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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

GOLDWATER INSTITUTE, Plaintiff, vs. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, Defendant.	No. CV-15-01055-PHX-SRB **MEMORANDUM IN SUPPORT OF PLAINTIFF'S RESPONSE TO DEFENDANT'S MOTION FOR SUMMARY JUDGMENT AND PLAINTIFF'S CROSS-MOTION FOR SUMMARY JUDGMENT**

INTRODUCTION

The Goldwater Institute brought this Freedom of Information Act ("FOIA") action after the Food and Drug Administration ("FDA") withheld public records related to how the United States government makes life-saving drugs available in emergency circumstances. The FOIA was designed precisely to open administrative processes, such as the U.S. drug approval process, to the public. Despite the FOIA's clear statutory mandate for the production of records at issue, throughout the administrative process and in this action, Defendant Department of Health and Human Services ("HHS"), of which the FDA is a subcomponent, has refused to provide public records by claiming FOIA exemptions that are either inapplicable or unconvincing. In its Motion for Summary Judgment, the Defendant has failed to carry the burden of showing that the claimed exemptions apply. Because the Defendant has wrongfully withheld records, and because there are no genuine issues of material fact, Defendant's Motion for Summary Judgment should be denied, and the Goldwater Institute's Cross Motion for Summary Judgment should be granted. If the withheld records are not released in their entirety, the Court should enter a finding on segregability and order the production of a *Vaughn* index.

FACTS

The Goldwater Institute is a public interest non-profit research and policy organization that conducts research and analysis on, *inter alia*, issues pertaining to government transparency and health care. PSSF ¶ 1.[1] The Goldwater Institute is currently engaged in research and analysis pertaining to the FDA drug approval process. *Id.*

On August 5, 2014, CNN reported that two American Ebola patients, Kent Brantly and Nancy Writebol, were successfully treated with an investigational drug, ZMapp, which had not been approved for use or marketing in the United States. PSSF ¶ 2. According to this

[1] Plaintiff uses the following acronyms to refer to relevant documents:
- DMSJ – Defendant's Motion for Summary Judgment.
- DSMF – Defendant's Statement of Material Facts.
- PSSF – Plaintiff's Separate Statement of Facts.

and other media reports, ZMapp was authorized for use in an incredibly expeditious fashion, and in a manner that did not appear to be in line with the FDA's traditional process for authorizing investigational drugs. *Id.*

Two days later, on August 7, 2014, the Goldwater Institute submitted a FOIA request to the FDA requesting:

> Any and all records that indicate the approval process, deliberations made during that process, and final approval records regarding provision or approval of the drug and serum 'ZMapp' to be administered to Dr. Kent Brantly and Ms. Nancy Writebol, or any other individuals suspected to be infected with the Ebola virus, under the 'compassionate use' process or any other approval process at the FDA.

PSSF ¶ 3. In other words, the Goldwater Institute sought three categories of records from the Defendant: (1) records pertaining to the government mechanism or process by which ZMapp was made available to Ebola patients; (2) records pertaining to government review and analyses made during that process; and (3) records indicating government determinations that were made to authorize the use of ZMapp for Ebola patients.

The Goldwater Institute requested these public records from the FDA in order to aid in research and analysis that is expected to contribute to the public's understanding of the drug approval process in the United States. PSSF ¶ 1.

Despite the fact that the Goldwater Institute requested only records pertaining to internal government processes and procedures, by letter dated September 29, 2014, Defendant denied the Goldwater Institute's FOIA request *in its entirety* on the grounds that it was exempt from disclosure under 5 U.S.C. § 552(b)(4) ("Exemption 4"), an exemption intended to protect trade secrets and other confidential commercial information. PSSF ¶¶ 8–9. Exemption 4 was the sole basis on which the Defendant initially denied the Goldwater Institute's request. *Id.*

The Defendant also identified nine volumes of responsive records in its initial denial letter. PSSF ¶ 10.

The Goldwater Institute timely appealed the denial of its FOIA request. PSSF ¶ 11.

