



## NEW MEXICO LAW REVIEW

---

Volume 41  
Issue 2 *Fall*

---

Fall 2011

### Drug User Fee Reform: The Problem of Capture and a Sunset, and the Relevance of Priorities and the Deficit

Margaret Gilhooley

#### Recommended Citation

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 (2011).

Available at: <https://digitalrepository.unm.edu/nmlr/vol41/iss2/3>

This Article is brought to you for free and open access by The University of New Mexico School of Law. For more information, please visit the *New Mexico Law Review* website: [www.lawschool.unm.edu/nmlr](http://www.lawschool.unm.edu/nmlr)

# DRUG USER FEE REFORM: THE PROBLEM OF CAPTURE AND A SUNSET, AND THE RELEVANCE OF PRIORITIES AND THE DEFICIT

Margaret Gilhooley\*

## I. INTRODUCTION

On the eve of the presidential election in 2012, drug reform will be on the legislative agenda because of the need to renew every five years the authority in the Prescription Drug User Fee Act (PDUFA, or user fee law) under which drug companies pay “user fees” when they apply for approval of a new drug.<sup>1</sup> The fees generated from the PDUFA enable the Food and Drug Administration (FDA, or “the agency”) to hire more medical reviewers and, thus, to reach a decision more quickly on whether a drug can be approved.<sup>2</sup> The enactment of the program has been described as “transformative” in leading to a “change in agency culture” that recognized performance goals as “a legitimate measure” of the work of medical reviewers.<sup>3</sup> The industry is willing to make these payments in order to obtain faster FDA action because the patent on the drug is “ticking away” while the FDA reviews the drug.<sup>4</sup> The fees have been viewed

---

\* Professor of Law (Retired), Seton Hall Law School. This article benefited from a summer research grant from Seton Hall Law School. The author worked in the Office of the Chief Counsel for the Food and Drug Administration from 1975 to 1981.

1. 21 U.S.C. §§ 379g, 379h (2006). Under PDUFA the fees expire on October 1 of the year in which renewal is needed. See Food and Drug Administration Amendments Act of 2007, PUB. L. NO. 110-85, § 106(a), 121 Stat. 842 (codified at 21 U.S.C. § 379g, “History” “Sunset date of amendments made by § 106(a) of Act September 27, 2007”). While the program is often referred to as PDUFA, this article refers to it by the more readily understandable term “user fees.”

2. See James L. Zelenay, *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, 337 (2005). This student paper won a second prize from the Food and Drug Law Institute in a writing competition. *Id.* at 261.

3. See Richard A. Merrill, *The Architecture of Government Regulation of Medical Products*, 82 VA. L. REV. 1753, 1840–42 (1996) (citing remarks of an FDA official). Richard Merrill is a former Chief Counsel for the FDA. *Id.* at 1753.

4. See Zelenay, *supra* note 2, at 274. For a review of the history from the industry perspective, see Bruce N. Kuhlik, *Industry Funding of Improvements in the FDA’s New Drug Approval Process: The Prescription Drug User Fee Act of 1992*, 47 FOOD &

by some as a payment for an increased “service” by the agency.<sup>5</sup> These fees “sunset” every five years.<sup>6</sup>

PDUFA provides that the agency is to develop goals for the time to decide whether a new drug application can be approved, and to report to the relevant congressional committees on its progress in meeting the performance goals.<sup>7</sup> By law, before the user fees are renewed, the agency is to have “negotiations with the regulated industry” about the performance goals.<sup>8</sup> While the meeting is closed, the public has an opportunity to comment on the recommendations made as a result of the negotiations.<sup>9</sup> A congressional renewal of the fees in 2012 is virtually certain since the fees provide a critical part of the resources for the drug program. A key question is whether reforms are needed to address the capture problem and pressure on the agency created by making a significant part of its funding dependent upon industry fees that sunset unless legislatively renewed.

Drug user fees were first authorized in 1992 and have been renewed every five years since then.<sup>10</sup> The fees now provide for more than half of the agency’s budget that is designated toward funding the medical reviewers who consider applications for new drugs.<sup>11</sup> The Institute of Medicine (IOM) found that “[m]any” on the agency staff and in public advocacy groups believed that relying so heavily on the drug industry is “inherently inappropriate to the reputation and functioning” of the drug user fee pro-

DRUG L.J. 483 (1992); Bruce N. Kuhlik, *The Assault on Pharmaceutical Intellectual Property*, 71 U. CHI. L. REV. 93, 96–97 (2004) [hereinafter Kuhlik Intellectual Property] (reporting that the effective patent life for drugs is approximately seven years shorter than other industry averages).

5. See Anna Wilde Mathews, *Drug Firms Use Financial Clout to Push Industry Agenda at FDA*, WALL ST. J., Sept. 1, 2006, at 1 [hereinafter *Financial Clout*].

6. Act June 12, 2002, Pub. L. No. 107-188, § 502, 116 Stat. 687 (codified at 21 U.S.C. § 379g, “History” “Prescription Drug User Fee Amendments of 2002; findings”).

7. 21 U.S.C. § 379h-2 (a)(Supp.2011); see FOOD & DRUG ADMIN., DEP’T OF HEALTH & HUMAN SERVS., PERFORMANCE REPORT TO THE PRESIDENT AND THE CONGRESS FOR THE PRESCRIPTION DRUG USER FEE ACT 29–30, 33 (2010) available at <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/UserFeeReports/PerformanceReports/PDUFA/UCM243358.pdf> [hereinafter FY 2010 PDUFA PERFORMANCE REPORT].

8. 21 U.S.C. § 379h-2 (d)(1) and (2) (Supp. 2011).

9. 21 U.S.C. § 379-h-2(d)(4) (Supp. 2011). For concerns about the negotiations, see *Financial Clout*, *supra* note 5; and Zelenay, *supra* note 2, at 310–11.

10. See PETER BARTON HUTT, RICHARD A. MERRILL & LEWIS A. GROSSMAN, FOOD AND DRUG LAW 679 (3d ed. 2007) [hereinafter HUTT ET AL.]; Food and Drug Administration Amendments Act of 2007, PUB. L. NO. 110-85, § 103, 121 Stat. 826–32 (codified as amended at 21 U.S.C. § 379g) (authorizing PDUFA for another five years).

11. HUTT ET AL., *supra* note 10, at 680.

gram.<sup>12</sup> The extent of the funding, as well as the closed-door negotiations between the industry and the agency, can give rise to an appearance of the classic problem of “capture” of an agency by those regulated by it.<sup>13</sup> At this point, some believe it is “unclear” whether faster reviews are better for the public health because with a faster review the drug may have risks that would have been revealed by a more thorough review.<sup>14</sup> A recent article in a medical journal criticized the negotiations over performance goals between the agency and the industry as an “implicit[ ] and inappropriate political bargain.”<sup>15</sup> According to the author, the fact that the agency will commit to try to meet the performance goals in exchange for the industry’s support of the fees is problematic.<sup>16</sup> Instead the author recommended that the performance goals be eliminated entirely or that Congress establish them.<sup>17</sup> Conversely, another recent article noted that the faster drug reviews made possible by the drug user fee program have alleviated drug lag and increased the likelihood that drug companies will seek approval for a drug in the United States rather than overseas.<sup>18</sup> User fees are available for other government programs, but this article focuses on the special issues created by a drug user fee for a health-based program that faces a sunset.<sup>19</sup>

This article maintains that reforms are needed in the framework for drug user fees and that caution is needed when creating a permanent

---

12. INSTITUTE OF MEDICINE OF THE NATIONAL ACADEMIES, *THE FUTURE OF DRUG SAFETY: PROMOTING AND PROTECTING THE HEALTH OF THE PUBLIC* 195 (2007) [hereinafter IOM REPORT].

13. See George Stigler, *The Theory of Economic Regulation*, 2 BELL J. ECON. 3, 3–4 (1971) (maintaining that “as a rule, regulation is acquired by the industry and is designed and operated primarily for its benefit”); *Financial Clout*, *supra* note 5 (describing how the pharmaceutical industry bargained with the FDA over an increase in fees, “giving the industry a greater role in shaping the priorities of its regulator”).

14. Zelenay, *supra* note 2, at 328.

15. James Dabney Miller, *FDA Performance Goals for Approving Drugs and Biologics*, 302 J. AMER. MED. ASS’N 189, 189–90 (2009).

16. *Id.* at 189.

17. *Id.* at 190.

18. Mary K. Olson, *PDUFA and Initial U.S. Drug Launches*, 15 MICH. TELECOMM. TECH. L. REV. 393, 394–95 (2009). The availability of consumer advertising in this country may also influence pharmaceutical companies’ choice to seek approval in the United States. See NOAH LARS, *LAW, MEDICINE, AND MEDICAL TECHNOLOGY* 370 (2d ed. 2007) (noting that the European Union prohibits consumer advertisements and that New Zealand is the only other country that allows it).

19. See Clayton P. Gillette & Thomas D. Hopkins, *Federal User Fees: A Legal and Economic Analysis*, 67 B.U. L. REV. 795, 852 (1987) [hereinafter *Federal User Fees*] (recognizing that drug regulation to promote public safety can enhance consumer confidence in a way that supports some level of fees).

funding commitment under a set formula at a time of growing budget shortfalls. The article recommends that drug user fees be based on a health review rationale, rather than a fee-for-service rationale. To provide perspective on the health impact, a study is needed on the extent to which public health has improved because of the faster approval of drugs made possible by the drug user fee program. The study should also seek to develop better priority rankings than the simple one that underlies the present negotiated performance goals. For example, the priorities could be based on whether a drug offers a major health benefit compared to existing drugs or has only a modest, limited or standard advantage. The priorities and study could also provide guidance to Congress on the allocation of funding among government programs when budget cutbacks may lead to reduced support. The public interest at stake is better reflected by designating the payments, not as a “user fee,” but as a “health review fee.”

