IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF OREGON

CHRISTINA MCCLELLAN,

Plaintiff,

v.

I-FLOW CORPORATION, a Delaware corporation, et al.,

Defendants.

Civ. No. 07-1309-AA
OPINION AND ORDER

JUAN A. HUERTA,

Plaintiff,

v.

I-FLOW, INC., a Delaware corporation,

Defendant.

Civ. No. 07-1310-AA
OPINION AND ORDER

DANNY E. ARVIDSON,

Plaintiff,

v.

DJO, LLC, a Delaware corporation, et al.,

Defendants.

Civ. No. 08-478-AA
OPINION AND ORDER

Aiken, Chief Judge:

Before the court is plaintiffs' Motion to Admit Newly Discovered Evidence. Plaintiffs seek to introduce documents received from the Federal Drug Administration (FDA) in response to a Freedom of Information Act (FOIA) request and to use certain documents during their cross-examination of defense witnesses. The motion is granted.

The documents sought to be admitted comprise a regulatory file maintained by the FDA for the PainBuster Infusion Kit (PainBuster), a pain pump device manufactured by defendant I-Flow Corporation (I-Flow) and at issue in this products liability action. Included in the file is I-Flow's 510(k) application for the PainBuster submitted to the FDA in 1998 and a "Memo to the Record - 510(K) Review" (Memo) prepared by Irene Naveau, a FDA staff member who reviewed I-Flow's application. See Powers' Decl., Ex. A. A 510(k) application is an avenue a company may pursue when seeking FDA clearance to market a new device (or a new use of an existing device) based on its substantial equivalence to an existing or predicate device. See generally 21 U.S.C. § 360(k). The Memo prepared by Ms. Naveau constitutes the FDA's "Substantial Equivalence (SE) Decision-Making Documentation" with respect to I-Flow's 1998 510(k) application. Powers Decl., Ex. A, p. 19. In particular, the Memo describes the features of the PainBuster, summarizes the history of I-Flow's 510(k) application for the PainBuster, and makes findings that the 510(k) application meets the requirements for market approval based on a predicate, substantially equivalent device. Id. Ex. A, p. 19-22. Ultimately, the Memo recommends that I-Flow's 510(k) PainBuster application be approved based on the revised indications for use submitted by I-Flow on November 9, 1998. Id. Ex. A, p. 22. Shortly thereafter, I-Flow received a "Clearance Letter" to market the PainBuster in accordance with the revised indications for use. Id. Ex. A, pp. 14-15, 16.

In support of their motion, plaintiffs emphasize the following portions of the Memo:

> The 510k was originally submitted with an expanded indications for use, i.e., for continuous infusion of a local anesthetic directly into the intra-articular site for postoperative pain management, however, there was no accompanying data to demonstrate that this device may be used safely and effectively with this use. I had conferred with Marie Schroeder, Sahar Dawisha MD, and Bernard Berne MD, of REDB; Mark Melkerson of ORDB; Michael Bazaral MD of DCRND; and Hung Trinh and Patricia Cricenti of GHDB regarding the specific use for this device. It was generally agreed that additional information was required to determine the safety and effectiveness of the device with this use. The indications for use was modified on 11/04/98 by the deletion of intra-articular use and being replaced with ". . . for general and orthopedic surgeries." On 11/09/98, a fax was forwarded by the sponsor with another indications for use revision. The indications for use is now limited to general surgery. All references to orthopedic surgery and intra-articular use have been deleted [from] the 510k. I suggested to the sponsor that if they conduct a study related to the safety and effectiveness of this device for intra-articular use, they should identify a medication that can be used in a slow, continuous infusion for pain management in the intra-articular site. The sponsor was informed that, following the conclusion of such a study, the infusion pump would be a combination device and would have to be reviewed by both CDER and CDRH.
>
> The labeling for this device is adequate. It has been revised to delete any reference to use in the intra-articular [site]. It includes appropriate warnings, contraindications, and notes for the safe use of this device. The Directions for Use are clear and concise, and delivery time information for the Painbuster is provided in tabular form for the user. It includes flow rate, delivery time, and normal, maximum, and retained volume by ml. Labeling includes a prescription statement, and a drawing of the device.

