UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

IN RE: ETHICON PHYSIOMESH FLEXIBLE COMPOSITE HERNIA MESH PRODUCTS LIABILITY LITIGATION	MDL DOCKET NO. 2782 CIVIL ACTION NO. 1:17-md-02782-RWS
THIS DOCUMENT RELATES TO ALL CASES	

PLAINTIFFS' RESPONSE IN OPPOSITION TO DEFENDANTS' MOTION FOR PROTECTIVE ORDER REGARDING CONTACTS WITH TREATING PHYSICIANS

COME NOW, Plaintiffs and file their Response in Opposition to Defendants' Motion for Protective Order Regarding Contacts with Treating Physicians (Doc. 272), and show the following:

Argument and Citation of Authority

Because Plaintiffs bear the burden of proof, it is not only appropriate, but incumbent upon Plaintiffs' counsel to fully prepare their cases by eliciting information bearing on the legal issues in this litigation from all available sources – particularly from the Plaintiffs' treating doctors. To prevent Plaintiffs' counsel from discussing matters directly relevant to this litigation within these unique fact witnesses' exclusive knowledge would run counter to the very efficiency and economy that this MDL is intended to serve. Such limitations would severely and

unfairly restrict the Plaintiffs' ability to properly prepare their case and meet their burden of proof. Defendants' "inequity" argument is likewise unfounded; Defendants, through their sales, training and marketing representatives, have had regular interactions with these doctors for years without limitations, and those relationships and communications are on-going. Moreover, there is simply no legal basis to so limit Plaintiffs; Defendants' motion should be denied.

Plaintiffs and Defendants are in agreement in at least one respect: Plaintiffs' treating doctors are "critical" and "uniquely important" fact witnesses in this litigation, and not solely related to their treatment of the Plaintiffs. (Doc. 272, pp. 1 and 2). Therefore, Plaintiffs should not be limited to discussing their medical treatment, as Defendants urge here. As an example, Plaintiffs should not be restricted from addressing with their doctors matters bearing on the defenses presented in these cases relative to doctor fault and/or improper patient selection. In their Master Answer, for example, Defendants raise several "defenses" pointing the finger at the Plaintiffs' treating physicians,[1] or at least implicitly blaming the

[1] *See*, Ethicon Master Answer (Dkt. No. 266), 47th Defense ("[T]he sole proximate cause of the injuries and/or damages alleged by plaintiffs was the action, omissions or negligence of a person or persons, other than Ethicon, for whose actions, omissions or negligence Ethicon is in no way liable."); 54th Defense ("Plaintiffs' alleged injuries, losses, or damages…were solely caused by and attributable to the abnormal, unforeseeable, unintended, unreasonable, and improper use or misuse which was made of said product."); 55th Defense (intervening or superseding cause); 56th Defense ("Plaintiffs' alleged injuries, losses, or damages…were caused by the acts or omissions of third parties for which Ethicon has no legal responsibility."); 67th Defense ("the product at issue was altered after the product left the control…of Ethicon, and said alteration relieves Ethicon of any and all liability.").

doctor for selecting an improper patient.[2] The treating doctors' knowledge, skill, training and experience in implanting the Physiomesh product, selecting and advising patients, and treating Physiomesh complications will be scrutinized by the defense. Therefore, Plaintiffs' counsel have an obligation to inquire about these matters. What information was known or available to Defendants regarding patient risk factors and selection, causes and treatment of complications, and surgical qualifications, technique and training, and whether or not such information was provided to Plaintiffs' physicians, is crucial to this inquiry.

