Case No. 19-15615

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

GOLDWATER INSTITUTE,

vs.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

APPELLANT'S REPLY BRIEF

Appeal from the United States District Court for the District of Arizona
Case No. 2:15-CV-01055-SRB, Hon. Susan R. Bolton, presiding

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INTRODUCTION

In this case, the FDA seeks to transform a narrow Freedom of Information Act ("FOIA") exemption that was meant to protect commercial and financial information of *private* parties into a broad loophole that allows it to withhold public records about *non*commercial, *government* processes and procedures.

The FDA does this by asserting that *it alone* determines what records are part of a "file" for investigational new drug ("IND") applications. It says that *all* records that are "*related*" to an IND (Br. for Appellee ("Br.") at 23)—regardless of what those records are, who generates them, or what they discuss—are "part of the application file." (Br. at 29-30). And because the FDA, and the FDA alone, has decided that the entire contents of an IND file are exempt from disclosure under FOIA Exemption 4—voila!—every single record pertaining to an IND that the agency wants exempted from disclosure is thereby exempt from disclosure within the agency's *sole* discretion.

If the FDA's interpretation of Exemption 4 was the law, the agency could withhold any document about any subject from public disclosure by simply claiming that the record is part of an IND file because it "relates" to an IND. Fortunately, that is not the law. Rather, Exemption 4 is narrow, and protects from disclosure only specific records that are confidential commercial information that the government has obtained from private parties. 5 U.S.C. § 552(b)(4). The

agency's contention that anything that "relates" to an IND or "discusses" an IND is also exempt is far too broad.

The resolution of this issue and this case is much simpler than the FDA contends: If a record contains confidential commercial information of private parties, Exemption 4 applies. If the record does not contain such information, Exemption 4 does not apply, and the record must be disclosed. The FDA unlawfully withheld a large number of records that fall within the second category, and the decision below should therefore be reversed.

ARGUMENT

I. The FDA has failed to meet its burden of proof that Exemption 4 applies to government-generated records that do not include confidential commercial information of private parties.

In its brief, the FDA attempts to greatly expand the narrowness of Exemption 4 by claiming that it applies to anything "related" to an IND application, or to any record that discusses an IND application—including even government-generated records that do *not* include the confidential commercial information of any private party. But Exemption 4 applies *only* to (1) the commercial and financial information of (2) *private* parties that is (3) "privileged or confidential." *Pac. Architects & Eng'rs Inc. v. U.S. Dep't of State*, 906 F.2d 1345, 1347 (9th Cir. 1990). "These three requirements are conjunctive." *Id.* And the agency, not Appellants, have the burden of proof to prove that Exemption 4

applies. *Yonemoto v. Dep't of Veterans Affairs*, 686 F.3d 681, 688 (9th Cir. 2012) ("When an agency chooses to invoke an exemption to shield information from disclosure, it bears the burden of proving the applicability of the exemption"). The records at issue here are not commercial or financial, were not obtained from private parties, and are not confidential. The agency has therefore failed to carry its burden that the records satisfy *any*, let alone *all* of the requirements for Exemption 4.

Instead, the FDA attempts to expand Exemption 4 by recasting each of that exemption's three conjunctive requirements in ways the law does not support. First, the FDA tries to reshape the definition of "commercial and financial" to include any records that "relate to commerce" (Br. at. 24), even though the common meaning of those terms demonstrate that the information must be commercially valuable to qualify under the "commercial and financial," criterion. Indeed, the agency's own regulations implementing FOIA Exemption 4 specify a much narrower definition of "commercial and financial."

The agency also attempts to stretch Exemption 4's requirement that records must be obtained from outside the government in order to fall within the exemption; it argues that the exemption also applies to *government*-generated records by claiming that any record that includes a *discussion* of an IND *at all* is exempt (Br. at 4). This, however, is incorrect. Only records that include the

confidential commercial information of private parties may be exempt. *Watkins v. U.S. Bureau of Customs and Border Prot.*, 643 F.3d 1189, 1194 (9th Cir. 2011).

Finally, the agency erroneously contends that records of *its* operations are confidential under Exemption 4, whereas that exemption applies only to records that private parties have submitted to the agency.

