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12 AMERICAN CIVIL LIBERTIES UNION OF
NORTHERN CALIFORNIA AND
13 BAY GUARDIAN

14 UNITED STATES DISTRICT COURT
15 NORTHERN DISTRICT OF CALIFORNIA
16 SAN FRANCISCO DIVISION

18 AMERICAN CIVIL LIBERTIES UNION OF
NORTHERN CALIFORNIA and BAY
19 GUARDIAN,

20 Plaintiffs,

21 v.

22 U.S. FOOD AND DRUG
ADMINISTRATION,

23 Defendant.
24
25
26
27
28

Case No. _____

**COMPLAINT FOR INJUNCTIVE
RELIEF UNDER THE FREEDOM OF
INFORMATION ACT, 5 U.S.C. § 552**

1 INTRODUCTION

2 1. This is an action to enforce the Freedom of Information Act, 5 U.S.C. § 552,
3 (“FOIA”), under which the public is presumptively entitled to request and receive in their entirety
4 documents held by government agencies. On January 4, 2011, Plaintiffs the American Civil
5 Liberties Union of Northern California (“ACLU-NC”) and the *San Francisco Bay Guardian*
6 (“*Bay Guardian*”) submitted a FOIA request seeking from Defendant, the U.S. Food and Drug
7 Administration (“FDA”), records pertaining to the federal government’s role in overseeing, or
8 failing to oversee, state prisons’ procurements of lethal injection drugs. These drugs are subject
9 to regulation, including import restrictions, by the FDA. In response, FDA has failed to conduct
10 an adequate search, withheld certain entire documents in its possession that bear upon Plaintiffs’
11 request, and released others with redactions so heavy as to eviscerate them of meaningful content.
12 After months of letters and phone conversations, and the filing of administrative appeals, FDA
13 still refuses to turn over the withheld material or make a meaningful effort to justify itself under
14 statutory exemptions. FDA is in violation of FOIA, and is suppressing information that pertains
15 to an urgent matter of great public concern.

16 2. Thirty states, including California, employ a three-drug protocol for executing
17 condemned inmates by lethal injection. This protocol uses a single painkiller, sodium thiopental,
18 in conjunction with pancuronium bromide, a paralytic agent, and potassium chloride, a salt which
19 induces cardiac arrest when injected. Potassium chloride causes extreme pain as it stops the
20 heart. Pancuronium bromide paralyzes all voluntary muscles and prevents any visible movement;
21 it induces such total paralysis that even a person in extreme distress is rendered completely
22 motionless. Prevention of an excruciatingly but invisibly painful death thus depends on the
23 proper administration of sodium thiopental of sufficient quality and dosage.

24 3. Last year, the only domestic supplier of sodium thiopental encountered production
25 problems and a nationwide shortage of the drug ensued. Prisons began to seek the drug from
26 other sources. However, the FDA has not approved any foreign source for the importation of
27 sodium thiopental. Information requests and litigation have revealed the identities of some of
28 these sources, which were plainly not suppliers of first resort, and often appear to lack expertise.

1 For example, domestic and foreign media have reported extensively on British supplier “Dream
2 Pharma Ltd.,” which operates in a country where capital punishment is outlawed and which
3 shares an office with a driving school. Its owner, Mehdi Alavi, claims to have had “no idea” why
4 a prison in Arizona would want a shipment of sodium thiopental, pancuronium bromide, and
5 potassium chloride. These media reports have heightened concerns as to the quality of these
6 imported drugs. The efficacy of sodium thiopental, the only drug in the three-drug lethal
7 injection protocol which can lessen pain, depends upon factors such as its age, its purity, and how
8 it has been stored. If executioners use sodium thiopental that is deficient in any of these respects,
9 there is an increased risk of cruel and excruciatingly painful death.

10 4. Plaintiffs are also concerned that prisons are violating foreign and domestic laws
11 by purchasing drugs from unlicensed suppliers and in countries with laws that forbid their sale for
12 capital punishment. The public has a basic interest in understanding the role of the federal
13 government in overseeing the acquisition and use of federally-regulated drugs by states for the
14 purpose of executing inmates by lethal injection. The public also has a right to know how the
15 government spends public funds. The public’s need to know is especially keen where state
16 governments may be spending public money to circumvent or violate the law.

