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GOLDWATER INSTITUTE V. FDA

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Executive Summary

The Goldwater Institute is taking the U.S. Food and Drug Administration ("FDA") to court to bring transparency to the drug approval process. The FDA previously denied a Freedom of Information Act ("FOIA") request by the Goldwater Institute seeking information about the FDA's drug approval process that allowed two American doctors infected with Ebola to be successfully treated with a drug that is still in development. Although the Goldwater Institute sought only information about the government's internal operations in order to increase public awareness about the drug approval process in the United States, the FDA claimed that releasing the records would invade trade secrets of drug manufacturers. The FDA's arbitrary withholding of public information violates federal law and undermines the public's right to know the decisions a government agency is making on life and death matters.

Background

Last year, a deadly outbreak of the Ebola virus in West Africa captured the nation's attention and raised serious concerns about the lack of available treatments for the virus. After reports surfaced in August 2014 that two American doctors, Kent Brantly and Nancy Writebol, were successfully treated with an experimental medication, ZMapp, questions arose regarding how the drug was made available to the ailing doctors.[1]

The United States Food and Drug Administration ("FDA"), an agency that operates under the U.S. Department of Health and Human Services ("HHS"), has broad authority to regulate experimental drugs, including approving investigational new drugs.[2] Despite the public's substantial interest in the drug approval process in light of the Ebola outbreak, the FDA has declined to address questions regarding its role in the approval or administration of ZMapp and other experimental medications to patients infected with the disease.[3]

At the same time, the Goldwater Institute, a non-profit, national research and policy organization has extensively studied and offered policy recommendations and model legislation regarding the drug approval process in the United States. The Goldwater Institute developed and advocated for Right to Try laws, which allow terminally ill patients access to experimental medication without relying on the FDA's slow and laborious drug approval process. To date, nearly 20 states have enacted Right to Try legislation.[4]

On August 7, 2014, the Goldwater Institute sent a FOIA request to the FDA seeking records regarding the internal process the agency used to approve the use of ZMapp for Drs. Brantly and Writebol as well as others affected with the Ebola virus. The Institute sought these records to further its research and analysis of the drug approval process in the United States and to increase the public's understanding of that process.

Although the Goldwater Institute sought only records of the government's internal processes and procedures, the FDA denied the Institute's FOIA request in its entirety, claiming that the records were exempt from disclosure because they contained trade secrets and other confidential commercial information, purportedly exempt from disclosure under 5 U.S.C. § 522(b)(4) ("trade secrets exemption"). The FDA acknowledged having nine volumes of responsive records that it would not disclose in any part.

The Goldwater Institute administratively appealed the FDA's denial of its FOIA request to HHS, observing that the trade secrets exemption on which the FDA relied did not apply to the Institute's request for records about the agency's internal administrative review process.

Nearly four months later, on February 19, 2015, HHS denied the Goldwater Institute's administrative appeal, maintaining the applicability of the trade secrets exemption, and claiming several other new statutory and regulatory provisions purportedly preventing disclosure of the records.

Attorneys from the Goldwater Institute will now seek judicial review the FDA's administrative decision in U.S. District Court for the District of Arizona, where the Goldwater Institute is located.

Legal Analysis

The FOIA is predicated on a basic and fundamental tenant in our constitutional republic: open and transparent government. The central purpose of the FOIA is "to ensure that the Government's activities be opened to the sharp eye of public scrutiny,"[5] so that citizens in a free nation "are permitted to

know what their government is up to."[6] As courts have repeatedly held, freedom of information under federal law is the rule, secrecy is the exception.[7] To that end, there is a strong presumption in favor of disclosure.[8] As President Obama wrote in a memorandum to the heads of all executive agencies upon assuming office, "A democracy requires accountability, and accountability requires transparency. . . . The Freedom of Information Act should be administered with a clear presumption: In the face of doubt, openness prevails."[9]

Indeed, the FOIA specifically compels disclosure under certain circumstances. "Each agency *shall make available* to the public information as follows: . . . statements of the general course and method by which its functions are channeled and determined, including the nature and requirements of all formal and informal procedures available[.]"[10] In this case, the Goldwater Institute is seeking records expressly pertaining to "the general course and method by which [the FDA's] functions are channeled and determined," including the formal and informal *internal* approval procedures by which the drug ZMapp was administered to two American patients. In other words, the Goldwater Institute seeks records pertaining to the government's own administrative processes as they were applied in particular instances. Pursuant to 5 U.S.C. § 552(a)(1)(B), among other provisions, the FOIA requires disclosure of these records.

