

**PRIVITIZATION OF THE FDA: TOWARD A FASTER DRUG APPROVAL  
PROCESS**

by  
*Shawn Goldman*

**FOOD & DRUG LAW  
Professor Neal Fortin  
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# PRIVITIZATION OF THE FDA: TOWARD A FASTER DRUG APPROVAL PROCESS

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## INTRODUCTION

The average time it took the Food and Drug Administration (FDA) to approve a new drug from the time of application filing to final approval was 29 months in the first half of 2005.<sup>1</sup> The average time this process took in the first half of 2004 was 16 months.<sup>2</sup> It is no wonder, therefore, that there have been calls from various organizations, individuals, and even the FDA itself for reforms in the past.<sup>3</sup> These calls for reform largely contain some element of privatization.<sup>4</sup>

This idea of privatization of a fundamental function of the FDA is hardly a new one. Proposals for privatization date back at least as far as the tenure of President H.W. Bush, when Dan Quayle's Council on Competitiveness included in its recommendations on FDA reform a provision which called for the review of more routine drugs, such as antibiotics and anti-inflammatory drugs by private contractors with final authority still

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<sup>1</sup> Gardiner Harris, *FDA Responds to Criticism with New Caution*, N.Y. Times, Aug. 6, 2005.

<sup>2</sup> *Id.*

<sup>3</sup> Elizabeth M. Rutherford, *The FDA and "Privatization" – The Drug Approval Process*, 50 Food & Drug L.J. 203 (1995).

<sup>4</sup> *Id.* at 203.

resting in the hands of the FDA.<sup>5</sup> These calls for privatization continued when the Republican party regained control of Congress in 1994, when people such as then House Majority Leader Newt Gingrich described the FDA as “the leading job-killer in America” and described then FDA Commissioner David Kessler as a “bully and a thug”<sup>6</sup> For his part, former House Commerce Chairman Representative Thomas Billey vowed, “I promise you, this session in the Commerce Committee there will – repeat, there *will* – be reforms in the way the FDA does business”<sup>7</sup>

For all this hand ringing, regulation at the FDA remained largely the same throughout the 104<sup>th</sup> Congress, despite the announcement of a length list of reforms in 1995 in a grandiosely titled press release, “Reinventing Drug and Medical Device Regulation.”<sup>8</sup> This continued to be the case even after 1997 when Congress passed the FDA Modernization Act, which Robert Yetter, associate direct for policy at the FDA’s Center for Biologics Evaluation and Researched, declared in 1999, “...put into law many things that FDA was already doing.”<sup>9</sup> It is therefore of no surprise, that continued calls for steeper reforms and privatization continue to this day.

But what are the relative merits of privatization? Is it ultimately desirable? In this paper, the benefits and detrimental effects of privatization will be discussed. In so doing the paper will attempt to provide insight onto the true quality of proposals that call for the partial dismantling of one of the largest parts of the administrative state. Answers to criticisms of privatization, as well answers to the potential benefits of privatization will be presented and weighed.

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<sup>5</sup> Philip J. Hilts , *Proposal Seeks to Speed Up Federal Approval of Drugs*, N.Y. Times, Nov. 9, 1991.

<sup>6</sup> 50 Food & Drug L.J. at 205.

<sup>7</sup> *Id.*

<sup>8</sup> Henry I. Miller, *To America’s Health: A Proposal to Reform the Food and Drug Administration*, 49 (Hoover Institute Press 2000).

<sup>9</sup> *Id.* at 50.

After this analysis of the general merits of privatization, this paper will analyze the various specific proposals for privatization that have existed over the years. One proposal advocated by the Competitive Enterprise Institute, calls for the complete deregulation of the drug approval process, eliminating the standards of safety and efficacy and instead would leave the process strictly in the hands of the free market.<sup>10</sup> Another proposal was first put forth by the Progress and Freedom Foundation(PFF) in 1996 and involves Drug Certification Bodies(DCBs), non-governmental organizations that offer drug approval services directly to the pharmaceutical industry. This proposal was further outlined by Dr. Henry Miller in his book *To America's Health: A Proposal to Reform the Food and Drug Administration*.<sup>11</sup> The proposal of the PFF still leaves final approval of the drug in the hands of the FDA.<sup>12</sup> The final proposal that will be analyzed is very similar to the PFF proposal, only it goes a step further and eliminates the FDA from the final approval, and instead allows for these DCBs to perform the final approval themselves.

