. OF THE NAT'L ACADS., *supra* note 94, at 74.

[105] INST. OF MED. OF THE NAT'L ACADS., *supra* note 94, at 74 (identifying this role and power as the "core problem" in the relationship between industry and FDA). The negotiations over performance goals have been characterized by some critics as an "[i]mplicit and inappropriate political bargain." Margaret Gilhooley, *Drug User Fee Reform: The Problem of Capture and a Sunset, and the Relevance of Priorities and the Deficit*, 41 N.M. L. REV. 327, 329 (2011) (quoting James Dahney Miller, *FDA Performance Goals for Approving Drugs and Biologics*, 302 J. AMER. MED. ASS'N 189, 189–90 (2009)).

[106] Professor Gilhooley has proposed, for example, that user fees should be made contingent on performance goals more closely tied to health outcomes. Gilhooley, *supra* note 105, at 341–42.

[107] Zelenay, *supra* note 24, at 294.

[108] Pub. L. No. 105-115, 111 Stat. 2296 (1997).

[109] 21 U.S.C. § 393(b) (2006).

[110] Zelenay, *supra* note 24, at 295.

[111] 21 U.S.C. § 393(b) (2006).

> FDA is responsible for protecting the public health by assuring the safety, efficacy and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation. FDA is *also* responsible for advancing the public health by helping to speed innovations that make medicines more effective, safer, and more affordable . . . .[112]

Whether or not industry exerts such a great level of influence over the FDA and its Congressional overseers that it influences individual FDA regulatory decisions is an important question, but in the end the damage to the FDA's reputation and credibility depends as much on appearances as reality. As the Institute of Medicine report notes, many critics in government, academia, and from consumer groups have argued that the current reliance on industry funds is "inherently inappropriate and damaging to the reputation and function" of the agency because it gives the impression of "real or perceived 'capture' of the agency, that is . . . a sense of obligation 'to please' on the part of the agency."[113] Even if there is no actual agency capture (that is, even if the agency's reliance on industry funding does not color its regulatory choices, its legislative recommendations, or its decision-making in individual cases) the appearance of capture is itself problematic. The FDA's ability to protect the public depends on its credibility.[114] Agency credibility is no less important to drug companies themselves. Every legitimate pharmaceutical firm relies on a market that is fundamentally built on the public's confidence that FDA approval represents an accurate and unbiased assessment that a product is safe and effective; it was not so long ago in this country that scientific medicine had great difficulty competing against patent medicine and snake oil.

C. User Fees and Deficit Reduction: Triggers as a Shield and Some Open Questions

The same characteristics of the user-fee program that potentially create conflicts of interest and distort agency spending priorities also have another important policy impact. The existence of the triggers and limitations on how user fees can be spent give rise to challenging statutory questions in the context of federal deficit reduction.[115] Specifically, several obvious steps Congress can take to reduce the federal deficit appear to be in tension or direct conflict with the user-fee statutes. At the most basic level, across-the-

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[112] *What We Do*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/aboutfda/whatwedo/default.htm (last updated June 19, 2012) (emphasis added).

[113] INST. OF MED. OF THE NAT'L ACADS., *supra* note 94, at 13.

[114] *See* Zelenay, *supra* note 24, at 333 (discussing how lack of credibility harms the agency's vital "publicity power").

[115] *See* Patrick O'Leary, *Is FDA's 2013 Budget At Risk*, BILL OF HEALTH (Sept. 16, 2012), http://blogs.law.harvard.edu/billofhealth/2012/09/16/is-fdas-2013-budget-at-risk/#more-1406.

board reductions in discretionary spending risk bringing appropriations below the threshold levels required by the statutory triggers before any user fees can be collected. This plays out somewhat differently from program to program. For triggers like PDUFA's, which are tied to appropriations to the agency as a whole, the effect is theoretically to establish a floor on the scale of any budget reduction Congress can impose, since at a certain point the reduction of an additional dollar would trigger the elimination of user fees that would then have to be at least partially replaced with additional budget-authority funds. For triggers tied to program-specific appropriations, even a more modest hit to the agency's appropriated budget could force difficult decisions, as the agency is forced to ration its budget internally. In some sense, this is an exacerbated version of the phenomenon, already discussed above, of program-based triggers creating perverse incentives for setting internal budget priorities.