Powers' Decl., Ex. A, p. 21. I-Flow opposes plaintiffs' motion on grounds that the documents, and specifically this Memo, were obtained after the relevant discovery deadlines and are inadmissible hearsay, irrelevant and prejudicial.

I recognize plaintiffs obtained, and in two cases sought, this information after the applicable discovery deadlines. At the same time, it is abundantly clear that the parties have continued to exchange information beyond the discovery deadlines, and plaintiffs cannot be faulted for the lapse of time between the FOIA request and the FDA's response. Moreover, the vast majority of the

documents were submitted to the FDA by I-Flow, and the Memo does not contain information unknown to I-Flow or otherwise implicate new subject matter unrelated to plaintiffs' claims. Given these circumstances, the expiration of the discovery deadlines does not warrant exclusion of this information.

Further, I find that the documents received from the FDA fit squarely within the public records exception to the hearsay rule. The rule excepts from the prohibition on hearsay:

> Records, reports, statements, or data compilations, in any form, of public offices or agencies, setting forth (A) the activities of the office or agency, or . . . (C) in civil actions and proceedings . . . , factual findings resulting from an investigation made pursuant to authority granted by law, unless the sources of information or other circumstances indicate lack of trustworthiness.

Fed. R. Evid. 803(8). Notably, "the public records exception is one of the few hearsay exceptions that does not require a foundation. Instead, documents that fall under the public records exception are presumed trustworthy, placing the burden of establishing untrustworthiness on the opponent of the evidence." United States v. Loyola-Dominguez, 125 F.3d 1315, 1318 (9th Cir. 1997) (citation and internal quotation marks omitted); United States v. Weiland, 420 F.3d 1062, 1076 n.13 (9th Cir. 2005) ("*Unlike* public records admitted under Rule 803(8), records of a regularly conducted activity admitted under Rule 803(6) require additional foundation.") (emphasis added).

I find that the FDA documents and Memo constitute "records, reports, statements, or data compilations" of a federal agency "setting forth the activities of the agency" as well as "factual findings resulting from an investigation made pursuant to authority granted by law." Fed. R. Evid. 803(8)(A) and (C). In particular, the documents depict the FDA's activities in reviewing 510(k) applications and include factual findings resulting from Ms. Naveau's review of I-Flow's 510(k) application, an investigation made pursuant to authority granted by law. See 21 C.F.R. § 807.100

(describing FDA actions with respect to premarket notification, such as determining whether substantial equivalence is established). Further, the circumstances of the Memo's creation and its subsequent discovery by plaintiffs do not indicate a lack of trustworthiness, given that the Memo was 1) prepared pursuant to a lawful review of I-Flow's 510(k) application, 2) relied on by the FDA to support the FDA's eventual 510(k) clearance of the PainBuster, and 3) provided by the FDA in response to a FOIA request. Although I-Flow raised the Memo's authentication and foundation generally, I-Flow does not contest the factual basis of the Memo or suggest that Ms. Naveau failed to perform her "duties properly without motive or interest other than to submit accurate and fair reports." Gilbrook v. City of Westminster, 177 F.3d 839, 858 (9th Cir. 1999) (citation omitted).

