UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

UNITED STATES OF AMERICA *ex rel*. MELISSA STAGGERS and RHONDA KURDELMEYER,

Plaintiff-Relators,

v.

Case No. 1:15-cv-392-TSC-RMM

MEDTRONIC, INC.,

Defendant.

MEMORANDUM OPINION

This is a *qui tam* action brought by Relators Melissa Staggers and Rhonda Kurdelmeyer (collectively "Relators") on behalf of the United States. Relators allege that Defendant Medtronic, Inc. ("Medtronic") violated the False Claims Act, 31 U.S.C. § 3729 *et seq.* ("FCA"), by causing physicians to falsely certify to the United States that their surgical implantation of Medtronic's InterStim medical device in patients covered by Medicare met all criteria necessary for obtaining payment for the procedure from the United States. Seven years into litigation, Relators have requested an order requiring nonparty physicians across the United States who implanted the InterStim device in patients on or after January 1, 2003, to preserve related medical records. Medtronic opposes issuance of such an order. District Judge Tanya S. Chutkan referred all discovery disputes in this matter to the undersigned. *See* May 3, 2019 Referral Order. Having reviewed the pleadings and the parties' briefs, ¹ as well as the relevant law, the Court will **GRANT-IN-PART** Relators' Motion.

¹ The relevant pleadings and briefs include: Relators' First Amended Complaint, ECF No. 18 ("Compl."); Relators' Motion for an Order Requiring Preservation of Medical Records, ECF No. 100 ("Mot."); the Memorandum of Points and Authorities in support, ECF No. 101

BACKGROUND

Medtronic is a medical device manufacturer that produces and sells InterStim, a sacral neuro-stimulator that can be surgically implanted in individuals to help control symptoms of incontinence. *See* Compl. ¶ 8–9, 25. Relators are former Medtronic employees who assisted Medtronic in marketing, selling, and providing product support for InterStim in Louisiana, Mississippi, and Tennessee. *See id.* ¶ 1, 23–24. They allege that Medtronic, motivated by its desire to increase InterStim sales, successfully encouraged physicians to implant the device in patients for whom it had not been shown to be medically necessary and to file related, falsely certified claims for payment from the United States. *See id.* ¶ 45, 83–84, 86–89. Over a challenge from Medtronic, Judge Chutkan held that Relators' claim satisfies the pleading standards of Federal Rules of Civil Procedure 12(b)(6) and 9(b). *See* Order at 3, ECF No. 36 (the "Dismissal Order").²

The parties have since disagreed vehemently about the appropriate scope and course of discovery in this case. Their disagreements—which both parties have repeatedly looked to this Court to resolve—have significantly delayed discovery as well as the resolution of Relators' claims. *See* Relators' Mem. at 1–2. Late last year, the parties agreed to a joint plan for discovery, *see* ECF No. 94-1 (the "Joint Discovery Plan"), which the Court adopted with slight modifications in December 2021. *See* Order, ECF No. 94 (the "Discovery Plan Order"). Under the Plan, "Phase One" discovery is first permitted into Relators' claims in a discreet, three-state territory during an approximately seven-year period, from May 1, 2008 through March 18, 2015.

^{(&}quot;Mem."); Defendant's Memorandum in Opposition, ECF No. 103 ("Opp'n"); and Relators' Reply, ECF No. 104 ("Reply").

² Judge Chutkan dismissed Relators' alternative theory for FCA liability. *See* Dismissal Order at 4.

See Joint Discovery Plan at 2. Once Phase One discovery is complete the parties may jointly propose a briefing schedule for dispositive motions. See Discovery Plan Order at 2. "What further discovery, if any, will be permitted will depend on the Court's disposition of the Parties' motions." Joint Discovery Plan at 4.

