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## A Legal Challenge of the Prescription Drug User Fee Act

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# A LEGAL CHALLENGE OF THE PRESCRIPTION DRUG USER FEE ACT

JIMMY J. ZHUANG\*

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## I. PDUFA AND ITS CONTROVERSY

From the 1970s through the early 1990s, the Food and Drug Administration (FDA) was heavily criticized for its slow approval process, which the agency in turn blamed on its lack of resources.<sup>1</sup> As a compromise, the Prescription Drug User Fee Act (PDUFA) was passed in 1992 to permit the FDA to charge drug manufacturers a user fee for reviewing new drug applications in order to supplement its Congressional appropriation.<sup>2</sup> Drug manufacturers pay this user fee to have their drug approvals reviewed on an expedited schedule.<sup>3</sup> Initially, PDUFA allowed the fees to be used only “to defray increases in the costs of . . . the review of human drug applications.”<sup>4</sup> Over time, this restraint of using PDUFA fees only as a “supplement” has eroded. By 2015, user fees accounted for 42% of the total FDA budget<sup>5</sup> and 64% of the FDA drug approval process budget.<sup>6</sup> For comparison, in 1997, PDUFA user fees only accounted

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<sup>1</sup> See generally, Ernst R. Berndt, Adrian H.B. Gottschalk, Tomas Philipson & Matthew W. Strobeck, *Assessing the Impacts of the Prescription Drug User Fee Acts (PDUFA) on the FDA Approval Process*, in 8 FORUM FOR HEALTH ECONOMICS & POLICY (Dana Goldman ed. 2005).

<sup>2</sup> PRESCRIPTION DRUG USER FEE ACT (PDUFA), <http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/> (last visited March 26, 2016).

<sup>3</sup> Patrick O’Leary, *Funding the FDA: Assessing the User Fee Provisions of the FDA Safety and Innovation Act of 2012*, 50 HARV. J. ON LEGIS. 239, 241-42 (2013).

<sup>4</sup> Pub. L. No. 102-571, § 736(g)(2)(B), 106 Stat. 4491, 4497 (1992).

<sup>5</sup> FY 2015 OPERATING PLAN NARRATIVE, FOOD AND DRUG ADMINISTRATION, available at <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/BudgetReports/UCM433147.pdf> (last accessed Feb. 23, 2015).

<sup>6</sup> *Id.*

for 8.5% of the total FDA budget.<sup>7</sup> This trend has raised questions about conflicts of interest as well as the drug approval process's quality.

Because PDUFA requires the FDA to respond to drug applications within 10 months, critics have noted the negative impacts this compressed timeframe could have on drug safety.<sup>8</sup> For every 10 month of reduced review time, there is a correlated 18% increase in serious adverse reactions, 11% increase in hospitalizations, and 7% increase in deaths related to an approved drug.<sup>9</sup> Even without gloomy empirical data, critics argue that this funding mechanism "systematically slants important policy choices," such as under-allocation of monies for post-approval safety surveillance, which drug manufacturers prefer not to be burdened with.<sup>10</sup> Finally, PDUFA opponents argue that its legislative history is replete with re-authorizations, extensions, and erosions of FDA independence, including explicitly allowing industry members to be on FDA advisory committees, which all point to thorough agency capture.<sup>11</sup>

However, PDUFA proponents also present compelling counterarguments. Recent empirical studies show that there has been "[n]o significant effect of PDUFA . . . on the rate of withdrawals of new-drug approvals" when comparing drug safety data before and after the Act's passage.<sup>12</sup> Furthermore, proponents argue that "nearly all of the decrease in approval times [after the PDUFA passage] would have been achieved . . . if the FDA received these funds as direct appropriations rather than relying on industry user fees,"<sup>13</sup> which makes PDUFA an economically efficient piece of legislation for having the drug industry internalize its own costs of safety. Furthermore, analytically, FDA bias for specific instances of drug approvals seems unlikely, as the "FDA's decisions on drug applications are functionally independent . . . [since] funds from the particular company are not paid directly to any individual reviewer or division within the agency."<sup>14</sup> In other words, PDUFA is not a quid pro quo; rather, it is a pay-to-play.

