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: SUPERIOR COURT OF NEW JERSEY
: LAW DIVISION: BERGEN COUNTY
: Master Docket No.: BER-L-13379-04MT

IN RE: DIET DRUG LITIGATION

Civil Action

OPINION

FRANKIE A. BRIGMAN,

Docket No. BER-L-2547-04MT

Plaintiff,

v.

WYETH,

Defendant.

SARAH ANN GIBSON,

Docket No. BER-L-2561-04MT

Plaintiff,

v.

WYETH,

Defendant.

PAMELA L. GRABER-KEITH,

Plaintiff,

v.

WYETH,

Defendant.

Docket No. BER-L-2562-04MT

LEA M. MORRISON,

Plaintiff,

v.

WYETH,

Defendant.

Docket No. BER-L-2565-04MT

ELIZABETH W. WARD,

Plaintiff,

v.

WYETH,

Defendant.

Docket No. BER-L-2571-04MT

SHEILA M. ALLEN,

Plaintiff,

v.

WYETH,

Defendant.

Docket No. BER-L-5599-04MT

INEZ E. BRYANT,

Plaintiff,

v.

WYETH,

Defendant.

Docket No. BER-L-2549-04MT

NAIDA T. CATERINA,

Plaintiff,

v.

WYETH,

Defendant.

Docket No. BER-L-2551-04MT

MAROLYN J. EFIRD,

Plaintiff,

v.

WYETH,

Defendant.

Docket No. BER-L-2554-04MT

PATRICIA GAUTHIER,

Plaintiff,

v.

WYETH,

Defendant.

Docket No. BER-L-2559-04MT

LINDA A. SEGAL,

Plaintiff,

v.

WYETH,

Defendant.

Docket No. BER-L-2567-04MT

MARION F. SHOLAR,

Plaintiff,

v.

WYETH,

Defendant.

Docket No. BER-L-2568-04MT

SHIRLEY A. WHITE,

Plaintiff,

v.

WYETH,

Defendant.

Docket No. BER-L-2572-04MT

Decided: April 28, 2005.

Amy M. Carter, Esq., Williams Bailey Law Firm, L.L.P., appearing on behalf of the plaintiffs Frankie A. Brigman, Sarah Ann Gibson, Pamela L. Graber-Keith, Lea M. Morrison, Elizabeth W. Ward, Sheila M. Allen, Inez E. Bryant, Naida T. Caterina, Marolyn J. Efird, Patricia Gauthier, Linda A. Segal, Marion F. Sholar, and Shirley A. White.

Connie A. Matteo, Esq., Porzio Bromberg Newman, P.C., and Anand Agneshwar, Esq., Arnold & Porter, L.L.P., appearing on behalf of defendant, Wyeth Corporation.

Walsh, J.S.C.

Pondimin® and Redux™ are two (2) prescription diet drugs manufactured by defendant, Wyeth (formerly known as American Home Products Corporation). Both drugs were approved by the United States Food & Drug Administration (“FDA”) for the treatment of obesity.¹ Both Pondimin® and Redux™ are anoretics, causing a decrease in one’s appetite. *Stedman’s Medical Dictionary* 90 (25th ed. 1990).

On July 8, 1997, physicians at the Mayo Clinic publicly reported findings of unusual heart valve lesions and/or valvular regurgitation in twenty-four (24) patients being treated for obesity with phen-fen. Mayo Clinic press release, July 8, 1997. Simultaneously, the FDA issued a Public Health Advisory to health care professionals notifying them of the twenty-four (24) Mayo Clinic cases and nine (9) additional cases of “unusual valvular morphology and regurgitation” in women who had received phen-fen therapy for an average of ten (10) months.

¹ In 1973, the FDA approved the New Drug Application (“NDA”) for Pondimin®, finding it to be safe and effective for the obesity indication. In April 1996, the FDA approved Redux™, which was thereafter marketed by AHP and another company.

During the next several weeks, these findings and subsequent developments related to them were widely reported in the media.² Wyeth responded by issuing a “Dear Doctor Letter” to health care providers and subsequently, at the direction of the FDA, revising the labeling on the drugs.³ However, after additional adverse information became available, Wyeth withdrew Pondimin® and Redux™ from the market on September 15, 1997.