I-Flow nonetheless argues that the Memo does not fall within the exception, because it is an "interim" report and recommendation by a FDA staff member and does not constitute the FDA's final findings regarding I-Flow's 510(k) application. However, the fact that the Memo "contains a recommendation or opinion does not remove it from the purview of Federal Rule of Evidence 803(8)." Id. at 858-59 (citing Beech Aircraft Corp. v. Rainey, 488 U.S. 153, 162 (1988)). To the contrary, "[o]pinions, conclusions, and evaluations, as well as facts, fall within the Rule 803(8)(C) exception." Bank of Lexington & Trust Co. v. Vining-Sparks Sec., Inc., 959 F.2d 606, 616 (6th Cir. 1992) (citing Beech Aircraft, 488 U.S. at 168-69). While the finality of findings may be relevant to the determination of whether an agency's reports is excepted from the hearsay rule, "[f]inality . . . is not the only factor to be considered." In re Ethylene Propylene Diene Monomer (EPDM) Antitrust Litig., 681 F. Supp. 2d 141, 154-55 (D. Conn. 2009) (citing cases allowing admission of "interim" or "non-final" reports or those containing "tentative" conclusions and findings); Jama v. United States Immigration & Naturalization Serv., 334 F. Supp. 2d 662, 678 (D.N.J. 2004) ("[T]he

fact that findings are subject to review or revision, though it bears on their trustworthiness, does not remove them from the category of findings for the purposes of the rule.").

Here, factors beyond finality support my consideration of the Memo as a public record within the purview of the hearsay exception. As I-Flow admits, "the 510(k) [application] which is the subject of Ms. Naveau's 'Memo to the Record' was cleared by the FDA" through issuance of a Clearance Letter for the PainBuster. I-Flow's Resp. in Opp'n to Pls.' Mot., p. 9. It is therefore undisputed that the FDA adopted Ms. Naveau's recommendation and found that I-Flow's 510(k) application, with the revised indications for use, was substantially equivalent to a predicate device. See also Powers' Decl., Ex. A, p. 17. Given that the Memo constitutes the "Substantial Equivalence Decision-Making Documentation" supporting the FDA's Clearance Letter, the Memo's description of agency activities and factual findings form the factual basis of the FDA's final decision. Accordingly, I find that the Memo falls within the public records exception. See Gilbrook, 177 F.3d at 848, 858-59 (upholding the admission of an interim report with recommendations prepared by a citizens' committee); McGonigle v. Combs, 968 F.2d 810, 825 (9th Cir. 1992) (admitting into evidence a file memorandum written by a Director of Securities staff member and memorializing a meeting between the Director and an attorney, explaining that the public records exception "includes memoranda like the one at issue in this case"); Zeneca Inc. v. Eli Lilly and Co., 1999 WL 509471, *3 (S.D.N.Y. July 19, 1999) (finding FDA meeting minutes admissible as public records that "set forth 'factual findings resulting from an investigation made pursuant to authority granted by law,'" as the minutes contained findings by the FDA concerning a product's efficacy for breast cancer prevention) (quoting Fed. R. Evid. 803(8)(C)).

Moreover, the cases cited by I-Flow are distinguishable or inapposite from the facts here and

do not persuade me that the public records exception is inapplicable. See, e.g., Smith v. Isuzu Motors Ltd., 137 F.3d 859, 862 (5th Cir. 1998) (upholding exclusion of interim memoranda not endorsed by the agency); Figures v. Bd. of Pub. Util., 967 F.2d 357, 360 (10th Cir. 1992) (upholding exclusion of a draft proposed letter that was not endorsed or adopted by the relevant agency); City of New York v. Pullman, Inc., 662 F.2d 910, 914 (2d Cir. 1981) (upholding exclusion of interim and incomplete staff report which noted a need for further investigation and was not accepted by the agency administrator); Equal Emp't Opportunity Comm'n v. Columbia Alaska Reg'l Hosp., 126 Fed. Appx. 382, 384 & n.6, 2005 WL 658940 (9th Cir. Mar. 18, 2005) (upholding exclusion of an investigator's "confidential report" prepared for a municipal Commission that included a "legal conclusion" regarding a discrimination complaint). While the Ninth Circuit recently found that a district court acted within its discretion in excluding as untrustworthy an internal report produced pursuant to a FOIA request, the court noted that the report was incomplete and had an unknown and unidentified author. Sullivan v. Dollar Tree Stores, Inc., ___ F.3d ___, 2010 WL 3733576, *4 (9th Cir. Sept. 27, 2010).