17 5. The documents Plaintiffs seek regarding the procurement of lethal injection drugs
18 go to the heart of FOIA’s statutory aims of promoting open government, preventing the
19 entrenchment of secret governmental practices, and permitting public scrutiny of federal and state
20 governmental action. Plaintiffs seek basic information regarding the price, quantity, source,
21 destination, and transportation of the drugs. Information about quantity, source, and destination
22 could, for example, help the public determine which states may possess drugs of substandard
23 quality. Similarly, more information about the transportation process could indicate whether or
24 not drugs like sodium thiopental have been properly stored so as to prevent premature
25 degradation. Pricing data would inform the public how officials are spending taxpayer funds.

26 6. FDA’s response to Plaintiffs’ FOIA request does not fulfill its obligations under
27 the law. Far from applying exemptions sparingly, as courts have held FOIA requires, FDA has
28 redacted from documents information that cannot plausibly fall under any exemption. FDA has

1 also failed to conduct an adequate search for relevant documents. Plaintiffs have filed multiple
2 administrative appeals, citing to specific judicial opinions defining the scope of FOIA
3 exemptions, but FDA has yet to make any substantive reply.

4 7. Having exhausted their administrative remedies, Plaintiffs now respectfully
5 petition the Court to compel production of these documents without further delay.

6 PARTIES

7 8. Plaintiff American Civil Liberties Union of Northern California, a nonprofit
8 organization established under the laws of the state of California and headquartered in San
9 Francisco, California, is an affiliate of the American Civil Liberties Union, a national, non-profit,
10 non-partisan organization. Its mission is to protect civil liberties from government incursions,
11 safeguard basic constitutional rights, and advocate for open government. ACLU-NC has
12 approximately 50,000 members, and operates a communications department which disseminates
13 information to the public through newsletters, its website, and other publications.

14 9. Plaintiff *Bay Guardian* is a corporation organized under the laws of the state of
15 California and headquartered in San Francisco, California. It is a locally-owned, independent
16 newspaper of general circulation, published continuously since 1966, and has the largest
17 circulation of any newsweekly in Northern California, with an audited weekly distribution of
18 approximately 100,000. As a newspaper, its primary activity is publishing or otherwise
19 disseminating information to the public. *Bay Guardian* has published extensively on state efforts
20 to acquire sodium thiopental for use in executions, and is prepared to publish appropriate articles
21 concerning this subject based on information sought by the FOIA request at issue here. In 2011,
22 *Bay Guardian* received the California Newspaper Publishers Association's General Excellence
23 award for a weekly newspaper.

24 10. Defendant Food and Drug Administration is an agency within the United States
25 Department of Health and Human Services. FDA is an agency within the meaning of 5 U.S.C. §
26 552(f). It is headquartered in Maryland and operates a San Francisco field office.

27 JURISDICTION

28 11. This Court has subject matter jurisdiction over this action and personal jurisdiction

1 over the parties pursuant to 5 U.S.C. §§ 552(a)(4)(B) and 552(a)(6)(C)(i). Because this action
2 arises under FOIA against an agency of the United States, this Court also has subject matter
3 jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1346.

4 VENUE AND INTRADISTRICT ASSIGNMENT

5 12. Venue is proper in this district pursuant to 5 U.S.C. §552(a)(4)(B) and 28 U.S.C.
6 §§ 1391(e) and §1402.

7 13. Pursuant to Local Rule 3-2(c) and (d), assignment to the San Francisco division is
8 proper because a substantial portion of the events giving rise to this action occurred in this district
9 and division, and because both Plaintiffs are headquartered in San Francisco.

10 FACTUAL BACKGROUND

11 14. Many states use sodium thiopental as part of a process to execute condemned
12 prisoners. States that use the three-drug protocol administer sodium thiopental first, to induce
13 unconsciousness and render the inmate insensitive to pain, before injecting pancuronium bromide
14 and potassium chloride, which respectively paralyze the inmate's muscles and induce cardiac
15 arrest. The state of Washington uses sodium thiopental alone to carry out executions.

