

**Testimony of Peter Lurie, MD, MPH and Hillary Peabody, MPH  
Health Research Group at Public Citizen  
Before the FDA Transparency Task Force  
Washington, DC  
June 24, 2009**

Thank you for convening this Task Force and providing us with the opportunity to provide testimony before it. Public Citizen's comments today will make three main points: 1. Pre-approval documents should be made available to the public; 2. The FDA's Freedom of Information Act (FOIA) processes should be made more efficient and consistent; and 3. The FDA should expedite the production of standardized drug information for patients.

**1. Pre-approval documents should be made available to the public**

Generally, the FDA's approach to data disclosure has been that no public disclosure of information will take place until (and unless) a drug is approved.<sup>1</sup> Indeed, the agency will not even acknowledge that an Investigational New Drug application or a New Drug Application has been filed.<sup>2</sup> For those drugs that are evaluated by FDA advisory committees, there is an additional, brief window in which the New Drug Application is formally acknowledged and the data supporting the application are disclosed in summary form. If a drug is never approved and has not been the subject of an advisory committee meeting, the FDA will provide literally no information about the product.

Sponsors exploit this data drought in two ways. First, they may engage in policies of selective publication in which studies more favorable to the product are more likely to see the light of day.<sup>3,4,5</sup> Second, they can release the most favorable studies to the media, creating "buzz" for as yet unapproved products. In this age of the Internet, bloggers and

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<sup>1</sup> 21 C.F.R. § 314.430(b)-(d).

<sup>2</sup> The comments presented here refer to drugs, but apply equally to other FDA-regulated products, unless otherwise indicated.

<sup>3</sup> Meier B. Contracts keep drug research out of reach. *New York Times*, November 29, 2004, p. A1.

<sup>4</sup> Whittington CJ, Kendall T, Fonagy P, Cottrell D, Cotgrove A, Boddington E. Selective serotonin reuptake inhibitors in childhood depression: systematic review of published versus unpublished data. *Lancet* 2004;363:1344-5.

<sup>5</sup> Natanson C, Kern S, Lurie P, Banks SM, Wolfe SM. Cell-free hemoglobin-based blood substitutes and risk of myocardial infarction and death: a meta-analysis. *Journal of the American Medical Association* 2008;299:2304-12.

carefully orchestrated media leaks, the FDA's insistence on maintaining data secrecy seems particularly outmoded.

Ironically, while patients and physicians may be misled by these forms of selective data release, the companies' investors are relatively protected by requirements to provide stockholders with all relevant information in the form of the companies' periodic filings with the Securities and Exchange Commission. Stockholders have recourse to the courts if these filings are misleading. Patients and physicians have no similar recourse.

These practices have two major consequences. First, scientists may be unaware that prior research has detected either lack of safety or efficacy and may continue researching related products, squandering time and money going down roads already proved to be dead ends. Second, patients may be enrolled in research likely to prove fruitless, placing them at needless risk.

In essence, we are dealing with a fundamental clash of cultures. Progress in science is based on the free publication of study results and on the public release of data, allowing scientists to build on the experiences of others. In contrast, the governing ethic in the corporate sector is secrecy—the withholding of any information from which a competitor might arguably benefit. It is unfortunate that the procedures of an agency committed to the public health<sup>6</sup> favor corporate culture over scientific culture.

Public Citizen believes that the detailed results of all human trials of experimental agents—from phase 1 to phase 4—should be fully and expeditiously disclosed to the scientific and medical communities.<sup>7</sup> There are three arenas in which such a policy should be pursued.

First, Congress could reverse the FDA's current policy of treating all materials submitted during the product development process as confidential. As far back as three decades ago, the Review Panel on New Drug Regulation (the "Dorsen Report") questioned the longstanding practice of keeping investigational new drug and new drug applications confidential and concluded that "the need to make scientific data concerning the safety and effectiveness of drugs available to the public is urgent [and] can be achieved without eliminating the existing incentive to invest in drug research and development." The panel went on to recommend that "Congress immediately amend the Federal Food, Drug, and Cosmetic Act to provide that safety and effectiveness data are not trade secrets for

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<sup>6</sup> Hamburg MA, Sharfstein JM. The FDA as a public health agency. *New England Journal of Medicine* 2009;360:2493-5.