Finally, a policy recommendation will be made as to the proper direction that Congress should take in order to properly address the current problems that exist in federal drug regulation.

## I. BENEFITS AND PITFALLS OF FDA PRIVATIZATION

There are several frequently cited reasons to why privatization is desirable. Some of the more commonly cited benefits include reasons such as an increased speed from the point in time that the drug application enters the process from the point of final FDA

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<sup>10</sup> Elizabeth C. Price, *Teaching the Elephant to Dance: Privatizing the FDA Review Process*, 51 Food and Drug L.J. 651, 656.

<sup>11</sup> Henry I. Miller, *To America's Health: A Proposal to Reform the Food and Drug Administration* (Hoover Institute Press 2000).

<sup>12</sup> *Id.* at 72-73.

approval.<sup>13</sup> Another potential cited benefit of privatization is the elimination of the potential monopolistic abuse of power by the FDA.<sup>14</sup> Coupled with this monopolistic abuse is the idea that FDA decision-making is someone prone to arbitrariness and fear based decision making. These three things together, provide the impetus for much of the calls for reform of the FDA.

On the other hand, privatization has several potential pitfalls that critics of the proposals present. The first of these criticisms is that private reviewers will not have the same concern for public safety that the government reviewers at the FDA possess.<sup>15</sup> A second criticism is that since these third-party reviewers will engage in collusion with the pharmaceutical industry which is ultimately responsible for paying for their reviews.<sup>16</sup> A final criticism is that this private review process will result in a so called race to the bottom, whereby in an effort to attract clients from the industry, these organizations will engage in subpar work.<sup>17</sup>

### ***A. Benefits of Privatization***

The first, and ultimately perhaps most compelling reason for privatization is in order to quicken the drug approval process. A 1999 survey of emergency room physicians found that 64 percent of respondents considered the FDA too slow in approving new drugs and devices and 51 percent felt that the existing pharmaceutical regulations actually cost patients' lives.<sup>18</sup> A similar survey in 1998 found that 80 percent of respondent neurologists and neurosurgeons said that the FDA's current scheme hurt

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<sup>13</sup> 51 Food and Drug L.J. at 660.

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

<sup>15</sup> *Id.*

<sup>16</sup> *Id.*

<sup>17</sup> *Id.*

<sup>18</sup> *Miller, supra*, at 37.

their treatment of patients.<sup>19</sup> These surveys, conducted by the Competitive Enterprise Institute, the conservative think-tank responsible for one of the proposals for privatization, is not without its arterial motives, but even given that fact, these emergency room doctors are hardly the bulk wards of conservatism and a majority of them felt that the process was so slow that it was costing their patients' in some instances their lives. Clearly, if this truly is the case then anything that potentially speeds up the approval process is a good idea.

The second cited benefit to privatization of the FDA is potential abuse of its monopolistic power. Administrative agencies, such as the FDA, are given a wide amount of discretion in the modern state. This discretion is expressed in two forms. The first form it can take is the form of review of legal conclusions with regard to how to interpret the statute that defines the scope of the agency's authority.<sup>20</sup> Alternatively, this discretion can take the form of review of agency factual conclusions.<sup>21</sup> In both of these areas a wide degree of deference to the agency's decision-making is allowed, giving the administrative agency much authority in its decision-making. While the agency's authority in both factual and legal determination is far from absolute it is very powerful in many ways with very little check. A perfect example of this comes directly from the FDA itself. For many years the FDA was unwilling to regulate the tobacco industry due to its perception that it did not have the authority to do so. This all changed in 1996 when the FDA asserted the authority it had denied since its inception to regulate the tobacco industry.<sup>22</sup> Ultimately, the Supreme Court held that the FDA did not have the

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<sup>19</sup> *Id.* at 36-37

<sup>20</sup> *See* *Chevron U.S.A. v. Natural Resources Defense Council, Inc.* 467 U.S. 837 (1984).

<sup>21</sup> *See* *Universal Camera Corp. v. NLRB*, 340 U.S. 474 (1951).

