

# DISCLOSURE OF CLINICAL TRIAL DATA: WHY EXEMPTION 4 OF THE FREEDOM OF INFORMATION ACT SHOULD BE RESTORED

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## ABSTRACT

*Clinical trial data generated during the FDA drug approval process can be very valuable. While patients and doctors desperately need this information to make informed choices about medical treatment, drug sponsors strive to keep this resource secret to ensure their ability to profit from their own research. In the wake of the controversy over antidepressant use in children, both the public and Congress have called for the disclosure of all clinical trial data. However, rather than taking an all-or-nothing approach that could harm the development of new drugs, this iBrief argues that Congress should address the issue of trial data disclosure by restoring the proper balance to Exemption 4 of the Freedom of Information Act.*

## INTRODUCTION

¶1 Matt Miller was unhappy.<sup>2</sup> Having moved to a new neighborhood and a new school, Matt was thrust into unknown territory without his support system of old friends with whom he had grown up.<sup>3</sup> That summer, Matt was prescribed Zoloft, an antidepressant, and was told to call his doctor in a week.<sup>4</sup> On a Sunday night, after taking his seventh pill, Matt went to his bedroom closet, where there was a hook just a little higher than he was tall.<sup>5</sup> Matt hung himself, having to lift his legs off the floor and hold himself there until he passed out.<sup>6</sup> He was only thirteen years old.<sup>7</sup>

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<sup>2</sup> Transcript of the February 2, 2004 meeting of the Psychopharmacologic Drugs Advisory Committee with the Pediatric Subcommittee of the Anti-Infective Drugs Advisory Committee at 88-89 [hereinafter Transcript], available at <http://www.fda.gov/ohrms/dockets/ac/04/transcripts/4006T1.pdf>.

<sup>3</sup> *Id.* at 88.

<sup>4</sup> *Id.* at 89.

<sup>5</sup> *Id.*

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

<sup>7</sup> *Id.* at 88.

¶2 This was but one of many sad stories that were heard at the February 2004 meeting of the Food and Drug Administration (“FDA”) Psychopharmacologic Advisory Committee and the Pediatric Subcommittee of the Anti-Infective Drugs Advisory Committee. The meeting was convened to review reports of suicidal thoughts and behavior in children being treated for depression with antidepressants.<sup>8</sup> Suicide is the third leading cause of death for adolescents, exceeded only by homicide and accidents.<sup>9</sup> While only one antidepressant, Prozac, has been approved by the FDA for use in this age group, physicians are free to prescribe other antidepressants to young patients if they feel it would be the best course of treatment.<sup>10</sup>

¶3 The problem facing physicians and patients with regard to such prescriptions is a lack of information about the effect of antidepressants on adolescents. Physicians and patients need information on the risks and benefits of a drug to make an informed decision about whether it is worth taking in light of other treatment alternatives.<sup>11</sup> Clinical trial data can be a powerful source of this information as in the case of antidepressant pediatric trial data which, although they suggested a link between suicide and antidepressant use, were withheld from public view by both drug companies and the FDA.<sup>12</sup> Thus, public disclosure of all trial data, as was recently proposed by Representatives Markey and Waxman, *seems* to be a logical solution.<sup>13</sup>

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<sup>8</sup> *Id.* at 12-13.

<sup>9</sup> Gardiner Harris, *F.D.A. Links Drugs to Being Suicidal*, N.Y. TIMES, Sept. 14, 2004, at A1.

<sup>10</sup> Chris Mondics, *FDA, Firms Assailed on Antidepressant Studies*, PHILA. INQUIRER, Sept. 10, 2004, at A2.

<sup>11</sup> Michael D. Greenberg, *Information, Paternalism, and Rational Decision-Making: The Balance of FDA New Drug Approval*, 13 ALB. L.J. SCI. & TECH. 663, 670 (2003).

<sup>12</sup> Harris, *supra* note 9.