In the administrative appeal, the Goldwater Institute reiterated that it was seeking only records pertaining to "the general course and method" by which the FDA's functions in this case were "channeled and determined." PSSF ¶ 12. The Goldwater Institute informed the Defendant that it was expressly not seeking any trade secret or confidential commercial information of any private party. *Id.*

On February 19, 2015, Defendant denied the Goldwater Institute's administrative appeal in its entirety. PSSF ¶ 13. In addition to Exemption 4, HHS claimed, for the first time, that the requested records were also exempt from disclosure under 5 U.S.C. §§ 552(b)(3), (b)(5), (b)(6), "Exemption 3," "Exemption 5," and "Exemption 6," respectively. PSSF ¶ 14.

In the denial of the Goldwater Institute's administrative appeal, the Defendant expressly declared, "Information you requested is contained in an unapproved Investigational New Drug (IND) application. . . . The product at issue here is not the subject of an approved New Drug Application (NDA), but rather the subject of an IND that is still undergoing review for approval." PSSF ¶ 15. In other words, as early as February 19, 2015, the Defendant expressly affirmed the existence of an IND for ZMapp, and publicly disclosed that information in response to the Goldwater Institute's FOIA request.

The Defendant also indicated that the Defendant was prevented from disclosing the requested records by 21 C.F.R. § 314.430, a regulation that does not apply to drugs that are biological products, such as ZMapp. PSSF ¶ 17.

On June 9, 2015, the Goldwater Institute filed this action. PSSF ¶ 18.

On July 10, 2015, the Defendant answered the Goldwater Institute's Complaint. PSSF ¶ 19. In its Answer filed in this Court, Defendant stated that "Defendant is prohibited from disclosing whether an emergency IND exists." *Id.* In other words, the Defendant refused to acknowledge the *existence* of an IND for ZMapp in Defendant's Answer on July 10, 2015, despite the fact that Defendant had *already done so* nearly five months earlier in Defendant's denial of the Goldwater Institute's administrative appeal. PSSF ¶ 15.

In refusing to acknowledge the existence of an IND for ZMapp, the Defendant was apparently relying on federal regulations that purportedly make a distinction between

whether an IND has been "publicly disclosed" or not in terms of the ability of the agency to confirm or deny the existence of an IND. *See* 21 C.F.R. §§ 601.51(c), (d)(1). According to the Defendant, if the existence of an IND has *not* been publicly disclosed, the Defendant is prohibited from confirming or denying its existence. DMSJ at 6–7. If, on the other hand, an IND has been publicly disclosed, the FDA may confirm its existence, but is restricted in releasing the contents of the IND. *Id.*

On November 24, 2015 – the day on which Defendant's Motion for Summary Judgment was due in this Court – Defendant released a limited batch of records to the Goldwater Institute "in response to [the Goldwater Institute's FOIA] request dated August 7, 2014." PSSF ¶ 20.

Remarkably, the Defendant claims that it released these records on November 24, 2015, over 15 months after the Goldwater Institute submitted its public records request and over four months after this action was filed, because the Defendant had recently become aware that the existence of an IND for ZMapp had been publicly disclosed. DMSJ at 9–10.

This assertion is clearly disingenuous. As early as August 5, 2014, the existence of an IND for ZMapp was publicly disclosed in the media. PSSF ¶ 2. On February 19, 2015, the Defendant expressly disclosed the existence of the IND in its response to the Goldwater Institute's administrative appeal. PSSF ¶ 15. On July 10, 2015, however, in its Answer to this Court, the Defendant refused to acknowledge the existence of an IND for ZMapp asserting that it could not do so because that information had not been made publicly available. PSSF ¶ 19. And then on November 24, 2015, the Defendant made a limited quantity of records available, claiming the Defendant had only done so then because it learned that use of ZMapp had been publicly disclosed "[a]fter the Complaint and Answer in this case were filed." DSMF ¶ 36. The Defendant supported this astonishing claim by citing an interview conducted on October 2, 2014 and a medical report published in November of 2014, *over one year earlier*. *Id.*[2]

[2] Based on this remarkable sequence of events, regardless of the outcome of the remainder of this litigation, the Goldwater Institute intends to file a Motion for an Award of Attorneys'