Litigation ensued, with claims made that Pondimin® and Redux™ (“phen-fen”)⁴ cause valvular heart disease and that Wyeth, among other things, should have warned the plaintiffs’ health care providers of that risk. Thirteen (13) cases currently are scheduled for trial on May 31, 2005.⁵ In its April 7, 2005 Opinion, the Court held that the heeding presumption will apply to these thirteen (13) cases.⁶ Subsequent to that holding, Wyeth sought additional depositions of the plaintiffs’ prescribing physicians in order to attempt to rebut this presumption. This motion

² The FDA republished its Health Advisory in the *Journal of the American Medical Association. Health Advisory on Concomitant Fenfluramine and Phentermine Use*, JAMA, 278:5:379 (Aug. 6, 1997).

³ On August 29, 1997, the FDA approved revised labeling for Pondimin® that included a black box warning for valvular heart disease. On September 3, 1997, the FDA approved similar revised Redux™ labeling.

⁴ The term phen-fen, which is often written fen-phen, refers to the use of fenfluramine or dexfenfluramine in combination with phentermine. For purposes of this Opinion, phen-fen will refer to fenfluramine or dexfenfluramine, whether used in combination with phentermine or not.

⁵ Following the procedure discussed in its Opinion, *In re Diet Drug Litigation*, BER-L-7718-03 (August 4, 2004), the Court has consolidated five (5) cases for trial: *Frankie A. Brigman v. Wyeth*, BER-L-2547-04, *Sarah Ann Gibson v. Wyeth*, BER-L-2561-04, *Pamela L. Graber-Keith v. Wyeth*, BER-L-2562-04, *Lea M. Morrison v. Wyeth*, BER-L-2565-04, and *Elizabeth Ward v. Wyeth*, BER-L-2571-04, with the remaining cases serving as backups (*Inez E. Bryant v. Wyeth*, BER-L-2549-04, *Sheila M. Allen v. Wyeth*, BER-L-5599-03, *Marolyn J. Efird v. Wyeth*, BER-L-2554-04, *Naida Caterina v. Wyeth*, BER-L-2551-04, *Patricia Gauthier v. Wyeth*, BER-L-2559-04, *Linda Segal v. Wyeth*, BER-L-2567-04, *Marion “Frances” Sholar v. Wyeth*, BER-L-2568-04, and *Shirley A. White v. Wyeth*, BER-L-2572-04).

⁶ A heeding presumption will shift to Wyeth the burden of proceeding with evidence on the issue of whether a physician armed with appropriate risk information regarding the possibility of associated valvular disease nevertheless would have prescribed Pondimin® and/or Redux™. See *Coffman v. Keene Corp.*, 133 N.J. 581 (1993).

was granted and commissions to depose the physicians in North Carolina issued. Wyeth now seeks an order permitting its attorneys to meet *ex parte* with plaintiffs' treating physicians prior to their deposition testimony. That motion is the subject of this Opinion.

I.

Ex parte interviews are an informal discovery technique. Wyeth seeks to employ this technique in advance of the treating physicians' depositions. Plaintiffs' oppose this and challenge the availability of *ex parte* interviews where the plaintiffs' treating physicians live and practice in North Carolina. To resolve this dispute, the Court must examine federal preemption principles and the following competing interests: (1) the New Jersey Supreme Court's directives in *Stempler v. Speidell*, 100 N.J. 368 (1985);⁷ (2) plaintiffs' and their physicians' interests in privacy and the duty of loyalty as reflected in North Carolina law;⁸ and

⁷ The defendant in *Stempler* asked for the "right to interview decedent's treating physicians, rather than be restricted to the formality, expense, and inconvenience of depositions conducted pursuant to the Court Rules." *Stempler*, 100 N.J. at 381. The New Jersey Supreme Court aptly noted that defendant's "unexpressed interest" is the "hope that one or more of these physicians might provide evidence or testimony that would be helpful to the defendant at trial. Unquestionably, defendant's counsel would prefer to seek out such evidence or discuss the prospect of such testimony in an *ex parte* interview rather than during a deposition attended by plaintiff's counsel." *Id.* Wyeth has argued that the *ex parte* nature "serves to maximize unhampered access to information, to reduce unnecessary expenditure of time and resources by all concerned – including the physician – and to insure the presentation of a more streamlined and effective case at trial." Wyeth Brief at 8.

⁸ The *Stempler* Court identified plaintiff's interest as "twofold." *Stempler*, 100 U.S. at 381. The primary interest is "the desire to protect from disclosure by the physician confidential information not relevant to the litigation and therefore still protected by the patient-physician privilege and the physician's professional obligation to preserve confidentiality." *Id.* The other interest is "the desire to preserve the physician's loyalty to the plaintiff in the hope that the physician will not voluntarily provide evidence or testimony that will assist the defendant's cause." *Id.*

(3) the federal policy of uniformly guarding against the over disclosure of privileged patient information.⁹

II.

