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U.S. COURT OF APPEALS

**NOT FOR PUBLICATION**

UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

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| GOLDWATER INSTITUTE,<br><br>Plaintiff-Appellant,<br><br>v.<br><br>U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES,<br><br>Defendant-Appellee. | No. 19-15615<br><br>DC No. 2:15 cv-1055 SRB<br><br>MEMORANDUM* |

Appeal from the United States District Court
for the District of Arizona
Susan R. Bolton, District Judge, Presiding

Argued and Submitted February 7, 2020
Arizona State University, Phoenix, Arizona

Before: TASHIMA, HURWITZ, and MILLER, Circuit Judges.

Goldwater Institute submitted a Freedom of Information Act (FOIA) request to the Food and Drug Administration (FDA), seeking records related to the approval of ZMapp, an investigational drug intended for use in treating persons infected with the Ebola virus. The district court relied on FDA regulations to

* This disposition is not appropriate for publication and is not precedent except as provided by Ninth Circuit Rule 36-3.

conclude that the entire contents of the FDA's Investigational New Drug (IND) file on ZMapp were exempt from disclosure under FOIA Exemption 4, 5 U.S.C. § 552(b)(4), and granted summary judgment in favor of the Department of Health and Human Services (HHS). Goldwater timely appeals.

We have jurisdiction pursuant to 28 U.S.C. § 1291, and we review the grant of summary judgment de novo. *Animal Legal Def. Fund v. FDA*, 836 F.3d 987, 990 (9th Cir. 2016) (en banc) (per curiam). We vacate the order granting summary judgment and remand for further proceedings.

**1.** The district court erred in allowing the FDA to rely on its regulations governing the confidentiality of IND files to withhold the entire ZMapp file,[1] rather than requiring the agency to meet its burden of showing that a paticular FOIA exemption applies to the records it withheld. *See Hamdan v. U.S. Dep't of Justice*, 797 F.3d 759, 772 (9th Cir. 2015); *Civil Beat Law Ctr. for the Pub. Interest, Inc. v. Ctrs. for Disease Control & Prevention*, 929 F.3d 1079, 1089 (9th Cir. 2019) ("[O]ur general FOIA requirement [is] that, '[t]o justify withholding, the government must provide tailored reasons in response to a FOIA request. It may

[1] *See, e.g.*, 21 C.F.R. §§ 601.50 (providing, in part, that the existence of an IND notice will not be disclosed unless previously publicly disclosed), 601.51 (similarly providing, in part, that information in a biological product file is not available for public disclosure unless previously disclosed).

not respond with boilerplate or conclusory statements.'" (quoting *Shannahan v. IRS*, 672 F.3d 1142, 1148 (9th Cir. 2012))).

By concluding that FDA regulations governing IND applications barred disclosure of the IND file in toto, the court essentially concluded that the FDA regulations are coterminous with Exemption 4. This approach, however, is inconsistent with FOIA's "pro-disclosure purpose" and the requirement that we interpret its exemptions narrowly. *Animal Legal Def. Fund v. USDA*, 933 F.3d 1088, 1096 (9th Cir. 2019).

In order to claim Exemption 4, the FDA must establish that the information is (1) commercial or financial, (2) obtained from a person, and (3) privileged or confidential. 5 U.S.C. § 552(b)(4); *Food Mktg. Inst. v. Argus Leader Media*, 139 S. Ct. 2356, 2362 (2019). The FDA's *Vaughn* index and affidavits did not address the requirements of Exemption 4, but cited only FDA regulations governing IND applications. On appeal, the FDA again relies on broad, general arguments about the confidentiality of IND files, rather than addressing the specific documents at issue here and showing how they fall under Exemption 4 of FOIA. "No effort is made to tailor the explanation to the specific document withheld." *Wiener v. FBI*, 943 F.2d 972, 978–79 (9th Cir. 1991).

When examined under the requirements of Exemption 4, the FDA's blanket refusal to produce any records from the IND file does not warrant summary judgment in its favor. For example, although the FDA argues that all records at issue were obtained from a person as required by Exemption 4, so far as we are able to determine from the record, that is incorrect. Of the 58 records Goldwater seeks, it appears from the *Vaughn* indices that 41 are internal FDA emails, and 3 are FDA emails to others.[2] Only 11 of the records sought are correspondence from the commercial and expanded access IND sponsors (lines 38, 60, 72, 80, 81, 83, 85, 89, 101, 105, and 109). Two of the records are from the foreign treatment provider (lines 82 and 86), and one is the expanded access IND sponsor's submission of updated forms (line 107). The FDA's broad assertion is insufficient to establish that all of the information in the documents is obtained "from a person" for purposes of Exemption 4.