Perhaps most importantly, however, Plaintiffs should not be limited in their ability to address Defendants' failure to warn, and the related "learned intermediary" doctrine, about which Defendants agree Plaintiffs' doctors are *the* critical fact witnesses. (Doc. 272, pp. 2-4). Because, Plaintiffs contend, the Defendants knew of risks, complications and defects associated with Physiomesh that they failed to disclose to Plaintiffs' doctors, this information bears directly on the failure to warn and learned intermediary issues presented in these cases. What the physician was told – or *not* told – by the Defendants in light of Defendants'

[2] *See*, Ethicon Master Answer (Dkt. No. 266), 58th Defense ("Plaintiffs' causes of action are barred because the injuries and damages allegedly suffered in this action…were due to…preexisting condition, and/or another unrelated medical, genetic or environmental condition, disease or illness….").

knowledge are important questions of fact.[3] Likewise, what these doctors would have done had they been made aware of information known to the Defendants (whether or not the doctor would have implanted the Physiomesh, or counseled the patient differently) are fundamental questions with respect to the failure to warn claims in these cases. The only way for Plaintiffs to address these issues in preparation is to ask the doctor "did you know 'x' and 'y' that Defendants knew (about the Physiomesh risks, complications and/or defects)," and "would this information have made any difference in how you treated or advised this patient?" It is not only appropriate, it is necessary for Plaintiffs to address these important issues with Plaintiffs' treating physicians in preparing these cases for trial.[4]

Moving to restrict Plaintiffs' counsel's communications with their clients' treating physicians has become a routine defense practice in pharmaceutical and

[3] As set forth in *In re: Avandia Marketing, Sales Practices and Prods. Liab. Litig.*, 817 F.Supp.2d 535, 547 (E.D.Pa.2011), "the adequacy of a warning [under several states' laws] is determined based on what a manufacturer knew or should have known about a given risk at the time a patient is prescribed the drug or the cause of action arose, and whether the label warned of that risk. A manufacturer is not excused if it remains purposefully ignorant of a particular risk. The duty to warn is thus a continuing one, and obligates a manufacturer to conduct research and otherwise investigate risks associated with its products, and then update warnings as appropriate."

[4] *In re Levaquin Prod. Liab. Litig.*, 2012 U.S. Dist. LEXIS 116088, *2 (D.Minn. Aug. 17, 2012) (In denying motion to restrict plaintiffs' discussions with treating doctors, MDL court noted that "[t]o determine what information the [medical] provider does and did possess concerning the treatment of a plaintiff…, some discussion of the physician's knowledge of the risks of [the product], and when and how they became aware of those risks is appropriate," and therefore "some discussion of the scientific literature, product labels, or Plaintiffs' theory of liability may be necessary.").

medical device product liability MDLs. As discussed below, courts in other mesh device MDLs – including a Georgia MDL involving another J&J subsidiary, and another MDL which actually involved these same Defendants and defense counsel here – have uniformly refused to impose the sorts of limitations on plaintiffs' communications with their clients' physicians and what can be shown to these doctors. These holdings are consistent with the overwhelming majority of MDL courts that have addressed these issues.

Several other courts presiding over MDLs involving other surgical mesh devices have addressed similar attempts by defendants to restrict plaintiffs' communications with their doctors. In the *In re: Kugel Mesh Hernia Repair Patch Litig.*, another hernia mesh product liability MDL, the court first denied the defendants' motion seeking *ex parte* contact with plaintiffs' doctors, holding that "the just option…is to protect the relationship between a doctor and patient by restricting defendants from conducting *ex parte* communications with plaintiffs' treating physicians but allowing plaintiffs' counsel to engage in *ex parte* interviews with those doctors who have not been named as defendants." 2008 WL 2420997, *1 (D.R.I. 2008).[5] The court in *Kugel* relied on *In re: Vioxx Prods. Liab. Litig.*,

[5] Although Defendants' motion seeks to limit *Plaintiffs'* communications with treating doctors, they also make a cursory claim that *Defendants* should be allowed to communicate *ex parte* with Plaintiffs' treating doctors. (Doc. 272, § III). Plaintiffs have moved separately to preclude Defendants' *ex parte* communications (Doc. 271), and simply note here that the weight of MDL authority prevents defendants from contacting plaintiffs' treating physicians, with narrowly limited exceptions. *Kugel*, 2008 WL 2420997, *1; *Vioxx*, 230 F.R.D. 473, 477; *In re Xarelto*

230 F.R.D. 473, 477 (E.D.La. 2005). In rejecting the same "level playing field" argument raised by Defendants here, the MDL court in *Vioxx*, *supra*, observed that "[a]s a practical matter, the Defendants already have information, including documentation, regarding what its representatives told the treating physicians about [the subject devices]. Therefore, the Defendants don't need the doctors to tell them in ex parte conferences what they already know." Another MDL Judge recently put it more bluntly, stating "it is disingenuous for defendants to ask to be put on 'equal footing' with plaintiffs when to date the physicians have been subject to defendants' marketing communications which likely extolled the benefits of their [products]." *In re Benicar (Olmesartan) Prod. Liab. Litig.*, 2016 WL 1370998, *4 (D.N.J. Apr. 6, 2016).