16 15. Of these three lethal injection drugs, only sodium thiopental acts to alleviate pain.
17 Indeed, the other two drugs each inflict pain. *See Lethal Injection Web-Based Clearinghouse*,
18 <http://www.law.berkeley.edu/clinics/dpclinic/LethalInjection/LI/OA/9.html> (last visited July 21,
19 2011). Pancuronium bromide induces complete paralysis, preventing any visible movement.
20 This paralysis conceals any signs that an inmate has regained consciousness and is experiencing
21 pain, even the extreme pain caused by potassium chloride.

22 16. The efficacy of a given quantity of sodium thiopental diminishes with time; the
23 FDA-approved Hospira version of the drug has a shelf life of only two years. Its efficacy also
24 depends upon factors such as its purity and whether it has been properly stored.

25 Nationwide Shortage of Sodium Thiopental

26 17. On information and belief, in May 2010, Hospira, Inc. ("Hospira"), the only
27 domestic supplier of sodium thiopental approved by FDA, stopped selling sodium thiopental.
28 The resulting shortage of sodium thiopental led some states to postpone executions, or to rush to

1 conduct them before the expiration dates of their remaining supplies. As the shortage began to
2 impact executions, attorneys, community members, and journalists began expressing concern as
3 to how state corrections officials would obtain sodium thiopental, whether government officials
4 would violate any state or federal laws in their efforts to obtain the drug, and what other steps
5 officials might take in order to proceed with executions.

6 18. News media reported extensively on the scheduled execution of Albert Brown in
7 California, set for 9:00 PM on September 30, 2010 using sodium thiopental that was to expire on
8 October 1. This execution was to be the first following a four-year moratorium on executions that
9 a federal judge had imposed, citing concerns about California's lethal injection procedures. *See*
10 *generally Morales v. Tilton*, 465 F. Supp. 2d 972 (N.D. Cal. 2006). On August 30, 2010, a mere
11 month before the sodium thiopental's expiration, Judge Roger Luebs set Mr. Brown's execution
12 date. The execution was delayed beyond October 1 due to litigation relating to the re-
13 implementation of the death penalty. On appeal, the United States Court of Appeals for the Ninth
14 Circuit remarked that "it is incredible to think that the deliberative process might be driven by the
15 expiration date of the execution drug." *Morales v. Cate*, 623 F.3d 828, 829 (9th Cir. 2010).

16 **Extraordinary Measures by States to Acquire Sodium Thiopental**

17 19. On information and belief, at the end of September 2010, the state of Arizona
18 acquired a new supply of sodium thiopental. The state eventually revealed that it had imported
19 sodium thiopental from the United Kingdom, but did not explain how it had imported the drug,
20 given that federal law prohibits importation of controlled substances from sources that are not
21 registered with the FDA. *See* 21 U.S.C. §§ 360(i) (registration requirement) and 331(p)
22 (unlawful to fail to register); *see also* 21 C.F.R. §§ 1312.11(b), (c), 1312.18(c)(4). However,
23 there is no federally-approved source for the importation of sodium thiopental. Although Arizona
24 carried out two executions using sodium thiopental imported from the United Kingdom, the
25 Arizona Supreme Court later delayed another execution due to questions about the drug's origin
26 and efficacy, which had become the focus of an intense legal battle with extensive media
27 coverage.

28 20. Similarly, *The Bay Guardian* has reported that on October 6, 2010, the California

1 Department of Corrections and Rehabilitation (“CDCR”) disclosed in a court filing that it too had
2 recently obtained 12 grams of sodium thiopental, with a 2014 expiration date, despite the
3 nationwide shortage. The CDCR did not disclose the source of the drug or explain how it came
4 into possession of the substance. Various media outlets have reported that the last supply of
5 sodium thiopental produced by Hospira has a 2011 expiration date. Thus, on information and
6 belief, the sodium thiopental in the CDCR’s possession could not have been manufactured
7 domestically.

8 21. On October 7, 2010, Plaintiff ACLU-NC submitted to the CDCR a request for
9 records under the California Public Records Act, seeking documents pertaining to the CDCR’s
10 acquisitions of sodium thiopental. After the CDCR failed to deliver these documents, Plaintiff
11 ACLU-NC brought suit on November 17, 2010 in the California Superior Court for the County of
12 San Francisco. On December 8, 2010, following an initial hearing, the CDCR delivered a set of
13 documents to Plaintiff ACLU-NC. These documents revealed that California corrections officials
14 had gone to great lengths in their search for the drug, including attempting initially to import it
15 from Pakistan and exchanging lethal injection drugs with Arizona. (California provided
16 pancuronium bromide in exchange for imported sodium thiopental obtained by Arizona). The
17 records also revealed that Arizona corrections officials informed their California counterparts that
18 they had imported sodium thiopental from the United Kingdom and provided a roadmap for doing
19 so, and that California corrections officials then followed Arizona’s lead and also imported the
20 drug directly from the United Kingdom.