<sup>13</sup> On October 7, 2004, Representatives Markey and Waxman introduced the Fair Access in Clinical Trials Act (H.R. 5252). Fair Access to Clinical Trials Act, H.R. 5252, 108th Cong. (2004). The purpose of the Act was to “require researchers to register their clinical trials in a federal registry before starting them and report the results of those trials at the conclusion.” 130 Cong. Rec. E1882, 1883 (October 11, 2004) (remarks of Rep. Markey). However, the Act did not make it out of committee. A similar bill was introduced in the Senate (S. 2933), but it also did not make it out of committee. Fair Access to Clinical Trials Act, S.2933, 108th Cong. (2004). As of February 1, 2004, the Act had not been reintroduced in either the House or Senate. (*See* <http://thomas.loc.gov/home/search.html> for more information on the Act.). *See also* Alan Zarembo, *A Plan to End Secret Studies*, L.A. TIMES, Sept. 9, 2004, at A19.

¶4 Unfortunately, solutions to problems involving the drug industry are rarely so logical or simple. An all-or-nothing approach to disclosure could have serious implications for drug sponsors who have invested vast amounts of money and time in the high-risk drug development process. Disclosing clinical trial data to competitors would eat away at any advantage such data conferred, reducing profits and the incentive to engage in the drug development process itself.<sup>14</sup> The flow of new drugs to the market would thereby be reduced, much to the detriment of the health and welfare of society.

¶5 In light of the complexities presented by the disclosure of clinical trial data, this iBrief argues that an all-or-nothing approach to disclosure is not the correct course of action. Rather, Congress should revise Exemption 4 of the Freedom of Information Act (“FOIA”),<sup>15</sup> which provides a mechanism for disclosure of clinical trial data but has been debilitated due to unrestrained judicial interpretation. By restoring the balance between public and private interests in disclosure that Exemption 4 was meant to incorporate, both the interests of medicine and those of the drug industry can be taken into account.

#### I. CLINICAL TRIAL DATA: HURTLING TOWARDS DISCLOSURE

¶6 Prior to introducing a drug to the market, drug sponsors must prove with substantial evidence that their drugs are not only generally safe but also “effective for their intended uses.”<sup>16</sup> Under the “substantial evidence” requirement, the FDA can tailor clinical trials so as to generate the type of data necessary to satisfy its regulations.<sup>17</sup> This determination is based upon animal studies and other preliminary data submitted in a drug sponsor’s request for an investigational new drug application (“IND”).<sup>18</sup> If the FDA grants the IND, the drug sponsor can begin human trials.<sup>19</sup> These trials occur in three distinct phases, with Phase I generating general safety data, Phase II generating general efficacy data, and Phase III generating data on the overall positive and negative effects of the drug.<sup>20</sup> The results of these trials are submitted to the FDA in the drug sponsor’s new drug application

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<sup>14</sup> Thomas O. McGarity & Sidney A. Shapiro, *The Trade Secret Status of Health and Safety Testing Information: Reforming Agency Disclosure Policies*, 93 HARV. L. REV. 837, 849 (1980).

<sup>15</sup> 5 U.S.C. § 552(b)(4) (2000).

<sup>16</sup> Elizabeth A. Weeks, *Is it Worth the Trouble? The New Policy on Dissemination of Information on Off-Label Drug Use Under the Food and Drug Administration Modernization Act of 1997*, 54 FOOD DRUG L.J. 645, 653 (1999).

<sup>17</sup> *Id.* at 654.

<sup>18</sup> *Id.* at 654-55.

<sup>19</sup> *Id.* at 655.

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

(“NDA”), which, if approved, allows the drug to be marketed to consumers for its intended uses.<sup>21</sup>

*A. The Secrecy of Clinical Trial Data: Pros and Cons of Disclosure*

¶7 Public disclosure of clinical trial data generated during the FDA drug approval process poses the problem of free-riding.<sup>22</sup> In the absence of protection, competitors of drug sponsors can take advantage of the information conveyed in clinical trials without having dedicated the vast amount of resources required to generate it.<sup>23</sup> Such free-riding on the investment of pharmaceutical and biotechnology companies that sponsor drugs can inhibit the ability of these companies to profit from their own research, thereby stripping away the incentives to engage in drug development itself.<sup>24</sup>

¶8 The threat of free-riding, however, is particularly serious for drug development given that it is an inherently high-risk process.<sup>25</sup> Current estimates of the costs of new drug development range from \$400 million<sup>26</sup> to over \$800 million dollars.<sup>27</sup> Much of the increase in these costs from previous estimates is attributable to escalating clinical trial costs<sup>28</sup> which constitute approximately 70% of total expenditures during the development process.<sup>29</sup> These monumental costs accumulate over the estimated ten to fifteen years required to gain FDA approval.<sup>30</sup> The risk involved in

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<sup>21</sup> James T. O’Reilly, *Knowledge Is Power: Legislative Control of Drug Industry Trade Secrets*, 54 U. CIN. L. REV. 1, 6 (1985).