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<sup>7</sup> *Testimony on 1997 FDA Budget Proposal Before the Subcomm. on Agricultural, Rural Development, and Related Agencies of the S. Appropriations Comm.*, 104th Cong. (1996) (statement of David A. Kessler, Comm'r of FDA), available at <http://www.hhs.gov/asl/testify/t960502a.html> (last accessed Sept. 1, 2015).

<sup>8</sup> Donald W. Light, Joel Lexchin & Jonathan J. Darrow, *Institutional Corruption of Pharmaceuticals and the Myth of Safe and Effective Drugs*, 2013 J. LAW, MED. & ETHICS 590, 595.

<sup>9</sup> *Id.*

<sup>10</sup> Marc A. Rodwin, *Institutional Corruption and the Pharmaceutical Policy*, 2013 J. LAW, MED. & ETHICS 544, 548.

<sup>11</sup> James L. Zelenay, Jr., *The Prescription Drug User Fee Act: Is a Faster Food and Drug Administration Always a Better Food and Drug Administration?*, 60 FOOD & DRUG L.J. 261, 294 & 310 fn. 422 (2005).

<sup>12</sup> Henry Grabowski & Y. Richard Wang, *Do Faster Food and Drug Administration Drug Reviews Adversely Affect Patient Safety? An Analysis of the 1992 Prescription Drug User Fee Act*, 51 J. L. & ECON. 377, 410 (2008).

<sup>13</sup> Rochelle Lee, *FDA and Drug Safety: New Tufts Study Challenges Critics of the Prescription Drug User Fee Act*, 2006 J. L. MED. & ETHICS 131, 132.

<sup>14</sup> *Id.* at 131.

Thus, there are strong analytical and empirical arguments supporting both sides of this debate. Surprisingly, however, there is little legal analysis on PDUFA. In fact, the statute 21 U.S.C. § 379h on the FDA authority to assess user fees has hardly ever been litigated. Only three cases have been reported, and none of them challenge the legality or discretion of the FDA to charge these user fees, or even question the possible conflicts of interest PDUFA may pose.<sup>15</sup>

In Part II, I present a legal challenge to PDUFA from an administrative law perspective. While I share sympathies with those who believe PDUFA represents an unacceptable conflict of interest for the FDA, I posit arguments purely from the framework of permissible administrative agency discretion, so as to avoid ambivalent analytical and empirical arguments. My argument is that given the statutory and case law determinations of permissible federal agency discretion, the FDA cannot assess a flat user fee for widely variable types of services it renders during the drug approval process. Thus, the current implementation of PDUFA is legally impermissible. Subsequently, in Part III, I compare PDUFA to three other agency user-fee mechanisms and propose specific improvements to PDUFA to minimize its conflict of interest while maintaining its revenue efficiency.

## II. FDA'S OVERREACH

To start examining PDUFA's legal issues, one has to ask whether administrative law permits user fees to be as prominent of an agency's budget as PDUFA is for the FDA. The answer lies in 31 U.S.C. § 9701(a), which explains that "Congress [intends] . . . each service or thing of value provided by an agency . . . to be self-sustaining to the extent possible," and that the agency may "charge for a service or thing of value provided by the agency" to meet that self-sustaining goal.<sup>16</sup> At first glance, it seems that using PDUFA fees to sustain FDA operations is within an agency's discretion. However, the statute further elaborates that the agency discretion on the amount of fees to collect is to be based on four factors: equity, cost to the government for the service, value to the recipient of the service, and public interest.<sup>17</sup> PDUFA fails two of these factors: fees charged must be related to the value to the recipient and to the cost to the government for the service.