A. The FDA attempts to reshape the meaning of commercial and financial to include any records that relate to the FDA's consideration of an IND application.

The FDA contends that "Exemption 4 applies to *all* records related to the ZMapp INDs." Br. at 23 (emphasis added). Tellingly, however, the agency offers no definition of "commercial or financial." Instead, it cites to a Second Circuit case from the 1970s that "commercial surely means pertaining to or relating to or dealing with commerce." Br. at 23 (citing *Am. Airlines, Inc. v. Nat'l Mediation Bd.,* 588 F.2d 863, 870 (2d Cir. 1978)). But this Court has already defined the terms "commercial and financial," and this Court's definition of those terms is much narrower than the FDA contends.

"The terms 'commercial or financial' are given their ordinary meanings." *Watkins,* 643 F.3d at 1194. And this Court has held that commercial information is not related to a government process, but instead, is related to business, trade, or commerce. The definition of commercial information is *not* broad enough to include information about routine government processes and information. *Carlson*

v. U.S. Postal Serv., 504 F.3d 1123, 1125 (9th Cir. 2007) (rejecting the government's argument that information about postal operations, such as the name, address, telephone number, business hours, and collection periods at U.S. Post Offices, was exempt under FOIA Exemption 3 because it was not "information of a commercial nature"). In other words, basic information about government operations by government entities is not commercial information. *Id.* at 1128 ("USPS is a government entity, not a business, which provides a service, mail delivery, to the public.").

Surveying the common definitions of commercial information in *Carlson*, this Court found that:

> Webster's defines "commercial" as "occupied with or engaged in commerce or work intended for commerce; of or relating to commerce." The American Heritage Dictionary of the English Language provides a strikingly similar definition, viewing "commercial" as meaning "1.a. of or relating to commerce, b. engaged in commerce, c. involved in work that is intended for the mass market." Black's Law Dictionary adds that "commercial" may be defined as "relates to or is connected with trade and traffic or commerce in general; is occupied with business or commerce."

Id. (citations omitted). Thus, records that simply "*relate[] to* the ZMapp INDs" (Br. 23) (emphasis added) are not automatically commercial unless they actually deal with business matters or commerce.

Additionally, for information to fall within Exemption 4, it must be "commercially valuable." *Pub. Citizen Health Research Grp. v. FDA*, 704 F.2d

1280, 1288 (D.C. Cir. 1983). Based on the descriptions in the Revised Consolidated *Vaughn* Index, ER.045–109, ("RCVI") in this case, it is simply not possible to accept the FDA's claim that *all* records related to its consideration of an IND application are commercial, or commercially valuable. For example, there is simply no commercial or financial interest in government-generated records "concerning timing of submission of expanded access IND … and potential place of treatment in preparation for incoming expanded access IND." ER.045, line 3. Or records "addressing timing of expanded access IND submission." ER.054, line 18. Or information that describes an "[i]nternal FDA email regarding timing of submission of information from expanded access IND sponsor and information to be requested from and *provided to* expanded access IND sponsor" ER.055, line 19 (emphasis added). Or records that provide a "status update, and identify[] IND number to be assigned to expanded access IND." ER.085, line 79. These are purely government records about government functions that involve no secret commercial information of any private entity. Yet the FDA withheld them as commercial or financial information.

It is even more difficult to accept the agency's newly-minted definition of "commercial or financial" as anything that "relates" to an IND when the *agency itself*, through its own regulations, has set out a definition of "commercial or

financial" information under Exemption 4 that contradicts this position. Under FDA regulations, "commercial or financial" is:

> (a) … any commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. There must be a direct relationship between the trade secret and the productive process.
>
> (b) Commercial or financial information that is privileged or confidential means valuable data or information which is used in one's business and is of a type customarily held in strict confidence or regarded as privileged and not disclosed to any member of the public by the person to whom it belongs.

21 C.F.R. § 20.61. Nothing in either of these definitions could be read to include internal FDA e-mails related to the government processes and procedures that are the subject of this case.