<sup>22</sup> James T. O’Reilly, *Implications of International Drug Approval Systems on Confidentiality of Business Secrets in the U.S. Pharmaceutical Industry*, 53 FOOD DRUG L.J. 123, 123 (1998).

<sup>23</sup> McGarity & Shapiro, *supra* note 14, at 849.

<sup>24</sup> *See id.*

<sup>25</sup> Henry Grabowski, *Pharmaceuticals: Politics, Policy and Availability: Patents and New Product Development in the Pharmaceutical and Biotechnology Industries*, 8 GEO. PUBLIC POL’Y REV. 7, 19 (2003).

<sup>26</sup> *Id.* at 9; John F. Niblack, *Drug Development: Who Knows Where The Time Goes?: Why Are Drug Development Programs Growing in Size and Cost? A View from Industry*, 52 FOOD DRUG L.J. 151, 151 (1997).

<sup>27</sup> Grabowski, *supra* note 25, at 10; Tufts Center for the Study of Drug Development, *News Release: Tufts Center for the Study of Drug Development Pegs Cost of a New Prescription Medicine at \$802 Million* [hereinafter *News Release*], at <http://csdd.tufts.edu/NewsEvents/RecentNews.asp?newsid=6> (Nov. 30, 2001).

<sup>28</sup> *News Release*, *supra* note 27.

<sup>29</sup> Grabowski, *supra* note 25, at 9.

<sup>30</sup> Tufts Center for the Study of Drug Development, *Backgrounder: How New Drugs Move through the Development and Approval Process*, at <http://csdd.tufts.edu/NewsEvents/RecentNews.asp?newsid=4> (Nov. 1, 2001).

dedicating such vast sums of money over such a long period of time is compounded by the uncertainties of the approval process itself.<sup>31</sup> It has been estimated that only five in every five thousand potential pharmaceutical agents reach the clinical trial phase, and only one of those five will ever make it to the hands of consumers.<sup>32</sup> Furthermore, few FDA-approved drugs actually generate sufficient revenues to recoup the costs of research and development, which is essential to a drug sponsor's long-term success.<sup>33</sup> These factors contribute to the high-risk nature of drug development,<sup>34</sup> and, in this environment, information that can reduce costs or increase the probability of FDA approval is immensely valuable and greatly coveted by the companies that have access to it.

¶9 Clinical trials represent a significant source of such information. Trial protocols can present methods of providing sufficient data to satisfy FDA requirements with the least amount of time and investment involved.<sup>35</sup> Trial results can identify new avenues of research or confirm that such research leads only to a dead end.<sup>36</sup> As such, drug developers have sought to protect clinical trial data from disclosure to their competitors.

¶10 The zealous protection of clinical trial data, however, has come at the cost of hindering the public's ability to make informed choices about medical treatment.<sup>37</sup> Information forms the core of an individual's decision to take a new drug.<sup>38</sup> Because of the rigorous showing of safety and effectiveness required by the FDA regulatory scheme, clinical trials performed during the drug approval process represent the single greatest source of information concerning the risks and benefits for any given prescription drug.<sup>39</sup> Phase I trials, performed on healthy volunteers, produce evidence of "toxicity, dosage range, metabolism, absorption, bioavailability, and elimination."<sup>40</sup> Phase II trials, performed on patients with the particular disease the drug is designed to treat, produce evidence of

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<sup>31</sup> *See id.*

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

<sup>33</sup> Grabowski, *supra* note 25, at 17.

<sup>34</sup> *News Release*, *supra* note 27.

<sup>35</sup> *See id.*

<sup>36</sup> *See* McGarity & Shapiro, *supra* note 14, at 850.

<sup>37</sup> *See id.* at 844-45 (arguing that consumers should have access to health and safety data so that they can balance the risks and benefits unique to them).

<sup>38</sup> Greenberg, *supra* note 11, at 670.

