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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation,	No. 2:15-MD-02641-DGC **DEFENDANTS' RESPONSE TO PLAINTIFFS' BRIEF IN OPPOSITION TO BARD'S REQUEST TO DEPOSE PLC COUNSEL**

In their Brief in Opposition to Bard's Request to Depose PLC Counsel, the plaintiffs omit discussion of several key facts that support allowing the depositions of attorneys, John Dalimonte and Troy Brenes:

- Bard has exhausted less intrusive means to obtain the discovery that it seeks. Bard propounded interrogatories and follow-up correspondence to Mr. Dalimonte and Mr. Brenes in which it requested detailed information about their communications with FDA, but counsel provided only incomplete and vague responses.

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- Information that Mr. Dalimonte and Mr. Brenes possess is crucial to Bard's defense against five FDA letters that the plaintiffs have made centerpieces of the MDL. Biases and lack of trustworthiness in the letters that Mr. Dalimonte's and Mr. Brenes' testimony can demonstrate, impacts the admissibility and/or weight that the jury should give to the letters.

Similarly, the plaintiffs gloss over important issues and misstate several facts:

- Plaintiffs argue that Mr. Dalimonte and Mr. Brenes have provided verified interrogatory answers that they "did not discuss any of the matters contained in the warning letter." But Mr. Dalimonte and Mr. Brenes have not fully responded to Bard's discovery requests, and they have provided no information about the substance of the conversation(s) that they had with the FDA. Counsel's conclusory statement with no additional information should not suffice, particularly when the evidence that the FDA has provided via FOIA responses, including a memorandum that FDA produced earlier this week, strongly suggests that Mr. Dalimonte specifically broached the topic of warning letters with the FDA.
- Plaintiffs argue that even if they contacted the FDA, "so what"? The answer is that any information that they provided the FDA can demonstrate bias and untrustworthiness of the letters—crucial issues in the litigation that bear on the weight and admissibility of the letters at trial.
- Plaintiffs argue that Bard has "admitted to most" of the FDA's "findings of serious violations" after FDA conducted an "independent investigation." But Bard has not "admitted" to FDA's findings—in fact, Bard has vigorously disputed the findings. And the plaintiffs presuppose that the FDA's investigation was "independent"—another fact that Bard disputes.

Mr. Dalimonte and Mr. Brenes have turned themselves into fact witnesses about key pieces of evidence. Bard has done everything it can to obtain the discovery that it

seeks from other sources. With limited time left to conduct fact discovery, the Court should permit Bard to take the depositions of Mr. Dalimonte and Mr. Brenes.

FACTS

On September 6, the Court ordered the plaintiffs' lead counsel and members of the Plaintiffs' Steering Committee to respond to interrogatories and document production requests concerning five Section 483 and Warning letters[1] about IVC filters that the FDA sent to Bard ("the FDA Letters").

On October 5, John Dalimonte served responses to Bard's discovery requests, attached as Exhibit A. Mr. Dalimonte also produced a May 14, 2014, e-mail that he sent to FDA employee, William MacFarland, attached as Exhibit B. In the e-mail, Mr. Dalimonte wrote, "I have reached out to several folks here in Massachusetts about a year or so ago, but they have not followed up." Mr. Dalimonte's Interrogatory responses also mention making "several calls" to FDA's Massachusetts and New Jersey regional offices.

In response to FOIA Requests, the FDA produced a March 7, 2013, Consumer Complaint/Injury Report from its New England District Office (located in Stoneham, Massachusetts), attached as Exhibit C. The Complaint reports that "Complainant reported a problem with Bard's vena cava filters, labeled as G2 filters, manufactured between 2004 – 2008. Complainant knows of 1000 adverse events not reported to FDA. Complaints involve breakages, migrations, and perforation that resulted in serious injuries." The Complaint also shows that the call was referred to FDA's Los Angeles District Office, which is the office that sent the July 2015 Warning Letter. *See id.* The Complaint report also attached a memorandum with more details about the conversation with the complainant, which Bard received earlier this week, including that "He was calling NWE-DO after noting that our office issued a Warning Letter to Davol (division of CR Bard) in April 24, 2007. . . . After seeing our 2007 Warning Letter, he noted this appears to be a recurring problem at Bard." Attached as Exhibit D.