ANALYSIS

I. THE FOIA REQUIRES THE RELEASE OF THE RECORDS THE DEFENDANT HAS WRONGFULLY WITHHELD.

The FOIA is predicated on openness and transparency and, under the law, there is a broad presumption in favor of disclosure of records made and kept by federal agencies. "The basic purpose of FOIA is to ensure an informed citizenry, vital to the functioning of a democratic society, needed . . . to hold the governors accountable to the governed." *N.L.R.B. v. Robbins Tire & Rubber Co.*, 437 U.S. 214, 242 (1978). The Act's ultimate purpose is "to enable the public to have sufficient information in order to be able, through the electoral process, to make intelligent, informed choices with respect to the nature, scope, and procedure of federal governmental activities." *Renegotiation Bd. v. Bannercraft Clothing Co.*, 415 U.S. 1, 17 (1974) (internal citations omitted). In other words, the chief purpose of the FOIA is rooted in "citizens' right to 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). As a result, under the FOIA, there is a broad presumption in favor of disclosure. *Yonemoto v. Dep't of Veterans Affairs*, 686 F.3d 681, 692 (9th Cir. 2012) (noting the FOIA's "strong presumption in favor of disclosure.").

A. The FOIA expressly compels disclosure of the records at issue in this case.

The FOIA expressly compels disclosure of public records under certain circumstances. "Each agency *shall make available* to the public information as follows:

. . . statements of the general course and method by which its functions are channeled and determined, including the nature and requirements of all formal and informal procedures available[.]" 5 U.S.C. § 552(a)(1)(B)(emphasis added). "Congress has already determined the relevant public interest [in FOIA litigation]: if through disclosure the public would learn something directly about the workings of the *Government*, then the information should be

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Fees, as this lawsuit was clearly necessary to obtain at least some of the records the Defendant wrongfully withheld and a casual nexus exists between this action and the Defendant's release of records on November 24, 2015. *See* 5 U.S.C.§ 552(a)(4)(E)(ii)(II); *Maynard v. CIA*, 986 F.2d 547, 568 (1st Cir. 1993).

disclosed unless it comes within a specific exemption." *Pub. Citizen Health Research Grp. v. FDA*, 185 F.3d 898, 904 (D.C. Cir. 1999) (internal citations omitted) (emphasis in original).

In this case, the Goldwater Institute is seeking records expressly pertaining to "the general course and method by which [the FDA's] functions are channeled and determined," including the formal and informal *internal* procedures by which the drug ZMapp was administered to two American patients. In other words, the Goldwater Institute seeks records pertaining to the government's own administrative processes as they were applied in particular instances. This is precisely the type of information covered by 5 U.S.C. § 552(a)(1)(B) and is directly in line with the relevant public interest of learning about the workings of government under the FOIA. As a result, the records at issue are clearly public records within the meaning of the FOIA, and must be released unless an exception – which the government has the burden of proving – applies.

Moreover, although a requester's reasons for seeking public information are generally immaterial to the government's duty to disclose public records, in this case, the general purpose of the FOIA is directly aligned with the Goldwater Institute's objectives in seeking these records. The Goldwater Institute not only conducts research and analysis on issues pertaining to government transparency and health care, but the Institute is specifically engaged in research and analysis pertaining to the FDA drug approval process. The public records the Goldwater Institute requested from the FDA will be used to aid in that research and analysis and is expected to contribute to the public's understanding of the drug approval process in the United States. Opening administrative processes, such as the drug approval process, to the scrutiny of the general public for study and examination is one of the principal purposes of the FOIA. *See Bannercraft Clothing Co.*, 415 U.S. at 9 (purpose of the FOIA is to open administrative processes to the scrutiny of the general public).

B. No agency regulation prevents the disclosure of the records at issue.

Federal regulations do not prevent the disclosure of records the Goldwater Institute requests. The Defendant argues at length, and without legal support, that federal regulations prevent or limit the disclosure of the records at issue. DMSJ at 6–8.

Specifically, relying on 21 C.F.R. § 312.130(a), Defendant argues that "FDA is expressly prohibited from publicly disclosing the *existence* of an IND or an unapproved BLA unless the application's existence has previously been publicly disclosed or acknowledged, because such information is [*sic*] trade secret/CCI." (*Id.* at 6–7). As described, *supra*, the existence of an IND for ZMapp had been publicly disclosed as early as the time the Goldwater Institute made its public record request in August 2014. PSSF ¶¶ 2–3. Moreover, the FDA itself acknowledged the existence of an IND for ZMapp in its response to the Goldwater Institute's administrative appeal on February 19, 2015 (PSSF ¶ 15), and in any event, the FDA has now expressly provided records indicating that ZMapp was the subject of an emergency use IND ("eIND"). DMSJ 9–10. The Goldwater Institute's request, therefore, never was, and clearly is not now, within the ambit of 21 C.F.R. § 312.130(a).