<sup>39</sup> *See id.* at 672-73 (describing the FDA-approval process as "a device for generating a special kind of information about new drugs"); *see* Weeks, *supra* note 16, at 659 (describing the FDA-approval process as an "exhaustive review of the product and its indications" requiring "a high quantum of proof of safety and efficacy" prior to approval).

<sup>40</sup> Weeks, *supra* note 16, at 655.

“efficiency, side effects, and risks.”<sup>41</sup> While Phase I and II trials are performed on only a small number of patients, Phase III trials involve large numbers of individuals affected with the disease and generate evidence of “the overall benefits and risks of the drug.”<sup>42</sup> By denying access to these data, the formation and execution of rational decisions by patients and their physicians are impeded, thereby jeopardizing the health and well-being of patients and society as a whole.<sup>43</sup>

### *B. Public Clamor for Disclosure: The Problems of Off-Label Use*

¶11 Hindering the public’s ability to make informed medical choices is most costly when a drug is put to an off-label use. Off-label use “occurs when the drug is employed in a manner not described in the product’s FDA-approved labeling” and “include[s] administration at a new dosage, through a new route (e.g., oral, intravenous, or intradermal), to a new patient population or, most controversially, for a new indication.”<sup>44</sup> Off-label use is extremely common, accounting for up to 40-60% of all drug prescriptions and upwards of 80-90% of all prescriptions in children and individuals suffering from rare diseases.<sup>45</sup> Off-label use is so well established in the medical field that, “in some cases, failure to prescribe a drug for an off-label use would be the basis for a malpractice action.”<sup>46</sup> Indeed, prescribing drugs in ways not contemplated on their labels has had some very notable success.<sup>47</sup> For example, Viagra was initially only approved for chest pain but later proved to be a successful treatment for erectile dysfunction.<sup>48</sup> Similarly, the use of aspirin to prevent heart attacks was only approved by the FDA in 1998.<sup>49</sup>

¶12 However, off-label uses pose substantial danger to patients because of the absence of reliable information from which informed decisions can be made.<sup>50</sup> The FDA does not regulate either the practice of medicine or the

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

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

<sup>43</sup> See Greenberg, *supra* note 11, at 671-72.

<sup>44</sup> Shane M. Ward, *WLF and the Two-Click Rule: The First Amendment Inequity of the Food and Drug Administration’s Regulation of Off-Label Drug Use Information on the Internet*, 56 FOOD DRUG L.J. 41, 41 (2001).

<sup>45</sup> *Id.* at 45.

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

<sup>47</sup> See James O’Reilly & Amy Dalal, *Off-Label or Out of Bounds? Prescriber and Marketer Liability for Unapproved Uses of FDA-Approved Drugs*, 12 ANN. HEALTH L. 295, 298 (2003).

<sup>48</sup> *Id.*

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

<sup>50</sup> See Steven R. Salbu, *Off-Label Use, Prescription, and Marketing of FDA-Approved Drugs: An Assessment of Legislative and Regulatory Policy*, 51 FLA. L. REV. 181, 202 (1999).

off-label use of drugs, and it has consistently held to its policy that “[o]nce a product has been approved for marketing, a physician may prescribe it for uses or in treatment regimens or patient populations that are not included in approved labeling.”<sup>51</sup> The consequence of this hands-off policy is that off-label uses are not subject to the rigorous scrutiny of the FDA’s safety and efficacy regulations and “therefore also lack the consumer safeguarding we usually associate with prescription drugs.”<sup>52</sup> While patients and physicians can rely on information contained on drug labels to make informed choices about on-label use, they are forced to “rely on anecdotal information from colleagues or on information contained in scientific journals” to make such choices about off-label use.<sup>53</sup> This dramatically increases the danger that “physicians and consumers will be misled into relying on scientific logic or scanty data supporting a particular use, without adequate well-controlled clinical trials that prove definitively that the drug works.”<sup>54</sup> A tragic example of this is the fen-phen disaster involving the off-label combination of fenfluramine and phentermine, which caused an estimated 285,000 users to develop serious heart complications.<sup>55</sup>

¶13 The danger posed by this dearth of information has become clear from the recent revelation that both drug makers and the FDA have withheld trial data suggesting that antidepressants are no more effective than placebo and increase the risk of suicidal behavior in depressed children.<sup>56</sup> Anecdotal evidence of the link between antidepressants and suicidal tendencies in children has circulated the medical field “for a very long time”<sup>57</sup> but such rumors have been largely dismissed by drug makers and the FDA.<sup>58</sup> However, during its review of the data submitted for the antidepressant Paxil in the spring of 2003, the FDA discovered that “events suggestive of suicidality” in pediatric trials appeared to have been collected under a more general term of “emotional liability.”<sup>59</sup> While British regulators, in response to disclosures made by several drug sponsors of antidepressants, reacted strongly by prohibiting the use of all but one

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<sup>51</sup> James M. Beck & Elizabeth D. Azari, *FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions*, 53 FOOD DRUG L.J. 71, 76-78 (1998).