Since then, Relators have served at least twelve subpoenas on third-party physicians consistent with the Joint Discovery Plan. *See* Mem. at 4. Of those twelve physicians, three responded that all or a portion of their records for patients who received InterStim implants between 2008 and 2015 were no longer available because the records were not preserved beyond the time required by state law. *See id.* Relators then returned to this Court seeking an order requiring other nonparty physicians who performed InterStim surgeries anywhere in the United States "at any time from and after January 1, 2003," to preserve all related medical records "until further Order by the Court." Mot. at 1.3

DISCUSSION

Federal courts have the inherent power to issue orders preserving information relevant to the claims and defenses brought before them. *See Deggs v. Fives Bronx, Inc.*, No. 19-cv-406,

³ The Discovery Plan Order requires counsel for the parties to "confer in good faith" to resolve any discovery dispute and, if counsel are unable to resolve the dispute, to "JOINTLY submit, via email to Judge Meriweather's chambers . . . a clear, concise description of the issues in dispute, each party's position on the disputed issues, and the parties' joint availability for an on-the-record telephone conference." Discovery Plan Order at 1 (emphasis original). "Counsel shall not file any discovery-related motion without a prior telephone conference with the Court and opposing counsel." Id. at 2 (emphasis original). Counsel for Relators did not comply with this command, as their Rule 7(m) Report makes clear. See ECF No. 102 (noting that counsel for Medtronic provided its position on Relators' motion only on May 16—several days after Relators docketed the instant motion). The Court can and will waive both Local Rule 7(m) and its own procedural requirements for considering this motion. Neither party should anticipate further concessions, and both are reminded that a party who does not prevail on its discovery motion "may be ordered to pay the costs involved, including reasonable attorney's fees." Discovery Plan Order at 2.

2020 WL 3100023, at *2 (M.D. La. June 11, 2020); *Gambino v. Hershberger*, No. 16-cv-3806, 2017 WL 2493443, at *3 (D. Md. June 8, 2017). "Because of their very potency," these inherent powers "must be exercised with restraint and discretion." *Chambers v. NASCO, Inc.*, 501 U.S. 32, 44 (1991). Yet there is no binding authority instructing this Court how to weigh preservation order requests. *See O.K. v. Bush*, No. 04-cv-1136, 2005 WL 8177541, at *1 (D.D.C. Oct. 27, 2005); *El-Banna v. Bush*, No. 04-cv-1144, 2005 WL 1903561, at *1 n.3 (D.D.C. July 18, 2005). The critical question is accordingly "under what circumstances a preservation order should be issued." *Treppel v. Biovail Corp.*, 233 F.R.D. 363, 370 (S.D.N.Y. 2006).

Courts facing this question have applied three principal tests. *See id.*; *accord. Deggs*, 2020 WL 3100023, at *2; *O.K.*, 2005 WL 8177541, at *1. Relators urge the Court to use either a two- or three-pronged balancing test derived from *Pueblo of Laguna v. United States*, 60 Fed. Cl. 133 (2004), or *Capricorn Power Co. v. Siemens Westinghouse Power Co.*, 220 F.R.D. 429 (W.D. Pa. 2004). *See* Mem. at 5–6; Reply at 6–7. Medtronic urges the Court to instead apply the "same analytical framework as a motion for injunctive relief," as other courts in this District have done. Opp'n at 4 (quoting *Competitive Enter. Inst. v. Off. of Sci. & Tech. Pol'y*, No. 14-cv-765, 2016 WL 10676292, at *2 (D.D.C. Dec. 12, 2016)).

I. Personal Jurisdiction

Before deciding which substantive test to apply, however, the Court must address Medtronic's concern that the Court lacks personal jurisdiction over many physicians who would be subject to a nationwide preservation order. *See id.* at 4–5. In addition to considering *whether* to issue the order, in other words, the Court must consider *who* the order would command and whether the Court has the authority to command them to preserve records. Medtronic has pointed to cases holding that district courts are "powerless to proceed' in the absence of

personal jurisdiction," *id.* at 4–5 (quoting *Khatib v. All. Bankshares Corp.*, 846 F. Supp. 2d 18, 25 (D.D.C. 2012)), and "must have personal jurisdiction over a nonparty in order to compel [the nonparty] to comply with a valid discovery request under Federal Rule of Civil Procedure 45." *Id.* at 5 (quoting *Gucci Am., Inc. v. Weixing Li*, 768 F.3d 122, 141 (2d Cir. 2014)).