This article also addresses the two major issues that have arisen with respect to the drug user fee program. First, it will address the possible responses to the concern that the extent of industry funding creates a risk of “capture” of the agency. The IOM reported that an industry official was concerned that as user fees approached half of the budget, there could be a “perception that this is an industry-driven program.”<sup>20</sup> The IOM favored full funding of new drug safety responsibilities from government appropriations, but that level of support seems unlikely given the concerns about the deficit.<sup>21</sup> This article supports, at a minimum, limiting user fee support to half of the cost of the drug approval program, with the rest coming from government appropriations.

Second, this article will examine the proposal that the drug user fee program be made permanent, so as to end the closed-door negotiations with the drug industry that occur when the fees are up for renewal, and the pressure this can create. The agency’s need for a renewal of the fees creates an opportunity for the industry and agency to link the passage of the bill to certain statutory changes, which can create the appearance that the agency has been held “hostage.”<sup>22</sup> The agency’s need for renewal can also result in the adoption of provisions that might otherwise have not

---

20. See IOM REPORT, *supra* note 12, at 196.

21. *Id.* at 197–98.

22. See Zelenay, *supra* note 2, at 294 (stating that in the 1997 reauthorization of PDUFA “the pharmaceutical industry and Congress decided to use the re-authorization . . . as a vehicle for broader reforms,” however, there were concerns that such renewals could hold the agency “hostage” to industry’s demands). The absence of a specific legislative proposal for permanent funding complicates analysis, but it is important to consider the potential implications of the underlying concept.

been adopted but for the renewal requirement.<sup>23</sup> In addition, making the program permanent seems particularly appropriate in the wake of *Citizens United v. Federal Communication Commission* (*Citizens United*), as it may permit the expansion of corporate financing for independent political statements about a candidate that are not coordinated with the campaign.<sup>24</sup>

While making the fees permanent has advantages, a major drawback is that it could create another “uncontrollable” item in the budget at a time when the deficit is a controversial emerging issue. The 2010 report of the President’s National Commission on Fiscal Responsibility and Reform (Fiscal Commission)<sup>25</sup> drew attention to the importance and difficulty of the budget issues.<sup>26</sup> In 2011, after a heated battle over raising the federal debt ceiling, Congress established a bipartisan legislative committee to recommend spending cuts and revenue measures to reduce the deficit by \$1.5 trillion over ten years, to be approved by Congress with an up-or-down vote on November 23, 2011.<sup>27</sup> Nevertheless, Standard & Poor’s

---

23. *Id.* (illustrating, as an example, that in the 1997 reauthorization of PDUFA the “FDA would have preferred a ‘clean bill’ . . . without any sweeping reforms, [but] it was forced to accept Congress’ and industry’s desires for broader changes for fear that, unless it did so, PDUFA would not be re-authorized and FDA would be forced to fire most of its review staff”).

24. See 130 S. Ct. 876, 886 (2010).

25. THE WHITE HOUSE, THE NATIONAL COMMISSION ON FISCAL RESPONSIBILITY AND REFORM: THE MOMENT OF TRUTH (Dec. 2010). available at [http://www.fiscalcommission.gov/sites/fiscalcommission.gov/files/documents/TheMomentofTruth12\\_1\\_2010.pdf](http://www.fiscalcommission.gov/sites/fiscalcommission.gov/files/documents/TheMomentofTruth12_1_2010.pdf) [hereinafter FISCAL COMM’N REPORT]. The report was expected to be approved by a majority of the members and to be influential in congressional decision-making, although it did not receive enough votes for immediate congressional consideration. See Jackie Calmes, *Fiscal Plan Is Expected to Fall Short of Votes*, N.Y. TIMES, Dec. 3, 2010, at A22.

26. For example, some economists were concerned about making spending cut-backs while the recession continues. See, e.g., Christina D. Romer, *Now Isn’t the Time to Cut the Deficit*, N.Y. TIMES, Oct. 24, 2010, at BU5. Another criticized the Fiscal Commission for recommending tax cuts that benefit the wealthy, but tax increases that hurt the middle class, such as a proposed elimination of the deductibility of mortgage interest. See Paul Krugman, *The Hijacked Commission*, N.Y. TIMES, Nov. 12, 2010, at A31. For an exercise in the challenges in cutting the deficit, and the readers’ views, see David Leonhardt, *O.K., You Fix The Budget*, N.Y. TIMES, Nov. 13, 2010, <http://www.nytimes.com/2010/11/14/weekinreview/14leonhardt.html>, and David Leonhardt, *7,000 Ways to Fix the Deficit*, N.Y. TIMES, <http://graphics8.nytimes.com/packages/pdf/weekinreview/20101121-deficit-graphic.pdf> (last visited Sept. 5, 2011).

27. See Jennifer Steinhaur & Robert Pear, *Debt Bill Signed, Ending Crisis and Fractious Battle*, N.Y. TIMES, Aug. 3, 2011, at A1. This paper was completed and forwarded for publication before the report of the congressional deficit committee became available.

still reduced the credit rating for U.S. bonds from AAA to AA+ because the “gulf between the political parties” had reduced its confidence in the “effectiveness” of American political institutions.<sup>28</sup>

The general significance of the deficit and what should be done is not the concern of this article. The focus here is on a more limited equity and policy question. Specifically, if deficit concerns lead to general cuts in federal spending, should a program partially funded by user fees be considered nondiscretionary and not subject to the cuts? The Fiscal Commission recommended a cap on discretionary federal spending and a return to funding at pre-recession levels.<sup>29</sup> In his 2011 State of the Union message, President Obama supported a “five-year partial freeze” on non-security domestic spending.<sup>30</sup> As a result, the criteria for the categorization of a program as discretionary will become critical to whether the program receives funding. If the drug user fee program is not subject to reductions because it is “nondiscretionary” or “permanent,” additional questions arise about the impact of cutbacks in related agency programs such as drug enforcement.

This article suggests that any across the board freeze or cut should apply to the user fee-supported drug program, unless Congress and the President make a specific exemption and identify the reason for doing so. That approach would ensure that our elected officials are responsible for decisions on the equity of the allocation of the burden of funding cutbacks. Moreover, the resources to ensure compliance with the drug laws should not be cut back when the number of new drugs approved continues to grow, supported in part by user fees.

The current drug user fee program needs to be renewed by October 2012, which sets the timeframe for addressing the issues raised here.<sup>31</sup> This article aims to identify the key issues with respect to the structure of the present program, and provide a perspective on alternatives. What constitutes adequate reform is an important question that warrants more attention by legal academics, the medical community, and the public.

---

28. Binyamin Appelbaum & Eris Dash, *S.&P. Downgrades Debt Rating of U.S. for the First Time*, N.Y. TIMES, Aug. 6, 2011, at A1.

29. FISCAL COMM’N REPORT, *supra* note 25, at 20, Recommendation 1.1; see also Damian Paletta, *Key Tax Breaks at Risk as Panel Looks at Cuts*, WALL ST. J., Oct. 25, 2010, at A1 (reporting that the Commission was looking at freezing domestic discretionary funding).

30. Sheryl Gay Stolberg, *Obama Proposing Bipartisan Effort to Win the Future*, N.Y. TIMES, Jan. 26, 2011, at A1. President Obama also supported \$78 billion in cuts to the Pentagon’s budget over five years. *Id.*

31. *See supra* note 1 and accompanying text.

In exploring the reforms needed, Part II provides an overview of the drug approval requirements and the history of the drug user fee program. The discussion surveys the present basis for determining user fee funding, the accomplishments of the program, and the responses that have already been made to the criticisms of the program.

Part III examines reforms needed in the drug user fee program that relate to its overall aims and justifications. The discussion criticizes the “service” rationale for user fees and identifies an alternative health rationale based on drug risks and health priorities. This Part also urges a study to establish priorities for drugs that reflect these health factors. If user fees are limited in the future because of budget deficits or to avoid the risk of capture, there may be a delay in meeting review goals. The priorities for review will become more important in a time of constricted funding. Additionally, manufacturers may be concerned about the impact of delay on the remaining patent life of a drug, an issue also noted in this Part.

Part IV examines measures to deal with the capture problem associated with relying on industry fees to support a major part of the costs of the drug review. The discussion covers why, at a minimum, the fees should not exceed the amount appropriated from government funds.

Part V considers whether the drug user fee program should be made permanent as a way to deal with the linkage problem and the concerns about industry influence that result from the periodic sunset of the drug user fee program. One argument against this type of change is that it could lessen Congress’s role in allocating scarce funds if concerns about the deficit lead to general cutbacks in government programs. The adoption of a permanent program, therefore, should provide that the drug fees are subject to general cuts in funding, absent a specific exemption. This will reinforce Congress’s responsibility to make the difficult decisions on funding priorities in the face of cutbacks.

Part VI concludes the article by emphasizing the need for user fee reform to deal with the risk of capture and the leverage that the current sunset provision provides the drug industry. Solving these problems by providing for a formula to govern the level of support for the drug user fee program is questionable given the cutbacks that other programs may face because of the deficit. Congress needs to retain responsibility for determining the level of support for the drug user fee program in relationship to similar public programs when there is not enough to meet all of the needs.



## II. FRAMEWORK FOR DRUG USER FEE PROGRAM AND HISTORY

This Part will provide an overview of the FDA's statutory authority for approval of drugs, and the drug user fee program. Additionally, the discussion will survey positive accomplishments, criticisms, and the responses to concerns that have arisen. The Parts following will explore further reform approaches to deal with the concerns about capture and the sunset of the fees.

### A. Drug Approval Requirements

Before a new drug can be sold in the United States, the FDA must find that the drug is "safe and effective" for its use based on "adequate and well-controlled studies" submitted to the agency in a new drug application (NDA).<sup>32</sup> Drugs can contain powerful chemicals that may pose serious or life-threatening side effects.<sup>33</sup> Their safety has to be determined on a risk-benefit basis.<sup>34</sup> In evaluating the risks and benefits of a potential drug, and to guard against the placebo effect, the agency conducts controlled tests before determining that the drug is safe and effective for use.<sup>35</sup>

### B. Framework of the Drug User Fee Program

This subsection will provide an overview of the need for additional funding for the FDA, the fee levels, and the agency's goals on timeliness.