The *Kugel* MDL defendants later filed a "Motion to Define the Scope and Subject Matter of Plaintiffs' Ex Parte Contact With Treating Physicians" which, like Defendants' present motion, sought to restrict Plaintiffs' communications with

(Rivaroxaban) Prod. Liab. Litig., 2016 WL 915288, *6-*8 (E.D.La. Mar. 9, 2016) (discussing general rule that defendants are prohibited from *ex parte* communications with plaintiffs' doctors, and the "limited exceptions" that some MDL courts have allowed (i.e., hiring experts, but only with specific restrictions)); *In re Abilify (Aripiprazole) Prod. Liab. Litig.*, 3:16-md-02734 (N.D.Fla. Mar. 9, 2017) (copy attached as **Exhibit 1**) (defense counsel generally prohibited from ex parte communications, except within narrow confines of order); *In re Invokana (Canagliflozin) Prod. Liab. Litig.*, C.A. No. 3:16-md-2750 (D.N.J. May 30, 2017) (CMO No. 13, copy attached as **Exhibit 2**) (J&J agreeing that "Defendants' counsel…are not permitted to engage in ex parte communications with Plaintiffs' prescribing/treating healthcare providers.").

their physicians. The court in *Kugel* rejected the defense's arguments, concluding that "Defendants' proposed limitations are unnecessary and unworkable" and observing that "Defendants do not specifically identify any substantial prejudice or injustice resulting from the challenged contacts," and that the limitations proposed would be difficult to monitor and would generate unnecessary "side-litigation." (A copy of the Jan. 12, 2012 *In re: Kugel* Order is attached hereto as **Exhibit 3**).

The issue of whether Plaintiffs should be restricted in their meetings with their doctors was also addressed in the transvaginal mesh ("TVM") MDLs, several of which were coordinated in the Southern District of West Virginia. Ethicon and J&J were defendants in one of the West Virginia TVM MDLs.[6] When Bard, another of the TVM defendants, moved to restrict Plaintiffs' ability to meet with their doctors, the TVM MDL Magistrate Judge denied the motion, reasoning as follows:

> Neither a statute nor a rule suggests that such limits are appropriate; in fact it is accepted that attorneys are expected to prepare their witnesses for the rigors of giving testimony…. It is important to develop facts as to what the defendants knew about their products' effects on women's pelvic organs and when they knew those facts.

[6] As the Court is aware, these Defendants produced documents related to their hernia repair mesh products, including Physiomesh, in the TVM litigation – where Defendants were represented by the Butler Snow firm, their defense counsel here. In PPO # 4 (Doc. 269), Defendants agreed to produce these documents to Plaintiffs here, subject to the confidentiality agreement entered in the TVM MDL. Given that Defendants and their counsel (as well as many of the Plaintiffs' counsel involved in this MDL) have operated under this TVM confidentiality agreement and rulings with respect to these "*ex parte* communication" issues in similar litigation for the past several years, Plaintiffs submit that the TVM MDL court's analysis and treatment of these issues is particularly instructive here.

> Contents of corporate documents and statements of sales representatives to treating physicians and surgeons are appropriate areas of inquiry as to whether full disclosure would have changed a doctor's mind about implanting a pelvic mesh product. (Aug. 3, 2012 MDL 2187 Pretrial Order #48, copy attached hereto as **Exhibit 4**) (Emphasis added).