Although a requester's reasons for seeking public information is generally immaterial to the government's duty to disclose public records, in this case, the general purpose of the FOIA is directly aligned with the Goldwater Institute's objectives in seeking these records. The Goldwater Institute not only conducts research and analysis on issues pertaining to government transparency and health care, but the Institute is specifically engaged in research and analysis pertaining to the FDA drug approval process. The public records the Goldwater Institute requested from the FDA will be used to aid in that research and analysis and is expected to contribute to the public's understanding of the drug approval process in the United States. Opening administrative processes, such as the drug approval process, to the scrutiny of the general public for study and examination is one of the principal purposes of the FOIA.[11]

The trade secrets exemption on which the FDA relies to deny these public records in their entirety simply does not apply. As a general matter, exceptions to disclosure of records under the FOIA are to be narrowly construed.[12] The trade secrets exemption, in particular, should be read narrowly to exempt only records that would undermine its specific and limited purpose of encouraging individuals

to provide certain kinds of information to the government.[13] Additionally, the burden is on the government to prove that the records requested are exempt from disclosure under the trade secrets exemption.[14] In other words, the government must establish that the exemption applies.

In this case, the Goldwater Institute seeks neither trade secrets, nor confidential commercial information; indeed, the Goldwater Institute seeks no commercial information whatsoever. The Goldwater Institute seeks only records pertaining to the FDA's own internal approval processes and procedures regarding an experimental drug over which the FDA has apparent authority. Because the Goldwater Institute seeks records pertaining the government's own internal operations, the majority of which are presumably prepared by the government, these records, by their very nature, cannot be commercial, as the government ostensibly has no proprietary interest in its own internal review and approval processes.

The FDA's reliance on other FOIA exemptions and regulations is equally unavailing. The FDA claims the records are also exempt from disclosure because they contain privileged deliberative process information[15] as well as information that, if released, would cause "a clearly unwarranted invasion of personal privacy."[16] The FDA's deliberative process assertion is unconvincing because the Goldwater Institute seeks records that are not predecisional as well as records that pertain to the *application* of administrative procedures, not deliberative policy *development*. Additionally, the FDA's argument that Goldwater's request would invade personal privacy interests is inapplicable as Goldwater requested information on government procedures not personally identifiable information about individuals, and in any event, there is a significant public interest in the drug approval process, particularly during a medical calamity.

Finally, to the extent any records contain information to which an exemption is actually applicable, the FDA was and is required to evaluate alternatives to full disclosure.[17] In this case, the FDA has withheld documents contained in *nine volumes* in their entirety. Based on the size of the responsive records alone, it does not appear as though the FDA has evaluated alternatives to full disclosure such as partial disclosure or selective redaction. As a result, the FDA has failed to comply with its obligations to disclose public information under the FOIA.

The Goldwater Institute is, therefore, challenging the FDA's arbitrary withholding of public records in court. A successful outcome in this case will not only allow access to records that may aid in research and analysis regarding the drug approval process in the United States but also uphold significant principles of transparency and open government.

Case Logistics

The Plaintiff in this case is the Goldwater Institute. The Defendant is the HHS and the FDA. The case will be filed in U.S. District Court for the District of Arizona.

The Goldwater Institute seeks an order compelling the production of public records.

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[1] Sanjay Gupta and Danielle Dellorto, *Experimental Drug Likely Saved Ebola Patients*, CNN, August 5, 2014 *available at* http://www.cnn.com/2014/08/04/health/experimental-ebola-serum (http://www.cnn.com/2014/08/04/health/experimental-ebola-serum).

[2] Suzanne While, *FDA and Clinical Drug Trials: A Short History*, *available at* http://www.fda.gov/AboutFDA/WhatWeDo/History/Overviews/ucm304485.htm (http://www.fda.gov/AboutFDA/WhatWeDo/History/Overviews/ucm304485.htm).

[3] Gupta, *supra* note 1.

[4] *See generally* http://righttotry.org (http://righttotry.org/).

[5] *U.S. Dep't of Justice v. Reporters Comm. For Freedom of Press*, 489 U.S. 749, 774 (1989).

[6] *Envtl. Prot. Agency v. Mink*, 410 U.S. 73, 105 (1973).

[7] *Wellford v. Hardin*, 315 F. Supp. 768, 770 (D.D.C. 1970).