### A. Value to the Recipient

As a constitutional matter, the Supreme Court held in *National Cable Television v. FCC* that Congress granted federal agencies the power to exact self-sustaining fees, but not a power to tax.<sup>18</sup> A fee "bestows a benefit on the applicant, not shared by other members of society," whereas a tax theoretically bestows benefits on everyone in

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<sup>15</sup> *Pharmaceutical Research and Manufacturers of America v. HHS*, 2014 WL 2171089 (D.D.C. 2014) was litigated over a question of discounting the user fee for orphan drugs, *State-Trade Inc. v. FDA*, 869 F.Supp.2d 95 (D.D.C. 2012) was litigated over a question of whether a manufacturer seeking approval of two strengths of same drug should be assessed one user fee, and *Winston Labs v. Sebelius*, 2009 WL 8631071 (N.D. Ill. 2009) was litigated over a question of waiving the user fee for small businesses.

<sup>16</sup> 31 U.S.C. § 9701 (a)-(b) (2012).

<sup>17</sup> *Id.* at §(c).

<sup>18</sup> *Nat'l Cable Television Ass'n v. United States*, 415 U.S. 336, 341-42 (1974).

society.<sup>19</sup> Thus, the Court held that any user fees charged by a federal agency should be scrutinized for and tied to a specific “value to the recipient.”<sup>20</sup> In the related *Federal Power Commission v. New England Power* case, the Supreme Court clarified this standard by explaining that a federal agency may charge a user fee related to a measurable unit of service rendered for a specific recipient, but may not charge a fee based on an average from an entire industry, which would be equivalent to taxation.<sup>21</sup> Given these two seminal holdings, the § 9701(b) factor of value to the recipient limits agency discretion so that user fees must be charged on the basis of, and intrinsically measured by, the benefit received by a specific recipient.

PDUFA fails to meet this factor because it assesses a flat fee for almost all drug manufacturers.<sup>22</sup> Despite that, the FDA provides widely varying degrees of evaluation and guidance to manufacturers during the drug approval process. For example, drug sponsors can request different types of sponsor-FDA meetings;<sup>23</sup> additionally, many drugs now receive accelerated approvals: in 2012, 56% of all FDA-approved drugs had a faster-than-“normal” approval;<sup>24</sup> that number rose to 66% for 2014.<sup>25</sup> These examples all indicate that different drugs’ approvals take up highly variable amounts of regulatory attention. Nevertheless, the FDA assesses one flat \$2.3 million fee for all drug applications, regardless of the services received.<sup>26</sup> Therefore, the PDUFA user fee is not inherently tied to or measured by the amount of services received by an applicant, failing the standard enunciated in *National Cable Television*.<sup>27</sup>

#### B. Cost to the Government

The D.C. Circuit in *Capital Cities Communications v. FCC* explains that the cost to the government statutory factor “requires the fee assessed to bear a reasonable relationship to the cost of the services rendered [to the agency] . . . . This standard is not met where the persons who receive essentially the same physical services from the

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<sup>19</sup> *Id.* at 342.

<sup>20</sup> *Id.* at 343.

<sup>21</sup> *Federal Power Commission v. New England Power Co.*, 415 U.S. 345, 351 (1974).

<sup>22</sup> *Cf. Exceptions to Fee Requirements*, FDA, available at: [http://www.fda.gov/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/ucm069943.htm#P112\\_8652](http://www.fda.gov/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/ucm069943.htm#P112_8652) (last accessed Feb. 24, 2015).

<sup>23</sup> *See, e.g.*, GUIDANCE FOR INDUSTRY: FORMAL MEETINGS BETWEEN THE FDA AND SPONSORS OR APPLICANTS, FDA, 5, available at: <http://www.fda.gov/downloads/Drugs/Guidances/ucm153222.pdf> (last accessed Feb. 24, 2014) (“division director or designee who receives a meeting request will determine whether to hold the meeting.”).

<sup>24</sup> Jonathan J. Darrow, Jerry Avorn & Aaron S. Kesselheim, *New FDA Breakthrough-Drug Category – Implications for Patients*, 370 NEW ENG. J. MED. 1252, 1255 (2014).

<sup>25</sup> *FDA Approving More Drugs, Fighting Abuse Of Opioids, Acting Commissioner Says*, 43 PRODUCT SAFETY & LIABILITY REP. 550 (Apr. 27, 2015, Bloomberg).

<sup>26</sup> Prescription Drug User Fee Rates for FY 2015, 79 Fed. Reg. 44,807 (Aug. 1, 2014).

