**IN THE UNITED STATES DISTRICT COURT**
**FOR THE NORTHERN DISTRICT OF ILLINOIS**
**EASTERN DIVISION**

RANDY J. AFRICANO,

Plaintiff,

v.

ATRIUM MEDICAL CORPORATION,

Defendant.

Case No. 17-cv-7238

Judge Mary M. Rowland

**ORDER**

In motion in limine no. 2, Defendant moves to exclude statements made by FDA employees via the warning letter and two sets of 483 observations on the basis that these statements constitute hearsay and would introduce unfair prejudice as well as confuse and mislead the jury. [302]. Plaintiff counters that these materials fall within the public records exception to hearsay under Federal Rule of Evidence 803(8). Rule 803(8) admits a "record or statement of a public office" if it sets out in a civil case "factual findings from a legally authorized investigation" and the "opponent does not show that the source of information or other circumstances indicate a lack of trustworthiness."

As one federal court explained, the FDA conducts on-site inspections of the facilities of manufacturers of products subject to FDA regulation. *In re Tylenol (Acetaminophen) Mktg., Sales Pracs. & Prod. Liab. Litig.*, 181 F. Supp. 3d 278, 297 (E.D. Pa. 2016). At the end of the inspection, the FDA issues a Form 483, which sets

forth the observations of any conditions an FDA investigator believes constitute violations of laws or regulations. *Id.* A Form 483 "is interim FDA feedback." *Schaeffer v. Nabriva Therapeutics plc*, No. 19 CIV. 4183 (VM), 2020 WL 7701463, at *9 (S.D.N.Y. Apr. 28, 2020). Likewise, FDA warning letters do not represent final agency action subject to judicial review. *Holistic Candlers & Consumers Ass'n v. Food & Drug Admin.*, 664 F.3d 940, 944–45 (D.C. Cir. 2012) ("The letters plainly do not mark the consummation of FDA's decisionmaking."); *see also Cody Labs., Inc. v. Sebelius*, 446 F. App'x 964, 969 (10th Cir. 2011) ("It appears that every court to consider the question has held that an FDA warning letter does not constitute final agency action.") (internal quotation marks omitted).

Relying upon the non-final nature of warning letters and Form 483s, Defendant argues that they do not set forth "factual findings" of the FDA. [302] at 8–9. However, Rule 803 does not limit public records to "final" factual findings, and the Supreme Court has endorsed a "broad approach to admissibility" under the rule. *Beech Aircraft Corp. v. Rainey*, 488 U.S. 153, 169 (1988). The Rule also "encompasses opinions and conclusions and is not limited to purely factual findings." *United States v. Sutton*, 337 F.3d 792, 797 (7th Cir. 2003) (citing *Beech Aircraft*, 488 U.S. at 158).

Given the Supreme Court's liberal treatment of the public records exception, the balance of authority has held that FDA warnings letters and Form 483s constitute public records excepted from the bar against hearsay under Rule 803(8). *See In re Bard IVC Filters Prod. Liab. Litig.*, No. CV-16-00474-PHX-DGC, 2018 WL

1109554, at *4 (D. Ariz. Mar. 1, 2018) (collecting cases); *Sadler v. Advanced Bionics, Inc.*, No. 3:11-CV-00450-H, 2013 WL 1311148, at *2 (W.D. Ky. Mar. 26, 2013) (admitting Form 483s and a warning letter based upon the public records exception); *but see Newman ex rel. Newman v. McNeil Consumer Healthcare*, No. 10 C 1541, 2013 WL 4460011, at *18 (N.D. Ill. Mar. 29, 2013) (holding that FDA warning letters do not fall under the public records exception to the rule against hearsay).

Defendant also argues that the documents should be precluded under Rule 403 because they will leave jurors with the "confusing notion that the FDA has already determined that Atrium acted negligently and may hesitate to substitute their own judgment for that of a regulatory agency." [302] at 14. But Defendant will have an opportunity to "show that the statements in the documents" are non-final agency documents, and this Court can also "issue a cautionary instruction at trial" to temper undue weight as to the statements contained in the FDA documents. *Sadler*, 2013 WL 1311148, at *2.

