EXHIBIT 6

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

CASE NO. 20-MC-82327-BER
20-MD-2924-RLR (Master Case)

IN RE: SUBPOENA DATED JUNE 18, 2020
(Case No. 20-MC-82327-BER)
_____/

IN RE: ZANTAC (RANITIDINE)
PRODUCTS LIABILITY LITIGATION
(Case No. 20-MD-2924-RLR)
_____/

ORDER GRANTING MOTION TO QUASH AMENDED SUBPOENA [ECF No. 27]

This third-party subpoena dispute arises from the Zantac Multidistrict Product Liability Litigation. In that MDL, Plaintiffs allege that entities at all levels of the manufacturing, supply, and sales chains concealed that Zantac contained dangerous levels of a carcinogen.

BACKGROUND AND PROCEDURAL HISTORY

In or about March 2020, the FDA contracted to have movant Spaulding Clinical Research, LLC ("Spaulding"), conduct a clinical study called the "Clinical Study to Investigate Urinary Excretion of N-nitrosodimethylamine (NDMA) after Ranitidine Administration." ("the NDMA Study"). The contract for the study was signed on March 16, 2020. ECF No. 4-2 ("Contract") at 1. The Contract period was March 16, 2020, through December 19, 2020. *Id.* at 11. The purpose of the study was to evaluate "if and how much NDMA is produced from ranitidine in the human body and whether

nitrite-containing foods may potentiate formation of NDMA in vitro." *Id.* at 5–6. The methodology was to give 300 mg doses of ranitidine to 16 healthy subjects to see if the amount of NDMA they excreted was affected by the amount of nitrites in their diet. *Id.* at 6.[1]

Spaulding was to complete five tasks under the contract: (1) finalize the clinical study protocol for submission to the FDA Research Involving Human Subjects Committee, (2) receive approval from the local Institutional Review Board, (3) screen the study participants and begin clinical study dosing, (4) execute the clinical study, and (5) help produce a post-study scientific manuscript. ECF No. 4-2 at 8–10. The Contract called for Spaulding to carry out the NDMA Study at its own facilities. *Id.* at 11. It also called for weekly status meetings, a monthly progress meeting, and monthly written progress reports. *Id.* at 12–13.

On June 18, 2020, Plaintiffs issued a subpoena to Spaulding commanding production of records related to the NDMA Study. Spaulding filed a timely motion to quash the subpoena in the Eastern District of Wisconsin. ECF No. 1. That motion was subsequently transferred to this court, where the MDL is pending. ECF No. 12. Judge Rosenberg referred it to me. ECF No. 16.

I granted the motion to quash after Plaintiffs failed to file a timely response.

[1] The NDMA Study collected data from 18 patients between June 22 and July 1, 2020. https://clinicaltrials.gov/ct2/show/record/NCT04397445?id=NCT04397445&draw=2&rank=1; *see also* ECF No. 30 at 10, ECF No. 32 at 2.

ECF No. 20. Plaintiffs moved to reconsider and explained that there had been an administrative mix-up. ECF No. 22. They also explained that they had served an Amended Subpoena. *Id.* at 3. I granted the motion to reconsider and vacated my prior order, without prejudice to Spaulding moving to quash the Amended Subpoena. ECF No. 26.

Spaulding has filed a motion to quash the Amended Subpoena with a supporting memorandum of law. ECF No. 27, 28. Spaulding moves for a protective order, reimbursement of its costs, and attorney's fees. ECF No. 27 at 1. The Government separately moved to quash the Amended Subpoena. ECF No. 30.[2] Plaintiffs filed a Response. ECF No. 32. Spaulding and the Government filed Replies. ECF No. 33, 34. I held oral argument on April 8, 2021. ECF No. 37. This matter is now ripe for decision.

THE SUBPOENA

The Amended Subpoena calls for Spaulding to produce five categories of documents:

> 1. Copies of documents, memos, correspondence, emails, notes, communications, agreements, case study reports, and/or other reports of any type (including all attachments and appendices) regarding the NDMA Clinical Study.

