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Superior Court of Massachusetts,
Middlesex County.
In re PELVIC MESH **GYNECARE** LITIGATION.

No. 13–4903.
April 9, 2014.

MEMORANDUM OF DECISION AND ORDER ON MOTIONS TO QUASH SUBPOENAS

DIANE M. KOTTMYER, Justice.

INTRODUCTION AND PROCEDURAL HISTORY

*1 On November 12, 2013, Plaintiffs in the consolidated action entitled *In re Pelvic Mesh/* ***Gynecare*** *Litigation,* Atlantic County New Jersey Superior Court, Master Case No. L–6341–10, Case No. 291, filed a Petition for Order Allowing the Service of Deposition Subpoenas Ad Testificandum and Duces Tecum in the Middlesex Superior Court pursuant to G.L. c. 223 A, § 11. They sought to depose Gregory J. Curfman, M.D., Executive Editor of the New England Journal of Medicine (the "NEMJ" or the "Journal"), and Jeffrey Drazen, M.D., its Editor–in–Chief (the "Deponents"). The requested discovery relates to an article entitled *Anterior Colporrhaphy Versus Transvaginal Mesh for Pelvic Organ Prolapse* (the "Article") that was published in the NEMJ on May 12, 2011. [FN1]

FN1. Daniel Altaian et al., *Anterior Colporrhaphy Versus Transvaginal Mesh for Pelvic Organ Prolapse,* 364 New Eng. J. Med. 1826 (2011).

On November 13, 2013, this Court (Curran, J.) entered an order authorizing the service of subpoenas on Drs. Drazen and Curfman. After allowing the petition, the Court dismissed the action. On November 27, 2013, Drs. Curfman and Drazen filed a Notice of Intent to File Motion to Quash Subpoenas and, on January 24, 2014, a Motion to Vacate the Dismissal to Hear Motion of Drs. Drazen and Curfman to Quash Subpoenas. The motion was allowed on January 24, 2014, and the matter was referred to the undersigned.

In their Memorandum in Support of the Motion to Quash, the Deponents argue that the subpoenas are unreasonable, oppressive and burdensome because 1) the Deponents have no specific knowledge of the facts relating to the underlying litigation and no specific recollection of the scientific content of the Article; 2) the subpoenas seek documents and information that should be kept confidential, *e.g.,* peer review comments; and 3) the subpoenas seek information and documents that are irrelevant to the underlying litigation and can more easily be obtained elsewhere.

In response, the Plaintiffs filed a Memorandum in Opposition supported by exhibits establishing the relevance of the subpoenaed information and documents. They further argued that there are no applicable privileges under Massachusetts law. Plaintiffs noted that they do not have an alternate source for the information because the principal author of the study reported in the article, Dr. Daniel Altaian, is in Europe and not subject to process. In a Reply filed on January 31, 2014, the Deponents, citing *Matter of Pappas.* 358 Mass. 604, 612 (1971), aff'd. sub nom. *Branzburg v. Hayes,* 408 U.S. 665, 92 S.Ct. 2646, 33 L.Ed.2d 626 (1972), argued that the First Amendment applies and that the public interest in protecting the free flow of information to the press outweighs the public interest in everyman's evidence.

After reviewing the papers, the Court inquired of counsel through the Assistant Clerk whether, given the complexity of the litigation and the issues raised by

the motions to quash, it would not make more sense to have the motions heard by the New Jersey Superior Court handling the underlying cases, *i.e.,* the court that issued the letters rogatory. The Deponents responded as follows on February 19, 2014, in a pleading entitled "Movants' Response to Court's Inquiry Regarding the Pending Motion to Quash Subpoenas":

> ***2** In the context of the motion to quash, the answer is a resounding "no." The motion involves important Massachusetts constitutional rights, raises important issues of Massachusetts civil procedure, and is necessary to curtail abuses of the Massachusetts subpoena process by over-reaching out-of-state litigants.

The Deponents pointed out that the New Jersey Superior Court could not compel their presence and indicated that they were unwilling to go to New Jersey to contest the subpoena. Thereafter, a hearing was scheduled.