#### 1. Origins and Concern with Drug Lag

David Kessler, who was the FDA commissioner when user fees were approved in 1992, saw the program as a way to respond to the criticisms that new drug therapies were approved faster in Europe than in the

---

32. 21 U.S.C. § 355(b), (d)–(e) (Supp. 2011). For an overview of the law see Merrill, *supra* note 3, at 1764–69.

33. See Zelaney, *supra* note 2, at 264–65 (describing the Elixir Sulfanilamide Tragedy of 1937 where "over 100 people, many of whom were children, died after ingesting S.E. Massengill's new antibiotic product" and Congress reacted by passing the Federal Food, Drug, and Cosmetic Act of 1938); Merrill, *supra* note 3, at 1764 ("Drugs [are], after all, biologically active agents and thus inherently posed some risk.").

34. See HUTT ET AL., *supra* note 10, at 694–96 (quoting the testimony of FDA Commissioner George Larrick from a 1964 House hearing where he stated "[t]he decision to approve a drug for marketing, or to withdraw an earlier approval requires a weighing of the benefit to expected from use . . . against the risk inherent in its use").

35. See Merrill, *supra* note 3, at 1771.

United States, thus creating a “drug lag” in the U.S. approval process.<sup>36</sup> At that point, the time between the testing and obtaining approval of an NDA had reached a remarkable thirteen years.<sup>37</sup> The drug user fee program was intended to decrease the amount of time that passed between when a drug company submitted an NDA and the time at which the agency determined whether the NDA would be approved.<sup>38</sup> The AIDS crisis provided a dramatic illustration of the health drawbacks of delay in approving therapies to treat life-threatening conditions, which, because of the AIDS crisis, led the agency to develop measures to expedite approval of promising drugs even before full testing was completed.<sup>39</sup> The drug industry was also willing to support the user fees because the lag time between submission of the NDA and the drug’s approval dramatically cut into the remaining patent life of the drug, thereby reducing one’s revenue.<sup>40</sup> Furthermore, the growth in the federal deficit may have provided additional support for obtaining funding from fees rather than general government appropriations.<sup>41</sup>

## 2. Fee Determinations and Impact on Industry

The law provides that each drug manufacturer who seeks approval for an NDA has to pay a fee,<sup>42</sup> which originally was \$100,000 but rose to \$896,200 in 2007.<sup>43</sup> The amount for applications involving clinical data for

---

36. See Zelenay, *supra* note 2, at 271–72, 275–78 (describing the genesis and consequences of the drug lag and outlining a history of the events and consensus leading up to the creation of PDUFA in 1992).

37. See *id.* at 272.

38. See *infra* note 57 and accompanying text.

39. See HUTT ET AL., *supra* note 10, at 648–50.

40. See Zelenay, *supra* note 2, at 278 (during negotiations with the FDA over the approval of PDUFA, the pharmaceutical companies’ lobbying group “asserted it would support user fee legislation only if FDA agreed to certain requirements,” including that fees were “wed to a long-term commitment by FDA to reduce drug approval times,” which the FDA agreed to); *id.* at 272 (noting that the drug lag “obviously translated into greater research and development (R&D) costs for the pharmaceutical industry”); see also *infra* note 116 and accompanying text (describing how the time lag for drug approval decreases the number of years the drug is on the market with patent protection).

41. See Zelenay, *supra* note 2, at 276 n.138. For a history of the FDA’s reluctance to impose user fees and its later acceptance, see *Federal User Fees*, *supra* note 19, at 851–52.

42. See 21 U.S.C. § 379h(a).

43. WHITE PAPER, PRESCRIPTION DRUG USER FEE ACT (PDUFA): ADDING RESOURCES AND IMPROVING PERFORMANCE IN FDA REVIEW OF NEW DRUG APPLICATIONS 14–16 (2005), available at <http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM149130.pdf> [hereinafter FDA WHITE PAPER 2005].

fiscal year 2012 is \$1,841,500.<sup>44</sup> In fiscal year 2012, companies must also pay an establishment fee of \$520,100 and a product fee of \$98,970.<sup>45</sup> The basis for the fees is set by a formula that builds on the 1992 levels, and takes both inflation and workload adjustments into account.<sup>46</sup>

The constantly escalating fees have led to criticism (and greater scrutiny).<sup>47</sup> Industry participants have questioned whether the FDA needs to have ten or twenty staff people attend a meeting with a drug company when only two or three participate in the discussion.<sup>48</sup> The agency has recently completed a new building complex in White Oak, Maryland, and it is possible that some of the increase in fees may be attributable to the drug user fee program's share of the construction costs. A full exploration of the reasons for the growth are beyond the scope of this article, and would need a separate study.

Another concern, from the drug industry's perspective, is that the easy ways to speed up the review process have already been made, and there would be "diminishing returns" for the industry in simply expanding the scale of funding.<sup>49</sup> One author suggests that to "get more drugs approved faster," there is a need to focus on the entire process, including requirements for pre-clinical studies.<sup>50</sup> Given this view of the program's aim, the next reauthorization process may seek to have changes in the pre-clinical stage as well.

### 3. Commitments on Performance Goals for Priority and Standard Drugs

The FDA's "performance goals" for reviewing an application for approval distinguish between two categories, that of priority drugs and that

---

44. Notice: Prescription Drug User Fee Rates for Fiscal Year 2012, 76 Fed. Reg. 45831 (Aug. 1, 2011) [hereinafter FY 2012 PDUFA User Fee Rates].

45. *Id.*

46. See 21 U.S.C. § 379h(c)(1), (c)(2) (2006).

47. See, e.g., Henry I. Miller, *The FDA's Imprudent Caution*, POL'Y REV., June–July 2010, at 73, 78–79, available at <http://www.hoover.org/publications/policy-review/article/5325> (criticizing the "constantly escalating" user fees as a discriminatory tax on the drug sector and one that small companies can "ill-afford").

48. See HUTT ET AL., *supra* note 10, at 684.

49. See HUTT ET AL., *supra* note 10, at 682–83 (citing Steve Urslin, *Diminishing Returns*, BIOCENTURY, Feb. 13, 2006 at A1) (describing how each year drug user fees account for more of the costs paid for reviewing applications but "most of the progress in reducing review and approval times was made in the first two years—between 1993 and 1995").

50. *Id.* at 683.

of standard drugs.<sup>51</sup> The current goal for priority drugs is for the FDA to complete ninety percent of the reviews in six months, while the goal for standard drugs is to complete 90 percent in ten months.<sup>52</sup> The agency commitments are not part of the law but are stated in letters to the congressional committees as goals the agency will seek to observe.<sup>53</sup>

### C. Positive Accomplishments

This subsection notes the improvements in the timing of reviews made possible by the fees and the added authority the agency has received as part of the user fee renewal process.

The drug user fee program has largely alleviated the drug lag between drugs approved in this country as compared to Europe, increased the likelihood that drugs will be sold here first,<sup>54</sup> and changed the agency's culture.<sup>55</sup> By fiscal year 2010, the agency anticipated it would meet almost all of the performance goals, helped by the decline in the number of filings for original NDAs.<sup>56</sup>

The drug user fee program was originally aimed at providing funding and performance goals to permit faster agency action on the applications for new drugs.<sup>57</sup> As discussed below, some believe that the need to renew the fees can hold the agency hostage to accepting debatable measures.<sup>58</sup> The need to renew fees can also lead to changes that strengthen the agency's authority. A notable example occurred when cardiovascular risks were found in the widely used arthritis drug Vioxx after it was on the market.<sup>59</sup> The public's concerns led Congress to require a better sys-

51. See FY 2010 PDUFA PERFORMANCE REPORT, *supra* note 7, at Executive Summary (unnumbered page) (noting the different performance goals for standard and priority drugs).

52. *Id.* at 16.

53. 21 U.S.C. § 379 h-2 (a) (Supp. 2011). See FY 2010 PUDFA PERFORMANCE REPORT, *supra* note 7; HUTT ET AL., *supra* note 10, at 679; Miller, *supra* note 15, at 189–90.

54. See Olson, *supra* note 18, at 394–95.

55. See Merrill, *supra* note 3, at 1842.

56. See FY 2010 PDUFA PERFORMANCE REPORT, *supra* note 7, at Commissioner's Report (unnumbered page). In fiscal year (FY) 2008 and 2009, the agency met only one-third or one-half of the performance goals because of the added workload created by statutory amendments. See *id.*

57. See Zelenay, *supra* note 2, at 278–79; *supra* Part II.B.1.

58. See *infra* Part V.A.

59. See Margaret Gilhooley, *Vioxx's History and the Need for Better Procedures and Better Testing*, 37 SETON HALL L. REV. 941, 950–53, 957–58 (2007) (describing the FDA's immediate reactions after the discovery of Vioxx's high cardiovascular risks and the agency's now existing authority to withdraw drugs from the market); *id.*

tem for detecting post-approval risks and to strengthen the agency's authority to take action with respect to the risks.<sup>60</sup>

#### *D. Responses to Criticisms of the Renewal Negotiation and Inflation Adjustments*

The drug user fee program has received its share of criticism involving capture and linkage, which will be discussed in Parts V and VI. This section notes the responses to the criticisms of renewal negotiations and inflation adjustment calculations.

##### 1. Closed-Door Negotiations on Renewal and Minutes

User fees expire every five years, leading the industry and the agency to negotiate behind closed-doors for months about renewal.<sup>61</sup> These negotiations include the performance goals and commitments that the agency will seek to follow in reviewing applications.<sup>62</sup> In 2006, Commissioner Kessler stated that the negotiations raise "troubling questions" since the industry gains "leverage on setting the agency's priorities" and especially so when "a growing percentage" of the budget comes from the fees.<sup>63</sup> Nonetheless, he did not think the FDA had been compromised so far.<sup>64</sup>

To deal with this problem of leverage and the risk of extraneous arguments that might be made in private negotiations, the law now provides that the minutes of the meetings between the industry and the agency are to be publicly available and are to summarize any "substantive

at 960-61 (providing an overview of legislative changes that provide post-approval testing and warnings that strengthen the FDA's enforcement powers).