In *In re Mentor Corp. ObTape Transobturator Sling Prod. Liab. Litig.*, a TVM device MDL pending before the Hon. Clay D. Land in the Middle District of Georgia, the defendant filed a motion seeking to restrict communications between plaintiffs' counsel and their clients' treating doctors. The defendant in that MDL, Mentor Corp., is another J&J subsidiary. Citing to the decisions in *Vioxx* and the *Bard* TVM MDL, Judge Land stated that he "finds their rationale persuasive and adopts it," and denied the J&J subsidiary defendant's motion. *In re Mentor Corp. ObTape Transobturator Sling Prod. Liab. Litig.*, 2015 WL 12990485 (M.D.Ga. May 28, 2015).

Notwithstanding these instructive rulings, Ethicon and J&J filed another motion in the Ethicon TVM MDL, again seeking to limit any communications between Plaintiffs' counsel and their treating physicians to only matters related to their medical treatment (the same motion they filed here).[7] The TVM MDL court rejected these same arguments, and denied these Defendants' motion. (Oct. 13,

[7] Defendants' failure to mention this ruling or any of the other mesh MDL rulings addressing the same issues, including a Georgia MDL involving another J&J subsidiary, is conspicuous.

2015 MDL 2327 Pretrial Order # 197, copy attached hereto as **Exhibit 5**). In denying these Defendants' motion, the court reasoned as follows: (1) no statute or rule would support such a limitation on Plaintiffs' contacts with their treating doctors; (2) limiting the scope of Plaintiffs' counsel's communications with physicians would unfairly impair Plaintiffs' ability to prepare their case; and (3) the defendant can explore the subject of any communications with Plaintiffs' counsel by way of deposition. *Id.* Defendants' same arguments rehashed here fail for the same reasons.

While these rulings from other mesh device MDLs are persuasive here, they are far from the only MDL decisions addressing the sort of restrictions urged by Defendants here. With very few exceptions, MDL courts have refused to impose the sort of limitations urged by these Defendants.[8] Indeed, in a recent MDL

[8] *In re Prempro Prod. Liab. Litig.*, 4:03-cv-01507-BRW (E.D.Ark. Sept. 28, 2005) (copy attached as **Exhibit 6**) (plaintiffs allowed to meet *ex parte* with treating doctors and discuss documents produced by defense, provided documents shown to doctors identified prior to deposition); *In re Yasmin and Yaz (Drospirenone), etc., Prod. Liab. Litig.*, 3:09-md-01200 (S.D.Ill. Mar. 4, 2011) (copy attached as **Exhibit 7**) (denying defendants' motion to limit plaintiffs' counsel's meetings with their physicians); *In re Levaquin Prod. Liab. Litig.*, 2012 U.S. Dist. LEXIS 116088 (D.Minn. Aug. 17, 2012) (denying defendants' motion seeking to prohibit plaintiffs from discussing scientific literature, product labels or plaintiffs' theories of liability with physicians); *In re E.I. DuPont de Nemours and Co. C-8 Personal Injury Litig.*, 2:13-md-2433 (S.D.Ohio May 16, 2014) (copy attached as **Exhibit 8**) (denying defense motion to restrict plaintiffs from discussing with physicians "matters outside the scope of their treatment of Plaintiffs"); *In re Testosterone Replacement Therapy Prod. Liab. Litig.*, 167 F.Supp.3d 936 (N.D.Ill. Mar. 7, 2016) (defense motion seeking to impose limitations on plaintiffs' ability to communicate with treating physicians denied, and noting number of other MDL courts in agreement); *In re Xarelto*, 2016 WL 915288 (E.D.La. Mar. 9, 2016) (denying defendants' motion to limit the scope of *ex parte* contacts by plaintiffs with their doctors); *In re Benicar*, 2016 WL 1370998 (D.N.J. Apr. 6, 2016) (denying defendants' motion to limit plaintiffs' ex parte

involving J&J's drug Invokana, J&J and its subsidiaries actually **agreed in writing** that plaintiffs' counsel could provide treating physicians with documents not previously seen by the healthcare providers, including research documents, scientific studies and related materials, internal defendant documents, documents identified as confidential, and product warnings or labels, "and may inquire into how said documents might have changed the healthcare providers' prescribing/treating decisions, if at all." *In re Invokana* (**Exhibit 2**). J&J's written agreement in the *Invokana* MDL that plaintiffs' counsel are allowed to do precisely what it urges the Court to prevent Plaintiffs' counsel from doing in this MDL only underscores the invalidity of Defendants' position here.

