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June 11, 2010

VIA FAX: 301-443-1726
Food and Drug Administration
Division of Freedom of Information
Office of Shared Services
Office of Public Information and Library Services
5600 Fishers Lane
Rockville, MD 20857

RE: Freedom of Information Act Request

Dear FOIA Officer:

This letter constitutes a request to the Food and Drug Administration ("FDA") under the Freedom of Information Act ("FOIA"),[1] and is submitted on behalf of the Electronic Privacy Information Center ("EPIC"). EPIC seeks agency records in the possession of FDA, including the contract between FDA and Harvard Pilgrim Health Services, Inc. ("Harvard Pilgrim") concerning the Sentinel Initiative, as well as communications between these two parties.

Background

In September 2005, Health and Human Services ("HHS") Secretary Mike Leavitt asked FDA to expand its system for monitoring medical product performance.[2] The following year, the Institute of Medicine suggested that FDA develop a system to access other health-related databases so as to support studies of product safety and efficacy.[3]

In 2007, FDA began exploring the feasibility of creating a national electronic system for monitoring medical product safety.[4] In September of that year, the Food and Drug Administration Amendments Act of 2007 ("FDAAA") was signed into law.[5] The

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1 5 U.S.C. § 552 (2009).

2 U.S. Food & Drug Admin., The Sentinel Initiative: A National Strategy for Monitoring Medical Product Safety 3 (May 2008).

3 Institute of Medicine, The Future of Drug Safety: Promoting and Protecting the Health of the Public (2006); *see also* U.S. Food & Drug Admin., *supra* note 2, at 4.

4 U.S. Food & Drug Admin., *supra* note 2, at 4.

5 Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, § 905, 121 Stat. 823,

FDAAA calls for active postmarket safety surveillance and analysis, requiring that the HHS Secretary develop methods to obtain access to disparate data sources and to establish a postmarket risk identification and analysis system to link and analyze healthcare data from multiple sources.[6]

In 2008, FDA launched the Sentinel Initiative in accordance with calls to streamline monitoring of medical product safety and as part of efforts to comply with the FDAAA.[7] In its official announcement, FDA described the Sentinel System as "a national, integrated, electronic system for monitoring medical product safety."[8] Sentinel will "enable [FDA] to access the capabilities of multiple, existing data systems (e.g., electronic health record systems, medical claims databases)."[9]

In June 2009, FDA issued a Request for Proposals ("RFP") inviting private parties to submit proposals for a project entitled "Efforts to Develop the Sentinel Initiative"[10] in anticipation of awarding a five-year contract.[11] The RFP explained that the contractor would directly access electronic health record systems, administrative claims databases, and registries containing patient data.[12] The RFP further described "continuous direct access to various regularly updated automated healthcare data sources containing patient-level health encounter data" and "a computerized system able to link each patient to all relevant medical care data including enrollment status, medical product exposure data, and coded medical procedures and outcomes."[13] On September 25, FDA awarded the contract to Harvard Pilgrim.[14]

At an event in January of this year, Janet Woodcock, director of the Center for Drug Evaluation and Research at FDA, reported that at that time FDA was already implementing "Miniature Sentinel—Mini Sentinel—or the start-up for Sentinel."[15] At that same event, Richard Platt, Harvard Pilgrim's project manager on the Sentinel contract,

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823–978.

6 U.S. Food & Drug Admin., *supra* note 2, at 4; *see also* Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, § 905(a), 121 Stat. 823, 944, (codified at 21 U.S.C. § 355).

7 *Id.*

8 *Id.* at 13.

9 *Id.*

10 U.S. Food & Drug Admin., Solicitation No. 09-223-SOL-00112 (June 19, 2009), *available at* https://www.fbo.gov/utils/view?id=22d47f8a63afc545720c1124f8d707a7.

11 *Id.* at 2.

12 *Id.* at 8.

13 *Id.*

14 Federal Business Opportunities, Detection and Analysis of Adverse Events related to Regulated Products in Automated Healthcare Data: Efforts to Develop the Sentinel Initiative, https://www.fbo.gov/spg/HHS/FDA/DCASC/FDA-SOL-09-1056109/listing.html (last visited June 9, 2010).

15 The Brookings Institution, Transcript of Second Annual Sentinel Initiative Workshop 108 (Jan. 11, 2010), *available at* http://www.brookings.edu/~/media/Files/events/2010/0111_sentinel_workshop/TRANSCRIPT%20Sentinel%201%2022%2010.pdf.

described Harvard Pilgrim as "the effecter arm for FDA."[16] Platt reported that the data environments participating in Mini Sentinel at that time included 60 million individuals, with 10 million linked to electronic medical records;[17] Platt also reported the participation of "88 inpatient facilities and a large number of device and disease registries."[18]

As an integrated electronic system designed to query and analyze vast amounts of potentially sensitive patient health data, the Sentinel System may have important implications for patient privacy. Indeed, in anticipation of arising privacy concerns, legislators included provisions in the FDAAA mandating that no later than 18 months after the date of its enactment the Government Accountability Office (GAO) evaluate privacy, confidentiality, and security issues relating to FDA's new system.[19] In accordance with these provisions, GAO provided a briefing to Congressional Committees on March 24, 2009, and published a related report in June of that year.[20] GAO stated that FDA would likely face significant challenges in the field of privacy and security protections and that, as of the date of the report, "FDA [had] not yet developed a plan or set milestones for when it expect[ed] to have these issues addressed."[21] In particular, GAO noted that "protecting the privacy of [medical] information has long been recognized as an essential element in the administration of health care systems"[22] and identified challenges associated with, *inter alia*:

> - ensuring that appropriate legal mechanisms are established to protect privacy and implement security consistently across all elements associated with the Sentinel system;
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> - defining a clear and specific purpose for the system and ensuring that partners with varying interests and business missions use personal health information only for specified purposes;
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> . . . .
>
> - ensuring that de-identified information . . . is not re-identified and that the use of personal health information in individually identifiable form is minimized and adequately protected;

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[16] *Id.* at 135.

