CAUSE of ACTION INSTITUTE
Advocates for Government Accountability
A 501(c)(3) Nonprofit Corporation

December 21, 2016

VIA FAX

FOIA Officer
Food and Drug Administration
Division of Freedom of Information
Office of the Executive Secretariat, OC
5630 Fishers Lane, Room 1035
Rockville, MD 20857
Fax: (301) 827-9267

Re: Freedom of Information Act Request

Dear FOIA Officer:

I write on behalf of Cause of Action Institute ("CoA Institute"), a nonprofit strategic oversight group committed to ensuring that government decision-making is open, honest, and fair.[1] In carrying out its mission, CoA Institute uses various investigative and legal tools to educate the public about the importance of government transparency and accountability. To that end, we are examining the role of the Food and Drug Administration ("FDA") in regulating laboratory developed tests ("LDTs").

In July 2014, the FDA announced its intent to begin regulating LDTs for the first time.[2] The FDA claims that its authority to regulate LDTs stems from legislation passed in 1976, and that the FDA has simply opted not to exercise its regulatory authority for nearly 40 years.[3] In the absence of FDA regulation, the development and use of LDTs flourished. Today, thousands of LDTs are available to doctors in the course of treating their patients,[4] and qualified laboratories have had the freedom to develop tests that meet patients' unique needs.[5]

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[1] *See* CAUSE OF ACTION INSTITUTE, *About*, www.causeofaction.org/about/.

[2] *See* FOOD AND DRUG ADMINISTRATION, ANTICIPATED DETAILS OF THE DRAFT GUIDANCE FOR INDUSTRY, FOOD AND DRUG ADMINISTRATION STAFF, AND CLINICAL LABORATORIES: FRAMEWORK FOR REGULATORY OVERSIGHT OF LABORATORY DEVELOPED TESTS (LDTS) (2014), *available at* http://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/UCM407409.pdf.

[3] *Id.* at 5.

[4] *See* Thomas M. Burton, *Is Lab Testing the 'Wild West' of Medicine?*, WALL ST. J., Dec. 10, 2015, http://www.wsj.com/articles/is-lab-testing-the-wild-west-of-medicine-1449800707.

[5] Oscar Segurado, *FDA Hold on Guidance for Laboratory Developed Tests is a Wise Action*, THE HILL, Nov. 29, 2016, http://thehill.com/blogs/pundits-blog/healthcare/307919-fda-hold-on-guidance-for-laboratory-developed-tests-is-a-wise ("LDTs are the cornerstone of personalized medicine, depending on sufficient

Last month, after developing guidance on the use of LDTs for over two years, the FDA announced its decision to pause finalization of the guidance in light of the presidential election.[6] While this step is good news for those who question the agency's legal authority to regulate LDTs, and particularly the propriety of doing so through guidance rather than through notice-and-comment rulemaking, the decision has created an uncertain regulatory environment for hospitals, clinical laboratories, and healthcare providers who wish to offer patients high-quality, cutting-edge care.

For example, the FDA's guidance scheme has impacted the ability of hospitals and laboratories to develop and offer tests for Zika virus infections. Earlier this year – in the midst of the Zika virus outbreak – the FDA stated that certain LDTs used to aid in the diagnosis of Zika virus infections appear to be "devices" which are subject to FDA jurisdiction under the Federal Food, Drug, and Cosmetic Act.[7] The FDA sent numerous inquiry letters to hospitals and laboratories that, the FDA suggested, were marketing unauthorized Zika virus tests.[8] Before the FDA issued guidance in order to begin regulating LDTs, the agency likely would not have interfered with laboratories offering such tests.

CoA Institute is interested in learning more about the FDA's attempts to regulate LDTs and the impacts such regulation may have on the ability of patients and doctors to access testing services, such as laboratory developed Zika virus tests. Pursuant to the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, CoA Institute hereby requests access to the following records:[9]

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flexibility for research, development and clinical adoption. . . . [Regulation] could cause halting or slowing down of research and development efforts.").

[6] *See* Michael D. Williamson, *FDA Delays Lab Test Changes Until Trump Takes Office*, BLOOMBERG BNA, Nov. 21, 2016, https://www.bna.com/fda-delays-lab-n73014447523/.

[7] *See, e.g.*, Letter from James L Woods, Deputy Director, Patient Safety and Product Quality, Food and Drug Administration, to Dr. James Versalovic, Texas Children's Hospital, and Dr. James M. Musser, Houston Methodist Hospital (Mar. 2, 2016), *available at* http://www.fda.gov/downloads/MedicalDevices/ResourcesforYou/Industry/UCM490410.pdf.