On February 24, 2014, the Court gave the Deponents leave to file a Supplemental Memorandum in Support of their Motion to Quash Subpoenas. For the first time, the Deponents argued that New Jersey's Shield Law, N.J. Stat. Ann. 2A:84A–21, which they assert establishes an absolute privilege to refuse to testify about editorial decision-making, applies and that it would therefore "be futile to require them to attend a deposition where they will assert the statutory privilege in response to any questions regarding editorial decisions" relating to publication of the Article and the Correction. The Plaintiffs filed an opposition noting that, consistent with the Deponents' original position, Massachusetts law governs depositions taken in Massachusetts pursuant to G.L. c. 223A § 11 and Massachusetts does not recognize a privilege for the sources of and information gathered for publication.

THE RECORD

A. *The NEMJ*

The NEMJ is weekly journal owned and published by the Massachusetts Medical Society ("MMS") that reaches over 600,000 medical professionals. It is the most frequently cited medical journal in the world and thousands of healthcare practitioners and institutions rely on information published in the Journal to follow developments in medical research and to improve patient care. (Ex. 3) [FN2] The Journal is described as "the gold standard for quality biomedical research and for the best practices in clinical medicine." (Ex. 4). It is viewed by over two million online users and studies published in the NEJM receive extensive coverage in the news media worldwide. (Drazen Aff. ¶¶ 3–5) The NEJM is known for its stringent standards. All scientific reports in the NEJM are subject to peer review, *i.e.,* all articles are analyzed and screened by experts in the subject matter discussed in the Article. (*Id.* ¶ 7) The peer reviewers are volunteers who are asked to provide confidential, frank, honest evaluations of a manuscript's scientific validity and their opinions whether it is worthy for publication; they are assured that their identity, comments and opinions will be confidential. (*Id.* ¶ 7, 8; Ex. 6). The peer review system, based on a network of academic reviewers used by NEJM, represents a key step in determining whether a manuscript is worthy of publication in the Journal and is critical to the process of scientific review of new research. Drazen Aff. ¶ 7. At the same time,

> FN2. Unless otherwise specified, citations are to the exhibits to the Affidavit of Adam M. Slater, Esq.

> ***3** Publication of clinical research findings in respected peer-reviewed journals is the ultimate basis for most treatment decisions. Public discourse about this published evidence of efficacy and safety rests on the assumption that clinical-trials data have been gathered and are presented in an objective and dispassionate manner. This discourse is vital to the scientific practice of medicine because it shapes treatment decisions made by physicians and drives

public and private health care policy." Ex. 7 (NEMJ Editorial 9/13/01)

Concern about the financial relationships between corporate sponsors and investigators conducting clinical trials led the NEMJ to require authors to disclose "the sponsor's role in study design; in the collection, analysis and interpretation of data; in the writing of the report, and in the decision to submit for publication ." (Ex. 7) If the sponsors had no such role, authors are required to so state. *Id.* The NEJM has established these policies "to ensure that authors disclose all relevant financial associations and that these financial associations do not influence the published content." (Ex. 8)

B. *The Relevance of the Subpoenaed Testimony and Documents*

The cases in which the depositions are sought are products liability cases involving a pelvic mesh device called the Prolift Pelvic Floor Repair System (the "Prolift System") manufactured and marketed by Ethicon, Inc., ("Ethicon"), a subsidiary of Johnson & Johnson, for use in surgery to treat a condition known as pelvic organ prolapse. The Plaintiffs (in excess of one thousand in the consolidated New Jersey cases) claim that the device was defective and they suffered severe complications after surgery, including erosion of the mesh implanted during surgery. Their claims include design defect and inadequate warnings.

The Prolift System was first marketed in March 2005. In February of 2007, a Practice Bulletin was published by the American College of Obstetrics and Gynecology ("ACOG") in its medical journal which stated, in part, that pelvic mesh procedures should be considered "experimental." Plaintiffs obtained documents in discovery establishing that physicians who were consultants paid by Ethicon were instrumental in causing a revised Practice Bulletin to issue which omitted the word "experimental."