[17] *Id.* at 130.

[18] *Id.*

[19] Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, § 905(e), 121 Stat. 823, 949; *see also* Gov't Accountability Office, Report to Congressional Committees: Privacy and Security: Food and Drug Administration Faces Challenges in Establishing Protections for Its Postmarket Risk Analysis System 2 (June 2009).

[20] Gov't Accountability Office, *supra* note 19.

[21] *Id.* at 4.

[22] *Id.* at 1.

- establishing adequate security controls to protect the personal health information associated with Sentinel from unauthorized disclosure, modification, and destruction . . . [23]

It is important for the public to understand how electronic management, analysis, and transfer of sensitive personal information may impact patient privacy values and concerns, as well as how FDA and Harvard Pilgrim are working to protect patient privacy and to address specific concerns highlighted by GAO. Mini Sentinel already has access to information on 60 million patients;[24] as the system expands to engage the records of a greater and greater percentage of the population, public oversight may be critical to ensure that new developments properly contemplate and honor patients' privacy values.

Documents Requested

EPIC requests the following agency records related to the development of the Sentinel Initiative (including but not limited to electronic records):

1. Any and all contracts between FDA and Harvard Pilgrim relating to the Sentinel Initiative, between January 1, 2008 and present.

2. Any and all communications between FDA and Harvard Pilgrim clarifying terms relating to the contract(s) described in item 1 above.

3. Any and all documents establishing or clarifying procurement specifications relating to the contract(s) described in item 1 above.

4. Any and all minutes from meetings between FDA and Harvard Pilgrim in relation to the Sentinel Initiative, between January 1, 2008 and present.

5. All Workplans relating to the contract(s) described in item 1 above.

Request for Expedited Processing

This request warrants expedited processing because it is made by "a person primarily engaged in disseminating information"[25] and it pertains to a matter about which

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[23] *Id.* at 4.

[24] THE BROOKINGS INSTITUTION, *supra* note 15, at 130.

[25] 5 U.S.C. § 552(a)(6)(E)(v)(II) (2009).

there is an "urgency to inform the public about an actual or alleged federal government activity."[26]

There is a particular urgency for the public to obtain information about privacy protection in the Sentinel Initiative. In spite of the privacy-related concerns and challenges identified by GAO almost a year ago, neither FDA nor Harvard Pilgrim has released a description of Mini Sentinel sufficient to explain how such concerns are being addressed and challenges met. As of January of this year, Mini Sentinel was already engaging with information about 60 million patients, with 10 million linked to electronic medical records,[27] and the FDAAA of 2007 sets a goal of access to data from 100 million patients by July 1, 2012.[28] The Sentinel System is rapidly expanding. The public has the right to know what agreements have been made between the FDA and Harvard Pilgrim relating to privacy concerns associated with the Sentinel Initiative.

Request for "News Media" Fee Status

EPIC is a non-profit educational organization that routinely and systematically disseminates information to the public. This is accomplished through several means. First, EPIC maintains a heavily visited website (www.epic.org) that highlights the "latest news" concerning privacy and civil liberties issues. The site also features scanned images of documents EPIC contains under FOIA. Second, EPIC publishes a bi-weekly electronic newsletter that is distributed to over 15,000 readers, many of whom report on technology issues for major news outlets. The newsletter reports on relevant policy developments of a timely nature (hence the bi-weekly publication schedule). It has been published continuously since 1996, and an archive of past issues is available at our website. Finally, EPIC publishes and distributes printed books that address a broad range of privacy, civil liberties, and technology issues. A list of EPIC publications is available at our website.

For the forgoing reasons, EPIC clearly fits the definition of "representative of the news media" contained in FOIA. Indeed, the U.S. District Court for the District of Columbia has specifically held that EPIC is "primarily engaged in disseminating information" for the purposes of expedited processing,[29] and is a "representative of the news media" for fee waiver purposes.[30] Based on our status as a "news media" requester, we are entitled to receive the requested records with only duplication costs assessed. Further, because disclosure of this information will "contribute significantly to public understanding of the operations or activities of the government," as described above, any duplication fees should be waived.

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[26] Al-Fayed v. U.S. Cent. Intelligence Agency, 254 F.3d 300, 306 (D.C. Cir. 2001).

[27] The Brookings Institution, *supra* note 15, at 130.

[28] Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, § 905(a), 121 Stat. 823, 944, (codified at 21 U.S.C. § 355).

[29] Am. Civil Liberties Union v. U.S. Dep't of Just., 321 F. Supp. 2d 24, 29 n. 5 (D.D.C. 2004).

[30] Elec. Privacy Info. Ctr. v. U.S. Dep't of Def. 241 F. Supp. 2d 5 (D.D.C. 2003).

Thank you for your consideration of this request. As 5 U.S.C. § 552(a)(6)(E)(ii)(I) provides, I will anticipate your determination on our request for expedited processing within ten business days.

Sincerely,

Laura Moy
EPIC Clerk

John Verdi
Director, EPIC Open Government Project