<sup>52</sup> Salbu, *supra* note 50, at 202.

<sup>53</sup> Weeks, *supra* note 16, at 648.

<sup>54</sup> Salbu, *supra* note 50, at 202 (quoting Nancy K. Plant, *Prescription Drug Promotion on the Internet: Tool for the Inquisitive or Trap for the Unwary?*, 42 ST. LOUIS U. L.J. 89, 129 (1998)).

<sup>55</sup> *Id.* at 202-03.

<sup>56</sup> See Harris, *supra* note 9; Mondics, *supra* note 10.

<sup>57</sup> Transcript, *supra* note 2, at 231.

<sup>58</sup> Harris, *supra* note 9.

<sup>59</sup> Transcript, *supra* note 2, at 235-236.

antidepressant in children by the end of 2003,<sup>60</sup> the FDA suppressed the initial findings of its analysts<sup>61</sup> and discouraged the efforts of several drug sponsors to add stronger label warnings about their products' use in children.<sup>62</sup> Public outcry for disclosure of all clinical trial data ensued, leading to a legislative proposal that would "require researchers to register their clinical trials in a federal registry before starting them and report the results of those trials at the conclusion."<sup>63</sup>

### C. A Better Solution

¶14 Such an all-or-nothing approach to the disclosure of clinical trial data, however, fails to recognize that there are valid arguments both for *and* against disclosure. Requiring disclosure of data without regard to the potential competitive harm that could be inflicted upon drug sponsors could diminish the number of companies willing to risk the time and effort required to bring drugs to market, thereby diminishing the health and welfare of society. The controversy surrounding disclosure requires a more nuanced approach that takes account of the arguments for and against disclosure. Such an approach could be achieved by rejecting the judicially imposed limitations on Exemption 4 of the FOIA and restoring the balance between the public's interest in disclosure and private interests in confidentiality.

## II. THE BALANCE OF EXEMPTION 4 OF THE FOIA

¶15 Enacted in 1966, the FOIA<sup>64</sup> was meant as a tool for all Americans to "pierce the veil of administrative secrecy and to open agency action to the light of public scrutiny."<sup>65</sup> To achieve this, the FOIA requires "federal government agencies to disclose 'agency records' upon request to 'any person' requesting those records."<sup>66</sup> It was hoped that, by providing access to agency records, the FOIA would "ensure an informed citizenry, vital to the functioning of a democratic society, needed to check against corruption

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<sup>60</sup> Mondics, *supra* note 10.

<sup>61</sup> Harris, *supra* note 9.

<sup>62</sup> Shankar Vedantam, *FDA Urged Withholding Data on Antidepressants; Makers Were Dissuaded from Labeling Drugs as Ineffective in Children*, WASH. POST, Sept. 10, 2004, at A2.

<sup>63</sup> 130 Cong. Rec. E1882, 1883 (October 11, 2004) (remarks of Rep. Markey). For more information on the proposed legislation see footnote 13.

<sup>64</sup> 5 U.S.C. § 552 (2000).

<sup>65</sup> *Anderson v. Dep't of Health and Human Servs.*, 907 F.2d 936, 941 (10th Cir. 1990)(quoting *Wren v. Harris*, 675 F.2d 1144, 1145 (10th Cir. 1982)(quoting *Dep't of Air Force v. Rose*, 425 U.S. 352, 361 (1976))).