21 22. CDCR revealed to selected journalists in December 2010 that it had ordered 521
22 grams of sodium thiopental manufactured by a company in the United Kingdom. CDCR stated
23 that it had paid more than \$36,000 to acquire the drug, and that the controlled substance had
24 arrived in the United States and was awaiting inspection by the FDA.

25 23. Plaintiff ACLU-NC posted the records produced by CDCR to its website promptly
26 upon receipt. Since posting, the web page has had more than 2,000 unique visitors and has been
27 viewed more than 3,000 times. From December 8, 2010 to December 13, 2010, it was the most
28 frequently viewed page on the ACLU-NC website. The records are available at

1 [http://www.aclunc.org/issues/criminal_justice/death_penalty/cdcr's december 8, 2010 response](http://www.aclunc.org/issues/criminal_justice/death_penalty/cdcr's_december_8,_2010_response)
2 [to aclu public records act request.shtml](http://www.aclunc.org/issues/criminal_justice/death_penalty/cdcr's_december_8,_2010_response).

3 24. The records disclosed by CDCR raise questions about the conduct of state officials
4 in importing a controlled substance from abroad and exchanging controlled substances with
5 another state, and in particular, whether California corrections officials have complied with the
6 Controlled Substances Act and the Food, Drug, and Cosmetics Act. See, *e.g.*, 21 U.S.C. §331(a),
7 (c) (unlawful to introduce, deliver for introduction, or receive in interstate commerce adulterated
8 or misbranded drugs); 21 U.S.C. §355(a) (unlawful to introduce or deliver for introduction new
9 drug); 21 U.S.C. § 829 (unlawful for person other than physician to dispense Schedule III
10 substance without prescription); 21 C.F.R. § 1312.11(b) (requirement of authorization to import);
11 21 C.F.R. §314.410(a) (regulations governing import); 21 C.F.R. § 207.40(b) (“No drug may be
12 imported or offered for import into the United States unless it is listed as required in subpart C of
13 this part and manufactured, prepared, propagated, compounded, or processed at a registered
14 foreign drug establishment”).

15 25. Critically, the records sought by Plaintiffs in their FOIA requests raise questions
16 about the role of federal officials in overseeing – or failing to oversee – the importation process.

17 26. Records produced through other FOIA requests and state public record act requests
18 across the country have now revealed that eight states imported sodium thiopental from a
19 distributor in the United Kingdom, Dream Pharma, in 2010 and 2011. Dream Pharma is not an
20 FDA-approved source of sodium thiopental; indeed, as noted above there is no approved foreign
21 source for the importation of sodium thiopental. In addition to California and Arizona, Alabama,
22 Arkansas, Georgia, Kentucky, South Carolina, and Tennessee have also imported controlled
23 substances from Dream Pharma. A private company in the state of Georgia also provided some
24 of the imported sodium thiopental to prison officials in Kentucky. Two other states, Nebraska
25 and South Dakota, imported a controlled substance purporting to be sodium thiopental from a
26 company in India.

27 27. These procurement methods have generated public outcry, legal challenges, and
28 media attention in the United Kingdom, United States, and elsewhere. Following disclosure that

1 states in the United States were acquiring execution drugs from sources in the United Kingdom,
2 the government of the United Kingdom imposed new restrictions preventing the export of all
3 controlled substances for purposes of execution.

4 **FDA Has Denied Plaintiffs' Lawful Request Under FOIA**

5 28. On January 4, 2011, Plaintiffs ACLU-NC and *The Bay Guardian* submitted a
6 FOIA request to FDA. This request sought documents relating to state governments' acquisitions
7 of sodium thiopental, pancuronium bromide, and potassium chloride for the purpose of execution.
8 A copy of Plaintiffs' January 4, 2011 FOIA request, without attachments, is attached hereto as
9 Exhibit A.