60. See IOM REPORT, *supra* note 12, at 4-5, 11 (recommendations 5.1 and 5.2 ask that Congress ensure that the FDA has the ability to make post-marketing risk assessment and risk management programs to monitor and ensure safe use of drug products and to provide the FDA the authorized authority to carryout its drug safety responsibilities); Gilhooley, *supra* note 59, at 960-61 (describing a law that authorizes the FDA "to require a drug sponsor to conduct post-approval studies or clinical studies for a drug" and "strengthen[s] the [FDA's] enforcement powers by giving . . . the authority to impose fines or civil money penalties"). At one point, the FDA's removal of seven drugs from the market was seen by some as an indication that drugs were being approved too fast because of the user fee program. Zelenay, *supra* note 2, at 308-309, 308 n.410 (listing the seven drugs withdrawn from the market).

61. See 21 U.S.C. § 379 h-2(d)(1)(F) (2006) (permitting the FDA to have negotiations with the regulated industry over reauthorization); *supra* Part IV.A (describing the risk of undue influence of the pharmaceutical industry over the FDA because of the user fees the industry pays).

62. See 21 U.S.C. § 379 h-2(d) (2006).

63. *Financial Clout*, *supra* note 5.

64. *Id.*

proposals” made and any significant controversies.<sup>65</sup> The law also requires the agency to consult with experts, health care professionals, and representatives of “consumer advocacy groups” in developing recommendations, as well as two congressional committees.<sup>66</sup> Although the minutes can help provide some safeguard against inappropriate trade-offs, questions remain about the impact of the closed negotiations with the drug industry. Making the fees permanent would alleviate this downside of the present approach.

## 2. Complications in Making Inflation Adjustments

In the early years of the drug user fee program, user fees were available only if the appropriations for the drug user fee program were maintained at the 1992 level adjusted for inflation.<sup>67</sup> The formula, as it operated, meant that the agency had to shift appropriated funds to the drug review approval account from other programs in order to obtain user fees.<sup>68</sup> These shifts came at a cost of cutting back the support for funding of post-approval monitoring and even the food safety program.<sup>69</sup>

Congress alleviated the problem of having an exact match between appropriations and fees by authorizing a 3 percent flexibility range or cushion for determining compliance with the formula.<sup>70</sup> The lesson here might be that if Congress makes the drug user fee program permanent, and requires that it not exceed appropriated funds, there could be complications in working out the level of funds available, and a cushion may well be needed. The formula is important, but its working is beyond the scope of the present endeavor.

---

65. 21 U.S.C. § 379h-2(d)(6)(B).

66. *Id.* § 379h-2(d)(1)(A)–(E). The agency is to seek public input and hold public meetings “prior to beginning negotiations with the regulated industry on the reauthorization.” *Id.* § 379h-2(d)(2).

67. *See Zelenay, supra* note 2, at 277, 283–84.

68. *Id.* at 293. In 1997, the FDA was reported to have begged Congress to proceed quickly on user fee renewal because “it *needed* user fee reauthorization by June to maintain its programs and to avoid layoffs.” *Id.* at 294 n.302 (citing Jill Wechsler, *Congress Debates FDA Fees and Funding; Determination of Its Budget for Fiscal Year 1998 Will Be More Complex Than Usual*, BIOPHARM, Apr. 1997, at 12).

69. *See id.* at 293, 312 (indicating that shifting of funds may have come from food safety monitoring and post-market surveillance activities).

70. *See id.* at 318 (quoting 21 U.S.C. § 379h(g)(2)(B)).

### III. RATIONALE FOR USER FEES: SERVICE OR HEALTH REVIEW AND PRIORITIES

Before turning to the issues about capture and the need for a permanent program, this Part examines the need to move away from the fee-for-service rationale for user fees to one based on the need for a health risk-benefit review (Health Review). The Health Review rationale can provide better guidance to the agency and Congress on the priorities for the program that may become more significant in case of funding shortfalls.

#### A. *User Fees, Service Rationale, and Delegation Cases*

The imposition of user fees for government programs has been viewed as one that enables the agency to provide the “service” of making possible faster reviews in exchange for the fees paid by the industry under the law.<sup>71</sup> This characterization of the drug user fee program reflects the Supreme Court’s decision in *National Cable Television Ass’n v. United States*, which avoided issues about Congress’s constitutional ability to delegate authority to an agency to impose a tax by reading the statute as authorizing fees based on the value given to the recipient, rather than the public interest.<sup>72</sup> The standards used by the Court in reaching this decision have been described as failing to provide “a model of clarity.”<sup>73</sup>

Later, in *Skinner v. Mid-America Pipeline Co.*,<sup>74</sup> a case involving pipeline safety, the Court found that the validity of a delegation does not depend on whether it is made under the taxing power or some other

---

71. See *Financial Clout*, *supra* note 5 (stating that in the “early 1990s, companies unhappy with the pace of drug approvals agreed to pay the FDA millions of dollars in annual fees to help speed its performance”); Andrew C. von Eisenbach, *State of the FDA*, 62 *FOOD DRUG L.J.* 423, 425 (2007) (quoting a speech by the FDA Commissioner that his view on those “who question the current reliance on user fees, I would say only that user fees are simply that: a fee for a service”); see also Miller, *supra* note 15, at 190 (criticizing the linkage between the fees and performance measures as unnecessary and “appear[ing] to have a deleterious effect on public health”).

72. 415 U.S. 336, 341 (1974) (“A ‘fee’ connotes a ‘benefit’ and the Act by its use of the standard ‘value to the recipient’ carries that connotation. The addition of ‘public policy or interest served, and other pertinent facts,’ if read literally, carries an agency far from its customary orbit . . .”).

73. See, e.g., *Federal User Fees*, *supra* note 19, at 822–24 (suggesting the difficulties created by *National Cable Television* in distinguishing between taxes and fees and noting the Court’s concern for “constitutional constraints on the ability of Congress to delegate taxing power to agencies”).

74. 490 U.S. 212, 218 (1989).

power, but on whether the law provides adequate standards.<sup>75</sup> The Court found the standards to be adequate because the fees could only be spent for the pipeline safety program, and were set generically on the basis of miles or revenue.<sup>76</sup> Another important limit was that the agency could not expand its budget because the fees could not exceed 105 percent of the congressional appropriation in that year.<sup>77</sup> In effect, the agency was obliged to “set a fee that corresponds to some conception of what is ‘fair,’” rather than merely have the goal of making the agency self-sustaining.<sup>78</sup>

The drug user fee program meets this standard for delegation. The fees are authorized specifically for the drug user fee program and increases are largely driven by a formula that builds on a benchmark of spending in 1992.<sup>79</sup> The formula is, if anything, too automatic and has led to increases that cover over half of the cost of the drug approval program.<sup>80</sup> Being able to fairly impose fees requires consideration of the public interest as well as the industry’s concerns. As discussed next, a health review rationale serves that interest.

### *B. Health Risk-Benefit Review Rationale for Drug Fees*

The characterization, terminology, and rationale behind drug user fees are important issues, especially in light of competing demands on government funds. Thus, it is appropriate to consider alternatives to the “service” rationale for the drug user fee program and the adequacy of the standards.

---

75. *Id.* at 218 (“[S]o long as Congress provides an administrative agency with standards guiding its actions such that a court could ‘ascertain whether the will of Congress has been obeyed,’ no delegation of legislative authority trenching on the principle of separation of powers has occurred.”) (quoting *Mistretta v. United States*, 488 U.S. 361, 379 (1989)); see also Ronald J. Krotoszynski, *Reconsidering the Nondelegation Doctrine: Universal Service, the Power to Tax, and the Ratification Doctrine*, 80 IND. L.J. 239, 317–18 (2005) (suggesting difficulties for courts to analyze and react to statutes that fail to provide any limits on the amount of the tax or the ability of the agency to spend monies raised).

76. *Skinner*, 490 U.S. at 219–20.

77. *Id.* at 220; see also Krotoszynski, *supra* note 74, at 275 (noting that the Court limited the use of funds “only for purposes of administering the Pipeline Safety Acts, and that the fees had to be set generically”).

78. See *Federal User Fees*, *supra* note 19 at 827 (citation omitted).

79. See *supra* note 67 and accompanying text.

80. See HUTT ET AL., *supra* note 10, at 681–82 (as of 2005 user fees paid for over 50 percent of costs).



Under PDUFA, the fee is called a “user fee,”<sup>81</sup> but that term makes sense only for those who receive a special benefit from using government facilities, such as a visitor to a national park, or a driver on a highway who has to pay a toll. A drug company, however, is not like a visitor to a national park, as the drug company must obtain FDA approval before selling a new drug to the public.<sup>82</sup> The user fee, therefore, is a means of assisting the government in protecting the public from potential hazards.<sup>83</sup> The approval requirement was not intended as a benefit or service to the company, although, in practice, it may actually operate as one, since a lack of approval may serve as a barrier to entry and competition.<sup>84</sup> The fee may also increase “public confidence” in drug products.<sup>85</sup> While drug companies pay fees that allow the FDA to hire more reviewers, the ultimate aim of the agency review, and the fees, should be recognized as a means of protecting the public health.

Instead of a service rationale for fees, the drug user fee program and its fees should be guided by the need for a Health Review. New drugs contain powerful chemicals that can cause harm to users. Like other risky activities, such as pipeline safety, the government should be able to charge user fees that permit the agency to determine the risks. An analogy exists with respect to the government’s requirements for automobile emission testing and the imposition of fees by the state or a private company that does the emissions testing.<sup>86</sup> These fees are not to aid the indi-

---

81. See Prescription Drug User Fee Act of 1992, PUB. L. NO. 102-571, § 101, 106 Stat. 4491 (codified as amended at 21 U.S.C. § 379g (2006)).