There can be no doubt that courts lack authority to provide judicial relief in the absence of personal jurisdiction over the parties. That is the lesson of *Khatib*: There, another court in this District declined to award a plaintiff preliminary injunctive relief because the plaintiff could not show there was a basis for the court's exercise of personal jurisdiction over "the only named defendant." 846 F. Supp. 2d at 25–26. Rather than dismiss the case entirely, the court encouraged the parties to voluntarily transfer the matter to another district with "a much stronger basis for exercising personal jurisdiction over the parties." *Id.* at 34. *Khatib* thus illustrates the wholly uncontroversial principle that a court is "powerless" to provide relief in a case where the court lacks personal jurisdiction over the *parties*, even when the relief requested is preliminary or interlocutory. *See id.* at 25.

Gucci suggests another rule: That courts may not compel a *nonparty* to comply with a subpoena in the absence of personal jurisdiction over the nonparty. But *Gucci* does *not* hold that personal jurisdiction is required over nonparties to compel them to take any action whatsoever. The Second Circuit explained that personal jurisdiction over a nonparty bank was not necessary to compel the bank to "restrain a defendant's assets." 768 F.3d at 134. Personal jurisdiction was required to "enforce an injunction against [the] nonparty" or to "compel [the nonparty] to comply with a valid discovery request under Federal Rule of Civil Procedure 45," however. *Id.* at 134, 141. The court's personal jurisdiction over the *parties*, then, allowed the court to command the

nonparty bank to take certain actions (restrain assets) but not others (comply with a document subpoena under risk of monetary penalties or civil contempt proceedings). *See id.* at 125.

These cases do not convincingly counsel against issuing a preservation order—even one that contemplates that subpoenas will issue to nonparties, potentially nationwide. To hold otherwise solely on the basis of hypothetical concerns about personal jurisdiction over nonparties could undermine several important statutory schemes constructed by Congress, as well as the federal rules of both civil and criminal procedure. *See United States ex rel. Lutz v. Berkeley Heartlab, Inc.*, No. 14-cv-230, 2017 WL 5624254, at *3 (D.S.C. Nov. 21, 2017) (describing the nationwide subpoena powers contemplated by the FCA, RICO, and antitrust statutes, as well as Federal Rule of Criminal Procedure 17(e)); *see also* Fed. R. Civ. P. 45(a)(2), (b)(2) (permitting nationwide service of subpoenas issued by "the court where the action is pending").

If a nonparty physician becomes the target of a subpoena in this case, that physician may raise personal jurisdiction concerns here or in "the court for the district where compliance is required." Fed. R. Civ. P. 45(d)(2)(b)(i). Depending on the court addressed and the particular physician's involvement in the scheme alleged by Relators, the court may find it has general or specific personal jurisdiction over that physician. Additionally, because personal jurisdiction is "a personal right," the targeted physician could "choose to assert [it] or not." *Shatsky v. Palestine Liberation Org.*, 955 F.3d 1016, 1031 (D.C. Cir. 2020). Only if the right is asserted, and only if it is asserted in this Court, will this Court consider whether the concerns outlined in *Gucci* control or if the FCA or Federal Rules provide the Court with authority to compel a nonparty's compliance with a subpoena outside of this District. *Cf. Lutz*, 2017 WL 5624254, at *3 (taking the latter position); *United States v. Wyeth*, No. 03-cv-12366, 2015 WL 8024407, at *4 (D. Mass. Dec. 4, 2015) (same).

II. Preservation Order

Returning, then, to the question of *whether* to issue a preservation order, the Court need not determine which test for measuring the propriety of a preservation order applies, because Relators have demonstrated that a limited preservation order is warranted under any test advanced.

A. The Two-Prong Balancing Test

Under the two-prong balancing test of *Pueblo of Laguna*, Relators must show that (1) "absent a court order, there is significant risk that relevant evidence will be lost or destroyed" and (2) "the steps to preserve the evidence will be effective, but not overbroad." *Career Counseling, Inc. v. Amsterdam Printing & Litho, Inc.*, No. 15-cv-5061, 2016 WL 11725395, at *1 (D.S.C. May 13, 2016) (citing *Pueblo of Laguna*, 60 Fed. Cl. at 138). Relators have demonstrated that relevant records have already been destroyed in Louisiana. *See* Mem. at 4. Louisiana law requires physicians to retain medical records "for a minimum period of six years from the date a patient is last treated by [the] physician." La. Rev. Stat. § 40:1299.96.

