

2. A decision from the U.S. District Court for the Eastern District of Texas denying a motion to claw back a government report that Defendant had inadvertently produced, finding that the report was confidential and subject to the protective order in the case but was not covered by the attorney work-product doctrine.

In *Adams v. Medtronic, Inc.*, No. 19-cv-870-SDJ-KPJ, 2024 WL 265860 (E.D. Tex. Jan. 23, 2024), U.S. Magistrate Judge Kimberly C. Priest Johnson analyzed the circumstances under which a confidential but irrelevant or nonresponsive document may be clawed back.

Plaintiffs in this product liability action alleged that Defendant manufactured a defective surgical stapler that caused serious injuries during one of Plaintiff's surgeries. The parties subsequently became entangled in a discovery dispute concerning an Establishment Inspection Report (EIR) issued by the Food and Drug Administration (FDA) that was "shared with the company at the close of an inspection of a regulated facility to determine a company's compliance with applicable laws and regulations." *Id.* at *2. Defendants produced the EIR but subsequently moved to claw it back as a confidential document protected by the work-product privilege that was irrelevant because it did not concern the precise product at issue. In opposition, Plaintiffs argued that the EIR was a nonconfidential, nonprivileged document relevant to their allegations that Defendants' procedures for detecting defects were "slow and too late for most patients." *Id.* at *5.

After an in camera review of the EIR, Magistrate Judge Johnson first held that the version of the EIR produced to Plaintiffs was confidential. *Id.* at *2. Defendants argued that the EIR was "confidential and privileged and thus subject to clawback." Plaintiffs argued that EIR documents are public and available via Freedom of Information Act requests. Magistrate Judge Johnson agreed with Defendants that the publicly available versions of the EIR would be more redacted than the EIR produced by Defendants, which contained confidential information that "is customarily kept private or closely held" or that "could constitute trade secrets or other confidential information." Thus, Magistrate Judge Johnson concluded that the EIR was confidential and at least subject to the protective order in the case.

Nevertheless, Magistrate Judge Johnson held that the EIR was not subject to clawback by Defendants. She noted that although the clawback of documents is generally governed by FRE 502 and FRCP 26(b), Plaintiffs and Defendants here entered into a specific clawback arrangement as well. Defendants argued that the EIR was subject to clawback because it was "not responsive or relevant." *Id.* at *4. Magistrate Judge Johnson rejected that argument, holding that FRE 502 and FRCP 26(b) do not provide for the clawback of a document merely because it is nonresponsive because "both Rule 502(b)(3) and Rule 26(b)(5)(B) specifically apply to privileged communications or information." Because the parties' clawback agreement did not contain a provision "that expands the ability to claw back documents because of responsiveness

or relevancy,” Defendants could not claw back the EIR on the basis of its relevance. That arrangement specifically protected only documents “subject to attorney-client privilege, work-product protection, or any other privilege or protection recognized by law.” Still, “to resolve the disagreement between the parties,” Magistrate Judge Johnson addressed the issue of whether the EIR was relevant: She held that it was relevant to Plaintiffs’ allegations of Defendants’ deficient defect detection, complaint investigation, and standard operating procedures.

Magistrate Judge Johnson next rejected Defendants’ argument that the EIR was protected under the work-product privilege because “it was inadvertently produced based on counsel’s fact-gathering process during the course of discovery.” *Id.* at *5. Although the EIR was “prepared by the FDA ... at the close of an investigation” and was not completed in anticipation of litigation, Defendants argued that because the EIR was “collected in anticipation of litigation,” the fact of its production rendered the document itself protected by the work-product doctrine. Magistrate Judge Johnson rejected this argument and held that the production of the EIR did not “reveal the selection process used by Defendants’ counsel and, thereby, does not reveal their mental impressions or legal opinions.” As such, it was not subject to the work-product doctrine. Magistrate Judge Johnson thus denied Defendants’ motion to claw back the EIR.