The Defendant next argues that it is prevented from disclosing the records it has withheld under 21 C.F.R. § 601.51(d)(1). In processing the Goldwater Institute's FOIA request, the Defendant never raised 21 C.F.R. § 601.51(d)(1) as a bar to production, and it cannot do so for the first time here. Rather, in the Defendant's initial denial of the Goldwater Institute's FOIA request (PSSF ¶ 8), and in Defendant's denial of the Goldwater Institute's administrative appeal (PSSF ¶ 15), Defendant cited 21 C.F.R. § 314.430 to claim that the records were properly withheld. As the Defendant now concedes, 21 C.F.R. § 314.430 does not apply to biological products, such as ZMapp. DMSJ at 3, n.3.

But the Defendant cannot raise a new basis for withholding records for the first time in this litigation. The Ninth Circuit has squarely held: "On judicial review, we cannot consider new reasons offered by the agency not raised in the denial letter. Taken together, these principles lead us to the following conclusion: on judicial review, the agency must stand on whatever reasons for denial it gave in the administrative proceeding." *Friends of the Coast*

Fork v. U.S. Dep't of the Interior, 110 F.3d 53, 55 (9th Cir. 1997) (internal citations omitted). It is astonishing that the Defendant initially denied a request for records without properly identifying the basis for denial. It is even more astonishing that the Defendant did so even after responding to and denying (in a five page single spaced letter) a final administrative appeal. As the Ninth Circuit has made abundantly clear, the Defendant cannot now rely on new reasons for denying the Goldwater Institute's request for the first time in this Court. As a result, Defendant has waived the applicability of 21 C.F.R. § 601.51(d)(1) as a basis for denial.

Even assuming reliance on 21 C.F.R. § 601.51(d)(1) is not waived, that regulation also clearly does not prevent disclosure. 21 C.F.R. § 601.51(d)(1) (emphasis added) provides, in relevant part:

> "[i]f the existence of a biological product file has been publicly disclosed or acknowledged before a license has been issued, no data or information contained *in the file* is available for public disclosure before such license is issued, but the Commissioner may, in his discretion, disclose a summary of such selected potions of the safety and effectiveness data as are appropriate for public consideration of a specific pending issue…."

By its plain language, this regulation clearly does not apply to records the Goldwater Institute seeks. The regulation applies to information *in* the IND application file. By contrast, the Goldwater Institute has not and does not seek *any* information *in* an IND application. The Goldwater Institute seeks only records pertaining to government processes used to authorize the use of an investigational drug that the government alone has authority to authorize.

Moreover, the regulation expressly defines "file". "For purposes of this section the biological product file includes all data and information *submitted with* or incorporated by reference in any application for a biologics license, IND's incorporated into any such application, master files, and other related *submissions*." *Id.* at § 601.51(a) (emphasis added). Amazingly, despite this definition, Defendant contends that the "FDA treats every record relating to an application as part of the application file, including inter- and intra-agency emails relating to the application." DSMF ¶ 20. That is an extraordinary assertion that the Defendant has no lawful authority to make.

The plain language of the Defendant's own regulation applies expressly and directly to "information *submitted with*…a biologics license, IND's incorporated into any such application…and other *related submissions*." In other words, the regulation applies to information *provided to* the agency, not information or records *created by* the agency. As the FDA readily admits, the purpose of these regulations is to protect "commercial information" and "trade secrets" (DMSJ at 6–7). The agency cannot categorically claim that all inter-agency and intra-agency government e-mails contain commercial information or trade secrets. Some may. And some may not. And it is incumbent on the agency to produce those records that are not explicitly exempt from disclosure.