82. See 21 U.S.C. §§ 355d–355e (2006); *supra* Part II.A.

83. See Prescription Drug User Fee Act of 1992, PUB. L. NO. 102-571, § 102, 106 Stat. 4498 (codified as amended at 21 U.S.C. § 379g (2006)) (“[T]he public health will be served by making additional funds available for the purpose of augmenting the resources of the Food and Drug Administration that are devoted to the process for review of human drug applications.”).

84. See Joseph Jadow, *Competition and “Quality” in the Drug Industry: The 1962 Kefauver-Harris Drug Amendments as Barriers to Entry*, ANTITRUST L. & ECON. REV., Winter 1971–72, at 103, 103.

85. See Memorandum from the Office of Mgmt. & Budget for Heads of Exec. Dep’ts & Establishments, Transmittal Memorandum No. 1 (July 7, 1993), available at [http://www.whitehouse.gov/omb/circulars\\_a025/](http://www.whitehouse.gov/omb/circulars_a025/) (finding that a “special benefit” can accrue when a federal activity “contributes to public confidence in the business activity of the beneficiary,” such as “insuring deposits in commercial banks”); *Federal User Fees*, *supra* note 19, at 874 (arguing that a user fee should not be less than the agency’s full costs where the governmental service “lessens the risk or burden that a commercial activity imposes on third parties,” such as safety inspections).

86. For example, in the past, state employees in New Jersey did the emissions inspections and charged a fee. See *N.J. ends auto inspections, limits emissions testing*, ASSOC. PRESS, Aug. 2, 2010, available at <http://www.nj.com/news/index.ssf/2010/08/>

vidual motorist, but to guard against the car being a source of air pollution that can harm the breathing public.<sup>87</sup> Likewise, the fee paid by the drug industry should not be seen as primarily benefiting the drug company that is paying the fee, but instead should be seen as protecting and benefiting the public at large who may consume the drug. FDA regulation increases public safety and consumer confidence in the drug, which “redounds to the benefit” of the company.<sup>88</sup>

Drugs can be considered safe only if their proven benefits outweigh the risk.<sup>89</sup> Drugs that do so are beneficial to the public, and an unnecessary delay in their approval can be a detriment to public health. Thus, a fee program to permit timely reviews of the safety and effectiveness of new products is a benefit to the public, and not solely to the company. The rationale for the drug user fee program should be focused on the health interest of the public, and should not be viewed as a tax or as a service that the agency owes to the company, as if the company were a funder or customer. Recognizing health as the rationale for the fees also directs more attention to the extent to which the program and the priorities for review serve the public’s health interest.

### C. Better Identification of Drug Priorities

This subsection discusses the generality of the agency’s existing criteria, and suggests the need for a study based on health factors that would provide better guidance.

#### 1. Existing Criteria

The amount of user fees for the drug user fee program is largely set by a formula.<sup>90</sup> The agency’s role is shaped by the performance goals that

---

nj\_ends\_auto\_inspections\_limit.html. Now, however, the state requires private inspections at service stations that charge set fees. *Id.* The Clean Air Act calls for emission testing as a way to reduce air pollution. See U.S. ENVTL. PROTECTION AGENCY, MILESTONES IN AUTO EMISSIONS CONTROL, <http://yosemite.epa.gov/R10/airpage.nsf/283d45bd5bb068e68825650f0064cdc2/b62803941b6599e088256c080074b33f!OpenDocument> (last visited Aug. 26, 2011) [hereinafter MILESTONES IN AUTO EMISSIONS CONTROL].

87. MILESTONES IN AUTO EMISSIONS CONTROL, *supra* note 86.

88. See *Federal User Fees*, *supra* note 19, at 852 (summarizing the FDA rationale for user fees at the time the agency sought congressional authorization for the user fee program).

89. See HUTT ET AL., *supra* note 10, at 685–86 (citing Drug Safety, Hearing Before H. Subcomm. on Gov’t Operations, 88th Cong. 2d Sess. (1964) (“We require[ ] information about effectiveness for . . . drugs in order to reach a decision about safety.”) (quoting testimony of FDA Comm’r George Larrick)).

90. See *supra* note 42 and accompanying text.

are set for the reviews of priority drugs and standard drugs.<sup>91</sup> The basis for determining priority drugs is a key determination that requires further explanation.

The agency's performance goals already recognize that priority drugs are reviewed faster than standard drugs.<sup>92</sup> Currently, the criteria used in determining whether a drug is a priority drug is solely based on whether a drug will serve an "unmet need" or has a "significant improvement over current treatment."<sup>93</sup> A standard drug is one that does not meet the criteria for being a priority drug.<sup>94</sup> The overall performance goal is to complete 90 percent of the reviews for priority drugs within six months, and the goal for standard drugs is to complete 90 percent of the reviews within ten months.<sup>95</sup> All the priority drugs, though, are lumped together into one category.<sup>96</sup> The law provides for "fast track" expedited agency review of drugs to treat serious or life-threatening conditions such as AIDS or cancer.<sup>97</sup> Nonetheless, drugs for expedited review do not even receive separate recognition as a top priority in meeting performance goals, although these drugs likely receive that ranking in practice. The FDA has also established performance goals for procedural and processing goals with respect to matters such as responding to meeting requests and dispute resolution matters.<sup>98</sup> Recently, the agency met the 90 percent performance goal for reviews of standard drugs but failed to meet the performance goal for priority drugs, completing only 80 percent of the reviews in the required timeframe.<sup>99</sup> The increased workload due to implementing statutory changes lowered performance.<sup>100</sup>

---

91. *See supra* Part II.B.3.

92. *See supra* Part II.B.3.

93. *See* FOOD & DRUG ADMIN., PRESCRIPTION DRUG USER FEE ACT III—INITIATIVES & EVALUATIONS, INDEPENDENT EVALUATION OF FDA'S FIRST CYCLE REVIEW PERFORMANCE—FINAL REPORT 15–16 (exhibit 10) (2008), available at <http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm127982.pdf> [hereinafter INDEPENDENT EVALUATION OF FDA'S FIRST CYCLE].

94. *See* HUTT ET AL., *supra* note 10, at 709 (citing CDER MANUAL OF POLICIES AND PROCEDURES 6020.3, PRIORITY REVIEW POLICY, Apr. 22, 1996) (defining all known non-priority drug applicants as standard review applicants).

95. *See supra* Part II.B.3.

96. *See* FDA WHITE PAPER 2005, *supra* note 43, at 14–16.

97. *See* 21 U.S.C. § 356 (2006); Investigational New Drug, Antibiotic, and Biological Drug Product Regulations; Procedures for Drugs Intended to Treat Life-Threatening and Severely Debilitating Diseases, 53 Fed. Reg. 41516 (Oct. 21, 1988) (codified at 21 C.F.R. pts. 312 and 314).

98. *See* FY 2010 PDUFA PERFORMANCE REPORT, *supra* note 7, at 29–40.

99. *Id.* at Executive Summary (unnumbered page).

100. *Id.* at Commissioner's Report (unnumbered page).

As Commissioner Kessler has observed, the negotiation process gives the industry leverage over the agency's ability to set priorities.<sup>101</sup> Better identification of the criteria for priority drugs is a means to emphasize the health-based concerns that underlie the public interest. The criteria may need to be taken into account in assessing the procedural goals for different types of drugs.

## 2. Need for Health-Based Priority Criteria

A study to develop better criteria for priority rankings is needed. If there is a funding gap for reviews, priority determinations will assume greater importance. Moreover, the health-based priority criteria can help guide the timing and process for drug reviews instead of the closed-door negotiations between the industry and the agency that now occurs.<sup>102</sup> The determination of priority criteria raises issues that need to be assessed by experts in medical research and drug policy and a study is needed to develop better rankings. One approach would be to have categories that designate a drug as representing a major advance, a moderate advance, a limited benefit, a dosage convenience, or some other factor.

If it is determined that more priority grades would be useful and this change is adopted, it should not mean that drugs in lower grades are reviewed only after the reviews are completed on the higher priority drugs. There should still be goals for each priority category, although they may differ by category, as they do now between priority and standard drugs. Lower priority drugs still have a health or user benefit that needs to be respected. A novel lifesaving drug might take a considerable amount of review time, and a lower priority drug might be reviewed in a much shorter time. Thus there are likely to be difficult judgment decisions in allocating resources among the priority drugs.

The drug's priority may be initially determined by the claim for the drug and its initial showing of support. The full testing for the drug, though, may increase or weaken the basis for that priority ranking. While the determinations may be difficult, the overall priorities are important to the public, doctors, and the industry, and more should be done to make the criteria open to public assessment.

## 3. Priority Rankings for Function Claims

A product can be a drug even if it does not provide a medical benefit in preventing or treating disease, since the definition of a drug also

---

101. See *Financial Clout*, *supra* note 5; see also *supra* notes 63–64 and accompanying text.

102. See *Financial Clout*, *supra* note 5; *supra* Part II.D.1.

includes products that “affect the structure or any function of the body.”<sup>103</sup> This category covers products that claim to have physiological effects, especially when the use has a safety impact.<sup>104</sup> Drugs can provide improvements in the functioning of the body, such as a helping with hair growth, restless leg syndrome, erectile dysfunction, or contraception. If funds are limited, another issue may be the extent to which there should be a higher priority for new applications for drugs for disease treatment, rather than for improved function. A study on drug priority criteria should consider whether the function category should be a separate category all together. Alternatively, instead of creating a separate category for drugs that provide function improvement, the study should also consider: (1) grouping these drugs with the priority drugs that are fashioned for disease treatment, and (2) basing priority on case-specific factors, such as the drug’s potential benefit for an important function versus the existing treatments that are available for improving that function.

#### 4. The Debatable Relevance of Cost in Priority Rankings

A study on priority drug criteria should address whether cost factors should have any role with respect to the rankings. The enactment of health care reform has increased concern with health care costs, an issue in which the FDA plays a limited role.