<sup>66</sup> Sean E. Andrussier, Note, *The Freedom of Information Act in 1990: More Freedom for the Government; Less Information for the Public*, 1991 DUKE L.J. 753, 753 (1991).

and to hold the governors accountable to the governed.”<sup>67</sup> Under the FOIA, “the presumption in favor of disclosure is at its zenith,”<sup>68</sup> and courts must construe its terms broadly in favor of disclosure.<sup>69</sup> The FDA falls within the grasp of the FOIA,<sup>70</sup> and, as such, individuals can use the FOIA to gain access to records held by the FDA, including clinical trial data.<sup>71</sup>

### A. *The Balance Impaired*

¶16 However, when Congress enacted the FOIA, it realized “that legitimate governmental and private interests could be harmed by release of certain types of information and provided nine specific exemptions under which disclosure could be refused.”<sup>72</sup> Specifically, Exemption 4 permits nondisclosure of agency records if such records contain “commercial or financial information [that was] obtained from a person [and is] privileged or confidential.”<sup>73</sup> Clinical trial data qualify as commercial information under this exemption and will be withheld if they are deemed confidential; that is, if disclosure would “cause substantial harm to the competitive position of the person from whom the information was obtained.”<sup>74</sup> This competitive harm is established when both actual competition and the likelihood of substantial competitive injury are shown.<sup>75</sup> In carrying out this determination of confidentiality, courts must perform a “rough balancing” of the public interest in disclosure against the private interests in continued confidentiality, a balancing that plays a central role in whether the records should be withheld under Exemption 4.<sup>76</sup>

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<sup>67</sup> *Anderson*, 907 F.2d at 941 (quoting *MRO v. Robbins Tire & Rubber Co.*, 437 U.S. 214, 242 (1978)).

<sup>68</sup> *Washington Post Co. v. U.S. Dep’t of Health and Human Servs.*, 690 F.2d 252, 259 (D.C. Cir. 1982) (quoting *Grolier, Inc. v. FTC*, 671 F.2d 553, 556 (D.C. Cir. 1982) (per curiam)).

<sup>69</sup> *Anderson*, 907 F.2d at 941.

<sup>70</sup> *R&D Labs. Inc. v. FDA*, No. 00-cv-0165, 2000 U.S. Dist. LEXIS 20209, at \*14 (D.D.C. Sept. 7, 2000).

<sup>71</sup> *See Pub. Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1282 (D.C. Cir. 1983) [hereinafter *HRG 1983*].

<sup>72</sup> *Pub. Citizen Health Research Group v. FDA*, 185 F.3d 898, 904 (D.C. Cir. 1999) (quoting *FBI v. Abramson*, 456 U.S. 615, 621 (1982)) [hereinafter *HRG 1999*].

<sup>73</sup> *Id.* at 903 (quoting 5 U.S.C. § 552(b)(4)).

<sup>74</sup> *HRG 1983*, 704 F.2d at 1290-91 (quoting *Nat’l Parks & Conservation Assoc. v. Morton*, 498 F.2d 765, 770 (D.C. Cir. 1974)).

<sup>75</sup> *Pub. Citizen Health Research Group v. FDA*, 964 F. Supp. 413, 415 (D.C. Cir. 1997).

<sup>76</sup> *Pub. Citizen Health Research Group v. Nat’l Insts. of Health*, 209 F. Supp. 2d 37, 45 (D.D.C. 2002).

¶17 It is the courts' exceedingly narrow construction of the public interest, contrary to the clear policy of disclosure mandated by the FOIA, that has upset the balance under Exemption 4 and barred the public from its rightful access to information held by the government, including clinical trial data. This narrow construction has its roots in the 1989 Supreme Court decision *U.S. Department of Justice v. Reporters Committee for Freedom of the Press*,<sup>77</sup> which involved the disclosure of FBI rap sheets on an individual who was connected to the mob and whose company had received several federal defense contracts.<sup>78</sup> The FBI sought to withhold the documents under Exemption 7(C), which authorizes the withholding of "records or information compiled for law enforcement purposes, but only to the extent that the production of such [materials] . . . could reasonably be expected to constitute an unwarranted invasion of personal privacy."<sup>79</sup> In ruling against disclosure, the Court enunciated what has become known as the "central purpose" doctrine.<sup>80</sup> The doctrine holds that "the FOIA's central purpose is to ensure that the *Government's* activities be opened to the sharp eye of public scrutiny, not that information about *private citizens* that happens to be in the warehouse of the Government be so disclosed."<sup>81</sup> If the documents sought under the FOIA do not "directly reveal governmental operations or performance," they will not be disclosed because they fall "outside the ambit of the public interest that the FOIA was enacted to serve."<sup>82</sup>