<sup>22</sup> *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000).

authority under the relevant statute to regulate tobacco as a drug.<sup>23</sup> This was because the court ruled that Congress had created a distinct regulatory scheme to address the problems of tobacco and health, thus precluding the role of the FDA.<sup>24</sup> This case, however, is ultimately the exception that proves the rule. Unless Congress has specifically spoken on an issue in an expressed and unambiguous way, the Court must yield to any permissible agency construction of a statute. Most subjects of FDA drug regulation are not as openly debated in Congress as tobacco, and therefore in much of the area of FDA authority their decision-making authority is largely unquestioned. Ultimately, however, the real problem with the monopoly is not that the FDA attempts to regulate in new areas such as tobacco, but instead rests on their first power of factual determination. Courts are largely unwilling to question agency decisions that are made in the name of safety of efficacy.<sup>25</sup> This unwillingness to question in turn creates an often irrefutable presumption of validity for FDA decision-making.<sup>26</sup> This ultimately creates a real problem with monopoly, the lack of accountability for the decisions that are made.

This lack of accountability and monopoly ties directly into another problem with the current regulatory framework, that of arbitrary and fear-based decision making. The famed economist, Milton Friedman, was fond of saying that individuals and organizations are prone to act in their own self-interest.<sup>27</sup> Because of this desire for self-interest, much of the time spent by government officials, and FDA officials in particular is spent attempting to stay out of trouble and avoiding publicity.<sup>28</sup> This attempt to avoid

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<sup>23</sup> 529 U.S. at 161.

<sup>24</sup> 529 U.S. at 121.

<sup>25</sup> 51 Food and Drug L.J. at 660.

<sup>26</sup> *Id.*

<sup>27</sup> *Miller, supra*, at 41.

<sup>28</sup> *Id.*



publicity means that certain drugs that may otherwise be approved are not because of a fear of another recall such as VIOXX. While this is not entirely a bad thing, it does serve as a detriment to the time required for approval, placing it hand and hand with the first cited reason for privatization. Of course, not all officials are subject to this fear, with low level officials perhaps being most susceptible, both because of the tenuousness of the jobs, and also because of a desire to obey authority. It is also worth noting that this fear cuts both ways, with it leading to speedier approvals of certain drugs due to outside pressure from certain interests.

This outside pressure is yet another reason why the monopoly of the FDA is bad. The fact that advocates for certain segments of the industry need only appeal to one body, makes the efforts of formed special interest lobbying groups especially effective, and decision-making especially arbitrary as a result.<sup>29</sup> It is often said that the squeaky wheel is the one that gets the grease, and the FDA serves as a prime example of this analogy. No place is this better demonstrated than in the case of the AIDS lobby. By forming a powerful lobbying group, advocates of treatment of AIDS have been able to argue for, and win, expedited approval of drugs to treat their ailment.<sup>30</sup> Regulators, for their part, favor those groups that are able to successfully manipulate the media and skillfully apply political pressure.<sup>31</sup> That is not to say that AIDS is not an exceptional disease since it is in pretty much all cases terminal, but it does lead to situations where drugs for diseases with potentially greater health impact than other drugs, but less organized advocates, may receive desperate treatment.<sup>32</sup> Dr. Henry Miller, one of the people responsible for fleshing out of one of the privatization proposals that will be

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<sup>29</sup> *Id.*

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

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

<sup>32</sup> *Id.*

discussed later, had this anecdote to share with regard to his time in the FDA as a reviewer of new drug applications during the early 1980s. During that time, he was the head of the team an application for the first drug made with gene-splicing techniques for recombinant human insulin, at that time the average time for new drug application approval was two and a half years.<sup>33</sup> Dr. Miller's team was ready to approve the application after a mere four months, or slightly over an eighth of the average time.<sup>34</sup> Despite his indication to Dr. Miller that the data provided compelling evidence of efficacy and safeness, his supervisor refused to sign off on the application.<sup>35</sup> His comment to Dr. Miller at the time is perhaps the most telling statement that could be made with regard to the thinking of a large group within the FDA when he stated, "If anything goes wrong, think how bad it will look that we approved the drug so quickly"<sup>36</sup> Dr. Miller was able to convince his bosses' boss to approve the product, demonstrating that not all in the FDA share his supervisor's mentality, but the fact that it needed to get that far at all is very telling.<sup>37</sup>