I do not find such indications of untrustworthiness here, where the FDA ultimately issued a Clearance Letter based on the findings of the Memo. "A trial court may presume that public records are authentic and trustworthy. The burden of establishing otherwise falls on the opponent of the evidence, who must come forward with enough negative factors to persuade a court that a report should not be admitted." Gilbrook, 177 F.3d at 858 (citations omitted); Johnson v. City of Pleasanton, 982 F.2d 350, 352 (9th Cir. 1992). For the reasons explained above, I-Flow fails to do so.

I likewise reject I-Flow's contention that the documents are irrelevant to plaintiffs' claims.

Plaintiffs contend that the FDA did not clear specific indications for orthopedic or intra-articular uses of the PainBuster in 1998, because no predicate device had these indications and additional studies were necessary to establish the safety and efficacy of such uses. The Memo addresses and is relevant to these issues. Further, the Memo is relevant to plaintiffs' contention that the FDA refused to grant 510(k) clearance for the PainBuster until I-Flow removed orthopedic and intra-articular uses from the proposed indications for use. I-Flow maintains that plaintiffs' arguments misapprehend the nature of the 510(k) process, and that the absence of a predicate device establishing the safety and efficacy of a medical device is separate and distinct from the presence of safety and efficacy concerns about a medical device. According to I-Flow, the Memo and Ms. Naveau's findings simply reflect the former and not the latter. However, the fact that I-Flow disagrees with plaintiffs' interpretation of the Memo and the associated 510(k) clearance does not render the Memo irrelevant. In fact, I-Flow's stated defenses in these cases implicate the scope of FDA clearance for the PainBuster and any need for additional studies or information.

In I-Flow's opening statement, counsel agreed that a medical device must be cleared or approved by the FDA before it can be marketed or distributed and further asserted that if the FDA "truly had concern about the effectiveness, and importantly, the safety of [the PainBuster], the FDA would have mandated human studies or animal studies." Transcript of Proceedings (Tr.) p. 235 (Sept. 21, 2010). Counsel continued:

> What the FDA decided after we made our application for the PainBuster in 1998, [was that] you don't need clinical trials. You don't need clinical trials, not for this device. This is not markedly different than what a syringe offers. Do you have to do clinical trials on a syringe? Do you think you have to do clinical trials on an IV bag? Well, the FDA said you don't need to do one on the PainBuster either. So this isn't just something that, you know, we came up with. This is a sign of government action.

> When we submitted our application in 1998 for the PainBuster by way of a 510(k), the FDA could have said, No way. You have to do clinical trials. You have to do animal studies. You have to do human studies. . . . The FDA said it's not necessary, not for this kind of elementary device.

Tr. p. 237 (Sept. 21, 2010). These arguments render relevant the Memo's reference that in 1998 Ms. Naveau and her colleagues "generally agreed that additional information was required to determine the safety and effectiveness of the device with [continuous infusion of a local anesthetic directly into the intra-articular site]." Powers' Decl., Ex. A, p. 21.

Counsel also argued that the FDA's initial 510(k) clearance included indications for orthopedic and intra-articular uses:

> When we first applied for clearance under 510(k) to the FDA, the FDA said, You are cleared to market and sell this [device] for surgery in any operative site in the body. That would include ladies and gentlemen, orthopedics, and that would include the intra-articular joint of the shoulder, any intraoperative site. That's what the FDA gave us clearance for.

Tr. p. 240 (Sept. 21, 2010).

> [DJO] came to us and said, Well, before we get involved and start selling this thing, make sure and tell us you have clearance for orthopedics. And we did, and it showed in fact we did have clearance. . . The FDA had given clearance for orthopedics, had given clearance for any kind of intraoperative site on the body for the I-Flow PainBuster.

Tr. p. 243-44 (Sept. 21, 2010).