[2] The Government filed a Statement of Interest pursuant to 28 U.S.C. § 517 ("The Solicitor General, or any officer of the Department of Justice, may be sent by the Attorney General to any State or district in the United States to attend to the interests of the United States in a suit pending in a court of the United States, or in a court of a State, or to attend to any other interest of the United States."). Plaintiffs have not objected to the Government's standing to challenge the Amended Subpoena.

2. Copies of the results and/or outcomes from the NDMA Clinical Study.

3. Copies of the data collected from the NDMA Clinical Study.

4. Copies of all synopses, draft study reports, protocols and statistical analysis plans generated as part of the NDMA Clinical Study.

5. Color, high-resolution copies imaging of histopathology slides, taken as part of or related to the histopathology/microscopic pathology review performed as part of the NDMA Clinical Study.

ECF No. 29-1 at 10–11. The Amended Subpoena does not contain a date limitation.

At oral argument, the Court suggested, and Spaulding agreed, that the responsive documents could be separated chronologically as follows: (1) pre-contracting materials, (2) contracting materials, (3) post-contract, pre-study materials, including identifying and screening study participants, (4) materials derived from conducting the study, including raw data, clinical testing results, and communications with participants in the study, and (5) post-study materials. In all of these categories, there would be Spaulding's purely internal communications and Spalding's communications with the FDA. Hr'g Tr. Apr. 8, 2021 at 4:24-7:8.

The parties have narrowed the factual issues slightly. Plaintiffs do not seek the identities or personal information for the study participants. Hr'g Tr. Apr. 8, 2021 at 35:8–15. Spaulding submitted an uncontradicted declaration stating that it did not retain samples and specimens after the conclusion of the Study. ECF No. 4 at ¶ 12. It is also undisputed that Spaulding did not analyze the data collected during the NDMA Study. Finally, Spaulding asserts that there are no documents responsive to specification 5 of the Amended Subpoena because the NDMA Study did not use

histopathology. Hr'g Tr. Apr. 8, 2021 at 11:24–12:8.

THE PARTIES' ARGUMENTS

Spaulding argues that the Amended Subpoena should be quashed because: (1) the subpoenaed materials are property of the FDA, not Spaulding, (2) the contract with the FDA prohibits Spaulding from disclosing the subpoenaed records, (3) the Privacy Act prohibits Spaulding from complying with the Amended Subpoena, (4) Plaintiffs have not complied with the FDA's *Touhy* regulations regarding disclosure of the subpoenaed material, and (5) the subpoena is overbroad and compliance would be unduly burdensome. Spaulding also argues that the subpoenaed materials are protected confidential research information. *See generally* ECF Nos. 27 and 28.

The Government argues that the Amended Subpoena should be quashed because (1) it seeks confidential research information that belongs to the FDA, (2) it requires disclosure of privileged information, (3) it is an end run around the *Touhy* regulations, and (4) it contravenes public policy. Finally, the FDA notes that many documents related to the NDMA Study have already been made public and that it is required by law to release the results of the NDMA Study, along with the clinical data, no later than June 30, 2021. *See generally* ECF No. 30.

Plaintiffs respond that (1) a subpoena over-rides a private agreement to keep information confidential, (2) the Privacy Act does not apply, (3) the *Touhy* regulations do not apply to a subpoena to a private party, (4) the requested material are not confidential research materials, (5) the requested material falls within the broad

scope of civil discovery, (6) any burden to produce the documents is outweighed by their significance to this litigation, and (7) privacy and confidentiality concerns can be addressed under the existing confidentiality order (PTO # 26). *See generally* ECF No. 32.