A.

In order to further federal goals of increased access to health care, Congress passed The Health Insurance Portability and Accountability Act of 1996 (HIPAA).¹⁰ Congress sought to increase access by expanding portability and renewability of insurance. Diane Kutzko et al., *HIPAA In Real Time: Practical Implications Of The Federal Privacy Rule*, 51 Drake L. Rev. 403, 406 (2003) (citation omitted). During the legislative process, concern was expressed that innovations in technology might endanger the ability to protect health information; hence the adoption of privacy and security standards reflected in the HIPAA Privacy Rule (“the Privacy Rule”). Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. 82,462 (Dec. 28, 2000) (to be codified at 45 C.F.R. 160 and 164).¹¹ Congress delegated to the Secretary of the Department of Health and Human Services the task of adopting national standards

⁹ The physician’s interest was described by the *Stempler* court as “focus[ing] on prevention of inadvertent disclosure of information still protected by the privilege, since an unauthorized disclosure of such information may be unethical and actionable.” *Id.* at 382.

¹⁰ Pub. L. No. 104-191, 110 Stat. 1936 (1996).

¹¹ The Act’s first objective was not to protect privacy. See Tamela J. White & Charlotte A. Hoffman, *The Privacy Standards Under The Health Insurance Portability And Accountability Act: A Practical Guide To Promote Order And Avoid Potential Chaos*, 106 W. Va. L. Rev. 709, 713 (2004). Privacy concerns became prevalent with the advent of electronic information sharing, e.g., the Internet, facsimile, and cellular phone communications. *Id.* With this technology came the risk of unauthorized individuals accessing private medical information. *Id.*

“to ensure the integrity and confidentiality of the information.” *Id.* at 82,453; 42 U.S.C. § 1320d-2(d)(2)(A).

The Privacy Rule controls the “use and disclosure” of “protected health information” by “covered entit[ies].”¹² *See* 45 C.F.R. § 164.502 (explaining rules regarding use and disclosure of protected health information); 45 C.F.R. § 160.103 (defining relevant terms). It creates a foundation or “mandatory floor” for the protection of medical information. 65 Fed. Reg. 82,462, 82,471.¹³ Covered entities, including health care providers like doctors, must develop, implement, monitor, and maintain compliance policies and procedures to ensure against unauthorized disclosure of private health information. 45 C.F.R. § 164.530.

B.

In *Stempler v. Speidell*, 100 N.J. 368 (1985), the New Jersey Supreme Court was asked to determine whether defense counsel could conduct an *ex parte* interview with plaintiff’s decedent’s physicians. More specifically, the issue presented was whether a Court should compel a plaintiff to authorize *ex parte* communications between defense counsel and decedent’s physicians; and if compelled, what protective conditions would be imposed.” *Id.* at 373.

¹² “Protected health information” encompasses medical information, “in any form or medium,” *i.e.*, oral communications regarding medical information or information preserved on paper or in electronic format. Alex L. Bednar, *HIPAA Implications For Attorney-Client Privilege*, 35 St. Mary’s L.J. 871, 885 (2004) (citing 45 C.F.R. § 160.103).

¹³ It has been described as the “first comprehensive federal privacy rule protecting an individual’s medical information.” Diane Kutzko et al., 51 Drake L. Rev. at 405. “HIPAA provides a national floor for the protection of

There, the defendant Speidell diagnosed decedent with a fecal impaction. The day after the decedent was admitted to the hospital, she suffered cardiac arrest and died. Since the decedent had received medical care from numerous physicians, defendant sought authorizations from plaintiff to compel other physicians to release information about the decedent. Plaintiff resisted providing unrestricted authorizations permitting such interviews of these doctors by Speidell's counsel. The New Jersey Supreme Court "weigh[ed] the interests protected by the patient-physician privilege and the physician's professional obligation of confidentiality against the interests advanced by permitting defense counsel to conduct *ex parte* interviews with decedent's physicians regarding those conditions pertinent to the claims asserted in the litigation."¹⁴ *Id.* at 373-74.

The Supreme Court held that such *ex parte* interviews could be conducted. In doing so, the *Stempler* Court noted that personal interviews are "an accepted, informal method of assembling facts and documents in preparation of trial." *Id.* at

privacy interests pursuant to Congress' right to control interstate commerce, and to promote[] Equal Protection, Due Process, and First Amendment protections." Tamela J. White & Charlotte A. Hoffman, 106 W. Va. L. Rev. at 720.