The Defendant, moreover, cannot use its own regulation, let alone its own policy, without any basis in law, to try to end-around the requirements of the FOIA. That is, the Defendant cannot by policy "nullify a congressionally enacted law." *Teich v. FDA*, 751 F. Supp. 243, 247 (D.D.C. 1990). In *Teich*, a records requester sought information about silicone breast implants. *Id.* at 245. The FDA, however, had previously enacted 21 C.F.R. § 20.44, a regulation that assured confidentiality to those who fell under it. The D.C. District Court held that this regulation frustrated the FOIA. In invalidating the regulation, the court found that the regulation was "clearly an attempt by the agency to nullify a congressionally enacted law. While certainly the agency can deny access to records that the FOIA itself protects, its presubmission review cannot be used to forge a Northwest passage around the FOIA." *Id.* at 247.

Similarly, in this case, the FDA announces a categorical rule that it treats "every record relating to an application as part of the application file." DSMF ¶ 20. The Defendant has no legal authority to do so. If an administrative agency cannot enact a federal regulation that attempts to end-around the FOIA, it certainly cannot announce carte blanche a policy that has the effect of doing so.

II. THE DEFENDANT FAILS TO CARRY THE BURDEN OF PROVING THAT THE CLAIMED EXEMPTIONS PREVENT DISCLOSURE OF PUBLIC RECORDS.

In addition to the strong presumption in favor of disclosure in a FOIA action, the burden of proving an exemption applies is always on the government, and never shifts to the requester or the public. "When an agency chooses to invoke an exemption to shield information from disclosure, it bears the burden of proving the applicability of the exemption." *Yonemoto*, 686 F.3d at 688. "Deference to the determination of the agency that the exemption applies is not due; the burden of the proof that the request may be properly denied because of an exemption rests with the agency." *Favish v. Office of Indep. Counsel*, 217 F.3d 1168, 1172 (9th Cir. 2000). In other words, "the FOIA expressly places the burden on the agency to sustain its action." *U.S. Dep't of Justice v. Reporters Comm. For Freedom of the Press*, 489 U.S. 749, 755 (1989). FOIA exemptions, moreover, "are explicitly made exclusive, and must be narrowly construed." *Milner v. Dep't of Navy*, 562 U.S. 562, 565 (2011) (internal citations omitted). The Court shall determine whether an exemption applies de novo. 5 U.S.C. § 552(a)(4)(B).

The Defendant in this case raises exemptions that are either inapplicable or that do not outweigh the presumption in favor of disclosure. In its Motion for Summary Judgment and supporting affidavit, the Defendant has simply failed to prove that the public records requested are exempt from disclosure.

A. Exemption 4 pertains to trade secrets and is entirely inapplicable to the records requested.

The trade secrets exemption on which the Defendant relies to deny the Goldwater Institute's public records request *in its entirety* simply does not apply. Although *all* FOIA exemptions are to be narrowly construed, the (b)(4) exemption, in particular, is read narrowly to exempt only records that would undermine its specific and limited purpose. "[The (b)(4) exemption] is intended to encourage individuals to provide certain kinds of confidential information to the Government, and it must be read narrowly in accordance with that purpose." *Soucie v. David*, 448 F.2d 1067, 1078 (D.C. Cir. 1971). Under the FOIA, records may be exempt from disclosure under (b)(4) if the records include: (1) trade secrets and

commercial or financial information, (2) obtained from a person or by the government, (3) that are privileged or confidential. 5 U.S.C. § 552(b)(4). "These three requirements are conjunctive." *Pac. Architects & Eng'rs Inc. v. U.S. Dep't of State*, 906 F.2d 1345, 1347 (9th Cir. 1990).

In this case, the Defendant has failed to establish that the records the Goldwater Institute seeks meets these requirements. Specifically, the Goldwater Institute seeks neither trade secrets nor confidential commercial information. The Goldwater Institute seeks only records pertaining to the FDA's own internal approval processes and procedures regarding how the Defendant authorized an investigational drug for use over which it has authority. This request simply does not fall within the definition of a "trade secret" as the Goldwater Institute is seeking no "plan, formula, process, or device" that is secret and "commercially valuable." *Pub. Citizen Health Research Grp.*, 704 F.2d at 1288. Additionally, the Goldwater Institute seeks records pertaining to the government's own internal operations, the majority of which are presumably prepared by the government; records that by their very nature cannot be commercial, as the government ostensibly has no proprietary interest in its own internal review and approval processes. *See Gov't Accountability Project v. U.S. Dep't of Health & Human Servs.*, 691 F. Supp.2d 170, 174–75 (D.D.C. 2010).