DISCUSSION

1. Federal Rule of Civil Procedure 45

Federal Rule of Civil Procedure 45(d)(3) specifies when a court should, or must, quash a subpoena to a third-party. The applicable legal standard depends on the nature of the documents called for by the subpoena. As relevant here, a Court *must* quash or modify a subpoena that "(iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or (iv) subjects a person to undue burden." Fed. R. Civ. P. 45(d)(3)(A)(iii), (iv). A Court *may,* quash or modify a subpoena "if it requires: (i) disclosing a trade secret or other confidential research, development, or commercial information." Fed. R. Civ. P. 45(d)(3)(B)(i). In the latter situation, "the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party: (i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and (ii) ensures that the subpoenaed person will be reasonably compensated."

The objecting party bears the burden of establishing that (1) the requested materials are privileged, otherwise legally protected, or confidential research, development, or commercial information or that (2) compliance would entail an undue

burden. *See McNamara v. Gov't Employees Ins. Co.*, 8:17-CV-3060-T-23CPT, 2018 WL 8193869, at *2 (M.D. Fla. Dec. 21, 2018) ("Regardless of whether it is a party or non-party, a movant seeking to quash or modify a subpoena under Rule 45(d)(3) bears the burden of showing that it is entitled to the requested relief."). Rule 45(d)(3) explicitly places the burden on the party serving the subpoena to show a substantial need for the materials that cannot otherwise be met without undue hardship.

"[I]n considering a Rule 45 subpoena discovery dispute, the Court applies the relevancy and proportionality standards in Rule 26(b)(1)." *Davis v. Nationwide Ins. Co. of Am.*, 19-CV-80606, 2020 WL 7480819, at *3 (S.D. Fla. Dec. 18, 2020) (J. Matthewman); *accord Ocasio v. Nationstar Mortgage, LLC,* 2:17-CV-40-FTM-38MRM, 2017 WL 4958578, at *2 (M.D. Fla. Nov. 1, 2017). "While Rule 45 does not specifically identify irrelevance as a reason to quash a subpoena, it is generally accepted that the scope of discovery allowed under Rule 45 is limited by the relevancy requirement of the federal discovery rules." *Jordan v. Comm'r, Mississippi Dep't of Corr.,* 947 F.3d 1322, 1329 (11th Cir. 2020), *cert. denied sub nom. Jordan v. Georgia Dep't of Corr.,* 141 S. Ct. 251 (2020). Moreover, Rule 26(b)(1) instructs:

> Parties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense and proportional to the needs of the case considering the importance of the issues at stake in the action, the amount in controversy, the parties' relative access to relevant information, the parties' resources, the importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit.

By the plain language of Rule 26(b)(1), the proportionality factors (which include undue burden) limit what documents a requesting party may obtain, without regard

for whether the request is to another party under Rule 34 or to a non-party under Rule 45. *See, e.g., Hatcher v. Precoat Metals*, 271 F.R.D. 674, 675 (N.D. Ala. 2010) ("Rule 45 must be read in conjunction with Federal Rule of Civil Procedure 26 because the latter rule 'clearly defines the scope of discovery for all discovery devices.' ") *citing* 9 Wright & Miller, *Federal Practice and Procedure;* Civil 3rd § 2452 (3rd ed. 2008).

Rule 45(d)(3)(A)(iii) applies even if materials are not otherwise covered by an evidentiary privilege. *Jordan*, 947 F.3d at 1336 ("the text of Rule 45(d)(3)(A)(iii) indicates that the protection of that specific provision extends beyond the strict bounds of 'privileged' information to encompass 'other protected matter.' "). "Indeed, federal courts have recognized that privacy interests and confidentiality concerns can factor into a decision whether to quash a subpoena under Rule 45, even though the information requested by the subpoena is not subject to a federal evidentiary privilege." *Id.*

Here, there are contractual and legal bars to Spaulding disclosing the raw data and test results. The Contract contained multiple confidentiality provisions. One stated:

> Data and information either provided to the Contractor, or to any subcontractor or generated by activities under this contract or derived from research or studies supported by this contract, shall be used only for the purposes of the contract. It shall not be duplicated, used or disclosed for any purpose other than the fulfillment of the requirements set forth in this contract."