¹⁴ The Court also considered the sparse law relating to this procedure, noting that

[b]ecause such interviews would take place in a nontestimonial context, no statute or Court Rule expressly precludes defense counsel from interviewing decedent's treating physicians regarding confidential communications. Moreover, even if the testimonial privilege could be imputed to such interviews, no statute or rule expressly precludes *ex parte* interviews concerning unprivileged communications, and the initiation of suit abrogates the privilege as to medical conditions pertinent to the litigation. However, ... treating physicians are not likely to cooperate with defense counsel in the absence of authorization from the patient.

Stempler, 100 U.S. at 373. Interestingly, other courts have noted that the prohibition against *ex parte* contact "is derived from neither statute nor established common law; rather, it is an emerging court-created effort to preserve the treating physician's fiduciary responsibilities during the litigation process." *Crist v. Moffatt*, 389 S.E.2d 41, 45 (N.C. 1990) (quoting *Manion v. N.P.W. Medical Center of N.E. Pa., Inc.*, 676 F.Supp. 585, 593 (M.D.Pa. 1987).

382.¹⁵ However, the Supreme Court imposed procedural safeguards. While a plaintiff must provide an authorization for such *ex parte* interviews,¹⁶ defense counsel must: (1) give plaintiff’s counsel “reasonable” notice of the time and place for the interviews; and (2) provide the physician with a description of the expected scope of the interview and indicate, with “unmistakable clarity,” that the doctor’s participation in the interview is voluntary. *Id.* at 382.¹⁷

The Privacy Rule appears to have narrowed the scope of disclosure of relevant medical information in litigation. Because the Privacy Rule is federally directed to the disclosure of medical information, the Court must first consider federal preemption principles.

C.

Preemption is rooted in the Supremacy Clause of the United States Constitution.¹⁸ There are two (2) types of preemption, express and implied.¹⁹ The difference lies in whether “Congress’ command is explicitly stated in the statute’s

¹⁵ The interview is also recognized by various courts as a “more efficient and less expensive method of trial preparation.” *Stempler*, 100 N.J. at 378 (citing *e.g., Doe v. Eli Lilly & Co., Inc.*, 99 F.R.D. 126, 128 (D.D.C. 1983); *Trans-World Investments v. Drobny*, 554 P.2d 1148, 1151-52 (Alaska 1976)).

¹⁶ If the authorizations are “unreasonably” withheld, the defendant can move to compel their production. *Stempler*, 100 N.J. at 382.

¹⁷ In addition, the *Stempler* court indicated that plaintiff could get a protective order “if under the circumstances a proposed *ex parte* interview with a specific physician threatens to cause such substantial prejudice to plaintiff as to warrant the supervision of the trial court. Such supervision could take the form of an order requiring the presence of plaintiff’s counsel during the interview or, in extreme cases, requiring defendant’s counsel to proceed by deposition.” *Stempler*, 100 N.J. at 383.

¹⁸ The Supremacy Clause provides that: “This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.” U.S.CONST. art. VI.

¹⁹ According to the Third Circuit, there are three (3) types of preemption – express, implied, and conflict. *Hawkins v. Leslie’s Pool Mart, Inc.*, 184 F.3d 244, 247 (3d Cir. 1999).

language or implicitly contained in its structure and purpose.” *Jones v. The Rath Packing Co.*, 430 U.S. 519, 525 (1977) (citation omitted). Express preemption occurs when the federal law, statute, or regulation²⁰ contains explicit language regarding whether it preempts the State law, statute, regulation or common law. *See e.g., Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996) (interpreting statutory provision that expressly preempts state law); *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992) (same). Implied preemption is present when a Congressional intent to preempt can be discerned. *See e.g., Jones v. The Rath Packing Co.*, 430 U.S. 519 (1977) (dealing with labeling and packaging regulations and assessing preemption principles); *Florida Lime and Avocado Growers, Inc. v. Paul*, 373 U.S. 132 (1963) (dealing with state and federal regulations for maturity certification of avocados and assessing whether state regulation was obstacle to accomplishing purposes and objectives of Congress). Implied preemption is found where the state law conflicts with the federal law²¹ or the federal law is “so pervasive [in the field]

²⁰ “Federal regulations have no less pre-emptive effect than federal statutes.” *Fidelity Fed. Savings and Loan Ass’n v. de la Cuesta*, 458 U.S. 141, 153 (1982). *Accord Feldman v. Lederle Labs.*, 125 N.J. 117, 134 (1991) (citation omitted).