Moreover, the Goldwater Institute seeks no records that are privileged or confidential, and the Defendant has not proven that the records it has withheld are privileged or confidential. "To determine if information is privileged or confidential requires an analysis of whether the information will (1) impair the Government's ability to obtain necessary information in the future, or (2) cause potential harm to the competitive position of the person from whom the information was obtained." *Pac. Architects & Engineers Inc.*, 906 F.2d at 1347 (citation omitted).

Disclosure of records in response to the Goldwater Institute's request in no way impairs the ability of the Defendant to obtain necessary information from drug companies in the future. Drug companies will continue to be required to disclose clinical data, studies, and other information in order to get their drugs approved through various phases of the FDA

approval process. The companies have no choice in the matter. The government requires submission of the information as part of the drug approval process. "When submission of information is mandatory, 'there is a presumption that the Government's interest is not threatened by disclosure.'" *Inner City Press/Cmty. on the Move v. Bd. of Governors of the Fed. Reserve Sys.*, 380 F. Supp.2d 211, 216 (S.D.N.Y. 2005) (citing *Critical Mass Energy Project v. Nuclear Regulatory Comm'n*, 975 F.2d 871, 878 (D.C. Cir. 1992).

Moreover, there is no evidence whatsoever that the Goldwater Institute's request will cause competitive harm to the maker of ZMapp. The Goldwater Institute has requested information about government processes, not information about a drug. Indeed, the very fact that ZMapp has not appeared in this action demonstrates that the company does not see competitive harm from the Goldwater Institute's request. Of course, the onus is on the Defendant to prove that the information is confidential. The Defendant has offered no evidence on this point, and has therefore failed to do so.

The Defendant claims that "trade secret/CCI [information] is inexplicably [sic] intertwined with FDA reviewers' deliberations concerning these expanded access INDs and the deliberations themselves are therefore exempt from disclosure under Exemption 4." (DSMJ at 16). Of course, we have no way to know that, as the Defendant has neither disclosed records nor a *Vaughn* index. And, of course, the burden is on the Government to prove this is true, which the Defendant has not done. In any event, the Goldwater Institute finds it hard to believe that all government communications regarding authorization for an investigative drug include, or are "inextricably intertwined" with, trade secret information.

A request for information regarding government processes and procedures is not a request for trade secrets or confidential commercial information. The Government has fallen far short of its burden in proving that Exemption 4 prevents disclosure of records pertaining to government activities, not commercial information.

B. Exemption 5 does not prevent the disclosure of records pertaining to government processes and procedures.

The Defendant has also failed to prove that the records the Goldwater Institute seeks can be withheld under Exemption 5, a provision intended to protect information or evidence

that would traditionally be privileged in litigation. Section 552(b)(5) of the FOIA exempts from disclosure "inter-agency or intra-agency memorandums or letters which would not be available by law to a party other than an agency in litigation with the agency." 5 U.S.C. § 552(b)(5). Exemption 5 "has been construed narrowly to 'exempt those documents, and only those documents, normally privileged in the civil discovery context.'" *Julian v. U.S. Dep't of Justice*, 806 F.2d 1411, 1418 (9th Cir. 1986) *aff'd*, 486 U.S. 1 (1988) (quoting *NLRB v. Sears, Roebuck and Co.*, 421 U.S. 132, 149 (1975)). In order to invoke the protection of Exemption 5 the government must identify a privilege which it "enjoys under the relevant statutory and case law in the pretrial discovery context." *Id.* (citation omitted). Examples of such privileges that fall within the umbrella of Exemption 5 are the attorney–client privilege, the attorney work product privilege, and the executive "deliberative process" privilege. *Maricopa Audubon Soc. v. U.S. Forest Serv.*, 108 F.3d 1082, 1084 (9th Cir. 1997). If there is no such privilege, the exemption cannot apply.