[1] Ltr. from FDA to Bard, Mar. 2, 2016; Ltr. from FDA to Bard, Feb. 26, 2016; Ltr. from FDA to Bard, July 13, 2015; Ltr. from FDA to Bard, Jan 5, 2015; Ltr. from FDA to Bard, Nov. 25, 2014.

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After Mr. Dalimonte made "several calls" to "several folks" at FDA's Massachusetts office and New Jersey office in March 2013, Mr. Dalimonte and Mr. Brenes participated in a call with FDA employee, Mr. MacFarland, more than a year later on May 15, 2014. Ex. A, Dalimonte Resps. at 2. Mr. Dalimonte "told them [FDA] that we believe that we could only share publicly available information. At time [sic], we advised the FDA that we believe that we could share the decision denying the defendants' motion for summary judgment in Giordano v. C.R. Bard, inc., et al., San Diego Superior Court, Case No. 37-2011-00069363-CU-PO-ED, but would need to check to determine whether that was publicly available." The order denying Bard's motion for summary judgment was entered on September 27, 2013. Thus, Mr. Dalimonte's discovery responses claim that after trying to set up a call with the FDA about Bard's filters for over a year, the only thing discussed during the May 2014 call concerned the possibility of providing FDA with a court order that did not exist until six months *after* he contacted several people at FDA several times in March 2013.

Similarly, Mr. Brenes' discovery responses provide that "they [FDA] asked for any information we could provide relating to Bard's filters. My recollection is that I responded that nearly everything we had uncovered in litigation was bound by a secrecy order and that we could only share one of [sic] two documents that had been unsealed by the court or were otherwise public record. I don't recall actually forwarding any documents, but it is possible that I may have subsequently shared one or two documents that had been unsealed at that point in time." Brenes Resps., at 2-3, attached as Exhibit E.

Mr. Dalimonte further responded that more than a year later, in April 2015, he send FDA's Mr. MacFarland a trial brief from another case, *Jones v. C. R. Bard, Inc.* (N.D. Tex.). Ex. A, Dalimonte Resps. at 3. In June 2015, Mr. Dalimonte sent Mr. MacFarland several unsealed internal Bard documents from *Phillips v. C. R. Bard, Inc.* (D. Nev.) along with an e-mail stating as follows:

> We recently received a favorabe [sic] ruling allowing us to share with you documents that C.R. Bard, Inc. has held back from the FDA concerning its IVC filter product line. . . . [Bard] used the Recovery filter to serve as the

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> predicate device for its subsequent filter product line knowing full well that it was not the substantial equivalent and concealed information relating to the safety of this device from the FDA, doctors and public in order to gain a competitive advantage. I have hundreds of doucments [sic] that I can share, but it still only [sic] the tip of the iceberg. In the meantime, attached are a couple of documents for your review. I intend to forward all recently made public documents. I have many more concerning off label promotion, lack of sufficient testing prior to market, discovery of improper testing after market, refusal to follow up with post market surveillance after several physicians and medical centers reported significant failure rates, admission of a reactive/redesign policy essentially using people as Guinea pigs to test and get their product to market. This is the same conduct, if not worse, than what took place in the past that led to criminal indictments and millions in fines. . . . Ironically, Bard's defense at this trial was that they shared all their documents with the FDA and that the FDA gave their blessing.

E-mail from J. Dalimonte to W. MacFarland, June 3, 2015, attached as Exhibit F.

The following month, on July 13, 2015, FDA sent Bard a Warning Letter. Bard has submitted numerous responses to the Warning Letter, and in no way has Bard "admitted to the violations" as the plaintiffs claim in their opposition brief. In fact, the FDA Warning Letter does not reflect an adjudicative proceeding and does not represent official FDA findings.

Although both Mr. Dalimonte and Mr. Brenes deny that anything discussed with the FDA during the May 2014 call concerned issues related to the FDA Letters, they have provided no substantive information about what they discussed with FDA despite Bard's requests for further information (in fact, Mr. Brenes has ignored a written request for him to provide this information). Nor has Mr. Dalimonte, despite Bard's request, provided any information about the "several calls" to "several folks" at FDA's Massachusetts office and New Jersey office in March 2013. Thus, the plaintiffs' claim that Mr. Dalimonte and Mr. Brenes "did not discuss any of the matters contained in the warning letter" is not supported by the record.