10 29. FDA responded to the Plaintiffs' January 4, 2011 FOIA request with a series of
11 document productions dated January 19, February 8, March 21, March 31, April 20, and May 27,
12 2011.

13 30. FDA has failed to conduct an adequate search for relevant records. It has also
14 improperly withheld documents and portions of documents sought by Plaintiffs' FOIA request.
15 Specific examples are discussed below.

16 31. Plaintiffs appealed FDA's withholdings and redactions on February 15, 2011
17 (concerning documents from FDA's New Orleans office), April 29, 2011 (concerning documents
18 from FDA's Los Angeles office), May 10, 2011 (concerning additional New Orleans documents),
19 and July 8, 2011 (concerning additional Los Angeles documents). These appeals highlighted
20 specific examples of inadequate search, improper withholdings and redactions, and cited case law
21 to support these propositions. Copies of these appeals are attached as Exhibit B. FDA has not
22 responded substantively to any of these appeals, and the statutorily-allotted 20 working days for it
23 to do so have elapsed. Plaintiffs have thus exhausted their administrative remedies.

24 **Inadequate Search for Records**

25 32. FDA has failed to exhaustively search for and disclose to Plaintiffs all relevant
26 public records in its possession, withholding entire responsive documents as a result.

27 33. For example, FDA has failed to produce relevant records whose existence was
28 established in publicly-available court documents. In *Beaty v. FDA*, FDA submitted 70 pages of

1 administrative records to the District of Columbia District Court.

2 34. These records include various FDA emails regarding the importation of sodium
3 thiopental, communications with the media and the British government regarding the use of
4 sodium thiopental in the U.S., a November 10, 2010 letter to the FDA from the Arizona
5 Department of Corrections regarding one of its shipments of imported execution drugs, and a
6 December 29, 2010 document entitled "Sodium Thiopental Statement, Key Messages."

7 35. For example, as detailed in Plaintiffs' May 10, 2011 administrative appeal, the
8 December 29, 2010 document entitled "Sodium Thiopental Statement, Key Messages" references
9 a "longstanding policy" relating to imported sodium thiopental and a review of related
10 procedures. Plaintiffs' FOIA requests specifically sought documents related to any such policy
11 and review, yet none have been produced.

12 36. Additionally, the contents of the documents Plaintiffs have procured through
13 records requests to other agencies indicate that FDA possesses responsive records that it has not
14 produced nor identified as exempt. For example, a November 11, 2010 email that the Drug
15 Enforcement Administration ("DEA") produced to Plaintiffs shows an attached file named
16 "revised lethal injection memo 11 10 10.docx" that DEA identifies as an FDA document, yet
17 FDA has produced no such document. The DEA email describes the document as pertaining to
18 the importation of sodium thiopental for the purpose of lethal injection, which falls squarely
19 within Plaintiffs' FOIA requests.

20 37. Furthermore, FDA has failed to produce responsive information about the Dream
21 Pharma shipments. On information and belief, each shipment from Dream Pharma should have
22 the following: Notice of FDA Action (possibly several such notices), Entry/Immediate Delivery
23 Form, Invoice, Manifest, Airbill, DEA Registration Form, and one or more FDA OASIS database
24 entries. OASIS signifies "Operational and Administrative System for Import Support," and on
25 information and belief, is the database in which FDA stores information on the inspection and
26 processing of potential imports.

27 38. As detailed in Plaintiffs' May 10, 2011 administrative appeal, FDA has produced
28 only some of these documents for each shipment of drugs.

1 39. These withholdings violate FOIA and demonstrate that FDA has not conducted an
2 adequate search for records.

3 **Withheld Price, Quantity, Source, and Destination Information**

4 40. FDA has withheld documents and portions of documents that relate to the price
5 and quantity of drugs purchased by state officials. For example, FDA has redacted the quantity
6 and price columns of many invoices (and other documents which bear this information).

7 41. FDA has also withheld documents and portions of documents that relate to the
8 sources and destinations of drugs purchased by state officials, such as the names of importers,
9 transportation information such as flight numbers, and receiving party addresses.