Defendant also points out that the FDA documents present "multiple hearsay" problems. [302] at 11. On this point, this Court agrees that third-party statements contained in the FDA materials "do not become admissible for their truth by virtue of their presence in a public record and instead must have an independent basis for admissibility." *Jordan v. Binns*, 712 F.3d 1123, 1133 (7th Cir. 2013).

On this basis, the Court precludes references to MDR's. These are contained in (1) the 2012 483 at Observation 6; and (2) the 2013 483 Observations 7 & 8. Parties are precluded from introducing evidence on these topics via testimony or through other exhibits.

In the same vein, Defendant also argues that the FDA documents contain discussions of issues having nothing to do with sterilization or verification of the sterilization process of the Pro-Lite product at issue, and that those portions should be excluded as irrelevant. [302] at 18–19. This Court agrees that evidence of other products and other issues unrelated to sterilization are irrelevant and their introduction might be unduly prejudicial and confusing to the jury.

In a similar vein, Defendant moves to preclude evidence and argument regarding alleged findings of particulates. [304] at 13. Plaintiff attempts to introduce the testimony of contamination of Atrium's mesh "with particulates," pointing to one of the charges in the FDA warning letter referencing thirty-five "confirmed instances of hair being found in your sterile medical devices." [321] at 6. Defendant counters that the particulates at issue concern other products, not the ProLite at issue in this case. [304] at 14. Plaintiff does not dispute this in his response but argues nonetheless that evidence of the particulates constitutes circumstantial evidence that Plaintiff's mesh was unsterile and that Defendant maintained an attitude that "filth was acceptable." [321] at 6.

In this circuit, evidence of other incidents in products liability cases "is relevant to show the existence of a danger, the defendant's notice of the danger, and

the cause of the [incident]." *Chlopek v. Fed. Ins. Co.*, 499 F.3d 692, 699 (7th Cir. 2007). Before admitting such evidence, Plaintiff must "show that the other accidents occurred under substantially similar circumstances" because the "probative force of evidence of other accidents decreases 'as the circumstances and conditions of the other accidents become less similar to the accident under consideration.'" *Id.* (quoting *Nachtsheim v. Beech Aircraft Corp.*, 847 F.2d 1261, 1268 (7th Cir. 1988)).

Plaintiff has not persuaded this Court that the incidents involving the particulates occurred under substantially similar circumstances as those at issue in this case. Plaintiff makes no specific showing of substantial similarity in its opposition brief. And, as Defendant points out, the issues in this case concern whether the Pro-Lite mesh products were contaminated with bacteria, not whether they were contaminated with hair. Thus, whether other products were contaminated with hair is not relevant to whether the Pro-Lite mesh contained bacterial contamination. *See, e.g.*, *In re Bard IVC Filters Prod. Liab. Litig.*, No. CV-16-00474-PHX-DGC, 2018 WL 1109554, at *3 (D. Ariz. Mar. 1, 2018) (excluding evidence of certain other topics in an FDA warning letter as unrelated to the issues in the case). Moreover, even if Plaintiff could show substantial similarity, the probative value of the other incidents is substantially outweighed by the evidence's "potential to confuse the issues" and "mislead the jury." *Underhill v. Coleman Co., Inc.*, 54 F. Supp. 3d 983, 988 (S.D. Ill. 2014) (citing Fed. R. Evid. 403).

On this basis, the Court precludes (1) Observation 4 & 5 in the 2012 483; and (2) Observations 3 (C-Qur mesh only), 4, 5 & 6 in the 2013 483. Parties are precluded from introducing evidence on these topics via testimony or through other exhibits.

For these reasons, this Court **GRANTS IN PART AND DENIES IN PART** Defendant's Motion in Limine No. 2 and **GRANTS** Defendant's Motion in Limine No. 7.

E N T E R:

Dated: October 5, 2021

MARY M. ROWLAND
United States District Judge