Defendant points out that records must be maintained for ten years in Tennessee. *See* Opp'n at 7–8 (citing Tenn. Code Ann. § 68-11-305(a)(1)). But Defendant's point supports Relators' argument, not Medtronic's. Even in the first stipulated phase of discovery, nearly all of the medical records sought by Relators—dated between 2008 and 2015—are more than ten years old and fall outside these mandatory retention periods.

⁴ Mississippi—the other state in which discovery is currently permitted under the Joint Discovery Plan—does not appear to have a minimum medical record retention law that applies broadly to all physicians. The state's law covering hospital records generally requires retention for "ten (10) years in cases of adult patients of sound mind at the time of discharge." Miss. Code § 41-9-69.

Relators have made a less convincing showing that the nationwide preservation order they seek will be "effective, but not overbroad." Pueblo of Laguna, 60 Fed. Cl. at 138. A preservation order asking physicians to maintain relevant records beyond the term required by state law will effectively "preserve evidence" that may be both relevant and discoverable in this case. See Deggs, 2020 WL 31000023, at *2. But a nationwide preservation order commanding every physician in the country who performed an InterStim implant surgery at any time between 2003 and the present may not. The parties stipulated and this Court agreed to a discovery plan that only permits discovery into the records of physicians Relators supported in their sales territories in Louisiana, Mississippi, and Tennessee during the period of their active employment, between May 2008 and March 2015. See Opp'n at 7–8; Joint Discovery Plan at 1–2. "What further discovery, if any, will be permitted will depend on the Court's disposition" of the parties' anticipated motions for summary judgment. Joint Discovery Plan at 4. There is some concern, then, that a physician outside Louisiana, Mississippi, or Tennessee could be ordered to preserve for years beyond any applicable retention period records that will never be subject to discovery by Relators or presented to this Court as evidence. Because such an order would issue from the Court's inherent power, which "must be exercised with restraint and discretion," Chambers, 501 U.S. at 44, the Court believes Relators' request for a nationwide preservation order is overbroad. A more limited order addressed only to physicians in the Phase One discovery states—Louisiana, Mississippi, or Tennessee—is not. That more limited order passes the two-prong balancing test derived from Pueblo of Laguna.

B. The Three-Prong Balancing Test

Issuance of a limited preservation order is also appropriate under the three-prong balancing test articulated in *Capricorn Power*. That test suggests that courts consider (1) "the level of concern the court has for the continuing existence and maintenance of the integrity of the

evidence in question in the absence of an order directing preservation"; (2) "any irreparable harm likely to result to the party seeking the preservation of evidence absent an order directing preservation"; and (3) "the capability of an individual, entity, or party to maintain the evidence sought to be preserved." 220 F.R.D. at 433–34. The Court has serious concerns that information Relators seek during Phase One discovery could be spoiled by physicians' routine document destruction practices in Louisiana and Tennessee, where state record retention laws no longer cover the 2008 to 2015 period Relators are entitled to investigate, as well as in Mississippi, which seems to have no record retention law applicable to physicians unaffiliated with a hospital. Records are already disappearing, as Relators have made clear. *See* Mem. at 4.

Relators are also likely to be irreparably harmed if the Phase One evidence they seek is not protected by an order from this Court. The information sought by Relators, which is vulnerable to destruction, is crucial to their case against Medtronic. Relators contend InterStim patients' medical records are necessary to construct a statistical sample from a "sufficiently robust population of medical records," Reply at 9–10, as well as to identify which patients' procedures were paid for by the United States, whether any such procedure was in fact medically necessary, and the level of Medtronic employees' involvement in that patient's course of treatment—facts that would tend to show causation or lack thereof. *See* Joint Discovery Plan at 1–4. Relators can only proceed to Phase Two of discovery in this case—let alone prevail on their claim—if they establish a genuine issue of fact as to Medtronic's potential liability for causing a physician subject to Phase One discovery to submit false claims to Medicare for an identified patient. *See id.* at 4. The vulnerable records are crucial to meeting that burden, so Relators will be harmed if records continue to disappear.