ARGUMENT

The Ninth Circuit has not adopted a test that governs when to allow the deposition of counsel. Thus, whether the Eighth Circuit's *Shelton* test or the Second Circuit's *Friedman* test (or some other test) applies in the Ninth Circuit is unclear. *Compare*

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Younger Mfg. Co. v. Kaenon, Inc., 247 F.R.D. 586, 588 (C.D. Cal. 2007) (rejecting *Shelton* and applying the Second Circuit's "flexible approach"); *with Couturier v. Am. Invsco Corp.*, No. 2:12-cv-01104-APG-NJK, 2013 WL 4499008, at *4 (D. Nev. Aug. 20, 2013) (rejecting the Second Circuit's test and finding "that *Shelton* is the proper standard in this district").

Here, the Court should allow the depositions of Mr. Dalimonte and Mr. Brenes to proceed regardless of whether *Shelton* or *Friedman* test applies. As an initial matter, *Shelton* involved a deposition of in-house counsel who was being asked about the existence of documents that the plaintiff could have identified through other means—"In-house counsel in this case had nothing to do with this lawsuit except to represent her client." 805 F.2d 1323, 1327, 1330 (8th Cir. 1986). The defendant in *Shelton* also offered to provide answers to the plaintiff's questions through the depositions of non-attorney witnesses. *Id.* at 1327. In this context, the Eighth Circuit reasoned that "counsel's task for preparing for trial would be much easier if he could dispense with interrogatories, document requests, and depositions of lay persons, and simply depose opposing counsel in an attempt to identify the information that opposing counsel has identified is relevant and important to his legal theories and strategy." *Id.* And subjecting counsel to depositions in this context amounts to a "harassing practice" and "an adversary trial tactic that does nothing for the administration of justice . . . ." *Id.* at 1330. The Eighth Circuit later explained that its decision in *Shelton* was influenced by what it saw as the "ever increasing practice" of deposing opposing counsel, which it considered an "abuse of discovery." *Pamida, Inc. v. E.S. Originals, Inc.*, 281 F.3d 726, 730 (8th Cir. 2002).

The facts of *Shelton*, and the policy issues that the Eighth Circuit discussed in *Shelton* and *Pamida*, are entirely dissimilar to the scenario before this Court. Here, Mr. Dalimonte and Mr. Brenes affirmatively sought out the FDA to discuss Bard's IVC Filters. Mr. Dalimonte's last contact with the FDA purports to have been one month before FDA issued a Warning Letter to Bard in July 2015. In contacting the FDA about Bard's IVC filters, Mr. Brenes and Mr. Dalimonte have made themselves *fact witnesses*

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regarding a key issue in this lawsuit,[2] and Bard seeks to take their depositions for the limited purpose of discovering what they said and provided to whom at the FDA and when. Many courts in the Ninth Circuit and elsewhere have distinguished *Shelton* and allowed depositions of the attorneys to go forward when, like here, the attorneys were fact witnesses. *See, e.g., Devlyne v. Lassen Mun. Util. Dist.*, No. CIV. S-10-0286 MCE, 2011 WL 4905672, at *2 (E.D. Cal. Oct. 14, 2011) ("Jones is alleged to be a percipient witness to facts relevant to plaintiff's claims—facts which are outside the litigation proceedings. Accordingly, plaintiffs are not required to satisfy the three *Shelton* criteria before deposing Jones."); *Younger Mfg. Co. v. Kaenon, Inc.*, 247 F.R.D. 586, 589 (C.D. Cal. 2007) ("Of course, [opposing counsel] is also a fact witness about statements and declarations he made and statements about him made by others in declarations submitted by [defendant]. Thus, [counsel]'s deposition is like the deposition of any other percipient or fact witness, and should not be prohibited under Rule 26(c)."); *Am. Cas. Co. of Reading, Pa. v. Krieger*, 160 F.R.D. 582, 586 (S.D. Cal. 1995) (noting that "where an attorney's conduct itself is the basis for a claim or defense, there is little doubt that the attorney may be examined as any other witness," discussing numerous cases within the Third Circuit and other cases from around the country) (quotation omitted). The role of Mr. Dalimonte and Mr. Brenes as fact witnesses regarding a key issue, in itself, should be sufficient to allow their depositions.

Even if the *Shelton* test applies, however, Bard has met its burden.