ECF No. 4-2, ¶8.4. Another stated:

> any information provided to the contractor (and/or any subcontractor) by FDA or collected by the contractor on behalf of FDA shall be used

> only for the purpose of carrying out the provisions of this contract and shall not be disclosed or made known in any manner to any person except as may be necessary in the performance of the contract . . . The confidentiality, integrity, and availability of such information shall be protected in accordance with HHS and FDA policies. Unauthorized disclosure of information will be subject to the HHS/FDA sanction policies and/or governed by [applicable federal] laws and regulations.

Id. at 22; *see also id.* at 21-22 (Controlled Unclassified Information must be handled and disseminated in compliance with federal regulations and must be "returned to FDA control, destroyed when no longer needed, or held until otherwise directed.").

The Contract also incorporates a provision of the Federal Acquisition Regulations that precludes a contractor from using, releasing, reproducing, distributing, or publishing "any data first produced or specifically used by the Contractor in the performance of this contract" if doing so would be prohibited by federal law or regulation, or by other terms of the Contract. FAR 52.227-14 (Rights in Data – General) (May 2014), 48 C.F.R. § 52.227-14, *cited at* ECF No. 4-1 at 38.

In addition to the Contract, FDA regulations specify that the results of testing or research funded by the FDA, "such as toxicological testing, compliance assays, methodology studies, and product testing" become available for public disclosure "when the final report is complete and accepted by the responsible Food and Drug Administration official, after deletion of any information that would reveal confidential investigative techniques and procedures." 21 C.F.R. § 20.105(c). "Access to all raw data, slides, worksheets, and other similar working materials shall be provided at the same time that the final report is disclosed." 21 C.F.R. § 20.105(d).

A different regulation specifically addresses information obtained through

contractors such as Spaulding. It states:

> (a) All data and information obtained by the Food and Drug Administration by contract, including all progress reports pursuant to a contract, are available for public disclosure when accepted by the responsible agency official except to the extent that they remain subject to an exemption established in subpart D of this part, e.g., they relate to law enforcement matters as provided in § 20.88(b).

21 C.F.R. § 20.109(a).

These provisions are all designed to further important Government interests. As the FDA correctly states in its Motion to Quash:

> The policy considerations in protecting premature release of study information are clear: "Release of tentative data, preliminary reports, or similar material would seriously hinder regulatory efforts of the agency." 39 Fed. Reg. 44602, 44626 (Dec. 24, 1974) (preamble to final FDA rule implementing 5 U.S.C. § 552). As reflected in the contract between FDA and Spaulding, premature release of study information may hamper "open and vigorous debate, within the Government, of possible policy options" and release of study data without a contextualizing final report can lead to "erroneous conclusions" and be misleading. ECF No. 4-2 at 18–19.

Those interests are particularly acute here, where the study conclusions are being subjected to peer review.

In sum, for important Governmental policy reasons, the FDA uses contractual provisions and agency regulations to limit disclosure of clinical testing data until after a final report is issued. Taken together, these restrictions bring the subpoenaed materials within the definition of "protected" material within the meaning of Fed. R. Civ. P. 45(d)(3)(A)(iii) until the final study report is issued. This case is distinguishable from those involving a purely private agreement to keep information confidential; here, the Government is a party to the Contract and there are federal

regulations that directly preclude disclosure of the subpoenaed materials.[3] To the extent the Amended Subpoena calls for materials that the Contract or federal regulations preclude Spaulding from disclosing without FDA permission, the Motion to Quash is GRANTED.