Defendant points out that not *all* medical records will become unavailable if this Court declines to act. *See* Opp'n at 7. Medtronic notes that some physicians subpoenaed by Relators have produced responsive records, meaning those physicians retained records "beyond their state's retention period." *Id.* at 7. Relators need not show that they will suffer complete and total defeat in this litigation if this Court declines to issue a preservation order, however; the *Capricorn Power* test requires only "irreparable harm likely to result." 220 F.R.D. at 433. It is sufficient that Relators have shown that evidence helpful to their case has already and will continue to disappear, and that "once destroyed, the evidence cannot be used for any purpose and cannot be recreated." *Deggs*, 2020 WL 3100023, at *6.

Medtronic also suggests that Relators cannot show harm is certain "absent Court action" because Relators "never once attempted to send preservation requests" on their own, even to physicians and facilities they knew had implanted InterStim devices in patients. Opp'n at 8 (emphasis original). Yet several courts have noted that court-issued preservation orders are "all the more pressing" where nonparties are "under no duty to preserve absent a court order." *Deggs*, 2020 WL 3100023, at *3 (citing *Bright Sols. for Dyslexia, Inc. v. Doe*, No. 15-cv-1618, 2015 WL 5159125, at *3 (N.D. Cal. Sept. 2, 2015)); *accord Arkin v. Gracey-Danna, Inc.*, No. 16-cv-1717, 2016 WL 3959611, at *2 (M.D. Fla. July 22, 2016). Relators could of course "right now send requests" to physicians they know they may subpoena. Opp'n at 8. But Relators' entreaties would be *requests*, not *orders*, and this Court will not wait for a physician to refuse Realtors' request before exercising its authority to preserve vulnerable evidence relevant to this case.⁵

⁵ Naturally, a refused request would strengthen Relators' request. *See, e.g.*, *Arkin*, 2016 WL 3959611, at *1 (considering a similar situation). A nonparty's refusal to preserve evidence is simply not *necessary* for finding irreparable harm.

The final balancing factor of Capricorn Power also weighs in favor of a limited preservation order. This third consideration looks beyond Relators' need to the "capability" of evidence custodians "to maintain the evidence . . . , not only as to the evidence's original form, condition or contents, but also the physical, spatial and financial burdens created by ordering evidence preservation." Capricorn Power, 220 F.R.D. at 433–34. The physical and spatial burdens a preservation order would impose on physicians are minimal, as physicians "routinely preserve[]" patients' medical records, and the preservation order would affect only the portion of those records that relate to InterStim implantations. Deggs, 2020 WL 3100023, at *6. Whether compliance would be costly is less clear—certainly physicians will incur some financial burden if their offices have in place routine record retention and destruction procedures and, in order to comply with an order from this Court, the physicians must modify those procedures, train staff on how to segregate and preserve records subject to the order, and consider liabilities in the event the order is not followed or requires challenge. See Opp'n at 9. In addition, although not explicitly required by Capricorn Power, the Court finds significant the burden Relators' proposal places on Medtronic, as Relators want Medtronic to both identify physicians subject to any preservation order issued by this Court and to take responsibility for providing those physicians with notice of the Court's order. See Mot. at 1; Mem. at 8. Medtronic may be "uniquely suited" to carrying out that task, see Mem. at 8, but complying would still cost Medtronic valuable time and money.

On balance, however, the burdens imposed on physicians and Medtronic by a limited preservation order are outweighed by the Court's concern that evidence valuable to this case will be destroyed and that Relators will be irreparably harmed absent such an order. Medtronic's burden would be significantly lessened by a streamlined preservation order addressed only to

physicians in Louisiana, Tennessee, and Mississippi, as Medtronic has already identified physicians in that territory who performed InterStim implants between May 2008 and March 2015. *See* Joint Discovery Plan at 1–2. Additionally, if the financial or other burdens imposed on physicians by a preservation order are weightier than this Court currently anticipates, physicians may apply to this Court for relief. Relators, on the other hand, require urgent relief that only this Court can provide. Under the three-prong *Capricorn Powers* balancing test, therefore, Relators have demonstrated that this Court should issue a limited preservation order.