<sup>7</sup> For further discussion of this issue, see McGarity TO, Shapiro SA. The trade secret status of health and safety testing information: reforming agency disclosure policies. *Harvard Law Review* 1980;93:837.

purposes of federal prohibitions against release of confidential and privileged information.”<sup>8</sup>

A second, complementary approach would involve congressional modification of the Freedom of Information Act. Exemption 4 to the act permits the withholding by any federal agency of material deemed trade secret or confidential commercial information; it is the exemption most frequently cited by the FDA (see data below) and is the one most relevant in this setting. Courts have held that the exemption does not provide for a balancing of the commercial interest against the public interest.<sup>9</sup> That is, if the material sought is confidential commercial information, the exemption is triggered, regardless of the strength of the public interest in the disclosure of that information. A relatively minor alteration in the statutory language of exemption 4 to allow for consideration of the public interest would markedly increase data disclosure.

Finally, much attention has been directed toward clinical trial registries. This approach is independent of changes at the FDA level. Trials should be registered at their inception so that the failure to complete or publish a trial can be detected. The 2007 FDA reauthorization bill<sup>10</sup> provides for a database that includes ongoing trials as well as the eventual posting of study results and adverse effects. However, for now there is no requirement to post the results of studies of unapproved products. To fulfill the public interest in expanded dissemination of scientific information and to adequately protect patients, all three of these remedies must be enacted.

## **2. The FDA’s FOIA processes should be made more efficient and consistent**

In preparation for this testimony, we reviewed the FDA’s 1998-2008 Freedom of Information Annual Reports.<sup>11</sup> The data reveal a consistent decline in the number of FOIA requests received for 1998-2003, followed by a leveling off in requests for 2003-6 (see Figure 1). However, in that same period, the backlog of requests grew from about 13,000 to almost 20,000, as requests processed did not keep up with even the declining number of requests.

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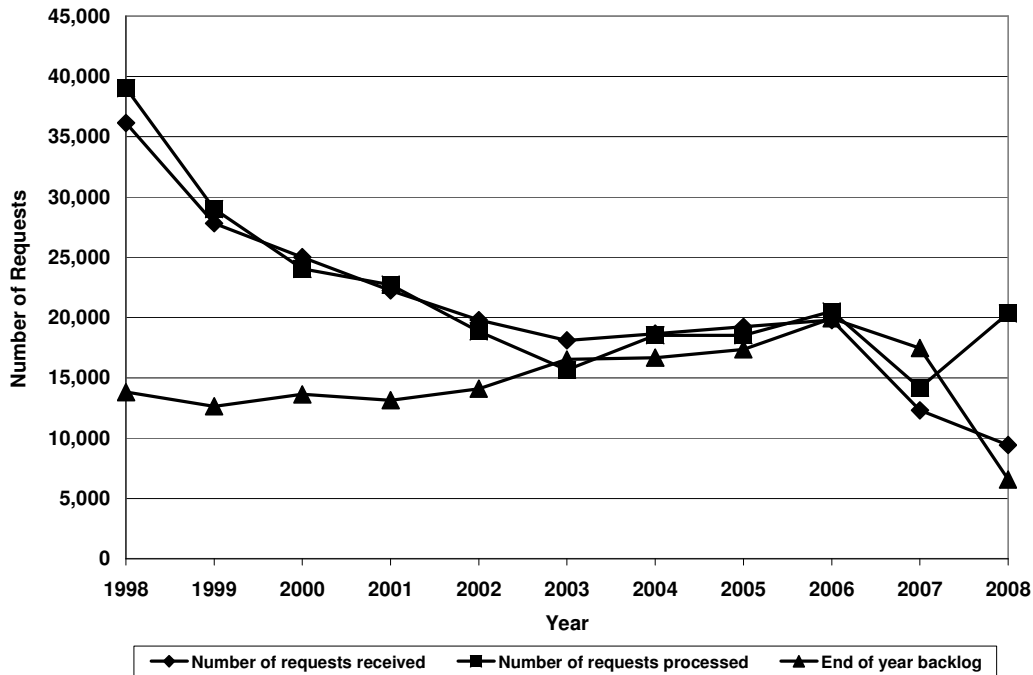
<sup>8</sup> Dorsen N, Weiner N, Astin A. Review Panel on New Drug Regulation: Final Report. Washington, DC: Dept of Health, Education, and Welfare, 1977.