²¹ “Conflicts” means either it is impossible to comply with both (*i.e.*, “irreconcilable conflict”) or the state law is an “obstacle” to Congress accomplishing its purposes and objectives. *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 248, 256 (1984) (citations omitted) (recognizing the “tension between the conclusion that safety regulation is the exclusive concern of the federal law and the conclusion that a state may nevertheless award damages based on its own law of liability. But as we understand what was done over the years in the legislation concerning nuclear energy, Congress intended to stand by both concepts and to tolerate whatever tension there was between them.”). “The test of whether both federal and state regulations may operate, or the state regulation must give way, is whether both regulations can be enforced without impairing the federal superintendence of the field, not whether they are aimed at similar or different objectives.” *Florida Lime and Avocado Growers*, 373 U.S. at 142. The Court continued that “[a] holding of federal exclusion of state law is inescapable and requires no inquiry into congressional design where compliance with both federal and state regulations is a physical impossibility for one engaged in interstate commerce.” *Id.* at 142-43 (citations omitted).

as to make reasonable the inference that Congress left no room for the States to supplement it.” *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (citation omitted), *rev’d on other grounds*, 331 U.S. 247 (1947).

Here, there is an express preemption provision contained in the Privacy Rule, 45 C.F.R. § 160.203. It provides that “[a] standard, requirement, or implementation specification adopted under this subchapter that is contrary²² to a provision of State law preempts the provision of State law.” However, if “[t]he provision of State law relates to the privacy of individually identifiable health information and is more stringent²³ [than the Act’s Privacy Rule,]” the preemption provision is inapplicable. *Id.* at 160.203 (b).²⁴ Hence, the Court must conduct a two-step analysis to determine whether a State law is preempted by the Privacy Rule. *See e.g., Stewart v. The Louisiana Clinic*, 2002 WL 31819130 (E.D.La.)

²² 45 C.F.R. § 160.202 defines “contrary.” It has the same definition as “conflict” above, *supra* note 21.

²³ 45 C.F.R. § 160.202 defines “more stringent.” For example, a state law is more stringent where it requires “express legal permission” from the individual before disclosure and “provides requirements that narrow the scope or duration, increase the privacy protections afforded . . . , or reduce the coercive effect of the circumstances surrounding the express legal permission. . . .” 45 C.F.R. § 160.202. The “catch-all” provision is that any state law providing “greater privacy protection for the individual who is the subject of the individually identifiable health information” is a “more stringent” state law. *Id.*

²⁴ The other exceptions, including one where the Secretary determines that the state law is not preempted, are contained in 45 C.F.R. § 160.203(a), (c), and (d). In addition, 45 C.F.R. § 164.512(e) provides, in pertinent part,

(1) Permitted disclosures. A covered entity may disclose protected health information in the course of any judicial proceeding or administrative proceeding:

(i) In response to an order of a court . . . provided that the covered entity discloses only the protected health information expressly authorized by such order; or

(ii) In response to a [] discovery request, or other lawful process, that is not accompanied by an order of a court . . . if:

(A) The covered entity receives satisfactory assurance . . . that reasonable efforts have been made . . . to ensure that the individual who is the subject of the protected information . . . has been given notice of the request; or

(B) The covered entity receives satisfactory assurance . . . from the party seeking the information that reasonable efforts have been made by such party to secure a qualified protective order”

(conducting preemption analysis to see if state law was contrary and whether it fell under an exception). First, a court must determine whether the State law is contrary to the Privacy Rule, *i.e.*, when compliance with both State and federal rules would be impossible; or the State law is an “obstacle to the accomplishment and execution of the full purposes and objectives of [the Privacy Rule].” 45 C.F.R. § 160.202. If the State law falls within this category, then the second step seeks to determine whether one of the exceptions enumerated in 45 C.F.R. § 160.203 applies.²⁵

²⁵ In *Medtronic*, the Court was dealing with an express preemption provision. The Court explained that

[w]hile the pre-emptive language of § 360k(a) [the preemption provision] means that we need not go beyond that language to determine whether Congress intended the MDA [Medical Device Amendments] to pre-empt at least some state law, we must nonetheless “identify the domain expressly pre-empted” by that language. Although our analysis of the scope of the pre-emption statute must begin with its text, our interpretation of that language does not occur in a contextual vacuum. Rather, that interpretation is informed by two presumptions about the nature of pre-emption.

* * * *

Congress does not cavalierly pre-empt state-law causes of action.

