UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

UNITED STATES OF AMERICA
ex rel. NILES ROSEN, M.D.,

Plaintiff,

v. **Case No. 8:19-cv-1526-MSS-AAS**

EXACT SCIENCES CORPORATION
and EXACT SCIENCES
LABORATORIES, LLC,

Defendant.
_____/

ORDER

Plaintiff United States of America *ex rel*. Niles Rosen, M.D. (collectively, the plaintiffs) move to compel documents and testimony from Defendants Exact Sciences Corporation and Exact Sciences Laboratories, LLC (collectively, Exact Sciences). (Doc. 85). Exact Sciences responds in opposition. (Doc. 87).

I. BACKGROUND

The plaintiffs initiated this *qui tam* action on June 29, 2019, alleging Exact Sciences violated the False Claims Act (FCA) through its violation of the Anti-Kickback Statute (AKS), 42 U.S.C. § 1320. (Doc. 1). The plaintiffs allege Exact Sciences offered illegal kickbacks through their Patient Compliance Program (PCP), wherein Exact Sciences offered $75 Visa gift cards to patients

in exchange for their use of Cologuard, a colon cancer screening exam. (*Id*. at ¶ 48–65).

On September 26, 2022, the court denied Exact Sciences' motion to dismiss. (Doc. 78). Exact Sciences filed its answer on October 24, 2022. (Doc. 80). The plaintiffs now move to compel Exact Sciences to "produce all evidence relevant to the subject matter of Exact Sciences' alleged 'good faith belief' that their actions with respect to offering and paying incentives to induce patients to order their product were lawful," or in the alternative "[prohibit] Exact Sciences, their witnesses, and current or former employees from contending they had a good faith belief the program was legal." (Doc. 95, Ex. 1, pp. 20–21).

II. LEGAL STANDARD

A party may obtain discovery about any nonprivileged matter relevant to any party's claim or defense and proportional to the needs of the case. Fed. R. Civ. P. 26(b)(1). Discovery helps parties ascertain facts that bear on issues. *ACLU of Fla., Inc. v. City of Sarasota*, 859 F.3d 1337, 1340 (11th Cir. 2017) (citations omitted).

A party may move for an order compelling discovery from the opposing party. Fed. R. Civ. P. 37(a). The party moving to compel discovery has the initial burden of proving the requested discovery is relevant and proportional. *Douglas v. Kohl's Dept. Stores, Inc.*, No. 6:15-CV-1185-Orl-22TBS, 2016 WL 1637277, at *2 (M.D. Fla. Apr. 25, 2016) (quotation and citation omitted). The

responding party must then specifically show how the requested discovery is unreasonable or unduly burdensome. *Panola Land Buyers Ass'n v. Shuman*, 762 F.2d 1550, 1559–60 (11th Cir. 1985).

III. ANALYSIS

In Exact Sciences' motion to dismiss (Doc. 38), Exact Sciences argued at length that the plaintiffs could not meet their burden of showing Exact Sciences acted with the proper intent in violating the AKS: that is, that Exact Sciences' "violation 'was committed voluntarily and purposely, with the specific intent to do something the law forbids, that is with a bad purpose, either to disobey or disregard the law.'" (Doc. 38, p. 14) (*citing United States v. Vernon*, 723 F.3d 1234, 1256 (11th Cir. 2013)). Exact Sciences specifically argues it had a "good faith belief" that its operation of the PCP was lawful. (Doc. 38, pp. 15–21).

On the basis of this argument from Exact Sciences' motion to dismiss, a handful of similar quotes from Exact Sciences executives, and a request for an advisory opinion by the Health and Human Services' Department's Office of the Inspector General, the plaintiffs request a court order finding a blanket waiver of Exact Sciences' attorney-client privilege objections. *See* (Doc. 95, Ex. 1, p. 20) (requesting the court's order "encompass, but not be limited to, those documents identified in Exhibit L" and "extend to witness testimony, both previously taken as well as future testimony"). The plaintiffs argue that by

raising the issue of their good faith belief in the legality of their actions, Exact Sciences raised the issue of "its belief in the lawfulness of its conduct" such that "any attorney-client privilege claims shielding relevant evidence" have been duly waived. (Doc. 95, Ex. 1, p. 14).

As a general rule, a party "waives the [attorney-client] privilege if it injects into the case an issue that in fairness requires an examination of otherwise protected communications." *Cox v. Administrator, U.S. Steel & Carnegie*, 17 F.3d 1386, 1419 (11th Cir. 1994). "Injecting" an issue into litigation in this context means "when a litigant 'place[s] information protected by it in issue through some affirmative act for his own benefit, and to allow the privilege to protect against disclosure of such information would be manifestly unfair to the opposing party.'" *Conkling v. Turner*, 883 F.2d 431, 434–435 (5th Cir. 1989) (*citing Hearn v. Rhay*, 68 F.R.D. 574, 581 (E.D. Wash. 1975)).

Exact Sciences argues it has not injected the issue of its good-faith belief in the legality of the PCP, and instead "merely den[ied] an element relating to [its] mental state." (Doc. 87). Exact Sciences is correct insofar as its answer (Doc. 80) does not specifically plead good faith as an affirmative defense and that denials of intent "without more . . . do not amount to a waiver of the [attorney-client privilege] protections." *Centennial Bank v. ServisFirst Bank, Inc.*, No. 8:16-cv-88-T-36CPT, 2020 WL 1061450, at *2 (M.D. Fla. Mar. 4, 2020).

However, as previously noted, Exact Sciences devotes six pages and two

subsections of its motion to dismiss on the exact contention that "Exact Sciences had a Good Faith Belief that its [PCP] Complied with the Law." (Doc. 38, pp. 15, 18). In denying Exact Sciences' motion to dismiss, the court acknowledged Exact Sciences "argue[d] it had a good faith belief that its [PCP] complied with the law and thus lacked the requisite intent for a violation of the AKS." (Doc. 78, p. 11).

Thus, Exact Sciences has certainly raised the issue of its good-faith belief in the legality of its conduct. Despite this, because Exact Sciences answer and affirmative defenses do not further allege Exact Sciences had a good-faith belief in the legality of their conduct, the undersigned concludes compelling a blanket waiver of attorney-client privilege would be manifestly unfair at this time.

The plaintiffs' Motion to Compel (Doc. 85) is thus **DENIED without prejudice**.

ORDERED in Tampa, Florida on February 2, 2023.

Amanda Arnold Sansone

AMANDA ARNOLD SANSONE
United States Magistrate Judge