EXHIBIT 7

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF FLORIDA

Case No. 9:20-MC-82327-ROSENBERG/REINHART

IN RE: SUBPOENA DATED JUNE 18, 2020
ISSUED TO SPAULDING CLINICAL
RESEARCH, LLC

_____/

ORDER OVERRULING OBJECTIONS TO ORDER
GRANTING MOTION TO QUASH AMENDED SUBPOENA

THIS MATTER is before the Court on the Magistrate Judge's Order Granting Motion to Quash Amended Subpoena ("Order"). DE 38. The Plaintiffs filed objections to the Order ("Objections"). DE 40. The United States of America ("Government") and Spaulding Clinical Research, LLC ("Spaulding") filed responses to the Plaintiffs' Objections (collectively, the "Responses") DE 42, 43. The Court has considered the Order, the Objections, the Responses, and the record, and is otherwise fully advised in the premises. For the reasons set forth below, the Court overrules the Plaintiffs' Objections.

After a magistrate judge issues an order on a non-dispositive matter, "[t]he district judge in the case must consider timely objections and modify or set aside any part of the order that is clearly erroneous or is contrary to law." Fed. R. Civ. P. 72(a). "A finding is 'clearly erroneous' when although there is evidence to support it, the reviewing court on the entire evidence is left with the definite and firm conviction that a mistake has been committed." *In re O'Keeffe*, 184 F. Supp. 3d 1362, 1366 (S.D. Fla. 2016) (quoting *Krys v. Lufthansa German Airlines*, 119 F.3d 1515, 1523 (11th Cir. 1997)). "An order is contrary to law when it fails to apply or misapplies relevant statutes, case law or rules of procedure." *Id.*

The Plaintiffs' subpoena ("Subpoena") calls for Spaulding to produce the following:

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. 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.

DE 29-1 at 10-11.

The Plaintiffs object to the Order insofar as it denies them access to "Spaulding's internal documents and its communications about its Ranitidine/NDMA Study that were not the property of the FDA." DE 40 at 1. The Magistrate Judge "ruled [that] the relevance of these documents was highly speculative and the request for these documents was unduly burdensome and not proportional to the needs of the case." *Id.* The Government suggests that it is unclear what subset of documents the Plaintiffs seek to obtain through their Objections. DE 42 at 1.

Taking the objections in turn, the Plaintiffs' first objection is that the Magistrate Judge erred in challenging the relevance of the requested documents *sua sponte* and finding their relevance to be highly speculative. DE at 40 at 2-5. The Plaintiffs argue that the documents are relevant and predict that they will cover a variety of topics. *See id.* at 3-4 (listing topics). This objection is unpersuasive for two principal reasons. First, as the Responses point out, the Magistrate Judge did not conclude that lack of relevance was a standalone basis for quashing the Subpoena. *See* DE 42 at 4; *see also* DE 43 at 3-5. Rather, the Magistrate Judge evaluated relevance along with other factors before concluding that the Motion should be granted based on the undue

burden and lack of proportionality of the requests. DE 38 at 13-16. Such an evaluation is appropriate given that the scope of permissible discovery under Rule 45 is limited by Rule 26(b)(1)'s requirement that discovery be relevant to a party's claim or defense. *See* DE 38 at 7 (citing *Jordan v. Comm'r, Miss. Dep't of Corr.*, 947 F.3d 1322, 1329 (11th Cir. 2020), *cert. denied sub nom. Jordan v. Ga. Dep't of Corr.*, 141 S. Ct. 251 (2020)). Second, the Court agrees with the Magistrate Judge's finding that the most relevant documents are publicly available. The Responses identify several categories of relevant documents that were already available to the Plaintiffs at the time that they filed their Objections in April 2021. DE 42 at 6-8; DE 43 at 4. And on June 28, 2021, the results of the study that is the subject of the Subpoena were published in *JAMA: Journal of the American Medical Association*. DE 44. Further, "the FDA has made the complete protocol, the statistical analysis plan, additional analytical methods and results details, and de-identified participant data available" on *JAMA*. *Id.*

The Plaintiffs' second objection is that the Magistrate Judge erred in the finding of an undue burden; Plaintiffs argue that it was error to premise this conclusion on the governmental interests identified in the Order. DE 40 at 5-9. In doing so, the Plaintiffs challenge the Magistrate Judge's reliance on *Jordan*, wherein the Eleventh Circuit concluded that undue burden can exist when enforcement of a third-party subpoena would compromise an important governmental interest. DE 40 at 5-6. The Plaintiffs distinguish *Jordan* as inapplicable because in that case, the identity of a company that supplied drugs for lethal injections to Georgia's Department of Corrections was protected by "statutory assurances of absolute confidentiality." *Id.* at 6 (quoting *Jordan*, 947 F.3d at 1330). Here, however, Spaulding's identity is public knowledge.