C. The Preliminary Injunction Standard

The same is true if this Court applies "the same analytical framework as a motion for injunctive relief." *Competitive Enter. Inst.*, 2016 WL 10676292, at *2 (adopting that test).⁶

Under the injunctive relief framework, in determining whether a preservation order is warranted, the Court "must consider (1) the likelihood that the party seeking the [preservation order] will prevail on the merits"; (2) "the likelihood that the moving party will be irreparably harmed"; (3) "the prospect that others will be harmed"; and (4) the public interest. *Id.* Courts in this Circuit balance these factors on a "sliding scale." *Id.*⁷

⁶ Medtronic suggests that other courts in this District have *agreed* to apply the framework used for preliminary injunctions, and that this Court should do so, too. *See* Opp'n at 3–4 (faulting Relators for citing "no cases from this District" because "the most recent decisions in this District considering motions seeking a preservation order have *agreed* that a '[m]otion to [c]ompel [p]reservation is subject to the same analytical framework as a motion for injunctive relief." *Id.* (quoting *Competitive Enter. Inst.*, 2016 WL 10676292, at *2). The better word would be *assumed. Competitive Enterprise* cites for the relevant standard the litigating parties' briefs. *See* 2016 WL 10676292, at *2. The second case cited by Medtronic acknowledges no other potentially applicable test. *See Cause of Action Inst. v. U.S. Dep't of Just.*, No. 18-cv-1800, 2019 WL 12070403, at *1 (D.D.C. Apr. 25, 2019). In the last case cited by Medtronic, the movant specifically requested relief in the form of a preliminary injunction. *See True the Vote, Inc. v. IRS*, No. 13-cv-734, 2014 WL 4347197, at *1 (D.D.C. Aug. 7, 2014). This Court will not *assume* the preliminary injunction standard applies when Relators have advanced compelling arguments that it should not. *See* Reply at 6 (quoting *Capricorn Power*, 220 F.R.D. at 429).

⁷ Although some circuits have interpreted the Supreme Court's decision in *Winter v. Natural Resource Defense Council, Inc.*, 555. U.S. 7, 22 (2008), to mean that the "sliding scale"

The second and third preliminary injunction factors, weighing the likely harms to Relators against the probable harms to others, were already resolved in favor of Relators above. The first factor, success-on-the-merits, also weighs in Relators' favor. When weighing this factor in the context of a request for a preservation order, "it will ordinarily be enough that the plaintiff has raised questions going to the merits so serious, substantial, difficult and doubtful, as to make them a fair ground for litigation and thus for more deliberative investigation."

Competitive Enter., 2016 WL 10676292, at *2 (quoting Washington Metro. Area Transit Comm'n v. Holiday Tours, Inc., 559 F.2d 841, 844 (D.C. Cir. 1977)); see also Cause of Action Inst. v. U.S. Dep't of Just., No. 18-cv-1800, 2019 WL 12070403, at *1 n.1 (D.D.C. Apr. 25, 2019) (agreeing and convincingly justifying use of the "relaxed" serious-legal-question formulation). Judge Chutkan's Order partially denying Medtronic's motion to dismiss this case is evidence enough that Relators have presented this Court with "serious, substantial" claims that are "fair ground for litigation." Competitive Enter., 2016 WL 10676292, at *2; Dismissal Order at 3.

The fourth factor, which considers the public interest, also weighs in favor of issuing a limited preservation order. Relators' FCA allegation—which Judge Chutkan has determined Relators should have a chance to litigate—is that Medtronic induced hundreds of physicians to treat patients with a medical device that was not medically necessary for their care, to falsely certify medical necessity to the United States, and in so doing, to commit a multi-million dollar

approach should no longer govern requests for preliminary injunctive relief, the D.C. Circuit has declined to determine whether that standard continues to govern such motions. *See Sherley v. Sebelius*, 644 F.3d 388, 392 (D.C. Cir. 2011) (finding it unnecessary to "wade into this circuit split"). As this Circuit has not spoken, the Court concludes that a sliding scale approach remains a valid means to evaluate requests for preservation orders notwithstanding *Winter. See Cause of Action Inst. v. U.S. Dep't of Just.*, No. 18-cv-1800, 2019 WL 12070403, at *1 (D.D.C. Apr. 25, 2019).

fraud on the United States. *See generally* Dismissal Order at 3; Compl.; Reply at 2. Relators need evidence to litigate their claim. The public interest thus favors preserving that evidence to permit them to present their claim to this Court.

CONCLUSION

For these reasons, the Court will **GRANT-IN-PART** Relators' preservation motion in a separate order issued herewith.

SO ORDERED this September 6, 2022.

ROBIN M. MERIWEATHER UNITED STATES MAGISTRATE JUDGE