[8] *Id*. *See also* Letter from James L. Woods, Deputy Director, Patient Safety and Product Quality, Food and Drug Administration, to Eddie Moradian, Chief Executive Officer, MD Biosciences (Mar. 4, 2016), *available at* http://www.fda.gov/downloads/MedicalDevices/ResourcesforYou/Industry/UCM490077.pdf; Letter from James L. Woods, Deputy Director, Patient Safety and Product Quality, Food and Drug Administration, to Lisa A. Shadorf, Official Correspondent, First Diagnostic Corporation (Mar. 10, 2016), *available at* http://www.fda.gov/downloads/MedicalDevices/ResourcesforYou/Industry/UCM490404.pdf; Letter from James L. Woods, Deputy Director, Patient Safety and Product Quality, Food and Drug Administration, to Eli Mordechai, Chief Executive Officer & Founder, Medical Diagnostic Laboratories (Mar. 23, 2016), *available at* http://www.fda.gov/downloads/MedicalDevices/ResourcesforYou/Industry/UCM492680.pdf; Letter from Alberto Gutierrez, Director, Office of *In Vitro* Diagnostics and Radiological Health, Food and Drug Administration, to Julie Kliegl, President, Viracor-IBT Laboratories (Oct. 21, 2016), *available at* http://www.fda.gov/downloads/MedicalDevices/ResourcesforYou/Industry/UCM526388.pdf.

[9] For purposes of this request, the term "present" should be construed as the date on which the agency begins its search for responsive records. *See Pub. Citizen v. Dep't of State*, 276 F.3d 634 (D.C. Cir. 2002). The term "record" means the entirety of the record any portion of which contains responsive information. *See Am. Immigration Lawyers Ass'n v. Exec. Office for Immigration Review*, 830 F.3d 667, 677-78 (D.C. Cir. 2016) (admonishing agency for withholding information as "non-responsive" because "nothing in the statute suggests

1. All requests for Emergency Use Authorization for laboratory developed Zika tests submitted to the FDA between January 1, 2016 and the present;

2. All denials of Emergency Use Authorization requests for laboratory developed Zika tests issued by the FDA between January 1, 2016 and the present;

3. All communications, including but not limited to emails, referring or relating to the demand for Zika tests, including but not limited to backlogs or wait times for test results, sent or received between January 1, 2016 and the present;

4. All communications, including but not limited to emails, referring or relating to the Centers for Disease Control and Prevention's clinical and epidemiological criteria for Zika testing, sent or received between January 1, 2016 and the present;

5. All communications, including but not limited to emails, referring or relating to Zika tests developed and offered by Viracor-IBT Laboratories, Texas Children's Hospital, Houston Methodist Hospital, MD Biosciences, First Diagnostic Corporation, and Medical Diagnostic Laboratories sent or received between November 8, 2016 and the present;

6. All communications, including but not limited to emails, referring or relating to the further enforcement or applicability of the interim guidance sent or received between November 8, 2016 and the present; and

7. All records of "known or suspected adverse events related to the use of an LDT," as the term is used in the FDA's interim guidance, from November 16, 2015 to the present.

Request for a Public Interest Fee Waiver

CoA Institute requests a waiver of any and all applicable fees. FOIA and applicable regulations provide that the agency shall furnish requested records without or at reduced charge if "disclosure of the information is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government and is not primarily in the commercial interest of the requester."[10]

In this case, the requested records would unquestionably shed light on the "operations or activities of the government," namely whether the FDA's regulatory scheme governing LDTs, including LDTs intended to aid in the diagnosis of Zika virus infections, inhibits patient access to testing services and the freedom of doctors to utilize all information relevant to their diagnosis and treatment decisions. Additionally, the requested records would inform the public about the FDA's controversial decision to regulate LDTs after declining to do so for nearly forty years. The public has an interest in becoming aware of and understanding why the FDA is taking such

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that the agency may parse a responsive record to redact specific information within it even if none of the statutory exemptions shields that information from disclosure").

[10] 5 U.S.C. § 552(a)(4)(A)(iii); 21 C.F.R. § 20.46(a)(1)-(2); *see also Cause of Action v. Fed. Trade Comm'n*, 799 F.3d 1108, 1115-19 (D.C. Cir. 2015) (discussing proper application of public-interest fee waiver test).

actions at this time, and whether regulating LDTs now would benefit or harm patients and doctors seeking access to testing services.

CoA Institute has both the intent and ability to make the results of this request available to a reasonably broad public audience through various media. Its staff has significant experience and expertise in government oversight, investigative reporting, and federal public interest litigation. These professionals will analyze the information responsive to this request, use their editorial skills to turn raw materials into a distinct work, and share the resulting analysis with the public, whether through the Institute's regularly published online newsletter, memoranda, reports, or press releases.[11] In addition, as CoA Institute is a non-profit organization as defined under Section 501(c)(3) of the Internal Revenue Code, it has no commercial interest in making this request.

Request To Be Classified as a Representative of the News Media

For fee status purposes, CoA Institute also qualifies as a "representative of the news media" under FOIA.[12] As the D.C. Circuit recently held, the "representative of the news media" test is properly focused on the requestor, not the specific FOIA request at issue.[13] CoA Institute satisfies this test because it gathers information of potential interest to a segment of the public, uses its editorial skills to turn raw materials into a distinct work, and distributes that work to an audience. Although it is not required by the statute, CoA Institute gathers the news it regularly publishes from a variety of sources, including FOIA requests, whistleblowers/insiders, and scholarly works. It does not merely make raw information available to the public, but rather distributes distinct work products, including articles, blog posts, investigative reports, newsletters, and congressional testimony and statements for the record.[14] These distinct works are distributed to the public through various media, including the Institute's website, Twitter, and Facebook. CoA Institute also provides news updates to subscribers via e-mail.