The FDA reviews the safety and efficacy of claims made for a drug, and does not consider cost factors. Cost considerations are generally left to health insurers, government payers, and individual patients, and some health insurers are now experimenting with ways to control costs, such as for the use of expensive drug combinations for cancer treatment.<sup>105</sup> Any

---

103. 21 U.S.C. § 321(g)(1)(C) (2006). The drug definition also includes products intended to prevent or treat disease. *Id.* § 321(g)(1)(B).

104. *See* *United States v. Article of Drug . . . Bacto-Unidisk*, 394 U.S. 784, 799 (1969) (classifying an antibiotic test laboratory aid to be a drug rather than a device based on the statutory purpose in protecting the public health); *United States v. An Article . . . Sudden Change*, 409 F.2d 734, 742 (2d. Cir. 1969) (classifying as a drug a face cream that claimed to provide “a face lift without surgery” because it constituted a representation that “affect[ed] the structure of the body in some medical—or drug-type fashion”); William Vodra et al., *Drug: General Requirements*, in DAVID ADAMS ET AL., *FOOD AND DRUG LAW AND REGULATION* 287 (2008) (finding that perhaps “the most difficult delineation of drug status” involves differentiating products that affect structure and function in a way covered by the drug definition from other FDA-regulated products).

105. *See* Reed Abelson, *Insurers Test New Cancer Pay System*, N.Y. TIMES, Oct. 20, 2010, at B1. Some former Medicare officials have also proposed that Medicare should pay for expensive treatments for three years but then cut the reimbursement rate to that of cheaper treatments if experience does not show that they work better.

study of the priority criteria to be used during the review process should consider whether cost factors should have any special relevance in the agency's determination of the timing of reviews. For example, if a drug manufacturer has expressly shown its drug to be cost effective, perhaps a higher priority ranking may be warranted.

#### *D. Study on Health Impact*

A study should also be conducted on the types of drugs approved since user fees started and on any differences before and after the program started with respect to the health status of the public. Such a study could help in developing priority criteria for the order in which drugs will be reviewed. Moreover, because the growing federal deficit seems likely to lead to cutbacks in many government programs, information about health impact can provide an important benchmark for determining an acceptable allocation of resources among programs when there is not enough to go around.

### IV. REFORM DIRECTIONS ON CAPTURE PROBLEM: FULL OR MATCHING GOVERNMENT FUNDING

This Part examines reforms to address the potential for agency capture when the fees paid by the industry cover a substantial amount of the costs for the drug approval program. The next Part focuses on the appropriateness of making the drug user fee program permanent to address the related concern about linkage when the fees have to be renewed.

#### *A. Capture Risks for Drug User Fees*

The risk of "capture" of an agency by the regulated industry is a problem that extends beyond the drug field. A leading article maintained that industries regulated or affected by government programs have a natural interest in influencing the program and seeking to shape its policies to serve the industry's interest, a problem referred to as the capture of an agency.<sup>106</sup> The ways in which capture can occur and the response needed is shaped by the nature and structure of the specific program.<sup>107</sup>

---

See David Leonhardt, *Proving Innovation in Medicare*, N.Y. TIMES, Oct. 20, 2010, at B1 (summarizing an article in Health Affairs in which this proposal is discussed).

106. See generally Stigler, *supra* note 13.

107. See *Federal User Fees*, *supra* note 19, at 873 (proposing an auction system as a response when "exclusive use or access to scarce resources" is at stake). For a reflection of the intensity of the debate about the grazing permits, see Robert H. Nelson, *Government as Theater: Toward a New Paradigm for the Public Lands*, 65 U. COLO. L. REV. 335, 337 (1994).

The user fees for drug reviews present a special risk of capture because the industry funding supports the salaries of the very individuals who review drugs for approval. Moreover, by 2005, user fees provided 56 percent of the funding for the drug user fee program.<sup>108</sup> The IOM reported that the industry itself was concerned with the perception that the “industry is paying for the review process.”<sup>109</sup> As noted above, in 2006 Commissioner Kessler stated that the negotiations over renewal of the fees raises troubling questions when “a growing percentage” of the budget comes from the fees, but he did not believe that the agency had been compromised so far.<sup>110</sup>

### *B. Reform Direction: Full Funding or a Match*

The options to alleviate the capture risks from industry funding, as discussed below, are to have no industry funding or to limit its extent.

#### 1. Full Government Funding and Added Revenue Sources

Eliminating user fees to support the agency’s drug user fee program would directly address the heightened concern about capture. Indeed, the IOM urged Congress to increase the resources provided to the FDA and favored having all of the funding for the drug user fee program come from general appropriations rather than user fees.<sup>111</sup> The IOM suggested studying additional revenue sources that could be used to support appropriations, including a tax on the revenues from prescription drugs that are directly advertised to consumers, commonly referred to as Direct-to-Consumer (DTC) advertisements.<sup>112</sup> Since newly approved drugs are often advertised on television to consumers, the tax might garner substantial revenues. On the other hand, the agency has to expend resources to review the advertisements with respect to any potential for deception or to address any new safety risks found in use,<sup>113</sup> which gives the linkage some basis, although an indirect one. The manner of calculating the tax is not

108. See HUTT ET AL., *supra* note 10 at 681–82 (citing Steve Urslin, *Cinderella’s Glass Slipper*, BIOCENTURY, Sept. 18, 2006, at A1).

109. IOM REPORT, *supra* note 12, at 196 (quoting a Pharmaceutical Research and Manufacturers of American (PhRMA) executive).

110. *Financial Clout*, *supra* note 5.

111. IOM REPORT, *supra* note 12, at 13, 197–98.

112. *Id.* at 198–99. The IOM also suggested a tax on drug sales but recognized the difficulties involved. *Id.* at 198. Fraud and abuse settlements in drug cases might arguably be another source, but these revenues may be viewed as a source of support health care.

113. See *infra* Part V.B.3 (relating FDA guidance principles and review of DTC ads); *supra* Part II.C.2 (discussing potential for post-approval risks that may create a need for an agency response).

clear though. In the end, a congressional enactment seems doubtful given the current political controversy about imposing new taxes.<sup>114</sup>

## 2. Capping User Fees and Its Impact

Another alternative is to ensure that the predominant part of the funding for the drug user fee program comes from government appropriations. Having the drug user fee program funded half by user fees and half by government appropriations is a reasonable alternative that provides added resources for the agency program while alleviating the capture problem.<sup>115</sup>

If Congress appropriates only a limited amount because of the increasing budget deficit, the agency may not be able to complete reviews within the performance time goals the industry or the agency would like. The agency should act as expeditiously as possible within the appropriations provided by Congress and do so first for priority drugs. The non-priority standard drugs will lag behind for approval if funds are short. That, however, does not mean that user fees should be allowed to exceed half of the amount appropriated. Instead, more attention needs to be given to the priority criteria that the agency should use if Congress does not find the means to provide additional funding. These priority criteria should be health-based, as discussed earlier, in Part III.

### C. *Manufacturer Patent Protections and Low Priority “Me-Too” Drugs*

If there is a limit on the funding for drug reviews because of budget deficit factors, the agency’s timeliness in making reviews is likely to be affected and especially so for the low-ranking priority drugs. The manufacturers of these drugs may be concerned with the impact that a longer time for agency review will have on the ticking patent clock.<sup>116</sup> Congress has already provided a patent extension of up to five years to reflect the

---

114. See Carol E. Lee & Damian Paletta, *Obama Stokes Deficit Fight—President Rips GOP Fiscal Plan, Says Mix of Taxes, Cuts Needed; Foes Dismayed*, WALL ST. J., Apr. 14, 2011 at A1 (stating that “Republicans reaffirmed their opposition to tax increases”); Jackie Calmes & Carl Hulse, *Part of the Budget Fight: Picking a Bad Guy*, N.Y. TIMES, Mar. 28, 2011, at A24 (noting that even “Democratic leaders have not pressed for raising taxes”).

115. A matching government appropriation can also provide added support for the delegation permitted under *Skinner v. Mid-America Pipeline Co.*, 490 U.S. 212, 218 (1989). See also Krotoszynski, *supra* note 75, at 241 (identifying the special concern about delegations of the taxing authority as related to ensuring that Congress takes “political responsibility for finding the means of paying for” a program it establishes).

116. See Kuhlik *Intellectual Property*, *supra* note 4, at 96–97 (noting that “[a]lthough the term of a patent is twenty years from filing, the effective patent life for pharmaceuticals—the time remaining following FDA approval—is approximately



time for FDA review and clinical trials, but if the time for review increases significantly, more relief may be sought.<sup>117</sup>

If additional patent protections are sought because of the “delay” in approval, ironically, the new protections may have the most benefit for drugs with the lowest priority ranking. The lowest priority is for a standard drug, which is a drug that does not provide a “significant improvement compared to marketed products.”<sup>118</sup> The FDA is likely to act slower on the least inventive drugs, resulting in more of their patent life expiring. Legislation providing for an extended patent life may benefit standard drugs that largely duplicate existing drugs and ones that have gone generic.<sup>119</sup> If additional patent protection is provided, consideration should be given to the need to have labeling and consumer advertising for a standard drug that adequately reflects the basis for the FDA’s non-priority ranking. The advertising, for example, might state that the drug is “another painkiller” or another drug for allergy relief or another therapeutic use for the drug. Consumers are unlikely to realize that drugs are not tested to show that they are an improvement over existing drugs when they do not claim to have a comparative advantage.<sup>120</sup> A disclosure like this, that the drug is an additional remedy to others in the class, can aid a doctor in advising a patient on the decision of which drug to choose. Trying to address the impact of delay in drug approvals for similar drugs raises difficult issues. This discussion aims to identify the issues at stake, and a possible way to address them.

---

eleven to twelve years in practice . . . [while] [e]ffective patent life for other industries averages approximately 18.5 years.”).

117. See 35 U.S.C. § 156(d)(5)(E)(g)(6)(A)–(B) (2006). See generally Suzan Kucukarslan & Jacqueline Cole, *Patent Extension Under the Drug Price Competition and Patent Term Restoration Act of 1984*, 49 FOOD & DRUG L.J. 511 (1994) (discussing the policy goals of the Patent Term Restoration Act and assessing the impact of the law on patent restoration).