The FDA attempts to bootstrap the government-generated records at issue in this case by contending that "companies developing FDA-regulated products have a commercial interest in information about their products." Br. at 24. Of course they do. But Exemption 4 only applies to a narrow range of documents: namely, to commercial and financial information *belonging to* a private company. What's more, the records the agency withheld are not records *about* a private company's products. They are records about the process by which a *government* agency made life-saving drugs available. This is precisely the type of information the FOIA is designed to make available so that the public can "be informed about what their

Government is up to." *U.S. Dep't of Def. v. Fed. Labor Relations Auth.*, 510 U.S. 487, 488 (1994).

Put simply, the FDA has failed to meet its burden under the FOIA to prove that the withheld records are "commercial or financial" in nature. Because the record is bereft of any such evidence, and, on the contrary, that the information that the agency continues to withhold is *non*commercial, *non*financial information, Exemption 4 simply cannot apply.

B. The FDA cannot extend an exemption meant to protect the information of private parties into one that protects government-generated records about government processes.

To reiterate: the appellants are seeking information about the FDA's own actions in approving the use of ZMapp when ZMapp had not completed the ordinary approval process. This is information about the government's activities—not information about any private party. The appellants are simply not interested in any private, commercial information—just in why and how the FDA approved the use of ZMapp in a rapid and totally unique way, virtually unheard-of in the normal process of drug approval.

The FDA is seeking to withhold this information on the theory that it is the private commercial information of drug makers. We know this is not true because the FDA's own regulations tell us that the *agency itself* must make a series of determinations on each and every IND application. *See* 21 C.F.R. §§

312.305(a)(1-3); 312.310(a)). There are also separate regulatory requirements for the personal importation of unapproved drugs. *See* 21 C.F.R. chpt. 1, subchpt. A, part 1, subpart E. Appellants are seeking to determine, *inter alia*, whether the agency made these determinations under its own regulations. These are quintessentially *government* functions. Records that speak to *that* process, such as those at issue in this case, cannot possibly originate "outside the government," because they are created by the government. Exemption 4 does not apply to such records.

Nevertheless, the FDA contends that Exemption 4 applies even "to records that originated with FDA." Br. at 26. *See also id*. at 32 (Exemption 4 is not "limited to information provided to the agency.") (internal quotations omitted). But the law is clear that "Exemption 4 … is limited…to information obtained [from] *outside* the Government." *Fed. Open Mkt. Comm. of Fed. Reserve Sys. v. Merrill*, 443 U.S. 340, 360 (1979) (emphasis added). The Supreme Court recently reiterated that Exemption 4 only applies to private information, *not* to government records. *Food Mktg. Inst. v. Argus Leader Media*, 139 S. Ct. 2356, 2366 (2019) (To fall within Exemption 4, the information must be *private-sector* "commercial or financial information."). The purpose of Exemption 4 is to "encourage individuals to provide certain kinds of confidential information to the Government," and that Exemption "must be read narrowly in accordance with that

purpose." *Soucie v. David*, 448 F.2d 1067, 1078 (D.C. Cir. 1971). The Exemption applies to information that private entities give to the government—not to records created by the government.[1]

The FDA, however claims that "any FDA record that sheds light on the status of an IND within the agency likewise reveals information provided by a person," and therefore qualities for the Exemption. Br. at 27. This is not a reasonable interpretation. The records at issue here involve *agency* operations and *agency* procedures—things no private party would be able to provide or control. Records related to how, when, and why an IND is approved by the FDA, or how a drug is made available for personal importation, are *government* records that are not obtained from private parties.

The FDA also contends that Exemption 4 applies to "internal FDA documents discussing the expanded access INDs." Br. at 18. In other words, according to the agency, as long as the records at issue involved *discussions* of expanded access INDs, then those records are exempt from disclosure, regardless of the substance of those discussions. But that position is contrary to the language of the FOIA and Exemption 4, which only protects *confidential commercial information from private parties*, not all information related to an IND. If

[1] While other FOIA exemptions may apply to certain kinds of *government* information (e.g., Exemptions 1, 2, 5, and 7), Exemption 4 is simply not one of them.

confidential commercial information is discussed in an agency record, that *portion* of the record may be exempt. But if *other* information is discussed, including information about government processes and procedures, that portion is *not* exempt.