<sup>9</sup> Public Citizen Health Research Group v Food and Drug Administration (Schering), 185 F3d 898 (DC Cir 1999).

<sup>10</sup> Food and Drug Administration Amendments Act of 2007, Pub L No. 110-85, 110th Cong, 1st Sess (2007).

<sup>11</sup> FDA. Freedom of Information Annual Reports. Available at: <http://www.fda.gov/RegulatoryInformation/FOI/FOIAAnnualReports/ucm148283.htm>. Last visited June 23, 2009.

**Figure 1: FDA FOIA Requests, 1998-2008**



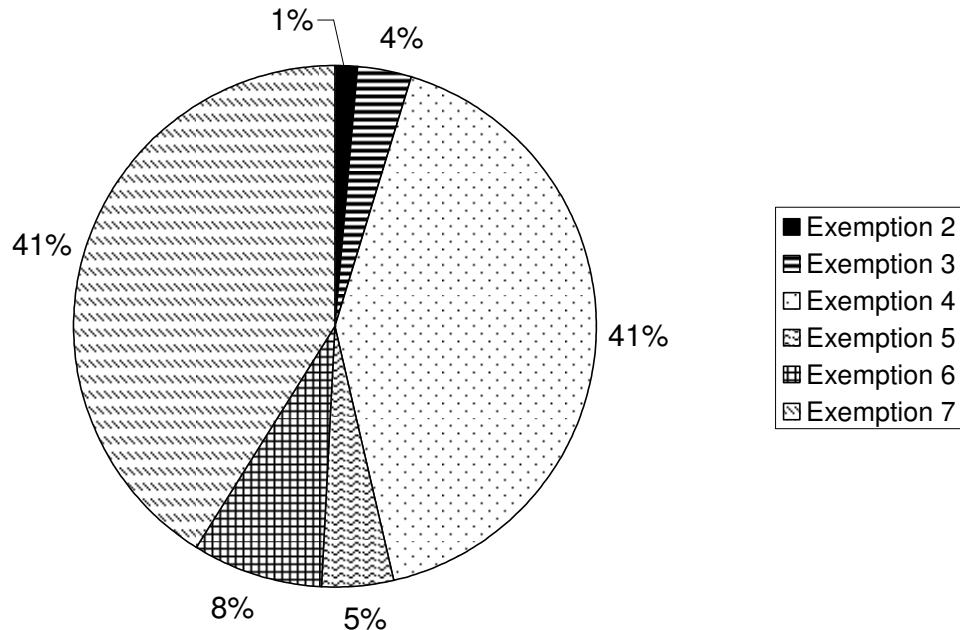
In the past two years, there appears to have been a substantial change in policy, with the backlog of requests dropping to 6568 in 2008. Two factors appear to have reduced the backlog. First, the number of requests dropped from 17,797 in 2006 to 9432 in 2008. Second, the number of withdrawn requests increased from 1955 in 2006 to 6586 in 2008. Anecdotally, during this same period we received a large number of calls from FOIA officers, often after requests had been pending for a year or more, inquiring whether we still wished to receive the documents requested, an apparent attempt to clear the backlog. This is hardly a permanent fix to the FOIA office's underlying problems. It remains to be seen whether the backlog can be maintained at this lower level.

For the period 1998-2006, there were steady increases in the time to process both simple and complex requests. (Data from 2007 and 2008 are not useful in this context as they appear to include a large number of very old requests that were withdrawn, driving up the median processing times.) The time to process a simple request rose from a median of about 15 days in the early part of the study period to 30 days in 2006. For complex requests, the processing time increased from a median of 51 days in 1998 to 473 days in 2006.

Figure 2 displays data on the FOIA exemptions invoked by the agency for the period 1998-2008. Exemptions 4 (confidential commercial information) and 7 (law enforcement records) were by far the most common (41% each). There is no evidence of a consistent increase or decrease over time in the fraction of claims processed that invoked these

exemptions. Exemptions 5 (inter- and intra-agency communications) and 6 (personal privacy) were next most common.