¶18 The Court, however, went further by refusing to consider any other interest that does not reveal, "what the [ ] government is up to,"<sup>83</sup> stating that "whether disclosure of a private document . . . is warranted must turn on the nature of the requested document and its relationship to 'the basic purpose of the Freedom of Information Act to open agency action to the light of public scrutiny' . . . rather than on the particular purpose for which the document is being requested."<sup>84</sup> This "derivative use" limitation<sup>85</sup> implies that the *only* public interest to be weighed under the FOIA is that embodied in the central purpose doctrine, and all other purposes, no matter how substantial they might be, are irrelevant.

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<sup>77</sup> 489 U.S. 749 (1989) [hereinafter *Reporters Committee*].

<sup>78</sup> Martin E. Halstuk & Charles N. Davis, *The Public Interest Be Damned: Lower Court Treatment of the Reporters Committee "Central Purpose" Reformation*, 54 ADMIN. L. REV. 983, 988 (2002).

<sup>79</sup> Andrussier, *supra* note 66, at 755 (quoting 5 U.S.C. § 552(b)(7)(c) (1988)).

<sup>80</sup> Christopher P. Beall, Note, *The Exaltation of Privacy Doctrines over Public Information Law*, 45 DUKE L.J. 1249, 1255 (1996).

<sup>81</sup> *Reporters Committee*, 489 U.S. at 774.

<sup>82</sup> *Id.* at 774-75.

<sup>83</sup> *HRG 1999*, 185 F.3d at 904 (quoting *Reporters Committee*, 489 U.S. at 773).

<sup>84</sup> *Reporters Committee*, 489 U.S. at 772.

<sup>85</sup> See Beall, *supra* note 80, at 1259-60.

¶19 The enormity of the impact of the central purpose doctrine and the derivative use limitation on the public's right of access to clinical trial data under the FOIA is illustrated in *Public Citizen Health Research Group v. FDA*.<sup>86</sup> In this case, the plaintiffs sought both preclinical and clinical studies for all drug applications that had been discontinued due to death or serious injury of patients or due to safety concerns arising from preclinical studies.<sup>87</sup> In reversing the order for release of the information, the Court of Appeals for the District of Columbia Circuit acknowledged that the plaintiff's desire to "review whether the FDA is adequately safeguarding the health of people who participate in drug trials" satisfied the central purpose doctrine because it directly revealed "what the [ ] government is up to."<sup>88</sup> However, the court firmly rejected the public interest in preventing "other drug companies from repeating [the drug sponsor's] mistakes, thereby avoiding risk to human health"<sup>89</sup> as an improper derivative use, stating that "[i]t is not open to [the plaintiff] . . . to bolster the case for disclosure by claiming an additional public benefit . . . [t]hat is not related to 'what the [ ] government is up to.'"<sup>90</sup> As the dissent soberly pointed out, "[t]his means that even if disclosure were the only way to prevent the loss of human life, that would count for nothing as against a showing . . . [of] substantial harm to [the drug sponsor's] competitive position."<sup>91</sup>

### *B. Restoring the Balance*

¶20 In light of both the loss of human life that occurred because the public did not have access to antidepressant clinical trials and the threat of complete disclosure without regard to the competitive harm that drug sponsors could suffer, the limitations placed on the public interest should be abandoned. The broad construction of Exemption 4 that the courts have adopted is contrary to the FOIA's clear policy of disclosure<sup>92</sup> and the narrow construction that should be applied to its exemptions.<sup>93</sup> Justice Ginsburg, in a concurring opinion, has declared that the plain language of the FOIA does not support the central purpose doctrine, which in fact

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<sup>86</sup> 185 F.3d 898 (D.C. Cir. 1999); see also Symposium, *Life Sciences, Technology, and the Law*, 10 MICH. TELECOMM. & TECH. L. REV. 175, 232-33 (2003) (discussing the classification of adverse event reports under the FOIA).

<sup>87</sup> *HRG 1999*, 185 F.3d at 901.

<sup>88</sup> *Id.* at 904 (quoting *Reporters Committee*, 489 U.S. at 773).

<sup>89</sup> *Id.* at 903.

<sup>90</sup> *Id.* at 904.