<sup>27</sup> *Id.*

agency are charged a grossly variable fee.”<sup>28</sup> The contrapositive is that an agency should not charge a flat fee for providing services with grossly variable costs.

PDUFA also fails to meet this test. In a survey of all clinical trials providing pivotal data used in FDA approvals from 2005-2012, investigators found substantial variance in the amount of clinical data submitted for various drugs in terms of size, duration, and repetition.<sup>29</sup> For example, cardiovascular drugs had on average three times as many patients in their clinical trials as dermatological drugs.<sup>30</sup> This suggests that the amount of data analyzed by the FDA is extremely variable across drugs. In fact, the FDA recognizes this variance as impacting its workload, which it admits varies “depending on factors such as therapeutic area, . . . amendment submissions, . . . [and] complex protocols.”<sup>31</sup> Therefore, the FDA charges a flat fee for services that cost the agency drastically differing degrees of effort and money, which fails the *Capital Cities*<sup>32</sup> standard of assessing agency user fees to reasonably correlate with the costs of rendering the service.

In summary, PDUFA is outside the permissible range of agency discretion. In assessing flat user fees not related to the dramatic variations in the services rendered to the payees and those services’ costs to the agency, the FDA is overstepping two 31 U.S.C. § 9701(b) statutory factors. Therefore, regardless of the analytical and empirical arguments for possible problematic conflicts of interest that user fees pose for the FDA, PDUFA could be challenged on purely legal grounds. An agency simply cannot assess a flat user fee for such variable services. In the next Part, I analyze three other user fee regimes for similar concerns and extrapolate from their structures improvements for PDUFA.

### III. WHAT THE FDA CAN LEARN FROM AIRLINES, ENVIRONMENTALISTS, AND PATENTS

Many federal and state agencies charge user fees to help sustain their operations. Unlike PDUFA, some of these fees have been heavily litigated. These disputes provide lessons for improving agency user fees schemes to ensure optimal service and efficiency. In this Part, I discuss three especially pedagogical user fee mistakes.

#### A. The FAA’s Overzealous Overflight

In 1996, the Federal Aviation Authority (FAA) sought to collect user fees on flights that crossed U.S. airspace but did not land or take off within the country.<sup>33</sup> The rationale was that without this additional fee, the FAA would only charge for a takeoff or landing event, which effectively provided no-cost FAA services to international

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<sup>28</sup> *Capital Cities Commc’n, Inc. v. Fed. Commc’n Comm’n*, 554 F.2d 1135, 1138 (D.C. Cir. 1976).

<sup>29</sup> Nicholas S. Downing et al., *Clinical Trial Evidence Supporting FDA Approval of Novel Therapeutic Agents, 2005-2012*, 311 J. AM. MED. ASS’N 368 (2014).

<sup>30</sup> *Id.* at 373.

<sup>31</sup> *Id.* at 12.

<sup>32</sup> *Capital Cities Commc’n, Inc. v. Fed. Commc’n Comm’n*, 554 F.2d at 1138.

<sup>33</sup> Federal Aviation Reauthorization Act of 1996, Pub. L. No. 104-264, 110 Stat. 3213 (1996).

airlines that only traversed through U.S. airspace.<sup>34</sup> This overflight user fee was quickly struck down by the D.C. Circuit in *Asiana Airlines v. FAA*, which held that these fees were not related to the cost of services provided by the agency, and that user “fees must be established in such a way that each flight pays according to the burden associated with servicing that flight.”<sup>35</sup> Thus, like my legal challenge of PDUFA, the FAA failed to consider the costs to the agency in its fee assessment discretion.

This FAA shortcoming stemmed from its failure to determine an appropriate user fee schedule. In estimating user fees, the FAA sought no input from the airlines themselves on how much usage there would actually be.<sup>36</sup> As a result, the actually assessed costs were extremely poor estimates of the real cost of servicing these overflights. A contemporary and analogous Canadian overflight user fee plan, which had much more rigorous fact-finding, assessed fees at only 1/3 of the American prices.<sup>37</sup> The lesson here is that industry input of potential costs of an agency service is invaluable in ensuring appropriately-priced user fees that reflect the costs of service to the agency.