10 42. For example, in the documents delivered to Plaintiffs on April 11, 2011, a
11 Customs Service form titled "ENTRY/IMMEDIATE DELIVERY" and dated June 28, 2010 is
12 redacted in fourteen places. FDA has redacted the destination ("ultimate consignee name"), the
13 importer ("importer of record name"), the flight numbers, the applicant's signature, and other
14 information.

15 43. FDA has principally cited 5 U.S.C. § 552(b)(4) ("Exemption Four") to justify
16 these withholdings. Exemption Four allows government agencies in receipt of a FOIA request to
17 withhold "trade secrets" and "privileged or confidential" information. The drafters included this
18 exemption to encourage voluntary reporting of sensitive commercial information to regulators.

19 44. The quantity, price, source, and destination of goods are neither "trade secrets" nor
20 "privileged or confidential" information. Exemption Four is not, therefore, a valid basis for FDA
21 to withhold this information. FDA has not explained how this information could possibly
22 constitute material covered by Exemption Four. In their administrative appeals, Plaintiffs
23 explained to FDA that courts have in fact ruled to the contrary. FDA also cites 5 U.S.C. §
24 552(b)(6) ("Exemption Six"), which covers "personnel and medical and similar files the
25 disclosure of which would constitute a clearly unwarranted invasion of personal privacy."

26 45. In the "ENTRY/IMMEDIATE DELIVERY" form cited above, for instance, the
27 "signature of applicant" field is redacted with a citation to Exemption 6.

28 46. An applicant's signature on a customs form is not a personnel or medical record or

1 similar file the disclosure of which would constitute a clearly unwarranted invasion of personal
2 privacy.

3 47. Exemption Six does not cover an applicant's signature. As with Exemption Four,
4 FDA has asserted Exemption Six to justify redacting data which courts have expressly held is not
5 within its scope.

6 48. FDA's improper and unjustified redactions of price, quantity, source and
7 destination information violate FOIA.

8 **Withheld Email Communications**

9 49. FDA has redacted the entire body text of emails. For example, in the documents
10 from the delivery dated March 31, 2011, FDA has redacted the entire text of a September 29,
11 2010 email from Huascar Batista, described in his signature block as "Imports & Exports
12 Compliance Team Leader" for the FDA. In that same delivery, FDA has also redacted other
13 emails, such as the September 29, 2010 email from John E. Verbeten.

14 50. FDA has cited 5 U.S.C. § 552(b)(5) ("Exemption Five") to justify these redactions.

15 51. Exemption Five allows government agencies in receipt of a FOIA request to
16 withhold inter-agency or intra-agency memorandums or letters which would not be available by
17 law to a party other than an agency in litigation with the agency. It does not apply to final
18 opinions or dispositions of an issue. Based upon the email response of Consumer Safety Officer
19 David Thomas to Huascar Batista's September 29, 2010 email, which includes a statement by
20 Thomas that, "[t]o confirm, CDER [Batista's division] is not objecting to the release of *the above*
21 *entry of 3 pharmaceuticals from U.K.*", it appears that Batista's email contains a final opinion or
22 disposition as to whether or not CDER objects to the release of "3 pharmaceuticals from U.K.,"
23 placing these redactions beyond the plausible scope of Exemption Five.

24 52. FDA's redaction of the body of these emails, and its failure to justify these
25 redactions on administrative appeal, violates FOIA.

26 **Withheld Arizona Supreme Court Case Name**

27 53. In a September 24, 2010 letter from Charles L. Ryan to David Thomas, included in
28 the March 31, 2011 set of documents, FDA has redacted a party name in a case cited for the

1 proposition that “this shipment of drugs was warranted by the Arizona Supreme Court,” leaving
2 the citation in the form of “State v _____.”

3 54. FDA has cited Exemption 6 to justify this redaction. Exemption 6 covers
4 “personnel and medical and similar files the disclosure of which would constitute a clearly
5 unwarranted invasion of personal privacy.”

6 55. The name of a party in a case before the Arizona Supreme Court is not a personnel
7 or medical record or similar file the disclosure of which would constitute an invasion of personal
8 privacy. FDA has not explained how the party’s name would implicate such personal privacy
9 concerns.

10 56. FDA’s redaction of the party’s name thus violates FOIA.