On the flip side of this lobbying coin is another reason why the FDA's monopoly is problematic, and that involves the appeals process of FDA decisions. Companies in the current regulatory framework have a well-founded fear of agency reprisal if they speak out. FDA employees have freely expressed contempt for those companies that question FDA decision.<sup>38</sup> Additionally, the FDA is usually the final arbitrator of the appeals process.<sup>39</sup> This means that even if a company were to not agree with a decision of the FDA regarding approval of their product, they would have to get pretty far up the

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<sup>33</sup> *Id.*

<sup>34</sup> *Id.*

<sup>35</sup> *Id.*

<sup>36</sup> *Id.* at 41-42.

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

<sup>38</sup> *Id.* at 98.

<sup>39</sup> *Id.*

process in order to face an adjudicator that does not have some sort of tie to the FDA itself. This problem ties directly into the problem of a lack of accountability that was mentioned previously.

Ultimately, it is argued, by the advocates of privatization that an increase in privatization of the approval functionality of the FDA would lead to elimination, or at least a lessening, of the negative effects of the current regulatory scheme.

### ***B. Pitfalls of Privatization***

Efforts at privatization are not without their problems. Amongst these problems are the issues of whether or not the private reviewers will have the same concern for public safety as their governmental counterparts. The second concern involves the fact that private reviewers will collude with industry. The last concern that efforts of privatization face is the fear that privatization will lead to a race to the bottom whereby the quality of work will suffer due to attempts to undercut others competing in the same market for the drug approval dollar of pharmaceutical companies.

Before a proper analysis of the pitfalls of privatization can be engaged in, it is necessary to first define some of the terminology used in this area of the law. The mistakes that a drug regulation body can make can be said to be divided into two distinct types of errors, *type 1* and *type 2*.<sup>40</sup> A *type 1* error occurs when a harmful product is approved for marketing, and a *type 2* error occurs when a product that is useful for treatment or prevention never reaches approval, is rejected, or delayed.<sup>41</sup> Obviously, both of these errors should be avoided, since both types cause detriment to society through their effect. *Type 1* errors can also be said to be the visible errors in the

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<sup>40</sup> *Id.*

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

drug approval process. These errors can be characterized as such because they are the errors that are most noticeable to the general consumer of a given product. Your average consumer never sees that pharmaceutical that never reaches final FDA approval, but you can be relatively certain that they will see the news story when a drug like VIOXX is recalled or a news story breaks about a potentially harmful side effect of a once thought relatively safe product is seen on their local evening news. The effort of regulators to minimize *type 1* error at all costs has led to an exorbitant amount of *type 2* errors, as typified by Dr. Miller's anecdote above. Bureaucrats, in fear of losing their job if they are deemed to be responsible for a highly visible *type 1* error will err on the side of caution in their drug assessment. Supporters of privatization argue that privatization is the best method to minimize *type 2* errors while still providing for effective control of *type 1* errors, but is it?

Critics of privatization argue that private regulatory bodies will not be concerned with public safety as much as the FDA currently is. They contend that these non-governmental bodies will sacrifice concerns with safety and efficacy in order to cater their drug manufacturing clientele. This argument is an interesting one, with several implications. Obviously in an ideal privatized economy there will be several different organizations all competing to approve a drug. This competition in the free market will by its very nature serve to minimize *type 2* error, as drug manufacturers will desire to do business with the speediest possible vendor of approval services. But what about *type 1* error? When the FDA engages in a *type 1* error in the current regulatory framework, they are often not the target of blame by the public at large. It is instead the drug manufacturer that faces the brunt of the attack for marketing drugs that are later proven to be unsafe. This is most likely the case because the FDA is a governmental