118. See HUTT ET AL., *supra* note 10, at 709 (quoting CDER MANUAL OF POLICIES AND PROCEDURES 6020.3, PRIORITY REVIEW POLICY, Apr. 22, 1996).

119. See Joshua J. Gagne & Nitesh K. Choudhry, *How Many “Me-Too” Drugs Is Too Many?*, 305 J. AMER. MEDICAL ASS’N 711, 711 (Feb. 16, 2011) (maintaining that newly approved me-too drugs are likely to be much more heavily marketed and prescribed than generic drugs even in the absence of data to show that there are differences in clinical outcomes that warrant the higher price).

120. See HUTT ET AL., *supra* note 10, at 691 (“A history 1962 Amendments reveals a Congressional decision that the FDA not refuse to approve a drug on the ground of ‘relative efficacy,’ *i.e.*, that a more effective drug is available.”); Gagne & Choudhry, *supra* note 119, at 711 (describing the untoward effects of “me-too” drugs, which are drugs that achieve the same outcomes as drugs already on the market).

## V. “PRESSURE” AND LINKAGE: REFORM BY MAKING FEES PERMANENT?

This Part considers the periodic sunset of user fees, and the debate about whether the Obama administration might be “pressured” to accept questionable changes in order to avoid having to layoff needed medical reviewers. The 2012 round for renewing PDUFA should consider making the drug user fee program permanent as a way to address this concern. Before the program is made permanent, it is important, of course, to be sure that the substantive provisions are adequate. This Part surveys the reasons for having a permanent program and the drawback of having an automatic commitment of government funding to match the fees on a continuing basis. This article suggests that if fees are made permanent, the law should ensure that Congress makes the important decisions on how to allocate funds among competing needs at a time when concerns about the federal deficit may lead to significant cutbacks.

### A. *Funding Sunset: Potential for Pressure and Linkage*

The discussion here will survey the reports that the sunset has affected reviewers, creates pressure to accept questionable changes and gives the drug law a more tentative aspect.

#### 1. Pressure on Reviewers?

The existing authority for levying user fees is for a limited five-year period, and the industry’s support is important if Congress is to renew the fees.<sup>121</sup> The agency faces, in effect, a funding sunset for a critical program every five years, and the prospect of having to let go of half of its drug review staff.<sup>122</sup> Some report that the dependence on industry funding created an implied pressure to approve drugs and an agency culture that leaned towards approvals.<sup>123</sup> How much this perception persists might re-

---

121. See *supra* text accompanying note 1; Zelenay, *supra* note 2, at 294 (stating that in the 1997 reauthorization of PDUFA the “FDA would have preferred a ‘clean bill’ . . . [but] it was forced to accept Congress’ and industry’s desires for broader changes for fear that, unless it did so, PDUFA would not be re-authorized and FDA would be forced to fire most of its review staff”).

122. Zelenay, *supra* note 2, at 288. This problem was exacerbated before Congress adopted a cushion in determining the match between user fees and earlier appropriation levels. See *supra* text accompanying note 70.

123. See Zelenay, *supra* note 2, at 309 n.415 (quoting several FDA officials, including Dr. Solomon Sobol, a former director of the FDA, who stated that the “basic message [under PDUFA] is to *approve*,” and a former FDA Deputy Commissioner, who stated that “*there are some who argue that what Congress really wanted was not just decisions, but approvals*,” and also citing a “1998 survey of 53 FDA reviewers, of

quire an anonymous survey of the reviewers. The temporary funding for the drug user fee program has the potential to create anxiety for reviewers, which by itself is a factor that weighs in favor of a permanent program.<sup>124</sup> Congress may have reauthorized user fees in bills without substantive changes out of a concern that experienced drug reviewers would leave the agency because the time required for negotiations could lead to a gap in funding.<sup>125</sup>

## 2. Linkage and the 1997 Experience

The 1997 renewal is also notable because of the number of substantive changes made in the legislation that accompanied the renewal of PDUFA.<sup>126</sup> These included authorizing the FDA to approve “fast-track drugs” that had the potential to treat a serious or life-threatening condition based on “surrogate indicators,” with the sponsor to do further testing after the drug was on the market.<sup>127</sup> The law also allowed accredited third parties to make recommendations about the classification and review needed for medical devices.<sup>128</sup> Congress did not provide that the third-party reviews would have presumptive weight with respect to the approval of the drug, a change that could have fundamentally altered the agency’s role.<sup>129</sup>

The 1997 renewal also made changes that set the stage for two important constitutional challenges. First, a limit on advertising about pharmacy compounding of drugs led to a major Supreme Court decision that found the restriction to be in conflict with the protections for commercial speech.<sup>130</sup> Pharmacy compounding originally was a means for making minor variations of a drug to meet individual needs, based on a prescription,

---

whom ‘19 identified a total of 27 drugs that they reviewed that they believed should not have been approved but were approved’”) (citations omitted).

124. See *supra* text accompanying note 64 (noting former Commissioner Kessler’s view that the agency had thus far not been compromised by the leverage involved in PDUFA negotiations); *Financial Clout*, *supra* note 5 (noting that the FDA stated “it needs more money for its drug-review process, to meet growing costs and to fund services sought by companies”).

125. See Zelenay, *supra* note 2, at 315–16 n.456 (suggesting that in 2002 Congress reauthorized user fees without substantive changes in order to avert layoffs at the FDA and loss of talented employees if the law had been delayed by further negotiations).

126. *Id.* at 295–300 (identifying key differences in 1997 PDUFA from the 1992 PDUFA).

127. See 21 U.S.C. § 356 (2006); Zelenay, *supra* note 2, at 293–94, 294 n.300.

128. See 21 U.S.C. § 360m (2006).

129. See Merrill, *supra* note 3, at 1857–63.

130. See *Thompson v. W. States Med. Ctr.*, 535 U.S. 357 (2002).

such as making a better-tasting form of an unpleasant medication that a child might refuse to take.<sup>131</sup> The Court's decision permitted advertising of compounds (to encourage a wider market), so long as there is a disclosure about the lack of FDA approval.<sup>132</sup> Another provision in the renewal law limited the distribution of reprints of medical articles about off-label uses; this led to a district court finding that the limit was inconsistent with commercial speech rights.<sup>133</sup> This district court decision remains influential even though it was vacated on appeal on the grounds that the provision was a non-binding safe-harbor.<sup>134</sup> Thus the PDUFA renewals can set the stage for litigation on constitutional issues that might not otherwise have arisen.

### 3. Policy Drawbacks of Linkage of Funding to Reauthorization of a Substantive Law

The desirability of legislative changes is a matter of judgment, and there can be different views on the merits of these reforms among legislators and the administration, as well as between FDA officials and staff members. Still, it seems like poor public policy to make a major source of the agency's funding contingent upon congressional renewal of the user fees in bills that can include permanent substantive changes.

Typically, agencies have to obtain appropriations from Congress, and they may not get all the funding they want.<sup>135</sup> Appropriation bills, though, are presumed not to make substantive changes in the law, and their effect is for a limited time, unless Congress clearly indicates otherwise.<sup>136</sup> The drug user fee program, however, is different because the reauthorization for the fees is part of the substantive law and can be accompanied by substantive changes.<sup>137</sup> The funding renewal bill is a "must pass" bill that can become a vehicle for broader permanent changes.

---

131. *Id.* at 377.

132. See Margaret Gilhooley, *Drug Regulation and the Constitution After Western States*, 37 U. RICH. L. REV. 901, 912–13 & 933 (2003).

133. See Wash. Legal Found. v. Henney, 56 F. Supp. 2d 81, 87 (D.D.C. 1999).

134. See Wash. Legal Found. v. Henney, 202 F.3d 331, 335 (D.C. Cir. 2000).

135. See U.S. CONST. art. I, § 9, cl. 7 ("No Money shall be drawn from the Treasury, but in Consequence of Appropriations made by Law . . .").

136. See *Whatley v. District of Columbia*, 447 F.3d 814, 816 & 818 (D.C. Cir. 2006) (finding a rebuttable presumption that federal appropriations acts do not amend substantive law unless Congress clearly indicates the change is permanent).

137. See *supra* Part V.A.2 (describing some of the substantive changes of the 1997 renewal).

#### 4. The Impact of a Five-Year Timeframe

The renewal period for user fees tends to put the agency on a five-year timeframe for trying to anticipate the emerging issues, and the political landscape. The issues can be affected by sudden developments, as illustrated by the safety risk for Vioxx while it was on the market, which ultimately led Congress to expand the agency's authority to identify and address post-approval risks.<sup>138</sup> While this strengthening of the agency's safety authority is a positive change, some may disagree with the need or the scope of the changes. The important point is that the need to renew user fees provides a platform for raising substantive changes, with a deadline for resolving any debate about the merit of the changes.

Those who work or teach in this field are aware of when a PDUFA renewal is approaching. The drug law increasingly seems to have a tentative subject-to-change aspect. This undercuts the advantage of having a "permanent" law where the prospect of change is not periodically on the table. Making the user fee law permanent is one way to deal with the drawbacks and linkage that are associated with a sunset provision.

#### 5. Impact of *Citizens United*

The potential for politics to be a factor in the renewal legislation may be enhanced by the *Citizens United* case.<sup>139</sup> In this case, the Supreme Court recognized corporations as persons with rights of free speech protected by the First Amendment and found limits on corporate spending for endorsements or criticisms of political candidates to be unconstitutional when independent of the official campaign.<sup>140</sup> However, a requirement for disclosure of the corporate funding source would be permissible.<sup>141</sup> As a result, representatives and senators facing election may consider the possibility that pharmaceutical companies may sponsor advertisements in light of their votes on the user fee bill. Presidential candidates may also take into account the impact of drug company advertisements when the election is close to a renewal period, as it will be in 2012. Ending the sunset on user fees will reduce the potential for that heightened pressure.