This lesson can be applied to PDUFA. Because each new drug application contains highly variable amounts of clinical data for the FDA to assess,<sup>38</sup> the FDA should determine an individualized user fee for each submission. In doing so, the FDA can directly solicit input from the manufacturer on the costs and workload associated with analyzing its clinical trials, so as to appropriately price the cost of the workload for the FDA’s analysis of the submitted data. Furthermore, because this assessment is individualized, and can even incorporate costs like sponsor-FDA meetings or the need for accelerated approvals, these additional fees can be assessed *post hoc* after a smaller initial payment. For instance, with each decision letter – grant or deny – to a drug manufacturer, there could be an additional bill for the FDA services rendered. This significantly lessens any potential conflicts of interest or perverse incentives, as the fees are paid *ex post* purely for the services rendered, regardless of the outcome decision. This also more efficiently allocates funding, as manufacturers only pay for the costs directly related to the services received. Finally, this change still ensures PDUFA’s revenue stream for the FDA.

The FAA mistakenly estimated how much overflight usage there would be without asking the airlines about actual usage; the FDA should learn from this and not use a pre-submissions flat fee as a poor estimate of its service costs. Instead, by assessing costs post-decision, the FDA can better gauge service costs via actual usage, and in turn better structure PDUFA to lessen its conflicts.

#### *B. The New York DEC’s Budget Shortfall*

In 1983, the New York Department of Environmental Conservation (DEC) started to collect user fees to regulate air emissions, waste water discharges, hazardous waste

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<sup>34</sup> Roy Goldberg, *Will it Happen Again? — FAA’s Disastrous Prior Experience with User Fees*, 71 J. AIR L. & COM. 37, 38 (2006).

<sup>35</sup> *Asiana Airlines v. Fed. Aviation Admin.*, 134 F.3d 393, 402 (D.C. Cir. 1998) (internal quotations omitted).

<sup>36</sup> See Goldberg, *supra* note 34, at 41.

<sup>37</sup> *Id.* at 42.

<sup>38</sup> See *supra* Fee Rates, note **Error! Bookmark not defined.**

treatment, and solid waste disposal.<sup>39</sup> The triggering event for this was a cutback in federal environmental grants, resulting in a huge budget deficit for the DEC.<sup>40</sup> Unlike the FAA, the NYDEC did try to tailor user fees to the amount of regulatory attention a company required.<sup>41</sup> However, the fees still created a massive budget shortfall by not accounting for agency overhead. The fee schedule overlooked the burden of litigating non-meritorious contests of assessed user fees: the DEC charged a company the same user fee, proportional to the needed regulatory workload, even as the agency absorbed the cost of resolving disputes regarding the amount of user fees to assess.<sup>42</sup> Under the DEC paradigm, there was no information-forcing incentive for industry to be candid with the regulators; rather, industry had incentives to dispute all user fee amounts because it would not have to pay a higher fee even if it lost the dispute.

Conversely, in a regime where firms providing faulty or non-meritorious information are assessed additional punitive fees, the penalty creates incentives for industry to carefully monitor the information provided to an agency. This lesson can be incorporated to improve PDUFA. If the current flat user fee regime was tailored not only to the required workload, but also based on the outcome of the applications and clinical trials, it would incentivize higher-quality drug manufacturer information. Under such a proposed regime, any drug applications with sub-standard clinical trial performance should be assessed a penalty in addition to the normal user fee. Such a regime would efficiently deal with the obvious examples of by-choice bad drug applications that waste the FDA's time. However, more relevant to today's clinical trials,<sup>43</sup> by-necessity drug applications that only have one clinical trial (instead of the conventional minimum of two trials) or uses dramatically compressed timelines (due to circumstances like dire-need drugs with a small trial population) could also be assessed a higher-than-normal user fee. In turn, if those drugs are approved, the FDA could use that additional revenue to communicate the circumstances of that drug's approval to patients and physicians so that informative due warning is provided. This stick would force the drug manufacturers to elect to either provide better clinical information and thus greater patient safety, or pay the FDA a penalty so that the agency could use the revenue to disseminate caveats about its approval. This proposal also still ensures (and may actually increase) the FDA's revenues.