The agency appears to agree with this, when it observes that "confidential information *provided by an IND sponsor* does not cease to be confidential because it is discussed in agency communications." Br. at 4 (emphasis added). That is correct. But the appellants do not seek records of discussions of confidential information *provided by an IND sponsor*, and that is not the information that the agency has withheld here. Rather, appellants seek only records pertaining to the FDA's own internal approval processes and procedures—that is, information regarding how the FDA authorized an investigational drug for use in an unusual way. That information is not commercial, it is not financial, it is not from a private party, it is not confidential, and it is not within Exemption 4.

So, for example, records that include or discuss "important developmental, compositional, safety, and manufacturing data," Br. at 18, or "information about the drug or biological product's safety, quality, purity, strength, and other attributes," Br. at 19, may be exempt from disclosure under Exemption 4. But the FDA has not withheld *this* information. Instead, the agency is "treat[ing] every record *relating* to an application as part of the application file, including inter- and

intra-agency emails *relating* to the application." Br. at 11; 29 (emphasis added). In other words, the FDA is trying to categorically exclude all inter-agency and intra-agency government e-mails from disclosure under FOIA on the grounds that they contain commercial information or trade secrets. Thus, the FDA's withholding in this case is *much* broader than email discussions of confidential commercial information. Under the FDA's rationale, the agency could withhold the entirety of a file relating to an IND application if its emails discussed the font used on IND applications—or if its emails simply discussed the "timing of expanded access IND submission[s]". ER.054, line 18. But Exemption 4 is simply not that broad.

To say otherwise is to eviscerate the "strong presumption in favor of disclosure" that applies under the FOIA, *U.S. Dep't of State v. Ray*, 502 U.S. 164, 173 (1991), and creates an enormous loophole for withholding records under Exemption 4 that has no basis in the law. A better reading of the agency's obligations, and of the law, is that if a record discussing information is actually discussing the confidential commercial information of a private party, then it is exempt. If it is not, as with the records in this case, then the exemption does not apply.

C. Information about how the government approves investigational drugs is not the confidential information of a private party.

The FDA next contends that information such as "'status updates, administrative and procedural matters' that reveal the state of FDA deliberations on the IND" is confidential within the meaning of Exemption 4. Br. at 30. This is incorrect.

As a threshold matter, the FDA appears to be conflating FOIA Exemption 5, which protects certain agency deliberations, with Exemption 4, which, of course, protects confidential commercial information supplied by private parties.[2] More to the point, FOIA Exemption 4 does not protect internal agency actions and deliberations *at all*. As the Supreme Court recently made clear, Exemption 4 only protects information "customarily and actually treated as private," and as to which private parties receive "an assurance of privacy" from the government. *Food*

[2] The FDA contends that the Goldwater Institute "continues to seek on appeal" records where the FDA invoked FOIA Exemption 5 and 6. Br. at 41, n.11. That is not correct. Appellants appealed only the district court's determination regarding records that FDA either labeled as "non-responsive" or exempt from disclosure under Exemption 4 on the RCVI. For most of these records, the FDA did not claim FOIA Exemptions 5 or 6, but instead, only claimed they were either nonresponsive or exempt under Exemption 4. *See* ER.045–108, lines 3, 7, 18, 23, 60, 79, 91-95, 101, 103, 105, 107, 109-111. To the extent the FDA claims that Exemption 5 or 6 also applies to certain records on the RCVI index where the agency claimed Exemption 4, the FOIA directs the agency to segregate and disclose the information that is not properly exempt. 5 U.S.C. § 552(b). *See e.g.* ER.045–103 at lines 2, 8, 13, 19, 22, 27–34, 41, 43-44, 53–44, 47–50, 56–58, 76, 96–98, 100, 104.

Mktg. Inst., 139 S. Ct. at 2366. As outlined above, private parties have no customary expectations of privacy in government processes. A private party does not direct agency actions and cannot control them. And the government cannot cloak its operations under a confidentiality standard that was designed to protect private entities, not government agencies.

Indeed, this shows why the FDA's interpretation of Exemption 4 is so pernicious in this case. According to the FDA, the agency "treats every record *relating to* an application as part of the application file, including inter- and intra-agency emails *relating to* the application." Br. at 11; 29. But if the FDA can both define the contents of an IND file, and then deem the entire file confidential, then the FOIA, and FOIA Exemption 4, would be rendered meaningless. In other words, if the FDA can unilaterally classify any record that is "related" (a term the FDA itself gets to define) to an IND file as confidential, regardless of its contents, then the agency can withhold *any* record under Exemption 4. The narrow FOIA Exemption 4 was never meant to be construed so broadly so that agencies can withhold public information about government processes.