organization, and therefore viewed to be above reproach with regard to impartiality and to be working in the best interests of the public. The company that markets the drug, on the other hand, has no such luxury. Opponents of privatization make the argument that these non-governmental regulatory bodies would be under no such presumed interest in acting in the best interest of the public. The argument fails for two reasons. The first reason is that unlike the FDA, these regulatory bodies will most likely not be viewed as beyond reproach, and would face much tougher scrutiny than the FDA performing a similar function. Now your average person will probably not realize which approval organization any given drug went through, but in the event of fallout, you can be sure that any company involved in the drug approval process will be subject to bad public publicity, much as the actual drug manufacturer. The second reason is that drug manufacturers will still desire to market a safe product, to avoid potential bad publicity down the road. Now, in the long run they may feel that they can make more money by marketing a less safe product and paying out settlements, but given the choice between a company with a minimum amount of *type 1* errors and a company with a large number of *type 1* errors, with comparable approval times, the drug manufacturer will always presumably choose the approver with lower *type 1* errors. In addition to this fact, companies with larger amounts of *type 1* errors will face problems with whatever body is responsible for approval of their designation as an approved drug certification body, in the end, even if they can price themselves well in the market, the errant drug approver will face other problems that will make cutting corners on drug approval ineffective.

Another criticism of privatization is that it will lead to collusion between industry and drug approval body, which will somehow compromise the drug approval process.

One of the most well known critiques of administrative agencies in general is the idea of

agency capture. Agency Capture is the idea that the staff of any given agency are drawn from the agency in which they regulate.<sup>42</sup> Naturally, when an agency engages in capture they become more liberal in their decision-making processes.<sup>43</sup> This is because while the agency is independent from the industry that it regulates, those in positions within the agency will either want to return to the industry at a later date, or be sympathetic to the industry that bore them. This creates the same problem as the AIDS example from above, where AIDS advocates were able to successfully lobby the industry for decreased approval times. If anything, this agency capture creates faster drug approval where it should not, instead of slower drug approval. This theory of agency capture also takes the wind out of the sails of the collusion argument. Under the theory of agency capture, this collusion already exists. It can even be argued that under a private regulatory scheme, this collusive effect will even be lessened. This is because under the new framework the regulatory agencies form their own industry within an industry competing not only against the pharmaceutical industry for qualified reviewers, but also with other review organizations. Therefore, there is less incentive to collude, since one can instead find work in the review sub-industry and not have to worry about alienating members of the pharmaceutical industry.

The last criticism involves the idea that increased privatization will involve a race to the bottom attitude developing whereby quality is decreased because of increased competition. As explained above, this is without weight in a world where the private regulatory bodies are certified by the government. In theory any such certification can be withdrawn, allowing for those in power to check errant approvers of products, and

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<sup>42</sup> Levine, M. E., & Forrence, J. L., *Regulatory Capture, Public Interest, and the Public Agenda. Toward a Synthesis.*, 6 J.L. Econ. & Org. 167.

<sup>43</sup> *Id.*

those that have become corrupt. In this way, the private reviewers will not only be competing to reduce *type 2* errors, but also to eliminate visible *type 1* errors, so as to avoid government scrutiny, which would be detrimental to their business.

Pharmaceutical companies for their part will avoid bodies that are subject to increased government scrutiny, because they will fear that it will result in more scrutiny to them in turn. Additionally, these bodies would not be free from liability for negligence and other torts, so there would be a strong disincentive to engage in the practice of a race to the bottom.<sup>44</sup>

Overall privatization seems to solve more problems that it purports to create, and the problems that are created largely already exist under the current scheme of regulation that is in place.

## **II. Three Proposals for FDA Privatization**

The three proposals that this paper will analyze for privatization of the Food and Drug Administration are; a free market deregulation of the drug approval process, the creation of drug certification bodies (DCBs) which review drug applications with final authority for approval resting on the FDA, and the creation of these same DCBs, without the final approval resting in the FDA.

### **A. Free Market Deregulation**

The first proposal, free market deregulation, was first put forth by the Competitive Enterprise Institute (CEI). Under this proposal a drug approval process would still exist, but instead of having veto power like the FDA does now, on the approval of new drugs, the agency would instead physicians could administer either

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<sup>44</sup> *Miller, supra*, at 81.