In this case, the Defendant claims that the withheld records are exempt from disclosure because they include "communications between or among FDA reviewers of the INDs." DMSJ at 16. But all such communications are not exempt from disclosure. Records only fall within Exemption 5 if they are "both predecisional and deliberative." *Assembly of State of Cal. v. U.S. Dept. of Commerce*, 968 F.2d 916, 920 (9th Cir. 1992). Generally, communications that are made after the decision and designed to explain it, which constitutes "opinions and interpretations" of policy and law of the agency, are not predecisional documents. *Sears, Roebuck & Co.*, 421 U.S. at 151.

Many of the records the Goldwater Institute requested may very well not be predecisional documents. For example, any records discussing the approval process that was used to authorize ZMapp after the authorization was granted would clearly not be predecisional. But, of course, we do not know that, because the Defendant has not told us, nor has the Defendant produced sufficient evidence to demonstrate that the withheld records are in fact predecisional.

The deliberative prong of the "deliberative process" privilege requires that the documents "reveal the mental processes of decision-makers." *Assembly of State of Cal.*, 968 F.2d at 921 (internal citations omitted). Records may be deliberative if they are "subjective" and "reflect the personal opinions of the writer rather than the policy of the agency." *Coastal States Gas Corp. v. Dep't of Energy*, 617 F.2d 854, 866 (D.C. Cir. 1980). "To test whether disclosure of a document is likely to adversely affect the purposes of the privilege, courts ask themselves whether the document is *so candid or personal in nature* that public disclosure is likely in the future to stifle honest and frank communication within the agency" *Id* (emphasis added). When the information is purely factual and will not reveal reasoning behind data garnered, it will not be "deliberative" and will fall outside of the protection of Exemption 5.

In this case, the Goldwater Institute did not ask the Defendant only for the *specific content* of drug approval deliberations by the agency, some of which may be protected by Exemption 5 and some of which may not, but also for records indicating *whether* such deliberations were ever made. Federal regulations require the Defendant to examine and evaluate certain criteria when determining whether to authorize an emergency IND. *See* 21 C.F.R. §§ 312.305, 312.310. The Goldwater Institute seeks to know whether the Defendant in fact performed that examination, and has requested records indicating the factual determinations that resulted from that deliberation. This is not information that is "subjective" or "personal in nature." Rather, these are records that get to the essence of determining how the drug approval process worked in a particular instance. 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. at 488.

Moreover, the purpose of Exemption 5 is ultimately to prevent injury to the quality of a government agency's decisions. *See Sears, Roebuck & Co.*, 421 U.S. at 151. Asking an agency *how* it made an investigational drug available, and *whether* the agency complied with existing federal requirements in doing so, cannot possibly adversely impact the Defendant's

decisions. On the contrary, in our democracy, increased accountability also enhances effective decision-making. *See Robbins Tire & Rubber Co.*, 437 U.S. at 242.

C. The Defendant has failed to establish the relevance and applicability of Exemption 6.

Exemption 6 does not apply to the records the Defendant has withheld because the Goldwater Institute seeks no private information about any individual. Exemption 6 protects from disclosure the "personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy." 5 U.S.C. § 552(b)(6). Exemption 6 was "intended to cover detailed Government records on an *individual* which can be identified as applying to that *individual*." *U. S. Dept. of State v. Washington Post Co.*, 456 U.S. 595, 602 (1982) (emphasis added). Additionally, in order for the exemption to apply, the requester must first seek "personnel and medical files and similar files," and only if such records are sought, the Court must then decide whether the production of those documents would be a "clearly unwarranted invasion of personal privacy." *Prudential Locations LLC v. U.S. Dept. of Hous. & Urban Dev.*, 739 F.3d 424, 429 (9th Cir. 2013). Neither requirement is met in this case.

The Goldwater Institute did not request medical files for any individual. The Goldwater Institute requested records pertaining to the *government's* administrative processes and procedures, as they were applied in specific instances. To the extent any of these records contain personal medical information, the Goldwater Institute does not want them, and requests that they be redacted if such information is included in otherwise public records. Thus, the first prong of the Exemption 6 test is simply not satisfied.