While ignoring the decisions from every other federal mesh device MDL and nearly every other MDL to consider these issues, Defendants cite to the few MDL cases where courts have restricted a plaintiff's counsel's ability to communicate with their clients' doctors.[9] Actually, in one of the cases cited by

communications with treating physicians); *In re Bard IVC Filters Prod. Liab. Litig.*, 2:15-md-02641 (D.Ariz. Feb. 6, 2017) (Docket Entry 4865 - Text order denying motion to limit plaintiffs' communications with physicians, and noting weight of recent authority denying similar proposed restrictions (copy attached as **Exhibit 9**)); *In re Abilify* (**Exhibit 1**) (plaintiffs can meet ex parte with physicians and show documents, provided documents identified before deposition).

[9] Defendants' reliance on New Jersey state trial court opinions is not persuasive here in light of the ample federal product liability MDL authority addressing these issues, including a recent New Jersey federal MDL decision (*Benicar*). Defendants' reliance on *Kilgore v. Synthes USA, LLC*, 2013 WL 12180604 (S.D.Ga.2015), a non-MDL case, is misplaced; plaintiffs' counsel there voluntarily agreed that neither party would communicate with doctors *ex parte*. The *In re Propecia* decision attached to Defendants' brief (Doc. 272-3) also does not support Defendants' position here; the court in *Propecia* expressly denied a defense motion seeking to limit the scope

Defendants, *In re NuvaRing Prod. Liab. Litig.*, 2009 WL 775442 (E.D.Mo.2009), the plaintiffs agreed that their discussions with physicians would be limited to the plaintiffs' medical condition, and the court held that this agreed limitation would apply. While the courts in *In re Ortho-Evra Prod. Liab. Litig.*, 2010 WL 320064 (N.D.Ohio 2010), *In re Chantix (Varenicline) Prod. Liab. Litig.*, 2011 WL 9995561 (N.D.Ala.2011), *In re Mirena IUD Prods. Liab. Litig.*, 2014 WL 11149641 (S.D.N.Y. 2014), entered orders imposing limitations on plaintiffs' counsel, no reasoning was provided by any of these courts. As other MDL courts have recognized in recent opinions, these outlier opinions provide no reasoning, and are contrary to the vast majority of MDL courts that have considered these issues.[10]

Based on the foregoing argument and citation of authority, and for the reasons shown here, Defendants' motion should be denied.

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of plaintiffs' discussions with their doctors.

[10] *See, e.g.*, *In re Testosterone Replacement Therapy*, 167 F.Supp.3d 936, 938 ("The Court is unpersuaded by [the defendant's] contentions" based on *Chantix*, *Ortho-Evra* and *Nuva-Ring*, and noting that "[i]n declining to impose the restrictions sought by [defendant], the Court finds itself in agreement with those courts in MDL litigation that have similarly declined to preclude plaintiffs' attorneys from unsupervised pre-deposition contacts with their clients' treating physicians."); *In re Xarelto*, 2016 WL 915288 at *4 (noting that neither *Ortho-Evra* nor *Chantix* "provide an explicit rationale for excluding discussion of liability theories from ex parte contacts between Plaintiffs' attorneys and prescribing or treating physicians," and decisions are contrary to "great weight of reasoning and persuasive authority"); *In re Bard IVC Filters* (**Exhibit 9**) ("The Court has reviewed cases cited by both sides, and finds that the weight of recent case law disfavors such limitations. Cases imposing such limitations [*Ortho-Evra*, *Chantix*, and *Nuvaring*] are older than these recent cases and generally lack analysis in support of the limitations they impose. The Court finds the more recent decisions persuasive.").

This 8th day of November 2017.

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FONT CERTIFICATION

Pursuant to Local Rule 7.1D, I hereby certify that the foregoing document was prepared using Times New Roman 14 point type as provided in Local Rule 5.1.

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CERTIFICATE OF SERVICE

I hereby certify that on November 8, 2017, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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