The statutory definition of a "representative of the news media" contemplates that organizations such as CoA Institute, which electronically disseminate information and

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[11] *See also Cause of Action*, 799 F.3d at 1125-26 (holding that public interest advocacy organizations may partner with others to disseminate their work).

[12] 5 U.S.C. § 552(a)(4)(A)(ii)(II); 21 C.F.R. § 20.46.

[13] *See Cause of Action*, 799 F.3d at 1121.

[14] *See, e.g.*, COA INSTITUTE, PRESIDENTIAL ACCESS TO TAXPAYER INFORMATION (October 2016), *available at* http://coainst.org/2eXd1Ga; COA INSTITUTE, MEMORANDUM: LEGAL ANALYSIS OF FORMER SECRETARY OF STATE HILLARY CLINTON'S USE OF A PRIVATE SERVER TO STORE EMAIL RECORDS (Aug. 24, 2015), *available at* http://coainst.org/2eXhXe1; *Cause of Action Testifies Before Congress on Questionable White House Detail Program* (May 19, 2015), *available at* http://coainst.org/2aJ8UAA; COA INSTITUTE, 2015 GRADING THE GOVERNMENT REPORT CARD (Mar. 16, 2015), *available at* http://coainst.org/2as088a; *Cause of Action Launches Online Resource: ExecutiveBranchEarmarks.com* (Sept. 8, 2014), *available at* http://coainst.org/2aJ8sm5; COA INSTITUTE, GRADING THE GOVERNMENT: HOW THE WHITE HOUSE TARGETS DOCUMENT REQUESTERS (Mar. 18, 2014), *available at* http://coainst.org/2aFWxUZ; COA INSTITUTE, GREENTECH AUTOMOTIVE: A VENTURE CAPITALIZED BY CRONYISM (Sept. 23, 2013), *available at* http://coainst.org/2apTwqP; COA INSTITUTE, POLITICAL PROFITEERING: HOW FOREST CITY ENTERPRISES MAKES PRIVATE PROFITS AT THE EXPENSE OF AMERICAN TAXPAYERS PART I (Aug. 2, 2013), *available at* http://coainst.org/2aJh901.

publications via "alternative media[,] shall be considered to be news-media entities."[15] In light of the foregoing, numerous federal agencies—including other agencies within the Department of Health and Human Services—have appropriately recognized the Institute's news media status in connection with its FOIA requests.[16]

Record Preservation Requirement

CoA Institute requests that the disclosure officer responsible for the processing of this request issue an immediate hold on all records responsive, or potentially responsive, to this request, so as to prevent their disposal until such time as a final determination has been issued on the request and any administrative remedies for appeal have been exhausted. It is unlawful for an agency to destroy or dispose of any record subject to a FOIA request.[17]

Record Production and Contact Information

In an effort to facilitate document review, please provide the responsive documents in electronic form in lieu of a paper production. If a certain portion of responsive records can be produced more readily, CoA Institute requests that those records be produced first and the remaining records be produced on a rolling basis as circumstances permit.

If you have any questions about this request, please contact me by telephone at (202) 499-4232 or by e-mail at jessica.conrad@causeofaction.org. Thank you for your attention to this matter.

Jessica M. Conrad
Counsel

[15] 5 U.S.C. § 552(a)(4)(A)(ii)(II).

[16] *See, e.g.*, FOIA Request 2016-11-008, Dep't of the Treasury (Nov. 7, 2016); FOIA Requests OS-2017-00057 & OS-2017-00060, Dep't of the Interior (Oct. 31, 2016); FOIA Request 2017-00497, Office of Personnel Management (Oct. 21, 2016); FOIA Request 092320167031, Centers for Medicare & Medicaid Services (Oct. 17, 2016); FOIA Request 17-00054-F, Dep't of Educ. (Oct. 6, 2016); FOIA Request DOC-OS-2016-001753, Dept. of Commerce (Sept. 27, 2016); FOIA Request 2016-09-101, Dep't of the Treasury (Sept. 21, 2016); FOIA Request 14F-036, Health Res. & Serv. Admin. (Dec. 6, 2013).

[17] *See* 36 C.F.R. § 1230.3(b) ("Unlawful or accidental destruction (also called unauthorized destruction) means . . . disposal of a record subject to a FOIA request, litigation hold, or any other hold requirement to retain the records."); *Chambers v. Dep't of the Interior*, 568 F.3d 998, 1004-05 (D.C. Cir. 2009) ("[A]n agency is not shielded from liability if it intentionally transfers or destroys a document after it has been requested under the FOIA or the Privacy Act."); *Judicial Watch, Inc. v. Dep't of Commerce*, 34 F. Supp. 2d 28, 41-44 (D.D.C. 1998).