The New York DEC mistakenly overlooked the power of regulatory sticks to incentivize desired behavior; the FDA should learn this lesson and not passively accept low quality clinical trials. Instead, by assessing a higher fee for sub-standard clinical data – those by choice or by necessity – the FDA can incentivize higher-quality manufacturer practices, which in turn ensures better patient safety.

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<sup>39</sup> *Declaratory Ruling 72-01 In re Genesee Central School Dist.*, N.Y. DEP'T OF ENVTL. CONSERVATION, [http://www.dec.ny.gov/docs/legal\\_protection\\_pdf/72\\_01.pdf](http://www.dec.ny.gov/docs/legal_protection_pdf/72_01.pdf).

<sup>40</sup> David P. McCaffrey & Ronald H. Miller, *Improving Regulatory Information: New York's Transition to Environmental Fees*, 1986 PUB. MGMT. FORUM 75, 77.

<sup>41</sup> *Id.* at 78.

<sup>42</sup> *Id.* at 77.

<sup>43</sup> See Downing et al., *supra* note 29.



*C. Not All User Fees Are Created Equal*

The United States Patent and Trademark Office's budget is sustained almost entirely by user fees.<sup>44</sup> Critics argue that such structures set up perverse incentives for the USPTO to be trigger-happy about granting patents.<sup>45</sup> Professor Wasserman explains that

the fee structure of the PTO is such that fees from patent examinations cover less than one-third of the Agency's cost . . . . In contrast, the post-allowance [patent maintenance] fees the PTO collects are pure profits – these services cost the PTO practically nothing. Thus, the PTO has strong financial incentives to grant patents and this incentive systematically pushes the Agency's views on substantive patent law in the patent-protective direction.<sup>46</sup>

Thus, to mitigate this perverse incentive, one recommendation is to restructure the PTO user fees so that it is directly proportional to the cost of service to the agency, much like the *National Cable Television*<sup>47</sup> and *New England Power*<sup>48</sup> decisions had recommended. Therefore, the USPTO has been called upon to realign its fee structure so that the fees are paid primarily for the examination, rather than any costless-but-profitable post-grant maintenance.<sup>49</sup> In fact, the European Patent and Trademark Office has such a structure and charges almost three times as much as the USPTO for examining patent applications.<sup>50</sup>

The FDA and PDUFA face a very similar problem in its user fee structure. Of all the PDUFA user fees collected in 2013, only 35% are from the submission of a drug application.<sup>51</sup> The remainder is from either establishment fees – which each manufacturer with an active or submitted application pays annually – or product fees – which each drug with an active or submitted application pays annually.<sup>52</sup> While maintenance and surveillance of a marketed drug is obviously an active and costly

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<sup>44</sup> GLENN J. MCLOUGHLIN, CONG. RESEARCH SERV., RS20906, U.S. PATENT AND TRADEMARK OFFICE APPROPRIATIONS PROCESS: A BRIEF EXPLANATION 2 (2014) (USPTO has a \$3.458 billion budget for 2015, of which \$3.024 billion is collected from user fees.).

<sup>45</sup> Melissa F. Wasserman, *The PTO's Asymmetric Incentives: Pressure to Expand Substantive Patent Law*, 72 OHIO ST. L.J. 379, 432 (2011).

<sup>46</sup> *Id.*

<sup>47</sup> *Nat'l Cable Television Ass'n v. United States*, 415 U.S. 336, 341-42 (1974).

<sup>48</sup> *Federal Power Commission v. New England Power Co.*, 415 U.S. 345, 351 (1974).

<sup>49</sup> *A Glimpse under the Hood: How the USPTO Proposes to Adjust Patent Fees*, <http://www.patentdocs.org/2012/03/a-glimpse-under-the-hood-how-the-uspto-proposes-to-adjust-patent-fees-.html> (last visited Mar. 26, 2016).

<sup>50</sup> Wasserman, *supra* note 45.