* * * *

[And the] “purpose of Congress is the ultimate touchstone” in every preemption case. As a result, any understanding of the scope of a pre-emption statute must rest primarily on “a fair understanding of congressional purpose.” Congress’ intent ... primarily is discerned from the language of the pre-emption statute and the “statutory framework” surrounding it. Also relevant []is the “structure and purpose of the statute as a whole” as revealed not only in the text, but through the reviewing court’s reasoned understanding of the way in which Congress intended the statute and its surrounding regulatory scheme to affect business, consumers, and the law.”

Medtronic, 518 U.S. at 484-86 (citations omitted). Here, as noted, the Privacy Rule was intended as a framework or floor for privacy protection.

Here, HIPAA and the *Stempler ex parte* interview can co-exist.²⁶ The Court agrees with *Smith v. American Home Products Corp. Wyeth-Ayerst Pharmaceutical*, 372 N.J.Super. 105 (Law Div. 2003), to the extent that it found HIPAA preemption only with respect to the authorization. The *Stempler* interview itself is not preempted. In *Smith*, the court held that: (1) HIPAA does not preempt the informal interview authorized by *Stempler*; but (2) HIPAA does preempt *Stempler* with regard to the authorization content.²⁷ The *Smith* court reasoned that HIPAA does not conflict with the discovery techniques allowed under *Stempler*, but the *Stempler* safeguards in disclosure authorizations fall below the HIPAA requirements. *Id.* at 110, 131.²⁸ This Court’s preemption analysis agrees with that conclusion.

²⁶ In fact, Judge Marina Corodemus noted that “[n]owhere in HIPAA does the issue of *ex parte* interviews with treating physicians, as an informal discovery device, come into view. The court is aware of no intent by Congress to displace any specific state court rule, statute or case law (e.g., *Stempler*) on *ex parte* interviews.” *Smith v. American Home Products Corp. Wyeth-Ayerst Pharmaceutical*, 372 N.J.Super. 105, 128 (Law Div. 2003). In addition, “HIPAA, by its own terms, does not exclusively dominate the field of protecting individual privacy interests in health information.” Tamela J. White & Charlotte A. Hoffman, 106 W. Va. L. Rev. at 716 (citing 45 C.F.R. §§160.202-203). In fact, privacy protection, while of national importance, is being balanced with discovery issues, which would suggest that it is an area of traditional tort litigation, and therefore within the State’s control. Areas typically within the States police powers are not “superceded” by federal action unless it was the “clear and manifest purpose of Congress.” *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (citation omitted), *rev’d on other grounds*, 331 U.S. 247 (1947). See *Buckman Co. v. Plaintiffs’ Legal Committee*, 531 U.S. 341, 347 (2001) (citation omitted) (noting that there is a presumption against finding federal preemption where the field is one traditionally occupied by the states).

²⁷ Judge Corodemus classified this as “express but selective preemption” of New Jersey law. *Smith*, 372 N.J.Super. at 110.

²⁸ This is consistent with the notion that generally “HIPAA should be applied in *pari materia* with other federal and state laws, as in most instances the laws compliment one another.” Tamela J. White & Charlotte A. Hoffman, 106 W. Va. L. Rev. at 716 (citing 45 C.F.R. §§160.202-203)

D.

Privacy is a fundamental right.²⁹ The United States Supreme Court plainly has recognized personal health information as constitutionally protected. *Whalen v. Roe*, 429 U.S. 589, 599 (1977) (noting that “few experiences are as fundamental to liberty and autonomy as maintaining control over when, how, to whom, and where you disclose personal material.”). The filing of a Complaint against Wyeth clearly has eroded some of these plaintiffs’ privacy interests. By filing a personal injury suit, plaintiffs have placed their medical condition in issue and therefore waived significant rights to privacy. *See Stempler*, 100 N.J. at 372-73 (noting that “[p]laintiff concedes that instituting suit extinguishes the [patient-physician] privilege to the extent that decedent’s medical condition will be a factor in the litigation.”); *N.J.S.A.* 2A:84A-22.4 (providing that “[t]here is no privilege under this act in an action in which the condition of the patient is an element or factor of the claim or defense of the patient ...”). Generally, the procedural safeguards suggested in *Stempler* will serve to protect plaintiff’s privacy interest and does survive HIPAA’s adoption.³⁰

²⁹ Louis D. Brandeis and Samuel D. Warren defined it as “the right to be let alone.” *The Right To Privacy*, 4 Harv. L. Rev. 193 (1890).

³⁰ “[I]n light of the burgeoning importance of protecting an individual’s privacy, particularly in regard to his or her medical information, the broad use of *Stempler* must somehow be readjusted to ensure compliance with the federal objectives under HIPAA. The Privacy Rule affords the use and disclosure of an individual’s medical information for administrative and judicial proceedings, yet HIPAA safeguards (reasonable notice and patient’s opportunity to

III.