FDA approved drugs or drugs that were not approved, as long as they were properly labeled.<sup>45</sup> These alternative drugs would also require approval for another agency such as a foreign government, medical school, or specialty laboratory.<sup>46</sup>

This proposal provides a method for getting drugs in the hands of patients as quickly as possible, with many different avenues for drug approval existing. The unfortunate part of the plan, however, is that the drugs that are ultimately made available may not be of the highest quality, and therefore will provide severe risk to the patient. Since the non-FDA approved drugs must be dispensed by the patient's physician there is some check on the disbursement of unapproved drugs, but there are also many pitfalls. A physician, even more so than the FDA or a private regulatory body, is susceptible to direct marketing from drug manufacturers. They can only be given perks that, while regulated, often give the physician incentive to try and experiment treatment, when a non-experimental treatment may be better in the case of that particular patient. Some patients, on the other hand, might demand the latest and greatest drug, without knowing the true consequences of the given treatment, and many doctors, given this pressure and the desire to have their patients overcome whatever ailment strikes them, may cede to the pressure and prescribe the drug. Finally, the bodies themselves are so numerous and varied that its tough to pin down exactly what true approval looks like under this new scheme. Approvals from foreign governments look much different than approvals from medical schools, but under the proposal from the CEI, both are supposed acceptable methods of drug approval. Ultimately, a *lazier-faire* approach to drug regulation leaves itself open to too many abuses by both the pharmaceutical industry, and by the regulators themselves. For a true public policy

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<sup>45</sup> 50 Food & Drug L.J at 206.

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



stance to be effective it must have some sort of check and structure. While private review may ultimately be desirable the plan of the CEI does not go far enough in laying out exactly what that structure is.

### ***B. Drug Certification Bodies with Final FDA Approval***

The second proposal, initially proposed by the Newt Gingrich associated Progress and Freedom Foundation and fleshed out by Dr. Henry Miller is to create a system of DCBs with final authority for drug approval resting in the FDA.<sup>47</sup> Under the proposal by Dr. Miller, the drug regulation framework looks much the same, with the same functions performed by organizations, but only the organization that actually engages in the function being shifted.<sup>48</sup> Under the current regulatory scheme initial drug discovery is not performed by the FDA, and it would remain this way under the new framework.<sup>49</sup> The point, at which the FDA becomes involved in the current regulatory framework, is at the point when the drug is first made available for human clinical testing.<sup>50</sup> It is at this point that the drug's sponsor, usually a private pharmaceutical company, must apply for approval of an Investigational New Drug (IND) filing.<sup>51</sup> After the completion of the clinical trials, if the drug's sponsor is satisfied with the results of the trials, and thinks the drug is both safe and effective, the sponsor then applies to the FDA for the opportunity to market the drug by filing a New Drug Application (NDA).<sup>52</sup> These NDAs are thousands of pages long.<sup>53</sup> The FDA, by statute, must approve or disapprove of these

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<sup>47</sup> *Id.* at 205.

<sup>48</sup> *Miller, supra*, at 84

<sup>49</sup> *Id.*

<sup>50</sup> *Id.*

<sup>51</sup> *Id.*

<sup>52</sup> *Id.* at 87.

<sup>53</sup> *Id.*

NDA within 180-days, but this deadline is rarely met.<sup>54</sup> Instead, what often happens is that this deadline is extended, which it is permitted to be by agreement between the sponsor and the FDA.<sup>55</sup> It is at and before this NDA application process where Dr. Miller's proposed regulatory scheme goes to work. Under his proposal, the FDA becomes in effect a "certifier of certifiers" with the DCBs responsible for oversight, initial review of the NDA, and approval recommendations.<sup>56</sup> This oversight responsible is related to the IND clinical trials that are required before the NDA process is commenced.<sup>57</sup> These DCBs are funded through user fees, much as the current FDA is. The DCBs compete against each other for drug sponsors (clients).<sup>58</sup> These DCBs also compete against foreign regulatory bodies that can submit packets directly to the FDA, acting as much the same as a U.S. DCB.<sup>59</sup> Disputes between the FDA and the DCBs would be handled by an independent commission instead of by the FDA like what is currently the case under the existing regulatory framework when there is a dispute between the FDA and the drug sponsor.