[8] *Sharyland Water Supply Corp. v. Block*, 755 F.2d 397, 398 (5th Cir. 1985)

[9] Presidential Memorandum, 74 F.R. 4683 (Jan. 21, 2009).

[10] 5 U.S.C. § 552(a)(1)(B) (emphasis added).

[11] *See Renegotiation Bd. v. Bannercraft Clothing Co.*, 415 U.S. 1, 9, 94 S. Ct. 1028, 1033 (1974) (Purpose of the FOIA was primarily to open administrative processes to the scrutiny of the press and general public); *Pub. Citizen Health Research Grp. v. Food & Drug Admin.*, 185 F.3d 898, 904 (D.C. Cir. 1999) (The requester's main reason for seeking information on the FDA's drug trials was directly aligned with the purpose of the FOIA.).

[12] *Milner v. Dep't of Navy*, 131 S. Ct. 1259, 1262 (2011).

[13] *Soucie v. David*, 448 F.2d 1067, 1078 (D.C. Cir. 1971).

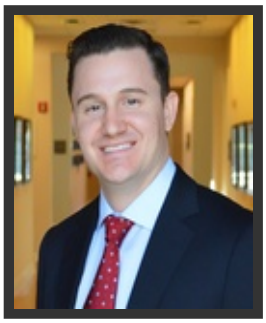
[14] *See Gov't Accountability Project v. U.S. Dep't of Health & Human Servs.*, 691 F. Supp. 2d 170, 180 (D.D.C. 2010).

[15] 5 U.S.C. § 552(b)(4).

[16] 5 U.S.C. § 552(b)(6).

[17] *See Grumman Aircraft Eng'g Corp. v. Renegotiation Bd.*, 425 F.2d 578, 580-81 (D.C. Cir. 1970); *see also Gov't Accountability Project*, 691 F. Supp. 2d at 181, *supra*, note 14.

Legal Team



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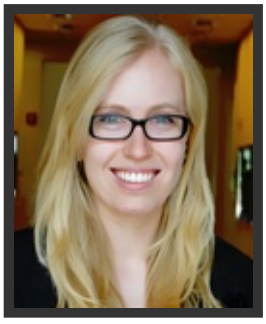
Jon Riches is an attorney at the Goldwater Institute's Scharf-Norton Center for Constitutional Litigation. He litigates in areas of taxpayer rights and fiscal policy, public union and pension reform, government transparency, economic liberty, and school choice, among others. Prior to joining the Goldwater Institute, Jon served on active duty in the U.S. Navy Judge Advocate General's (JAG) Corps, where he represented hundreds of clients, litigated dozens of Court-Martial cases, and advised commanders on a vast array of legal issues.



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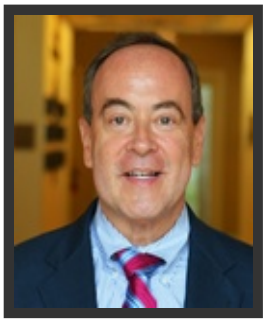

Clint Bolick (/en/authors/clint-bolick/)

Clint Bolick is the Goldwater Institute's litigation director. He has extensive success before trial judges and appellate courts, including free speech and economic liberty cases. He has won two cases before the U.S. Supreme Court. He was named as a Lawyer of the Year in 2003 by American Lawyer magazine.

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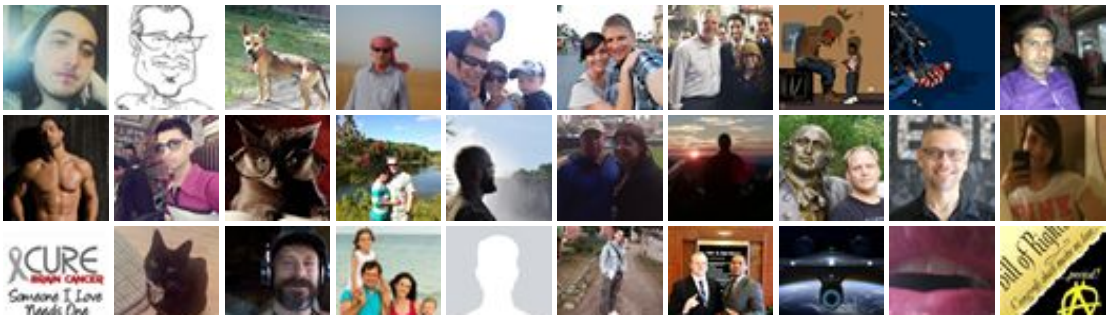

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