1. No Other Means Exist to Obtain the Information than to Depose Opposing Counsel: Bard has served written discovery on Mr. Dalimonte and Mr. Brenes, asking them to provide detailed information about what they said and provided to the FDA and when. Their responses, however, were vague and neither counsel identified any substantive information about Bard's IVC filters that they shared with the FDA during the May 2014 conference call. *See* Exs. A and E. Moreover, Mr. Brenes responded, "I don't

[2] The Court should note, however, that neither Mr. Dalimonte nor Mr. Brenes are counsel on any of the bellwether cases that the parties have submitted.

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recall actually forwarding any documents, but it is possible that I may have subsequently shared one or two documents that had been unsealed at that point in time." Ex. E. Despite Bard's follow-up request regarding this clearly deficient discovery response, Mr. Brenes has ignored the request and has not identified which documents, if any, that he provided to the FDA. And Mr. Dalimonte has not provided any information at all about what he said to the FDA during "several calls" to "several folks" at FDA in 2013. Bard has also submitted multiple FOIA requests to the FDA for this information, but the only relevant information that FDA has produced to date is a Consumer Complaint/Injury Report and a heavily redacted memorandum from March 2013 (Exhibits C and D). With the window for fact discovery rapidly closing, Bard has no other way to learn about what Mr. Dalimonte and Mr. Brenes said and sent to the FDA other than to take their depositions.

2. The Information Sought Is Relevant and Nonprivileged: In its Order compelling the plaintiffs to respond to Bard's written discovery about their communications with the FDA, the Court has already found that "Plaintiffs have placed and will continue to place much emphasis on the FDA letters, and information regarding Plaintiffs' role in securing those letters or otherwise influencing the FDA's actions is plainly relevant to the defense." (Doc. 3312.) Additionally, communications and documents sent to a third party, and in particular a government agency subject to the Freedom of Information Act, are neither protected by the attorney-client privilege or the work-product doctrine. *Id.* (finding that "courts have widely held that communications with government regulators that might prompt government action that could prove beneficial in private litigation waive any work product protection"); *In re Pac. Pictures Corp.*, 679 F.3d 1121, 1126-27 (9th Cir. 2012) (finding that voluntarily providing privileged material to third parties will generally destroy attorney-client privilege).

3. The Information Is Crucial to the Preparation of the Case:[3] The plaintiffs incorrectly argue that Bard must prove that "the requested discovery relates to a core or

[3] This prong of the *Shelton* test appears to be where the plaintiffs aim their rhetorical questions: if the "Plaintiffs' counsel contact with the FDA [] spurred the FDA to investigate Bard . . . the question becomes 'so what?'"; and "Does Bard hope to argue

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crucial issue in the litigation." Pl. Opp. at 2. The *Shelton* element is significantly broader, however, and requires a showing that the discovery is crucial *to the preparation of the case*. If the information sought is more than relevant and is unavailable from alterative sources, then courts in the Ninth Circuit have deemed the information "crucial to the preparation of the case." *See, e.g., Ditech Financial LLC v. SFR Invesstments Pool 1, LLC*, No. 2:15-cv-476-JCM-VCF, 2016 WL 4370034, at *2 (D. Nev. Aug. 15, 2016) ("for information to be crucial, it must have some greater importance to the action than merely being relevant"); *XTO Energy, Inc. v. ATD, LLC*, No. CIV 14-1021 JB/SCY, 2016 WL 1730171, at *30 (D.N.M. Apr. 1, 2016) ("The requested discovery is therefore not crucial to Zurich Insurance's case" because they had alternative sources for the information).

Learning what Mr. Dalimonte and Mr. Brenes said and provided to the FDA is crucial to the preparation of Bard's case because the information is unavailable from other sources and bears directly on the biases and trustworthiness of the FDA Letters, which the plaintiffs are intent on making focal points at trial.[4] For example, shortly before FDA sent the July 2015 Warning Letter, Mr. Dalimonte sent an inflammatory e-mail to FDA making factual assertions about Bard and Bard's IVC Filters that Bard contends are false (Exhibit F, and block quoted above), providing the FDA with several cherry-picked internal Bard documents that were taken out of context, and suggesting that Bard's conduct concerning its IVC filters was criminal. The plaintiffs assume throughout their

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'our bad conduct and breach of laws and regulations would have never been discovered if the attorneys hadn't told on us?" *Id.* at 5, 6.