> What [plaintiffs are] complaining of here is we failed to warn doctors about a regulatory history. What are we going to tell them? We'll tell them the truth. This was cleared for orthopedic surgery. That's not - I mean, that is not something that we were negligent [about], because there was no regulatory history with respect to these pumps that these plaintiffs received that showed it was not cleared or authorized for sale for orthopedic surgery. . . . And the FDA, importantly, never even suggested that it believed there to be any kind of value in having pre-market or any other kind of testing of the device. . . .The FDA essentially told us, When it comes to pre-market testing, don't waste your time. We're clearing it. We're authorizing you to sell it for any kind of surgical environment.

Tr. p. 244-46 (Sept. 21, 2010).

Without question, I-Flow's opening arguments - and its subsequent cross-examination of plaintiffs' witnesses and direct examination of its own witness, Mr. Massengale - implicate issues explicitly discussed in the Memo: the scope of FDA clearance for the PainBuster and the need for additional information to support an indication for orthopedic or intra-articular uses. See Tr. p. 1642 (Sept. 28, 2010) (asking witness on cross-examination about FDA clearance for continuous infusion and pain pump devices); Tr. p. 2602 (Oct. 6, 2010) (asking witness on direct examination: "Now, can you tell the jury, in light of the intended or indication for use . . . what limitations or restrictions on the scope or the use of this device does the FDA and I-Flow agree can be applied here?" and witness answering: "In reference to the continuous infusion of a local anesthetic into the intraoperative site, it's a pretty broad umbrella, and so in essence that doesn't define any one particular intraoperative site. It basically defines surgical applications, so the intention there is all surgery."); Tr. p. 2665 (Oct. 6, 2010) (asking witness on direct examination whether FDA can and did require I-Flow to perform additional studies before granting 510(k) clearance, and witness answering that the FDA did not so require); Tr. 2669 (Oct. 6, 2010) (witness testifying on direct examination that "The FDA agreed that the data out there was sufficient to allow, obviously, the intraoperative umbrella, which was really basically just everything under the umbrella of surgery. And so to meet the threshold which required that particular label, number one, would not need to do studies."). The Memo is therefore relevant to the FDA's 510(k) clearance for the PainBuster and the asserted claims and defenses in this case.

As for prejudice, most of the information contained in the FDA documents either originated from I-Flow or was communicated to I-Flow. Even if I-Flow did not receive the Memo, I-Flow

acknowledges that the Memo "verifies what is already known and what the Clearance Letter and Indications for Use articulate, that the subject 510(k) was cleared with general indications for use as opposed to specific indications for use." I-Flow's Resp. in Opp'n to Pls.' Mot., p. 11. In other words, I-Flow was already aware of the substance of the memo, and this information should come as no surprise.[1] From the beginning, plaintiffs have contended that orthopedic and intra-articular uses of the pain pumps were not cleared by the FDA, as evidenced by the testimony of their regulatory expert Dr. Parisian, and admission of the Memo does not implicate or invite new claims or arguments by plaintiffs. The fact that admission of the Memo may, depending on how it is viewed, prejudice the viability or credibility of I-Flow's position or witnesses is not the type of prejudice that warrants exclusion of the evidence. In sum, any prejudice that I-Flow may suffer does not substantially outweigh the probative value of this evidence. See Fed. R. Evid. 403.

CONCLUSION

For these reasons and those stated on the record, plaintiffs' Motion to Admit Newly Discovered Evidence (docs. 688M; 843H; 683A) is GRANTED.

IT IS SO ORDERED.

Dated this 7th day of October, 2010.

/s/ ANN AIKEN
Ann Aiken
United States District Court Judge

[1]Plaintiffs also argue that admission does not result in unfair prejudice, because I-Flow likely received notice of the FOIA request from the FDA and was allowed to suggest redactions. I-Flow asserts and provides supporting declarations that it did not receive notice of the FOIA request, and I accept this representation. Regardless, for the reasons explained above, I do not find undue prejudice.