On October 20, 2008, the Food and Drug Administration ("FDA") issued a public health notice warning of complications following pelvic mesh surgery. (Ex. 23) In August of 2010, an article entitled "*Vaginal Mesh for Prolapse* " was published in ACOG's medical journal reporting the findings from a randomized controlled trial ("RCT") comparing Prolift implant surgery to traditional colporrhaphy surgery and reporting that the study was halted "due to a predetermined stopping criteria for vaginal mesh erosion," identified as a mesh erosion rate of 15%.

On May 12, 2011, the NEMJ published the Article. Consistent with its policies, the Article contained the following conflict disclosure:

> ***4** The manufacturer of the mesh lift [Ethicon] did not provide the products used in this trial and had no *involvement* in the study design, data collection, and analysis, the writing of the manuscript or the decision to submit the results for publication.
>
> (emphasis added) (the "Disclosure").

In the Disclosure as published, the word "involvement" was substituted for the word "influence" which was used in the final draft of the Article that was reviewed by Ethicon.

On July 13, 2011, the FDA issued an update of the 2008 public health notice in which it identified pelvic mesh surgery for POP [pelvic organ prolapse] as "an area of continuing serious concern." (Ex. 24) The Update advised that complications are not rare and "it is not clear that transvaginal POP repair with mesh is more effective" than traditional non-mesh repair in all patients with POP. (*Id.*) In testimony before a panel of the FDA's Medical Devices Advisory Committee in September of 2011, Piet Hinool, Ethicon's Medical Affairs Director for Women's Health and Urology, described the Article as a "landmark article" and stated that the study reported in the Article "provides

Level I evidence and is a clear indication that transvaginal mesh kits are a valuable treatment option from both an anatomic as well as a functional viewpoint...." (Ex. 32 at 143–144) Ethicon relied on the article notwithstanding its knowledge that the Disclosure did not accurately describe its involvement in the study design and in reviewing and commenting on drafts of the manuscript that was ultimately submitted to the NEMJ.

Materials obtained by Plaintiffs' counsel during discovery established that Ethicon was a co-sponsor of the study and, in that capacity, had paid $750, 00 to Dr. Daniel Altman, the lead investigator and principal author of the Article. Further, Ethicon had direct input in the design of the study, reviewed drafts of the Article and offered comments and suggestions relating, *inter alia,* to the presentation and interpretation of data resulting from the study. By way of example, in one e-mail dated August 19, 2010, to Hinool and others at Ethicon who had reviewed and commented the manuscript, Dr. Altman states: "I have performed most of the suggested changes, but not all." (Ex. 27) On December 6, 2012, Plaintiffs' counsel sent a letter to Dr. Drazen, enclosing documents and deposition testimony relating to the accuracy of the Disclosure. On January 24, 2013, NEJM published a correction as follows:

> In the Study Design subsections of Methods, the final paragraph ... should have read,
>
> As co-sponsor of the trial, the manufacturer of the mesh kit reviewed the original study protocol and a pre-submission draft of the manuscript. The manufacturer did not provide the products used in the trial and had no involvement in data collection and analysis or in the decision to submit the results for publication.
>
> (Ex. 2) (the "Correction").

DISCUSSION

1. *Applicable Law*

***5** Section 11 of G.L. c. 223A provides that a Massachusetts court may order a person within the state to testify and produce documents for use in a tribunal outside the state.[FN3] It continues:

> FN3. Massachusetts is one of a handful of states that adopted the Uniform Interstate and Intentional Procedure Act, § 302. The Uniform Act was withdrawn in 1977. In 2007, the National Conference of Commissioners on State Laws approved a new Uniform Interstate Deposition and Discovery Act. The Prefatory Note to the Act recognizes: "Perhaps the most difficult issues are whether the trial state or discovery state should determine issues of privilege, and which state's privilege law will apply." National Conference of Comm'rs on Unif. State Laws, Unif. Interstate Depositions and Discovery Act, Prefatory Note, § 2(j) (2007).

