IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF ARKANSAS
WESTERN DIVISION

SHARON CHISM and CECIL CHISM **PLAINTIFFS**

V. **4:08CV00341-WRW**

ETHICON ENDO-SURGERY, INC. and
JOHN DOES 1-10 **DEFENDANTS**

ORDER

Pending are Defendant Ethicon Endo-Surgery, Inc.'s Motion in Limine to Preclude the Testimony of Dr. William A. Hyman (Doc. No. 35) and Motion to Exclude Product Inquiry Verification Reports, Medwatch Reports, or Other Adverse Event Reports (Doc. No. 38). Plaintiffs have responded.[1]

I. The Testimony of Dr. William A. Hyman

The rules governing the admissibility of expert testimony (Fed. R. Evid. 702 and *Daubert Merrell Dow Pharms.*[2]) are known to the parties, and I will not repeat them here. After a review of the briefs and Dr. William A. Hyman's report, I believe his testimony chins the pole under both standards. It seems to me that Defendant's criticisms of Dr. Hyman's testimony may be fodder for cross-examination. Weighing the credibility of Dr. Hyman's conclusions rests with the jury. Accordingly, Defendant's Motion in Limine to Preclude the Testimony of Dr. William A. Hyman (Doc. No. 35) is DENIED.

[1]Doc. Nos. 42, 46.

[2]509 U.S. 579 (1993).

II. Product Inquiry Verification Reports, Medwatch Reports, or Other Adverse Event Reports

Plaintiffs seek to admit evidence of other similar incidents that comes in the form of medical device reports ("MDRs") and product inquiry verification reports ("PIVRs").[3] Defendant asserts that these reports are: (i) inadmissible under 21 U.S.C. § 360i(b);[4] and (ii) inadmissible as hearsay.

A. 21 U.S.C. § 360i

Title 21 U.S.C. § 360i(a) requires manufacturers of certain medical devices (including the device at issue here) to report to the FDA whenever the manufacturer receives or becomes aware of information that its device "may have cause or contributed to a death or serious injury, or . . . has malfunctioned and . . . would be likely to cause or contribute to a death or serious injury if the malfunction were to recur . . . ."[5] Section 360i(b) requires device user facilities[6] -- hospitals, for example -- to report to the FDA when a device has or may have contributed to the death of a patient, and to the manufacturer if there has been serious illness of or injury to a patient.[7] Under § 360i, no report made by a device user facility may be "admissible into evidence or otherwise used in any civil action involving private parties . . . ."[8] Although device user

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[3]Doc. No. 47.

[4]Doc. No. 39.

[5]21 U.S.C. § 360i(a).

[6]21 U.S.C. § 306i(b)(6) defines a device user facility as a hospital, ambulatory surgical facility, nursing home, or outpatient treatment facility which is not a physician's office.

[7]21 U.S.C. § 306i(b)(1).

[8]21 U.S.C. § 306i(b)(3).

facilities report to manufacturers, who then base their reports to the FDA on the user reports, § 360i does not prohibit the admissibility of manufacturer reports into evidence, or other uses of the reports in civil actions.

Under § 360i, the MDRs and PIVRs are admissible,[9] as long as they pass the substantially similar test, including that the device in the report operated in a similar manner as the device in this case. However, there is not enough information in the pleadings for me to determine, at this point, whether the reports pass the substantially similar test. Plaintiffs' counsel should be prepared to present this information during the pretrial conference the morning of trial.

B. Hearsay

To the extent that the comments in any reports are comments made by Defendant, they are not hearsay.