II. The FDA waived reliance on Exemption 4 for several records in this case because the agency continued to classify records as "nonresponsive" even after the District Court found those records responsive.

The FDA contends that Appellants "mistakenly suggest[] that FDA waived reliance on Exemption 4 by initially designating some records as nonresponsive,

rather than exempt." Br. at 34. This grossly mischaracterizes the agency's actions in this case. The agency did not "initially" designate some records as nonresponsive. On the contrary, the agency has designated these records as nonresponsive for *four years*, including in three separate *Vaughn* indices, and even *after* it was ordered by the district court to "either disclose [the records] or demonstrate their exemption." ER.023.

Following initial summary judgment briefing, the district court ordered the FDA to produce the first *Vaughn* index identifying the records withheld and the basis for withholding. ER.033.[3] After the second round of summary-judgment briefing, the district court ordered that the FDA produce yet another *Vaughn* index that more reasonably describes the records withheld and the basis for withholding, including any claimed FOIA exemptions. ER.026. In that same Order, the district court expressly found that large categories of records *were* responsive to the Appellants' request. ER.022–23.

Specifically, the court held that "many of Defendant's descriptions for purportedly nonresponsive records are arguably interchangeable with those used to describe responsive ones. As far as the Court can tell, then, these records are

[3] HHS produced a *partial* index on August 19, 2016 ER.165–293, and filed the remaining portion of the index ("Supplemental Index") for *in camera* review. Dist. Ct. Doc. 39. After motions regarding whether the Supplemental Index should be subject to *in-camera* review, the Court ordered HHS to produce the Supplemental (and second) Index. Dist. Ct. Doc. 43 at 2.

responsive and subject to disclosure unless an exemption applies." ER.023. These include records about the timing of IND submissions and FDA administrative and other actions on those submissions. *See* ER.045–085, lines 3, 7, 18, 19, 23, 38, 60, 72, 79. The district court also found that *all* of the records regarding personal importation of ZMapp were responsive. *See* ER.088–109, lines 82, 83, 85, 86, 89, 91–95, 101, 103, 105, 107, 109–111, 113. The court specifically held, "these records are responsive," and that the FDA "must either disclose them or demonstrate their exemption." ER.023.

Pursuant to that order, Defendant submitted its third *Vaughn* index, the RCVI, on March 8, 2018. ER.045–109. Yet rather than claim a FOIA exemption for records that the district court already determined *were* responsive, the FDA chose to hold fast to its prior determination, now reflected in its third *Vaughn* index, that the personal importation records and other process records are *not* responsive. In other words, in the RCVI, the FDA did not claim *any* FOIA exemption, including Exemption 4, for these records whatsoever. And, after *three* separate *Vaughn* indices, and a district court order finding the records at issue to be responsive, the FDA still did *not* claim a FOIA exemption.

The agency should not be allowed to assert that exemption for the first time in this Court. *LaCedra v. Exec. Office for U.S. Attorneys*, 317 F.3d 345, 348 (D.C. Cir. 2003) ("an agency could not raise FOIA exemptions seriatim and ordered the

Agency to produce all the relevant documents without regard to any belatedly asserted exemptions."). With respect to the personal importation and other agency process records[4]—which make up the vast majority of the records at issue in this case—the agency has waived any right to claim Exemption 4 because it did not raise that exemption below. Consequently, the district court's opinion reading FOIA Exemption 4 into the agency's arguments should be reversed and these records should be promptly disclosed.

Date: October 29, 2019

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[4] *See* ER.045–109, lines 3, 7, 18, 19, 23, 38, 60, 72, 79, 82, 83, 85, 86, 89, 91–95, 101, 103, 105, 107, 109–111, 113.

CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. P. 32(a)(7)(C), I certify that:

This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because this brief contains 3,961 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in a proportionately spaced typeface using Microsoft Office 2016 Times New Roman 14-point font.

Date: October 29, 2019

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CERTIFICATE OF SERVICE

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