Jordan is not inapposite merely because of the factual distinction that the Plaintiffs identify. Litigants routinely rely on prior cases that, although factually different, contain legal

principles that are relevant to their own disputes. Indeed, a case need not be factually identical for it to be instructive. DE 42 at 5; DE 43 at 5-6. Moreover, the Magistrate Judge's conclusion that "the FDA's and Spaulding's interests in non-disclosure far outweigh the Plaintiffs' interest in disclosure" is not clearly erroneous or contrary to law. DE 38 at 15. Although a protective order exists in the instant case, enforcing the Subpoena could nonetheless jeopardize the FDA's more general interest in having its research partners "engage in unfettered analysis, internal dialogue, and meaningful peer review." *Id.* at 14. Were the Court to issue an order requiring Spaulding's compliance with this Subpoena, Spaulding's employees—and perhaps employees of other FDA partners—might communicate less candidly during future FDA research projects for fear of having to turn over internal communications as part of future subpoenas. Relatedly, the Court could jeopardize the FDA's interest in finding and partnering with third parties that are willing to conduct research. *Id.* at 15. If faced with increased risks of receiving subpoenas and incurring associated costs, third-party researchers may be less willing to partner with the FDA.

Separately, reasons other than the Government's interests support the Magistrate Judge's conclusion. The Plaintiffs seek internal Spaulding documents; the declaration of Spaulding's CEO states that nearly all of Spaulding's 150-person staff was involved with the NDMA study. DE 4 ¶ 13. The declaration also addresses the significant volume of documents that Spaulding would need to review for possible production. *Id.* ¶ 10 ("[A]pproximately between 500 MB and 1 GB of data related to the NDMA Study."). Such a volume is especially cumbersome given that the most relevant documents concerning the study are now publicly available.

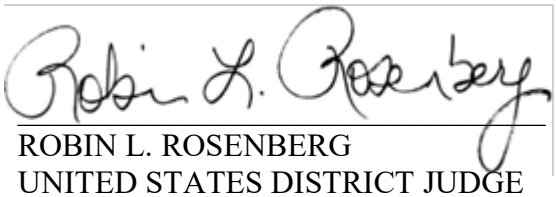
The Plaintiffs' third objection is that the Magistrate Judge erred in the conclusion that Spaulding's compliance with the Subpoena is not proportional to the needs of the case. DE 40 at 9. When evaluating the proportionality factors pursuant to Rule 26(b)(1), the Magistrate Judge

concluded that (1) the issue of whether ranitidine causes NDMA in humans is central to the MDL; (2) the amount in controversy in the MDL is substantial but does not affect Spaulding; (3) the parties have or will have equal access to the most relevant material; (4) there is no record evidence of the parties' resources; (5) the discovery requested through the Subpoena may help resolve the issues in the MDL but is likely cumulative of other scientific studies; and (6) the burden and expense of production outweighs its likely benefit. DE 38 at 16. The Plaintiffs suggest that the Magistrate Judge's analysis was contrary to law.

There is little doubt that the issue involved is important to the MDL and the amount in controversy is significant. Moreover, the Court recognizes that *what* the Plaintiffs seek through their Objections—Spaulding's internal documents and communications—is unavailable to them unless Spaulding complies with the Subpoena. DE 40 at 11. Yet as Spaulding notes, the *relevant information* that the Plaintiffs expect to find in those documents is (1) publicly available and thus accessible to the Plaintiffs; (2) FDA documentation that is covered by the portions of the Order that the Plaintiffs do not object to; or (3) information that does not fall within the scope of the Subpoena. *See* DE 43 at 3-4; *see also* DE 42 at 6-8. Since the most relevant information about the NDMA study is publicly available and Spaulding is not a party in the MDL, the Court questions whether Spaulding's internal documents and communications would help resolve issues in the MDL. And, the volume of work required of Spaulding to comply with the Subpoena would be significant. In light of these competing circumstances, the Court finds that the Magistrate Judge did not misapply the factors in Rule 26(b)(1).

For the foregoing reasons, the Plaintiffs' Objection to the April 14, 2021, Discovery Order [DE 40] is **OVERRULED**.

DONE AND ORDERED in Chambers at West Palm Beach, Florida, this 19th day of July, 2021.



ROBIN L. ROSENBERG
UNITED STATES DISTRICT JUDGE

Copies furnished to Counsel of Record