The plaintiffs complain that even if *Stempler* does not conflict with Federal law, North Carolina law does not permit *ex parte* interviews in cases such as these. The Court agrees that the North Carolina courts do not permit *ex parte* interviews with a plaintiff's treating physician absent consent. *See Crist v. Moffatt*, 389 S.E.2d 41 (N.C. 1990). Since the plaintiffs and their physicians reside in North Carolina, the Court must consider conflict of law principles. Plaintiffs' Complaints were filed in New Jersey. However, the treating physicians who are the subject of this motion reside in and are licensed in North Carolina. Moreover, it is almost certain that the *ex parte* interviews requested will take place in North Carolina. In any case, North Carolina plainly has a significant interest in regulating the conduct of its licensed physicians.

New Jersey is the forum. Accordingly, New Jersey's choice of law rules are followed. *Erny v. Estate of Merola*, 171 N.J. 86, 94 (2002), *Fu v. Fu*, 160 N.J. 108, 117 (1999), *Gantes v. Kason Corp.*, 145 N.J. 478, 484 (1996). New Jersey applies the "'governmental-interest' test that seeks to apply the law of the state with the greatest interest in governing the specific issue in the underlying litigation." *Fu*, 160 N.J. at 118 (citation omitted). The analysis is two-pronged. The first prong requires the Court to determine, on an issue-by-issue basis, whether

object) [should be included in the authorizations]." *Smith*, 372 N.J.Super. at 134. This Court accordingly orders that certain safeguards be employed, *see supra* part IV.

there is an actual conflict between the laws of the states. *Id.* (Citation omitted). If so, it must determine which State has the most significant relationship to the parties and occurrence. *Id.* at 119 (citation omitted).³¹

North Carolina generally prohibits *ex parte* communications between plaintiff's treating physicians and defense counsel. In *Crist v. Moffatt*, 389 S.E.2d 41 (N.C. 1990), the defendant's attorney had *ex parte* meetings with two (2) of plaintiff's physicians, who were expected to testify "as to facts and circumstances" surrounding the plaintiff's treatment. In both instances, the defendant's attorney also told the doctors that plaintiff had waived the physician-patient privilege when, in fact, she had not. The North Carolina court was guided by its public policy concerns that a physician might become liable for inadvertent disclosures and/or the interview might disintegrate into improper discussions beyond waived matters.³²

The *Crist* Court concluded that "considerations of patient privacy, the confidential relationship between doctor and patient, the adequacy of formal discovery devices, and the untenable position in which *ex parte* contacts place the

³¹ A court has to determine the interest each State has in resolving the specific disputed issue. *Gantes*, 145 N.J. at 485. This requires a court to "identify the governmental policies underlying the law of each state and how those policies are affected by each state's contacts to the litigation and to the parties." *Id.* (Citation omitted). There are various factors that guide a court's analysis: "(1) the interests of interstate comity; (2) the interests of the parties; (3) the interests underlying the field of tort law; (4) the interests of judicial administration; and (5) the competing interests of the states." *Fu*, 160 N.J. at 122. Contacts that are important in the analysis are: "(1) the place where the injury occurred; (2) the place where the conduct causing the injury occurred; (3) the domicile, residence, nationality, place of incorporation, and place of business of the parties; and (4) the place where the relationship, if any, between the parties is centered." *Erny*, 171 N.J. at 103 (citations omitted).

³² Interestingly, the procedural safeguards employed by the *Stempler* court would protect against these dangers.

nonparty treating physician supersede defendant's interest in a less expensive and more convenient method of discovery.... [T]hus ... defense counsel may not interview plaintiff's nonparty treating physicians privately *without plaintiff's express consent.*" *Id.* at 47 (emphasis added). The defendant there was thus left with traditional and more formal discovery methods, such as a deposition.

Notably, that court stressed its holding was not meant to discourage "consensual informal discovery." *Id.* But in North Carolina consent is a key component. This point is embodied in the Medico-Legal Guidelines of North Carolina, which provide:

Authorization. Proper authorization is necessary before a physician can release medical information. No attorney should request and no physician should furnish any medical information concerning the history, physical or mental examination, condition, diagnosis or prognosis of a patient except *with the written consent* of the patient, the patient's authorized representative, a *judicial or administrative order*, or in conformity with other applicable legal authority. The scope of the authorization determines the scope of the inspection, release, copying or report: If the requesting attorney wants information beyond what is authorized to be released, the attorney must obtain additional authorization.³³

Id. at IV.A.3.b at 575 (2004) (footnotes omitted) (emphasis added).³⁴

³³ These regulations are not inconsistent with *Stempler*.