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[9]The legislative history of § 360i supports this finding. The legislative history of the Safe Medical Devices Act of 1990 addressed whether user reports simply forwarded by manufacturers to the FDA are governed by § 360i(a):

> To implement the requirements of section 519(a) in current law, the FDA has established a reporting program for manufacturers commonly called the "Medical Devices Reporting (MDR) Regulations." This bill makes no changes in the requirements of section 519(a) and the MDR system developed under that provision.
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> * * *
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> [T]he Committee's intention [is] that this legislation will in no way affect public access to information contained in MDR reports to the FDA. Under the bill, the full requirements of reporting under section 519(a) will apply. If a manufacturer chooses simply to forward a user report to the FDA, that will then constitute a report described in section 519(a), not a report described in section 519(b), for purposes of public access to the contents of the report.

A. Records of Regularly Conducted Activity

The MDRs and PIVRs are records of regularly conducted activity for which Fed. R. Evid. 803(6) makes an exception to the hearsay rule. Rule 803(6) reads, in part:

> A memorandum, report, record, or data compilation, in any form, of acts, events, conditions, opinions, or diagnoses, made at or near the time by, or from information transmitted by, a person with knowledge, if kept in the course of a regularly conducted business activity, and if it was the regular practice of that business activity to make the memorandum, report, record or data compilation . . . .[10]

The reports were made during the course of a regularly conducted business activity, near the time of the incident, and by a person with knowledge. The reports fall under Rule 803(6) with respect being timely and made by a person with knowledge because device user facilities are required to report to the device manufacturer the serious illness of or injury to a patient within ten working days of the event.[11] The manufacturer must then ensure that it has all information reasonably known to it, must investigate each event, and must submit its own report to the FDA within 30 days.[12] Further, nothing in the pleadings shows that circumstances that indicate a lack of trustworthiness. The reports appear to be admissible as records of regularly conducted business activity.

B. Public Records and Reports

Even if the reports were not records of regularly conducted activity, it seems to me that they are public records and reports. Federal Rule of Evidence 803(8) provides that public records

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[10]Fed. R. Evid. 803(6).

[11]21 U.S.C. § 306i; 21 C.F.R. § 803.30.

[12]21 C.F.R. §§ 803.50, 803.52.

and reports are not excluded by the hearsay rule.[13] In *United States v. Johnson*,[14] the appellant contended that a serial number report admitted into evidence at trial was inadmissible hearsay. The report was created by the manufacturer of the gun, and federal regulations required the Bureau of Alcohol, Tobacco and Firearms to maintain custody of the report, because the manufacturer had discontinued operations.[15] The Eighth Circuit Court of Appeals noted that the "serial number report is a record which ATF has a duty to keep and report."[16] The Court of Appeals also pointed out that "[t]he 803(8) exception was designed to allow admission of official records prepared for purposes independent of specific litigation . . . . The record at issue here was kept in a ministerial fashion, pursuant to legal authority, and not in anticipation of . . . trial."[17] The Court of Appeals found no error in the admission of the report.[18]

The report in *Johnson* is very similar to the reports at issue in this case. The MDRs and VIPRs were created by the manufacturer and submitted to the FDA, as required by statute and regulation.[19] The "reports help [the FDA] to protect the public health by helping to ensure that devices are not adulterated or misbranded and are safe and effective for their intended use."[20]

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[13]Fed. R. Evid. 803(8).

[14]722 F.2d 407 (8th Cir. 1983).

[15]*Id*. at 409.

[16]*Id*. at 410.

[17]*Id*. (Internal citation omitted.)

[18]*Id*.

[19]21 U.S.C. § 360i; 21 C.F.R. § 803.

[20]21 C.F.R. § 803.1.

The FDA maintains a database of MDRs and makes certain information from those reports public.[21] Under *Johnson*, the MDRs and PIVRs are public record and admissible.

CONCLUSION

Based on the findings of fact and conclusions of law above, Defendants Motions (Doc. Nos. 35, 38) are DENIED.

IT IS SO ORDERED this 23rd day of September, 2009.

/s/Wm. R. Wilson, Jr.
UNITED STATES DISTRICT JUDGE

[21]Plaintiff notes that the information it seeks to admit does not include protectec information.