The Defendant rests the entirety of its argument as to why Exemption 6 is applicable on one sentence: "In light of the highly unusual circumstances surrounding the administration of ZMapp to individuals who contracted Ebola, FDA also properly withheld the records under Exemption 6 because the information would infringe on patient privacy with no countervailing public benefit." DMSJ at 17. There is no "unusual circumstances" exception to the FOIA, and this does not remotely measure up to Exemption 6 for multiple reasons. First, this argument is conclusory. Second, it does not come anywhere near meeting the

Defendant's burden to prove that Exemption 6 applies. Finally, taken as true, the statement actually supports a finding that Exemption 6 does not apply.

Under Exemption 6, the government must prove that there is a nontrivial privacy interest at stake, which the Defendant has not done. *Prudential Locations LLC*, 739 F.3d at 431. The government must also prove that the nontrivial privacy interest outweighs the public's interest in disclosure. *Id.*

In this case, the entire world is aware through countless media sources that Kent Brantly and Nancy Writebol contracted the Ebola virus in Africa and were treated with ZMapp. The Goldwater Institute requested no additional information about those two individual patients, but requested instead public records pertaining to *how the government* administered its own drug approval process. There is, therefore, no nontrivial privacy interest at stake, and certainly not one that is not already widely known. Any de minimis privacy interests that might exist are clearly outweighed by, in the words of the Defendant, "the highly unusual circumstances surrounding the administration of ZMapp." DMSJ at 17. If the government is going to administer an investigational drug under "highly unusual circumstances," and possibly in a manner that does not comport with its own traditional practices, the public absolutely has an interest in knowing how its government made these life and death decisions, and that public interest is substantial.

III. IN THE ABSENCE OF FULL DISCLOSURE OF THE RECORDS REQUESTED, A FINDING ON SEGREGABILITY AND PRODUCTION OF A *VAUGHN* INDEX ARE APPROPRIATE.

Although the Defendant has failed to meet its burden to prove that any exemption applies to the public records the government has withheld, should the Court decline to order the full production of the records at issue, the Goldwater Institute respectfully requests that the Court enter a finding on segregability and order the production of a *Vaughn* index.

Given the volume of responsive records in this case, if any exemption applies to any portion of them, a finding on segregability is appropriate. The FOIA requires that "[a]ny reasonably segregable portion of a record shall be provided to any person requesting such record after deletion of the portions which are exempt." 5 U.S.C. § 552(b). Moreover, "it is

error for a district court to simply approve the withholding of an entire document without entering a finding on segregability, or the lack thereof." *Church of Scientology of Cal. v. U.S. Dep't of Army*, 611 F.2d 738, 744 (9th Cir. 1979). Courts are therefore required to determine whether any of the documents contain material that can be segregated or disclosed without violating an exemption. *Krikorian v. Dep't of State*, 984 F.2d 461 (D.C. Cir. 1993).

In this case, the Defendant identified *nine volumes* of responsive records in its initial denial letter. PSSF ¶ 10. After the Complaint in this case was filed, Defendants apparently conducted an extensive search and identified substantially more responsive records. DSMF ¶¶ 32–35. Given the volume of records at issue, it seems exceedingly unlikely that the entirety of the withheld records are exempt from disclosure. Therefore, should the Court not order the production of all records the Defendant has identified as responsive, the Court should review those records for segregability.

In the absence of full disclosure, for the same reasons, and because "only the party opposing disclosure [has] access to all the facts," production of a *Vaughn* index is appropriate. *Church of Scientology Int'l v. U.S. Dep't of Justice*, 30 F.3d 224, 228 (1st Cir. 1994). *See also Lion Raisins Inc. v. U.S. Dep't of Agric.*, 354 F.3d 1072, 1082 (9th Cir. 2004) ("Because the court and the plaintiff do not have the opportunity to view the documents themselves, the submission must be detailed enough for the district court to make a *de novo* assessment of the government's claim of exemption.") (internal citations omitted).

CONCLUSION

For the foregoing reasons, the Goldwater Institute is entitled to summary judgment and respectfully requests that the Court enter an order requiring the Defendant to produce all responsive records the Defendant has withheld. In the alternative, the Goldwater Institute respectfully requests the Court enter a finding on segregability and order the production of a *Vaughn* index.

RESPECTFULLY SUBMITTED this 8th day of January, 2016 by:

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CERTIFICATE OF SERVICE

Document Electronically Filed and Served by ECF and Copies sent via e-mail this 8th day of January, 2015 to:

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