2. Touhy Regulations

Federal agencies can issue regulations limiting the disclosure of official records and setting forth procedures for agency review of requests for official records. The Housekeeping Statute, 5 U.S.C. § 301, authorizes the head of a government department to "prescribe regulations for the government of [the] department, the conduct of its employees, the distribution and performance of its business, and the custody, use, and preservation of its records, papers, and property. This section does not authorize withholding information from the public or limiting the availability of records to the public." These regulations can "place limits on how employees can disseminate information gained in the performance of their official duties." *Moore v. Armour Pharm. Co.,* 927 F.2d 1194, 1196–97 (11th Cir. 1991). In *United States ex rel. Touhy v. Ragen*, 340 U.S. 462, 467-69 (1951), the United States Supreme Court upheld a Department of Justice regulation promulgated under a predecessor version of the Housekeeping Statute." As a result, federal regulations enacted pursuant to

[3] In light of this holding, I need not reach the FDA's argument that the Amended Subpoena must be quashed under Rule 45(d)(3)(A)(iii) because it calls for materials covered by the deliberative process privilege. Nor must I reach the Plaintiffs' argument that this privilege objection was waived because no privilege log was provided.

the Housekeeping Statute are commonly known as *Touhy* regulations. *See In re 3M Combat Arms Earplug Products Liab. Litig.*, 3:19-MD-2885, 2020 WL 6274824, at *2–3 (N.D. Fla. Oct. 26, 2020) (tracing history of federal housekeeping statutes back to 1789).

The FDA has adopted *Touhy* regulations which apply to "[a]ny request for records of the Food and Drug Administration, whether it be by letter or by a subpena [sic] duces tecum or by any other writing." 21 C.F.R. § 20.2. A request for "existing records not prepared for routine distribution to the public shall be deemed to be a request for records pursuant to the Freedom of Information Act, whether or not the Freedom of Information Act is mentioned in the request." 21 C.F.R. § 20.23. If the *Touhy* regulations apply, they trump Rule 45. *In Re 3M Combat Arms Earplug Litig.*, 2020 WL 6274824, at *2–3.

Here, the Amended Subpoena is not directed to the FDA or a current or former FDA employee. Nevertheless, the FDA's *Touhy* regulations apply if the Amended Subpoena calls for "records of the Food and Drug Administration." The regulations do not distinguish between subpoenas to the FDA and subpoenas to third parties. Rather, the regulations, by their plain and unambiguous terms, apply broadly to all records of the FDA, without regard for who has possession, custody, or control of those records.

Although the contract lacks an express provision that certain study-related materials belong to the FDA, as discussed above, it contains multiple restrictions that broadly limit Spaulding's ability to disclose and use data and information "generated

by activities under this contract or derived from research or studies supported by this contract." These restrictions incorporate FDA regulations, federal contracting regulations, and federal statutes. Given the FDA's legal and contractual control over these materials, I find that they are "records of the FDA" sufficient to implicate the FDA's *Tuohy* regulations.

The reference to records "generated by activities under this contract" would include much of the material within the scope of the Amended Subpoena, including raw data, clinical results, communications between Spaulding and potential study participants and subcontractors, and communications between Spaulding and the FDA (including periodic reports required under the contract). These materials can only be obtained through compliance with the *Tuohy* regulations. To the extent they are within the scope of the subpoena, the Motion to Quash is GRANTED.

3. Undue Burden/Proportionality

Independently, I would grant the Motion to Quash in full based on undue burden and lack of proportionality.

> The undue burden analysis requires the court to "balance the interests served by demanding compliance with the subpoena against the interests furthered by quashing it." 9A Wright & Miller, Federal Practice and Procedure § 2463.1 (3d ed. 2019). *See also Virginia Dep't of Corr.*, 2017 WL 5075252, at *5, *10 (applying the undue burden analysis). Several factors have been identified as pertinent to the analysis, including the "relevance of the information requested" to the underlying litigation and the "burden [that would be] imposed" by producing it. *Wiwa v. Royal Dutch Petroleum Co.*, 392 F.3d 812, 818 (5th Cir. 2004). The status of the subpoena recipient as a non-party is also a factor that can weigh against disclosure in the undue burden inquiry. *See id.* ("[I]f the person to whom the document request is made is a non-

> party, the court may also consider the expense and inconvenience to the non-party.").