> The order may be made ... in response to a letter rogatory and may prescribe the practice and procedure, which may be wholly or in part the practice and procedure of the tribunal outside this Commonwealth, for the taking of the testimony or statement or producing the documents or other things. To the extent that the order does not prescribe otherwise, the practice and procedure shall be in accordance with that of the court of this Commonwealth issuing the order.

The Plaintiffs did not request, and the order authorizing issuance of the subpoenas does not provide for, application of New Jersey practice and procedure. Absent such a provision, the determination whether Massachusetts or New Jersey law governs the existence of a privilege should be resolved by reference to Massachusetts conflict of laws. In *Moses v. Albert Einstein Med. Ctr.,* 25 Phila. 389, 413 (Pa. Ct. Common Pleas March 30, 1993), the Court, citing Mullin,

Interstate Deposition Statutes: Survey and Analysis, 11 Balt. L.Rev. 1, 2 & n.n. 6–7 (1981), explained:

> When required to make a ruling on these subjects, discovery state courts apply their own doctrine including, when appropriate, their conflict of laws doctrine. The explanation can be traced to the fact that using any other doctrine would deprive the discovery state court of the "flexibility" that might be needed to protect their own domiciliary in "certain situations."

In *Bushkin Associates Inc. v. Raytheon Co.,* 393 Mass. 622 (1985), the Supreme Judicial Court adopted the "most significant relationship analysis" in accord with the general principles of the Restatement (Second) of Conflicts of Laws (1971). Applying traditional conflicts principles, Massachusetts clearly has the more significant relationship to the issue whether the NEMJ peer review and editorial decision making processes should be protected from disclosure. The Journal is owned by the Massachusetts Medical Society and is published in Massachusetts. Its offices are in Massachusetts. Manuscripts are submitted to editors in Massachusetts, comments of peer reviewers are received and discussed in Massachusetts and editorial decisions are made in Massachusetts. In contrast, New Jersey's connection to the issue whether a privilege apples to the subpoenaed discovery rests on the happenstance that the consolidated cases are pending in one of its courts.[FN4]

> FN4. Of course, the *admissibility* in evidence of documents and information provided by Deponents will be determined by the New Jersey Superior Court. See, *e.g., United States v. de la Jara,* 973 F.2d 746, 749 (9th Cir.1992) (compelled disclosure of an allegedly privileged item is not a waiver, and a compelled disclosure in one forum does not abrogate the privilege in any other forum.).

2. *Privilege Under Massachusetts Law*

The Deponents seek application of a privilege for information gathered for publication in the Journal and editorial decision-making. The Supreme Judicial Court has refused to create a privilege for news reporters' sources of information or for information gathered by reporters, advocating instead a common law approach as "more likely to result in principles that are flexible enough to maintain an appropriate balance between the competing interests involved ..." *Petition for the Promulgation of Rules Regarding the Protection of Confidential News Sources & Other Unpublished Information,* 395 Mass. 164, 171 (1985). A party seeking to avoid disclosure must first "make some showing that the asserted damage to the free flow of information is more than speculative or theoretical." *Id.* at 172, citing *Matter of Roche,* 381 Mass. 624, 635 (1980), and *Matter of Pappas, supra* 358 Mass. at 612. If the threshold showing is satisfied, the court will balance "the public interest in every person's evidence and the public interest in protecting the free flow of information," in order to determine whether disclosure should be prevented. *Id.* at 172, citing *Commonwealth v. Corsetti,* 387 Mass. 1, 5–6 (1982). In making this determination, the Court balances the Plaintiffs' need to know the subpoenaed information against the public interest in the free flow of information. *Ayash v. Dana Farber Cancer Inst .,* 443 Mass. 367, 403–404 & n. 33 (2005).

3. *Rule 26(b)(3)*

***6** Mass. R. Civ. P. 26(b) states in part that a party may obtain information "which is relevant to the subject matter involved in the pending action." Under Rule 26, information that is "reasonably calculated to lead to discovery of admissible evidence" is subject to discoverable. Mass. R. Civ. P. 26(b)(1). I recognize that the New Jersey trial court may apply the New Jersey Shield Law and exclude some or all of the evidence produced in response to the subpoenas. See n. 4, *supra.* Under section 11, however, the Massachusetts rules apply and I find that the evidence Deponents are being required to produce detailed below

is reasonably calculated to lead to the discovery of admissible evidence.