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[2] The following lines in the *Vaughn* index are internal FDA emails: 2, 3, 7, 8, 13, 16, 19, 22, 23, 27-34, 41, 43, 44, 47-50, 56-58, 76, 79, 91-98, 100, 104, 111, and 113. Line 18 is an "FDA email to commercial and expanded access IND sponsors responding to email dated 08/01/14 at 7:30 PM and addressing timing of expanded access IND submission." Line 103 is an "FDA email to expanded access IND sponsor and third party treatment provider holding the ZMapp to be imported for use under the expanded access IND number and discussing submission of paperwork." Line 110 is an "FDA email to expanded access and commercial IND sponsors responding to the email dated 09/14/14 at 7:04 PM regarding importation of ZMapp for use under expanded access IND."

Nor do the affidavits submitted establish that the withheld documents contain confidential commercial or financial information covered by Exemption 4. The agency's argument boils down to the assertion that the documents *must* contain such information because they are in the IND file.[3] But this is insufficient under FOIA. *See Wiener*, 943 F.2d at 983 (rejecting the CIA's reliance on an affidavit that stated, without justification, that "'disclosure of [the withheld] portions reasonably could be expected to lead to identification of the source of the information'").

The FDA may, of course, rely on affidavits to establish that certain documents are exempt from disclosure, but it must sufficiently explain why the documents qualify under Exemption 4. *See*, *e.g., Hamdan*, 797 F.3d at 774 (FBI affidavits gave specific explanations for withholding of particular groups of documents); *Berman v. CIA*, 501 F.3d 1136, 1139–44 (9th Cir. 2007) (CIA declaration explained information in documents and possible consequences of disclosure); *Lion Raisins Inc. v. U.S. Dep't of Agric.*, 354 F.3d 1072, 1080 (9th

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[3] The reason given in the *Vaughn* index for withholding lines 3,7, 16, 18, 23, 38, 60, 72,79, 91, 92, 93, 94, 95, 101, 103, 105, 107, 109, 110, and 111 was that "the document is protected from disclosure by FDA regulations because it pertains to ZMapp, an investigational new drug, and an expanded access IND for emergency treatment use of ZMapp." *Cf. Hamdan*, 797 F.3d at 775 ("the same explanation was not repeated unthinkingly for each document").

Cir. 2004) (USDA declarations included "detailed and specific descriptions" of documents withheld and the competitive harm that could result from their disclosure), *overruled in part on other grounds by Animal Legal Def. Fund*, 836 F.3d at 990.

We do not discount the FDA's expressed policy concerns regarding the need to protect confidential information in IND applications. Nonetheless, on the present record, the agency has failed to meet its burden of establishing that the documents it withheld are exempt from disclosure under Exemption 4. We therefore vacate and remand so that the district court can determine whether, under established FOIA criteria, the documents at issue are exempt from disclosure under Exemption 4. As part of its review on remand, the district court may also consider whether information in the documents is exempt from disclosure under Exemption 5 or Exemption 6.[4]

**2.** On remand, the district court also must make a finding of segregability as to any documents which the court concludes the agency may

[4] Goldwater challenges only the district court's determination as to Exemption 4, raising no challenge about records withheld under Exemptions 5 and 6. However, the district court did not specify in its January 2018 order which records were exempt under Exemptions 5 and 6. Although Goldwater originally sought 58 records, the parties seemed to agree at oral argument that as few as 29 documents might be at issue on appeal under Exemption 4.

withhold. *See Hamdan*, 797 F.3d at 778–79 ("We have held that '[i]t is reversible error for the district court "to simply approve the withholding of an entire document without entering a finding on segregability, or the lack thereof," with respect to that document.'" (quoting *Wiener*, 943 F.2d at 988)); *Yonemoto v. Dep't of Veterans Affairs*, 686 F.3d 681, 688 (9th Cir. 2012) ("An agency may withhold only that information to which the exemption applies, and so must provide all 'reasonably segregable' portions of that record to the requester." (quoting 5 U.S.C. § 552(b))), *overruled in part on other grounds by Animal Legal Def. Fund*, 836 F.3d at 990.

**VACATED and REMANDED.** Goldwater shall recover its costs on appeal.