Jordan, 947 F.3d at 1337. As the Eleventh Circuit concluded in *Jordan*, an undue burden can exist when an important Governmental interest would be compromised by enforcing a third-party subpoena.

In *Jordan,* several death-row inmates in Mississippi served a Rule 45 subpoena on the Georgia Department of Corrections to obtain information about Georgia's death penalty protocol, including the identity of Georgia's supplier of pentobarbital. *Id.* at 1324, 1326. By statute, Georgia protected the identity of its supplier, out of concern that publicly disclosing its identity would jeopardize Georgia's ability to obtain pentobarbital. *Id.* at 1326. The Court of Appeals affirmed the order quashing the subpoena for undue burden, concluding "(1) that Georgia has a strong interest in enforcing its criminal laws, including its death penalty laws; (2) that disclosure of the information requested in Plaintiffs' subpoena would clearly burden that interest; (3) that the relevance of the information to Plaintiffs' Mississippi case is marginal to non-existent; and (4) that Georgia's interests clearly outweigh Plaintiffs' interests in disclosure." *Id.* at 1340.

The same conclusion applies here. As discussed above, the FDA has a strong interest in being able to conduct clinical research in furtherance of its statutory duty to regulate markets for food, drugs, and cosmetics. It is imperative that researchers can engage in unfettered analysis, internal dialogue, and meaningful peer review. Premature release of information related to clinical trials can inhibit this analytic

process.

The FDA also has a strong interest in having third parties who will contract to conduct clinical trials. If those entities believe they will be subjected to wide-ranging subpoenas and the accompanying litigation costs (given that they are contractually prohibited from voluntarily releasing study-related documents), they may be unwilling to provide services to the FDA.

Spaulding has provided an uncontradicted declaration showing that compliance would entail a substantial logistical and financial burden. ECF No. 4. Spaulding will have to review up to 1 gigabyte of data to remove irrelevant and non-responsive materials, assert privileges, comply with the Privacy Act, and redact Personally Identifying Information and protected health information. *Id.* at 2. I acknowledge that this burden could be mitigated in part by shifting costs to the Plaintiffs and/or by producing documents under the existing Confidentiality Order. Nevertheless, I reject Plaintiffs' argument that Spaulding should produce responsive documents without redaction, subject to later clawback. Hr'g Tr. Apr. 8, 2021 at 50.

In sum, applying the undue burden balancing test, the FDA's and Spaulding's interests in non-disclosure far outweigh the Plaintiffs' interest in disclosure at this time. The most relevant documents – the study data, study protocols, and conclusions – either have been made public or will be made public in the next 75 days. Plaintiffs articulated a theory that other materials, such as Spaulding's internal communications and communications with the FDA, might include criticisms of the study design or implementation that would be relevant. Hr'g. Tr. Apr. 8, 2021 at 53.

This relevance theory is highly speculative and is insufficient to overcome Spaulding's and the FDA's countervailing interests.

Separately, disclosure is not warranted under the Rule 26(b)(1) proportionality factors, which are (1) the importance of the issues at stake in the action, (2) the amount in controversy, (3) the parties' relative access to relevant information, (4) the parties' resources, (5) the importance of the discovery in resolving the issues, and (6) whether the burden or expense of the proposed discovery outweighs its likely benefit. The issue of whether and when Ranitidine causes NDMA in the human body is central to this MDL. The amount in controversy in the MDL is substantial, but Spaulding is not a party who will be affected by the outcome of the litigation. The parties currently have equal access to some of the most relevant material and will have access to the remaining core data in 75 days. There is no record evidence of the parties' resources. The particular discovery requested here may help resolve the issues in this MDL but is likely to be partially cumulative of other scientific studies. For the reasons discussed above, the burden or expense of production outweighs its likely benefit. Considering all these factors, I find that requiring Spaulding to comply with the Amended Subpoena is not proportional to the needs of the case.