4. *The Balance of Competing Interests*

I find that the Deponents have satisfied their burden with respect to the issue whether identity of peer reviewers and internal discussions of the scientific merits of the Article should be protected from disclosure. The comments of peer reviewers on the scientific merits of the study and internal deliberations among editors relating thereto have little, if any, probative value. The editors are non-party fact witnesses and plaintiffs have no right to their opinions or to those of the peer reviewers regarding the scientific merits of the study. Any probative value of such discussions is outweighed by the fact that disclosure would have a detrimental effect on the peer review process which is "critical to the process of scientific review of new research." Drazen Aff. ¶ 7. However, the same is not true of communication between the editors and the authors of the study. In such communications, peer review comments "are reviewed, redacted and modified as needed by the editors assigned to the manuscript so as to preserve the confidentiality of the peer reviewer's identity." Drazen Aff. ¶ 20. The authors' responses to the questions posed by the editors are relevant, *e.g.*, to the extent to which Ethicon's concerns, comments and suggestions were incorporated in Dr. Altman's responses to the editors' questions. Based on the record, there is no impediment to disclosure of these communications by the authors. Moreover, nothing in the record suggests that any peer reviewer was involved in internal and external communications concerning the wording and adequacy of the Disclosure, the decision to publish a Correction and the wording and content of the Correction.

The claims asserted by the Plaintiffs in the New Jersey case include design defect and inadequate warnings. Both sides will rely on experts and, in the ordinary course, an article published in the NEMJ favoring defendants' position would be used to cross-examine the plaintiffs' experts. Because it is held in such high regard, publication of an article in the NEMJ carries with it an assurance of scientific merit. To the extent that the motion to quash is denied as set forth below, I find that the subpoenaed information is relevant to the reliability of the results of the study as reported in the NEMJ. Dr. Altman and the investigators are all located in Europe and plaintiffs cannot more easily obtain the information from them.

*7 In conclusion, I note that, apart from testimony and documents that would disclose, directly or indirectly, the identity of peer reviewers and internal discussions concerning the scientific merits of the manuscript that are not communicated to the authors, there is no conflict between the right to everyman's evidence and the public interest in the free flow of information. As noted, articles in the NEMJ are relied on by health care professionals in making treatment decisions and the FDA in regulating medical devices. As recognized by the NEMJ, disclosure of conflicts and potential conflicts on the part of the investigators are matters of public interest not only to practitioners and researchers in the medical speciality in question, but also, given the wide dissemination in the mass media of studies reported in the NEMJ, to the general public. The extent of Ethicon's involvement in the study design and drafting the manuscript and the accuracy of the Disclosure and Correction are matters of public interest. NEMJ has not met its burden of establishing that enforcement of the subpoenas (except to the extent that they seek testimony and documents that would identify peer reviewers and their comments and/or concern internal discussions relating to the scientific merits of the Article that were not communicated to the authors) would have an adverse effect on the public interest in protecting the free flow of information.

For the reasons stated herein, the Deponents motion to quash is allowed in part and denied in part as follows:

1) The motion to quash is allowed a) to the extent

that the subpoenas seek production of NEJM's entire file relating to the Article; b) to the extent that the subpoenas seek testimony and documents relating to communications between peer reviewers and the editors, except for communications, documentary or oral, described in ¶ 2a and 2b below; and c) to the extent that Plaintiffs seek testimony and documents relating to internal discussions concerning the scientific merits of the manuscript and study that were not communicated to the authors.

2) The motion to quash is denied a) to the extent that the subpoenas seek testimony and documents relating to communications concerning the Article, the Disclosure and the Correction between i) the Deponents and/or the NEMJ and any author of the article, including Dr. Daniel Altman; and ii) the Deponents and/or the NEMJ and any person then known by NEMJ to be an employee/consultant to Ethicon; and b) testimony and documents concerning the content and wording of the Disclosure and the Correction and the decision to publish the Correction.

DIANE M. KOTTMYER, Justice.

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