An even thornier statutory issue arises in the context of budget sequestration like that threatened under the Budget Control Act of 2011.[116] Determining how and if the sequester can legally be applied to user fees poses multiple challenges. A threshold matter is whether the funds received through the user-fee schemes should even be considered when calculating an agency's sequestration-eligible budget. Because sequestration is part of a legislative program intended to rein in government spending, it is not intuitive that non-budgetary authority funds should even enter the calculus.[117] If those managing the sequester are sincere about putting deficit reduction first, however, it makes sense to include user fees. By including these user fees in its calculation, the administration can inflate the amount sequestered and count the additional funds towards reducing the deficit. How this would look in practice is unclear. One possibility would be to calculate the budget reduction including user fees, and then to cap the amount of fees the FDA can collect to avoid exceeding this amount. This approach would avoid any conflict with the user fee use limitations but would result in the FDA collecting fewer or smaller fees, which would beg the question whether performance (the FDA's side of the user-fee bargain) must also be modified or adjusted down. A second possibility, and the one that would maximize deficit-reducing effects, would be to have the agency continue collecting all of the user fees authorized under existing law, but to sequester this revenue (which never came from the public purse) when it would put the FDA's budget over the reduced limit. In addition to questions about whether performance goals

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[116] Pub. L. No. 112-25, 125 Stat. 240 (2011).

[117] Regardless of this intuition, the Obama administration did consider user fees in calculating the amount to be sequestered from the FDA's budget. The Office of Management and Budget ("OMB") considered $3.873 billion of the FDA's FY 2013 budget sequestrable, whereas the agency was only supposed to receive $2.517 billion in appropriations. The implication is that over a billion dollars in user fees were considered by OMB. DEP'T OF HEALTH AND HUMAN SERVS., *supra* note 75, at 4. *See also OMB Report Suggests $318 Million Loss to FDA From Sequestration*, ALLIANCE FOR A STRONGER FDA (Sept. 14, 2012), http://strengthenfda.org/2012/09/14/omb-report-suggests-318-million-loss-to-fda-from-sequestration.

would have to be reduced commensurate to the reduced fee revenue, this plan would also seem to directly violate the use restrictions embedded in the user fee statutes.

Depending on what Congress does or does not do in the remaining months of 2012 to prevent the sequester required by the Budget Control Act, the Obama administration may be forced to make a final decision about how to handle user fees before this Recent Development goes to print. If so, this decision will set the stage for a serious revisiting of the user-fee program. If the administration chooses to ignore the use limitations built into the user fee statutes by sequestering user fees, these restrictions will have proved hollow. On the other hand, if the administration respects the restrictions and thereby allows FDA to retain crucial fee revenue above and beyond its capped budget, the limitations will have proved to be unexpectedly effective shields against otherwise universal budget cuts. In either case, legislators, regulators, and industry will all be forced to reassess the terms of the user fee bargain.[118]

VI. Proposals

The concerns about user fees can be addressed in several ways. One extreme position would be to eliminate user fees altogether, though as Zelenay notes, this proposal is not in fact all that radical, considering that the FDA functioned for most of its history without any user-fee funding.[119] Notwithstanding current budgetary woes, the amount of money it would take to entirely supplant user fees is still a drop in the proverbial bucket: projected user fees under the Obama Budget for PDUFA, MDUFA, GDUFA, and BsUFA together would be just over $1.1 billion, requiring a mere 0.03% increase on the President's $3.8 trillion budget.[120] A somewhat more conservative approach would be to simply limit the scope of the user-fee program and thus the scope of the FDA's dependence on industry funding, perhaps by setting a ceiling on the share of the FDA's total budget or of certain activities that can be funded through user fees.[121] Another option would be to simply eliminate the sunset provisions for the user fees, thereby removing the recurring noose from the agency's neck.[122] A last proposal

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[118] It should be noted that this is true even though, strictly speaking, we are unlikely to see any resolution of the *legality* of sequestering user fees in the near future, since to resolve that question, some party subject to fees would have to sue to challenge the legality of the administration's conduct. Regardless, the stance the administration takes on sequestration of user fees will shape both future legislative drafting of such fee arrangements and industry's willingness to participate in such schemes.