Under the new system, at the beginning of the IND application the drug sponsor will hire a DCB that will work closely with the drug sponsor throughout the preclinical trial process and grant an IND when the risk-benefit analysis indicates that clinical trials are acceptable to begin.<sup>60</sup> The DCB will monitor the drug throughout these clinical trial and offer advice about the prerequisites for NDA approval and what tests may be necessary for proof of safety and efficacy, much as the FDA does now.<sup>61</sup> After this

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<sup>54</sup> *Id.* 87-88.

<sup>55</sup> *Id.* at 88.

<sup>56</sup> *Id.* at 90.

<sup>57</sup> *Id.*

<sup>58</sup> *Id.*

<sup>59</sup> *Id.*

<sup>60</sup> *Id.* at 91.

<sup>61</sup> *Id.*

process when the sponsor is satisfied with the safety and efficacy of the product they will submit an NDA to the DCB and then the DCB after analyzing it will submit their approval recommendation directly to the FDA which will grant the ultimate final approval.<sup>62</sup>

This process allows for the FDA to certify the DCBs making sure that they meet minimum standards and will provide adequate analysis on the drug approval process. Some of the answers to the pitfalls of this method of privatization have been answered above, such as the problem of collusion with the industry, and the race to the bottom mentality. But ultimately the true benefit of such a program is the closeness and earliness that the DCB works with the client. This allows many pitfalls that may delay the NDA process later on to be solved early, since the DCB organization is able to work more closely with the individual client, then the expansive FDA would be able to.

The problem of the appeals process being biased will also be solved by this method of privatization since appeals will be between a DCB and the sponsor the FDA are to be handled by an independent commission that would oversee disputes between the FDA and the DCBs.

The final benefit that this system has over the current one is that it allows for uniformity amongst international bodies. In the past there has been an effort to harmonize the pharmaceutical oversight across nations.<sup>63</sup> Since this proposal allows for reciprocity with foreign governments, allowing them to act as DCBs, it will further serve to speed up the process of drug approval not only here, but also abroad, with increased competition not simply on a local level but also on an international one.

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<sup>62</sup> *Id.*

<sup>63</sup> *Id.* at 100.

### ***C. Drug Certification Bodies without Final FDA Approval***

In response to the arguments of Dr. Miller, researchers at the Jerusalem Institute for Market Studies and the University of Southampton have initiated their own proposal for the drug approval process.<sup>64</sup> This proposal shares much in common with Dr. Miller's proposal. The key major difference between the proposals is that the DCBs in this proposal are ultimately responsible for final drug approval.

They argue that there is no need for the final FDA drug approval because safety and efficacy of drugs would ultimately be reliably determined as a result of "market mechanisms and legal recourse."<sup>65</sup> They argue that these DCBs interest in maintaining clients and attracting new ones will keep them honest in the drug approval process, and that the existence of a free press and the legal system of liability for dangerous and corrupt decision-making are enough disincentives to keep these DCBs honest.<sup>66</sup>

The ultimate problem with this analysis is that it is only an after the fact assessment. With Dr. Miller's method there is a final gate at the FDA still that provides immediate pre-approval oversight, no such oversight exists in this proposal. Only after something has gone wrong can this system correct itself. This initial oversight is not to be discounted, government audit of these bodies is essential to them doing a proper job. This method does not provide an adequate safe guard pre-approval to make it viable as a good method of privatization.

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<sup>64</sup> Corinne Sauer and Sauer, Robert M., Is it Possible to have Cheaper Drugs and Preserve the Incentive to Innovate? The Benefits of Privatizing the Drug Approval Process (Jan. 11, 2006). (unpublished manuscript, available <http://ssrn.com/abstract=875359>)

<sup>65</sup> *Id.*

<sup>66</sup> *Id.*

## **CONCLUSION**

Ultimately, the benefits of privatization seem to outweigh the risks associated with its implementation. Obviously, there are initial startup costs to be considered, and any significant reforms such as those highlighted in this paper must pass through Congress first before being implemented, a task that is not to be considered to be easy by any stretch of the imagination. It is, however, in the final analysis the right decision and all effort should be made to implement it. As far as the various proposals go, it would seem that that of Dr. Miller has the most weight and will lead to the best results. It contains elements that have already been proven to be effective, and in an attempt to expedite them, applies principles of the free market, its easy inclusion into the greater world outside of the United States also makes it a strong candidate for succeeding in an increasingly global economy.