4. Remaining Arguments

Although I need not resolve the remaining issues raised by the parties, I address several of them briefly.

The Contract requires Spaulding to "design, develop, or operate a system of records on individuals" within the meaning of the Privacy Act. 5 U.S.C. § 552a. ECF

No. 4-2 at 28 (incorporating by reference other provisions). The evidentiary record before me does not demonstrate which subpoenaed materials (if any) were kept in such a system of records. While it seems logical that participant-related information would be kept in such a system of records, it is also logical that much of the material covered by the subpoena would not. Plaintiffs also cite cases holding that a subpoena falls within an exception to the Privacy Act. Because the Motion to Quash can be fully adjudicated on other grounds, I need not resolve the Privacy Act issues.

Spaulding does not contest that it has physical possession of responsive documents, but argues that it is contractually and legally prohibited from disclosing those materials. Plaintiffs argue that a subpoena trumps a contractual confidentiality provision. For the reasons stated above, I find that some of the materials in Spaulding's physical possession are nonetheless records of the FDA that can only be obtained through the *Touhy* regulations process. For the balance of any responsive documents in Spaulding's physical possession, I find that it would be disproportionate and/or unduly burdensome to require production. Therefore, I need not determine whether a subpoena otherwise would over-ride the contractual obligations between the Government and Spaulding.

Finally, Plaintiffs rely heavily on *Pennsylvania v. Navient Corp.,* 348 F. Supp. 3d 394 (M.D. Pa. 2018), where the district judge rejected the defendant's argument that a Rule 34 Request for Production should be quashed because the defendant's contract with the U.S. Department of Education prohibited it from disclosing the subpoenaed materials. Navient does not control, here. First, it is a non-binding, non-

precedential decision of a trial court. Second, it appears from the reported opinion that the contractual and regulatory restrictions on disclosure in *Navient* were not as robust as those in the Contract. Third, the *Navient* court found that several of the alleged restrictions did not, on their merits, preclude compliance with the document request. Fourth, the *Touhy* regulations at issue in Navient focused on who received the document request; they applied "when the Department or any employee of the Department receives a demand for [documents]." *See* 34 C.F.R. § 8.1 (a) *cited in Navient*, 348 F. Supp. 3d at 401 n.2. Here, the applicable *Touhy* regulations apply to "records of the" FDA, without regard to who possesses those records or to whom the request is made.

5. Attorney's Fees

Spaulding requests that the Court award attorney's fees and costs under Rule 45(d)(1), which states, "A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction – which may include lost earnings and reasonable attorney's fees – on a party or attorney who fails to comply."

Plaintiffs respond

> A party takes "reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena" when that party "me[ets] and confer[s] extensively with [the subpoena target] about the subpoena" and "reduce[s] the scope of their requests." *M & F Fishing, Inc. v. Certain Underwriters at Lloyds,* No. 06CV0934-DMS (BLM), 2007

> WL 9706491, at *5 (S.D. Cal. Apr. 13, 2007). Plaintiffs have done just that with regards to the Amended Subpoena here, which, as discussed above, is aimed specifically at documents from a single study that are crucial to resolving issues central to this MDL. Responding to the five requests therein poses no undue burden on Spaulding, let alone a burden warranting sanctions.

ECF No. 32 at 18-19. Looking to the totality of the record, I do not find that Plaintiffs failed to take reasonable steps to avoid undue burden or expense. Spaulding's request for attorney's fees is DENIED.

CONCLUSION

WHEREFORE, Spaulding's Motion to Quash is GRANTED. The request for attorney's fees and costs is DENIED.

DONE and ORDERED in Chambers this 14th day of April, 2021, at West Palm Beach in the Southern District of Florida.

BRUCE E. REINHART
UNITED STATES MAGISTRATE JUDGE