[119] Zelenay, *supra* note 24, at 335.

[120] Office of Mgmt. & Budget, Exec. Office of the President, Budget of the United States Government, Fiscal Year 2013 205 tbl.S-1 (2012), *available at* http://www.whitehouse.gov/sites/default/files/omb/budget/fy2013/assets/budget.pdf.

[121] *See* Zelenay, *supra* note 24, at 336–37.

[122] *See* Zelenay, *supra* note 24, at 337.

would be to continue using fees, but enable the agency to use them for a broader spectrum of regulatory activities and to grant it additional flexibility to reorient performance goals[123] and redistribute funds within the agency.[124] Commentators have urged variations on all of these approaches: Peter Barton Hutt and the Institute of Medicine Report have both made the case that the best solution is to add substantial non-fee revenues and more or less abandon a user-fee system.[125] Professor Zelenay has proposed the elimination of the five-year sunset provisions.[126] Professor Gilhooley has proposed that we may keep a fee system, but should set performance goals tied to public health rather than to the industry-advancing metric of review time.[127]

Given the current atmosphere of budget austerity and of suspicion of large government expenditure on the regulatory state, it seems unlikely that any Congress in the near future would decide to appropriate sufficient funds to supplant the user-fee system. The question, as Professor Gilhooley wrote in 2011 anticipating the reauthorizing debate, is not whether Congress will continue to reauthorize user fees, but "whether reforms are needed to address the capture problem . . . ."[128] The types of reform available to Congress without foregoing fee revenue are perfectly sufficient to this task: set performance goals that incentivize the FDA's public health mission above its industry boosting one, do away with all-or-nothing funding triggers, and structure the law's use limitations so that—once performance goals are met—remaining user-fee dollars can be spent on other program areas. This creates the strongest possible incentive for the FDA to efficiently use user-fee dollars to achieve its review goals and creates the opportunity to alleviate the haves-and-have-nots problem while maintaining a level of assurance for industry that their fees will, first and foremost, fund review programs. Such legislation is not unattainable—it simply requires a Congress willing to give a serious second look at the content of what has become an untouchable "must-pass" piece of legislation. It requires a Congress that remembers that, though PDUFA I may only have been able to pass by yielding substantial ground to industry, it has the authority to pass whatever user-fee law it wants, with or without industry approval.

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[123] For example, by setting performance goals more closely tied to public health outcomes rather than speed of review.

[124] For example, by replacing statutory triggers with provisions tying the amount of fees the agency can collect to the level of budget authority funding it provides, like BsUFA does.

[125] Hutt, *supra* note 89, at 452–53; INST. OF MED. OF THE NAT'L ACADS., *supra* note 94, at 13. The IOM report specifically proposed a number of alternative funding arrangements, acknowledging the harsh budget climate. These proposals included a tax on prescriptions and a tax on direct-to-consumer advertising by pharmaceutical firms. *Id.* at 198–99.

[126] INST. OF MED. OF THE NAT'L ACADS., *supra* note 94, at 196 (citing Zelenay, *supra* note 24).

[127] Gilhooley, *supra* note 105, at 341–42.

[128] Gilhooley, *supra* note 105, at 328.

VII. Conclusion

User fees are a vital source of funding for an extremely important but perpetually underfunded regulatory agency, and FDASIA does an admirable job of wresting enough increased fees from industry to help keep our drugs and devices safe and effective over the next five years. But FDASIA fails to address the major problems with the user-fee system: it indirectly addresses some of the concern over funding disparities by enlarging the user-fee tent with the GDUFA and BsUFA programs, but the Act contains no meaningful effort to expand the funds-eligible activities of the agency, nor does it address the problem of real and perceived agency capture, a problem that grows worse with every additional dollar of the FDA's budget that is funded through user fees.

Sooner or later, the FDA and the legislators who oversee it will have to take real steps to address these concerns. Whether it does so in the immediate future, in five years, or further down the road ultimately may turn on whether the user-fee statutes' triggers and use limitations bring the scheme's purposes into conflict with congressional deficit reduction measures. If that proves to be the case, the complicated statutory questions that scenario presents may well cause a wholesale reevaluation of what role user fees can or should serve in the modern administrative state.

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