<sup>51</sup> USER FEE COLLECTIONS, <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/UserFeeReports/FinancialReports/PDUFA/UCM398248.pdf> (last visited Mar. 26, 2016).

<sup>52</sup> FY 2013 PDUFA FINANCIAL REPORT, FDA, at 5, available at: <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/UserFeeReports/FinancialReports/PDUFA/UCM398248.pdf> (last accessed Feb. 25, 2015).

endeavor (much more so than the maintenance of a patent), this distortion in FDA fee collection still creates the possibility for perverse incentives. If the FDA is collecting the majority of its fees from maintaining drug approvals, what is to prevent it from taking a USPTO-like permissive attitude during the drug approval process? Moreover, the FDA already takes a rather passive role in post-approval market surveillance,<sup>53</sup> which lessens the justification for collecting the majority of user fees under such a purported maintenance purpose.

Therefore, as a third suggestion for improving PDUFA, the user fee structure should be adjusted to reduce incentives for the FDA to be overly permissive during drug approvals. To counteract allegations of agency capture from user fee funding, the majority of user fees should be collected for the drug application examination process itself, and not for anything post-approval. Even at the expense of over-collecting for application examination and having to redistribute these fees for other FDA purposes (such as overhead or post-market surveillance), the FDA should eliminate any systematic opportunities to profit from granted approvals. In essence, this conflict of interest is at the heart of PDUFA critics' arguments, and an appropriate user fee structure could go a long way to reassure such critics while still sustaining fee revenues from manufacturers.

#### IV. CONCLUSION

FDA Commissioner Hamburg has pointedly stated that the PDUFA user fees are not a quid pro quo.<sup>54</sup> Perhaps, in her mind, that seems to be the strongest counterargument to many critics' arguments about PDUFA's conflicts of interests. However, from a purely legal perspective, agency user fees need to be quid pro quo! 31 U.S.C. § 9701(a), *National Cable Television*<sup>55</sup>, *New England Power*<sup>56</sup>, and *Capital Cities Communications*<sup>57</sup> all explicitly hold that a federal agency's assessment of fees need to be tailored to the value of the services received and to the cost of the service to the agency. With so much variance among new drug applications in terms of services-needed and approval timelines, a flat user fee simply is not appropriate. Rather, working within permissible agency fee discretion can actually decrease

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<sup>53</sup> See, e.g., Leslie Pray & Sally Robinson, *Rapporteurs, Forum on Drug Discovery, Development, and Translation*, in CHALLENGES FOR THE FDA: THE FUTURE OF DRUG SAFETY, WORKSHOP SUMMARY 62-63 (2007)

At the time of approval, the FDA often negotiates hurriedly with a company to design a Phase IV study. While the company may have agreed to conduct the study prior to approval, the FDA has few options for ensuring that it actually meets that commitment once the drug is on the market. Because these studies may be negotiated quickly at the last moment, they [also] can be poorly designed. As a result, a company may have difficulty gaining approval for such a study from an institutional review board (IRB) or enrolling subjects, or may conduct the study but end up with meaningless results. *Id.*

<sup>54</sup> Margaret A. Hamburg, FDA Commissioner, Address at the Yale Law School FDA Law class (Apr. 22, 2015).

<sup>55</sup> *Nat'l Cable Television Ass'n Inc. v. Fed. Comm'n Comm'n*, 415 U.S. 336, 341-42 (1974).

<sup>56</sup> *Fed. Power Comm'n v. New England Power Co.*, 415 U.S. 345, 351 (1974).

<sup>57</sup> *Capital Cities Comm'n, Inc. v. Fed. Comm'n Comm'n*, 554 F.2d 1135, 1137-38 (Fed. Cir. 1976).

perceived conflicts of interest. For example, charging a reduced flat fee upfront and assessing additional cost-of-service fees *post-decision* mitigates concerns about fees impacting approval decisions, while also achieving cost tailoring. Similarly, penalizing sub-standard clinical data serves an information-forcing purpose without jeopardizing revenue. These structural changes do much more to alleviate conflicts while sustaining revenues than denying fee tailoring altogether. And most importantly, such user fee tailoring would actually make PDUFA legal.