[4] Throughout the MDL, the plaintiffs have conducted significant discovery about the FDA Letters, including a two-day Rule 30(b)(6) deposition of Bard on the issues surrounding the FDA Letters (Bard 30(b)(6) Dep. Trs., Dec. 15, 2015 & Jan. 20, 2016), and questioning numerous current and former Bard employees about the FDA Letters and their contents (*see, e.g.*, Brett Baird Dep. Tr., 382:22 to 383:8, June 9, 2016; Judy Ludwig Dep. Tr., *passim*, July 27, 2016; William Little Dep. Tr., 250:4 to 253:15; 401:17 to 418:20, July 27, 2016; John Wheeler Dep. Tr., 127:7 to 164:24, July 29, 2016; Maureen Uebelacker Dep. Tr., 12:22 to 14:5; 95:10 to 107:4, Aug. 9, 2016). After all of this effort, however, the plaintiffs claim that they are changing tack, arguing in footnote 2 of their brief that "[a]dmissibility of FDA-related evidence is questionable in medical device cases cleared via the 510(k) process," citing *Cisson v. Bard*. Although Bard believes that *Cisson* is inapplicable to products like IVC filters, the plaintiffs' argument in this regard is premature and is not the issue before the Court.

briefing that the FDA Letters were "the results of the independent investigation of the FDA," Pl. Opp. at 6, but without knowing everything that Mr. Dalimonte and Mr. Brenes said and gave to the FDA—particularly given the inaccurate and inflammatory information they did give the FDA—the plaintiffs' argument is supposition.

The *Shelton* court's concern about the "harassing practice" and "an adversary trial tactic" of deposing an opposing counsel is clearly not the case here. Rather, Mr. Dalimonte and Mr. Brenes should not be able to prevent Bard from learning, for example, the full scope of what they said to the FDA about Bard using patients as guinea pigs, allusions to criminal conduct, and withholding safety information from the FDA when the statements and documents may have biased the FDA and impacted the trustworthiness of the FDA Warning Letter that the plaintiffs seek to make a focal point of the litigation. As the Court has already recognized, such communications with government regulators should not be protected from discovery, Or., Sept. 6, 2016 (Doc. 3312), and the Court should allow the depositions of Mr. Dalimonte and Mr. Brenes.[5]

CONCLUSION

For the foregoing reasons, the Court should allow the depositions of Mr. Dalimonte and Mr. Brenes.

[5] The Court should also note that the cases that the plaintiffs cite in their opposition briefing are distinguishable from the facts at issue here. First, the plaintiffs cite *Ditech*, where the court precluded the deposition of the defendant's in-house counsel when the plaintiff could have, but did not, seek the same, non-unique information that it sought from defendant's counsel from four non-attorney witnesses. Second, the plaintiffs cite *Rojas v. Marko Zaninovich, Inc.*, No. 1:09-cv-00705 AWI JLT, 2011 WL 2636071 (E.D. Cal. July 5, 2011), where the depositions of counsel "would add to, rather than duplicate—the quantum of information already known on this topic" and, although defendants claimed that the depositions would "undermine completely the confidence" in the documents at issue, there was no evidence that counsel had any role in undermining the reliability of the documents. Third, the plaintiffs cite *Boughton v. Cotter Corp.*, 65 F.3d 823 (10th Cir. 1995), where the Tenth Circuit affirmed a protective order to preclude the deposition of counsel where "the plaintiffs failed to seek the information they desired from other sources." As discussed above, and unlike the cases that the plaintiffs cite, Bard has exhausted every other avenue to obtain the information that it seeks, which is uniquely available to Mr. Dalimonte and Mr. Brenes given Bard's inability to obtain the information from the FDA. And the evidence to date suggests that counsel did, in fact, have a role in influencing the FDA by selectively providing Bard internal documents, and writing an accusatory and inflammatory e-mail about Bard to the FDA shortly before FDA issued a Warning Letter to Bard.

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DATED this 22nd day of December, 2016.

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CERTIFICATE OF SERVICE

I hereby certify that on December 22, 2016, the foregoing was electronically filed with the Clerk of Court using the CM/ECF system which will automatically send email notification of such filing to all attorneys of record.

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