11 **Inconsistencies and Defects in Withholdings of Documents**

12 57. FDA’s responses to Plaintiffs’ FOIA request are generally defective and
13 inconsistent. FDA has frequently failed to provide the FOIA-mandated written explanations for
14 its withholdings of documents and portions of documents. This general deficiency demonstrates
15 that FDA’s undisclosed rationales are improper.

16 58. For example, in the April 11, 2011 documents, FDA relies on Exemption Six and
17 5 U.S.C. § 552(b)(7)(C) (“Exemption 7C”) interchangeably in redacting signatures and other
18 identifying information. The use of different exemptions for the same or substantially similar
19 information suggests that FDA itself is not sure which exemption applies, or why.

20 59. FDA also applies different exemptions and redactions to the same, or closely
21 analogous, information in the April 11 documents. In some cases, information is redacted in one
22 place and left unredacted in another. FOIA requires that information be redacted or withheld only
23 where the agency firmly believes the information to be exempt under a specific exemption.
24 Haphazard redaction undermines confidence that FDA has followed this principle.

25 60. For example, in an email from John McAuliffe to Christopher Boulmay dated
26 November 30, 2010, FDA cites Exemption Six to redact the name of a FedEx contact person.
27 Only a few pages earlier, in another copy of the same email, this person’s name is left unredacted.

28 61. Other examples are found in the Dream Pharma invoices. In some invoices, the

1 receiving party, delivery address, and total cost of the shipment are redacted under Exemption
2 Four, while in other invoices all of this information is disclosed.

3 62. At times, the FDA has labeled redactions with the text “NEC,” which is not a
4 FOIA exemption subsection and is without obvious meaning. For example, the set of documents
5 delivered to ACLU-NC on February 8, 2011 includes a letter dated September 24, 2010, which
6 replaces FDA’s DEA registration number with the notation “NEC”; in a copy delivered on March
7 31, 2011, that number is replaced with a citation to 5 U.S.C. § 552(b)(7)(E) (“Exemption 7E”).

8 **Other Withheld Information**

9 63. FDA’s redactions and withholdings are extensive, and this complaint does not
10 purport to review them all in detail.

11 64. Plaintiffs allege that all documents and portions of documents responsive to their
12 FOIA request and withheld by FDA ought not to have been withheld, and that FOIA does not
13 permit FDA to withhold such information.

14 65. Plaintiffs further allege that FDA has violated FOIA by failing to provide
15 sufficient written explanation to justify its withholding of documents.

16 **FIRST CLAIM FOR RELIEF**

17 **Violation of Freedom of Information Act For Failure to Conduct an Adequate Search and**
18 **for Wrongful Withholding Of Agency Records**

19 66. Plaintiffs incorporate paragraphs 1 through 65 above as if fully set forth herein.

20 67. FDA has failed to conduct an adequate search for records, has wrongfully withheld
21 agency records requested by Plaintiffs under FOIA, and has failed to comply with the statutory
22 timeline for the processing of FOIA requests.

23 68. Plaintiffs have exhausted the applicable administrative remedies with respect to
24 FDA’s failure to search and its wrongful withholding and redaction of the requested documents.

25 69. Plaintiffs are entitled to injunctive relief with respect to the release and disclosure
26 of the requested documents because FDA continues to improperly withhold agency records in
27 violation of FOIA. Plaintiffs will suffer irreparable injury from, and have no adequate legal
28 remedy for, FDA’s illegal withholding of documents pertaining to the subjects of Plaintiffs’

1 FOIA request.

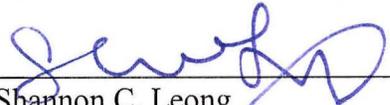
2 **PRAYER FOR RELIEF**

3 WHEREFORE, Plaintiffs prays that this Court:

- 4 A. Order FDA to make available immediately the requested records in their entirety;
- 5 B. Enter a preliminary and permanent injunction against FDA ordering the relief requested
- 6 herein;
- 7 C. Declare that FDA's failure to search for and disclose the records requested by Plaintiffs is
- 8 unlawful;
- 9 D. Award Plaintiffs their litigation costs and reasonable attorneys' fees incurred in this
- 10 action, pursuant to 5 U.S.C. § 552(a)(4)(E);
- 11 E. Grant such other relief as the Court may deem just and proper.

12 Dated: 8/11/2011

By:

13 
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