#### B. Permanent User Fees and the Deficit

Making the user fees permanent would alleviate these problems, but doing so could obscure Congress and the President's responsibility in

---

138. See *supra* notes 59–60 and accompanying text.

139. 130 S. Ct. 876 (2010).

140. *Id.* at 886.

141. *Id.*

making the important decision of how to allocate government funds when there is not enough to go around. The discussion below relates to the status of a permanent program, the applicability of a general spending freeze, the maintenance of enforcement resources, and the equity issue.

### 1. An “Uncontrollable” Cost?

Making the user fees permanent has a drawback because it can introduce another “uncontrollable” budget cost at a time when the size of the federal budget is emerging as an important public concern.<sup>142</sup> The federal deficit keeps growing, and an intense debate has started on the need for change.<sup>143</sup> Indeed, the election of a Republican-controlled House led to a near shutdown of the federal government over budget issues.<sup>144</sup> However, whether cutbacks are needed is not the focus of this article. The concern here is the appropriateness of insulating the drug user fee program from reductions if a freeze or cuts in discretionary spending affect comparable programs. The President’s Fiscal Commission supported a freeze and cutbacks in areas of discretionary spending.<sup>145</sup> And President Obama supported a freeze on discretionary non-security programs in his 2011 State of the Union message;<sup>146</sup> he had earlier ordered a freeze on federal salaries, an approach that affects federal programs generally.<sup>147</sup> Therefore, whether the drug user fee program will be considered discretionary will have an important impact on the program’s ability to receive funding, which makes important the criteria for determining what are discretionary programs as well as the basis for making reductions in such discretionary programs.

### 2. Equity of Immunity from a Freeze

The major focus of the deficit and budget debate relates to major spending programs, including entitlement programs, such as Medicare and Social Security. The drug user fee program is not comparable to these entitlement programs with respect to the scale of the funding involved

---

142. See *supra* note 114.

143. See, e.g., FISCAL COMM’N REPORT, *supra* note 25.

144. See Carl Hulse, *Last Minute Budget Deal Averts Government Shutdown*, N.Y. TIMES, Apr. 9, 2011, at A1.

145. See FISCAL COMM’N REPORT, *supra* note 25, at 20–21 (Recommendation 1.1).

146. See Sheryl Gay Stolberg, *Obama Proposing Bipartisan Effort to Win the Future*, N.Y. TIMES, Jan. 26, 2011, at A1.

147. Peter Baker & Jackie Calmes, *Obama Declares Two-Year Freeze on Federal Pay*, N.Y. TIMES, Nov. 30, 2010, at A1.

and the expectations of recipients.<sup>148</sup> Instead, the drug user fee program is similar to regulatory programs that implement or enforce health and environmental standards. An important issue is whether the drug user fee program should be insulated from reductions that may affect similar regulatory programs. For example, if the federal government were to require an across the board spending freeze or funding cut for “discretionary federal programs,” would the drug user fee program be affected? Congress has already considered cutbacks on funding for early childhood education and public health, as well as food safety.<sup>149</sup> If these programs are cut, should spending on the drug user fee program continue and grow based on a formula? These questions are so much a matter of judgment, and are so significant and open to debate, that Congress needs to assume the responsibility for deciding on any special treatment for the drug user fee program. Moreover, Congress should develop ways to assess the public benefit generated from the different discretionary programs, and analyze the achievements to be expected from the various programs through continued funding. A study on the public health benefit achieved by newly approved drugs since user fees were adopted could help provide a benchmark and criteria in making these difficult assessments.<sup>150</sup>

---

148. The drug review program is authorized to have \$392,783,000 in support from user fees, with workload and inflation adjustments and additional funding of roughly a similar amount from government appropriations. See 21 U.S.C. § 379h(b)(1)(A)–(B), (b)(4)(B) & (c) (2006). Medicare spending in 2010 accounted for 12 percent of the federal budget and is expected to increase from \$519 billion in 2010 to \$929 billion in 2020. HENRY KAISER FAMILY FOUND., MEDICARE: MEDICARE SPENDING AND FINANCING 1 (Aug. 2010), available at <http://www.kff.org/medicare/upload/7305-05.pdf>. Furthermore, the Social Security trust fund is projected to be exhausted by 2036. See Bruce Bartlett, *The Real Social Security and Medicare Problem (and a Doable Fix)*, N.Y. TIMES, May 17, 2011, <http://economix.blogs.nytimes.com/2011/05/17/the-real-social-security-and-medicare-problemand-a-doable-fix>. One analysis projected that the trust fund’s long-term deficit is 1.2 percent of the G.D.P., but the shortfall could be addressed by increasing the tax rate to 16 percent, from 12.4 percent. *Id.*

149. See Carl Hulse, *Republicans Propose More Cuts in Spending*, N.Y. TIMES, May 11, 2011, <http://www.nytimes.com/2011/05/12/us/politics/12spend.html> (reporting that House Republicans on the House Appropriations Committee are considering cuts in discretionary spending, including food safety, college aid, early childhood education, and national infrastructure). Cuts in food safety could affect foreign inspections. See *FDA Would Reduce Foreign Food Inspections If Budget Cuts Pass*, INSIDE U.S. TRADE, June 10, 2011 (reporting that the proposed \$87 million cut in food-related programs could reduce inspections of Chinese food imports).

150. See *supra* Part III.D.

### 3. FDA Enforcement Resources and Direct-to-Consumer Advertising

Additional problems arise if a freeze applies to the resources available to ensure enforcement of compliance with the drug laws, a problem that could be compounded since the number of drugs approved would continue to grow because of the support from user fees. With human nature being what it is, the potential for compliance problems is likely to occur at a similar rate.

The compliance issues can be particularly important with respect to DTC television advertising, which manufacturers may run for newly approved drugs. The FDA has issued draft guidance on matters that need to be considered in making adequate and non-misleading disclosures of risk and benefit information in the DTC advertising.<sup>151</sup> The guidance details the range of factors that the agency considers in its review of the DTC advertising.<sup>152</sup> Without adequate support for the agency's review, disclosures about risk information in the advertisements may not be adequate. Thus, a cut in enforcement support can be detrimental.<sup>153</sup>

### 4. Congress's Role

Congress should be responsible for determining how to allocate funds among worthy projects in a time when there may not be enough funding to go around. This does not mean that the drug user fee program should continue to have the five-year sunset that currently exists. The drug user fee program should be "permanent" in the sense that it does not have an automatic five-year time limit, but the law should make it clear that Congress can reduce appropriations for the program as part of an overall deficit allocation review and adjustment to deal with deficit problems. Indeed, the program should be subject to any general cutbacks or freezes that occur in discretionary programs unless Congress specifically exempts the drug user fee program. Congress needs to look at the full range of federal programs and make determinations on how to "share the pain." Taking account of budget shortfalls is likely to be a painful and onerous process and perhaps there will be some fiscal solution that makes it unnecessary to deal with this difficult problem or perhaps there are better solutions than those raised here. This discussion is an effort to

---

151. See F.D.A., U.S. DEP'T OF HEALTH & HUMAN SERVS., GUIDANCE FOR INDUSTRY: PRESENTING RISK INFORMATION IN PRESCRIPTION DRUG AND MEDICAL DEVICE PROMOTION (May 2009), available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM155480.pdf>.

152. *Id.* at 6–18.

153. If government funding for compliance were to be reduced because of the deficit, another option would be to have user fees support enforcement needs, but the merit of that approach needs more evaluation.



identify factors that affect a complex issue and the need for a benchmark for assessing the fairness of the allocations among programs.

### 5. Shortfalls and Priorities

If government appropriations are reduced, the amount of user fees would also need to be scaled back to avoid the capture problem. If the funding and the fees are cut back, the agency is likely to fall behind on meeting the performance goals for acting on drug approvals. If there is a shortfall in funding, the agency should make the reviews based on the priorities discussed previously in Part III. Additionally, an extended period of delay may raise issues about lengthening the patent life of a drug, an issue also raised previously, in Part III.C.

## VI. CONCLUSION

Enacting drug legislation requires Congress to weave between the desirable, the political, and the constitutionally permissible.<sup>154</sup> The drug user fee program makes it necessary at present to tackle that balance every five years. The next renewal will be in fall 2012, before the presidential election. The problems identified in this article that concern the structure of the present program should be addressed.

User fees now provide more than half of the support for the agency's review of whether to approve a new drug as safe and effective.<sup>155</sup> The fees are to support timely agency decisions, and the agency and industry negotiate on the timeliness goals for the reviews and the plans for meeting those goals. Any further increases in the level of industry support can create a risk of capture and perception of undue influence by the industry. The law should be changed to ensure that the level of the fees cannot exceed the amount of funding provided through government appropriations.

The drug user fee program also expires every five years unless renewed. The sunset and need for congressional action can set the stage for legislative changes that might not have passed separately.<sup>156</sup> The potential for politics to be an important factor may be enhanced by the protections afforded to corporations in the *Citizens United* decision. Ending the sunset on user fees will reduce the potential for that heightened pressure. Making the drug user fee program permanent, though, has a drawback

---

154. Provisions enacted as part of user fee renewals set the stage for successful challenges on commercial speech grounds, as discussed in *supra* Part V.A.2.

155. See HUTT ET AL., *supra* note 10, at 681–82.

156. See *supra* Part V.A.2.

since it can insulate the drug user fee program from the funding reductions that other programs may face. If the drug user fee program is made permanent, Congress needs to retain its responsibility for determining the need for reductions in order to deal with the federal deficit on an equitable basis. To ensure this, the drug user fee program should be subject to any general freeze in discretionary spending, unless Congress and the President specifically exempt the program.

If the deficit necessitates reductions in the appropriations for the drug user fee program, there may be a delay in reviewing applications for approval of new drugs. That delay will make the criteria for determining priority drugs even more important. The effect on the public's health provides an appropriate benchmark for judging how much support is needed for user fees in relationship to other funding needs.<sup>157</sup> Congress needs to retain its responsibility for deciding how to equitably share the pain of budget shortfalls when the reductions impact important programs, including the one for drug approvals.

---

157. *See supra* Part III.C.2.