<sup>91</sup> *Id.* at 908 (Garland J., dissenting).

<sup>92</sup> Andrussier, *supra* note 66, at 753-55; see Halstuk, *supra* note 78, at 994 (quoting *EPA v. Mink*, 410 U.S. 73, 80 (1973)).

<sup>93</sup> *Anderson*, 907 F.2d at 941.

“changed the FOIA calculus” against disclosure.<sup>94</sup> Indeed, the underlying purpose of the FOIA’s broad disclosure policy was “to remedy gaping loopholes in the FOIA’s predecessor, the public disclosure section of the Administrative Procedure Act of 1946.”<sup>95</sup> This predecessor was so weak in its mandate for disclosure, with such malleable language as exempting from disclosure “any function of the United States requiring secrecy in the public interest,” that it “came to be regarded by agencies as a tool to withhold information.”<sup>96</sup> Similarly, the limitations placed on the public interest have twisted the FOIA exemptions into the tools of government agencies to exclude from disclosure far more than was meant to be.<sup>97</sup>

¶21 In removing the judicially imposed limitations on Exemption 4, Congress should take heart in the fact that such action has been supported by its members in the past. Senator Leahy wrote in a report for the Electronic Freedom of Information Act, enacted in October 1996, that “[e]fforts by the courts to articulate a ‘central purpose’ for which information should be released imposes a limitation on the FOIA which Congress did not intend and which cannot be found in its language, and distorts the broader import of the Act in effectuating Government openness.”<sup>98</sup>

¶22 Furthermore, even if these limitations on the public interest are valid, they should only be applied to the FOIA’s privacy exemptions, Exemptions 6 and 7(C). Because these exemptions invoke individuals’ right to privacy, broader construction may be warranted. Indeed, in enunciating the central purpose doctrine, the Supreme Court emphasized that the FOIA was not meant “to require the government to be a central depository of information about *private citizens*, accessible at the request of any person for any reason.”<sup>99</sup> The desire to provide heightened protection for information implicating an individual’s right to privacy is particularly clear in Exemption 7(C), the language of which was gradually broadened from “would . . . constitute an unwarranted invasion of personal privacy” to “could be reasonably be expected to.”<sup>100</sup> In addition, the Supreme Court’s

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<sup>94</sup> Halstuk, *supra* note 78, at 1017 (citing U.S. Dep’t of Defense v. Fed. Labor Relations Auth., 510 U.S. 487, 509 (1994)); Beall, *supra* note 80, at 1261 (quoting U.S. Dep’t of Defense v. Fed. Labor Relations Auth., 114 S. Ct. 1006, 1017 (1994)).

<sup>95</sup> Halstuk, *supra* note 78, at 993; *Reporters Committee*, 489 U.S. at 754-55; see 5 U.S.C. § 1002 (1946).

<sup>96</sup> Halstuk, *supra* note 78, at 993 (quoting *E.P.A. v. Mink*, 410 U.S. 73, 79 (1973)).

<sup>97</sup> *Id.* at 995-96.

<sup>98</sup> *Id.* at 1016 (quoting S. Rep. No. 104-272, at 26-27).

<sup>99</sup> *Andrussier*, *supra* note 66, at 766 (emphasis added).

<sup>100</sup> *Id.* at 762.

rendering of the “central purpose” doctrine was inextricably connected to whether disclosure was “warranted,”<sup>101</sup> a term that appears only in these two exemptions.

#### CONCLUSION

¶23 By removing the judicially imposed limitations on Exemption 4, interests both for and against disclosure could be given their proper weight in determining whether clinical trial data should be released to the public. Of course, the public’s interest in monitoring the FDA’s administration of the drug development process and ensuring that the agency is fulfilling its statutory charge of protecting the public from dangerous drugs remains on the balance in support of disclosure. In addition to this interest in discovering “what the government is up to,” the public’s own interest in protecting human health and ensuring that physicians and their patients have as much information as possible to make informed choices about medical treatment weigh in favor of disclosure. In situations such as that with antidepressant use in children, where anecdotal evidence of serious side effects existed virtually since the drugs were introduced to the market, these factors tip the balance in favor of disclosure. In this way, both the needs of medicine and those of the drug industry can be accommodated.

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<sup>101</sup> *Reporters Committee*, 489 U.S. at 772.