**Figure 2: Exemptions Used by the FDA to Deny FOIA Requests, 1998-2008**



As frequent users of the FOIA, we'd like to share some of our personal experiences with you. Aside from the often-lengthy delays in obtaining requested documents, a consistent problem is the erratic nature of redactions. For example, we recently had an article examining drug-induced liver injury accepted for publication in a medical journal. For reasons unclear to us, many of the dates were redacted from the paper versions of the MedWatch forms we received from the agency and upon which the research was based. This prevented us from fully analyzing the time to onset of symptoms or the duration of symptoms, reducing the usefulness of our article. The dates of laboratory tests were also redacted. When we requested similar data for statin drugs for a previous article,<sup>12</sup> the dates were not redacted, suggesting over-redaction in the liver disease MedWatch forms. It is hard to see where a date would qualify for redaction under exemption 4.

We also consistently use the FDA approval packages in our work. However, these may not appear until months after the product is approved. (Transcripts of advisory committee meetings can be similarly delayed.) Moreover, we recently learned that product approval packages in the Center for Veterinary Medicine are not posted at all. We understand that the agency prioritizes postings according to real or expected

<sup>12</sup> Ardati A, Stolley P, Knapp DE, Wolfe SM, Lurie P. Statin-associated rhabdomyolysis (letter). *Pharmacoepidemiology and Drug Safety* 2005;14:287.

popularity, but certain critical documents, such as approval packages, should be consistently posted by all Centers.

Public Citizen has written a law journal article<sup>13</sup> (attached to this testimony) discussing the significant FDA exemption 4 FOIA cases. The article documents the legal efforts to obtain public access to information generated during the various stages of the drug approval process, with the FDA typically weighing in alongside the manufacturer and favoring nondisclosure.<sup>14</sup> A change in the agency's posture would certainly be welcome.

### **3. The FDA should expedite the production of standardized drug information for patients**

Many patients would like to depend on the FDA for accurate information about their drugs, as they do not trust the agency to be objective. But the intricacies of the FDA web site make it difficult to navigate. Much of the site seems more oriented toward professionals than patients, with a plethora of lengthy technical material but relatively little that addresses the risks and benefits of drugs in plain language. The more frequent publication of *FDA Consumer* suggests that the agency is making efforts in this regard, but that is still a far cry from what the public really wants: detailed, yet understandable, FDA-approved information on every approved drug.

In its waning days, the Carter administration proposed such information in the form of what were then called patient package inserts, but these were scuttled early in the Reagan administration. We now have Medication Guides,<sup>15</sup> a kind of successor to the patient package insert, but the FDA's website lists only 178 Medication Guides among the thousands of approved drugs. (None appears to have been translated into Spanish.) Inevitably, the pharmaceutical industry fills the information gap with direct-to-consumer advertisements; these bear little relationship to true public health needs.<sup>16</sup>

On February 27, 2009, the FDA's FDA's Risk Communication and Drug Safety and Risk Management Advisory Committees concluded that the unregulated patient information currently provided in pharmacies is seriously deficient in the information provided about safety and other important issues. It unanimously endorsed a mandatory, standardized, FDA-approved format for communicating drug risks and benefits to patients with each

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<sup>13</sup> Lurie P, Zieve A. Sometimes the silence can be like the thunder: access to pharmaceutical data at the FDA. *Law and Contemporary Problems* 2006;69:85-97.

<sup>14</sup> See also Kesselheim AS, Mello MM. Confidentiality laws and secrecy in medical research: improving public access to data on drug safety. *Health Affairs* 2007;26:483-91.

<sup>15</sup> FDA. Medication Guides. Available at: <http://www.fda.gov/drugs/drugsafety/ucm085729.htm>. Last visited June 24, 2009.

<sup>16</sup> General Accounting Office. Prescription drugs: FDA oversight of direct-to-consumer advertising has limitations." GAO-03-177, October 2002. Available at: <http://www.gao.gov/new.items/d03177.pdf>. Last visited June 12, 2009.

prescription filled. We urge the FDA to move as quickly as possible to implement this recommendation.

Thank you once again for the opportunity to address the Task Force. The notion of transparency is critical in both practical and symbolic terms, for an agency based in openness is one more likely to see its recommendations followed.