³⁴ The Court notes that another portion of the North Carolina regulations indicates that patients' physicians "may not communicate with an attorney or any other person about a patient's treatment, evaluation, or condition without the written consent of the patient or the patient's authorized representative, or a court order, or other lawful authority." MEDICO-LEGAL GUIDELINES OF NORTH CAROLINA, IV.B.1 at 575. However, this section apparently deals with discussions between the patient's physician and the *patient's* attorney. The Guidelines further note that normally the deposition is the method of communicating with the physician; "the attorney opposing the patient's claim is [generally] prohibited from communicating with the patient's physician prior to trial except at a deposition." *Id.* at IV.B.2 at 576 n. 32.

Clearly, if the plaintiff consents, New Jersey and North Carolina are in accord in concluding that treating physicians are free to participate in *ex parte* interviews with defense counsel. In this respect, New Jersey and North Carolina are consistent.³⁵

IV.

The Court concludes that *ex parte* interviews of plaintiffs' treating physicians can be allowed without compromising HIPAA, or colliding with North Carolina law. While the Court has not had the chance to fully explore all aspects of implementing the *Stempler* procedures due to the timing of this motion,³⁶ it intends to employ certain procedural safeguards. These safeguards, which the Court may well revisit and revise in the light of experience, will help to insure HIPAA compliance, while at the same time allowing Wyeth to conduct discovery consistent with *Stempler*.

Specifically, the Court will permit Wyeth to conduct *ex parte* interviews with plaintiffs' treating physicians subject to *Stempler's* constraints, but any interview must be recorded and transcribed. A copy of that transcript will be made

³⁵ If one were to conclude that these state laws conflict, New Jersey law would apply here because New Jersey has a greater interest and plaintiffs, by filing in our courts, have sought protection under our laws. In addition, as a matter of procedure (*i.e.*, discovery method), the law of the forum state controls. REST. (SECOND) OF CONFLICT OF LAWS (1971) § 127 (noting that "local law of the forum governs rules of pleading and the conduct of proceedings of court" including pre-trial practice like discovery); REST. (FIRST) OF CONFLICT OF LAWS (1934) § 585 (noting that "[a]ll matters of procedure are governed by the law of the forum.").

³⁶ As noted, the trial in these cases is scheduled for May 31, 2005.

available to plaintiffs' counsel at the time of each physician's deposition.³⁷ Plaintiffs will sign the Authorization, enclosed as Appendix A to this Opinion, permitting such interviews. After signing this release, the plaintiffs and their attorneys are directed to take no steps designed to interfere or discourage the physician's participation. However, plaintiffs' counsel may communicate with the physicians, in writing only, regarding any concerns about the scope and the extent to which the plaintiffs continue to assert the physician-patient privilege, and the Authorization shall clearly indicate that the physician's participation is voluntary.³⁸

This Court, though following the same path, reaches a somewhat different result than *Smith v. American Home Products Corp. Wyeth-Ayerst Pharmaceutical*, 372 N.J.Super. 105 (Law Div. 2003). There the court did not permit the *Stempler* interviews to proceed. But these seemingly different results are easily harmonized. In *Smith*, Judge Corodemus did not permit the *Stempler* interviews because approximately 300 PPA cases were docketed for trial in only one and a half (1 ½) months. The *Smith* court reasoned that the PPA cases were "extreme" cases and "[t]he holding in *Stempler* reserves judicial discretion with regard to the appropriateness of *ex parte* interviews even under 'extreme cases.'" *Smith*, 372 N.J.Super. at 136. According to the *Smith* court

³⁷ Any statement may be introduced during a subsequent deposition or during trial testimony under *N.J.R.E.* 803(a)(1) or (a)(2) as a prior statement of the witness.

³⁸ Authority to fashion this solution is found in *Stempler*, where the New Jersey Supreme Court noted that "the flexibility afforded by our decision will permit trial courts and counsel to fashion appropriate procedures in unusual

mass tort cases with their inherent complexity fall within the definition of extreme cases. Therefore under this court's authority, and given the magnitude of the potential intricacies of entirely redoing the discovery process to include informal discovery with HIPAA-compliant authorizations, the most practical recourse is to deny the use of *Stempler* interviews. This court sees no necessity for informal discovery so late into the PPA litigation. This however, does not imply that *Stempler* is not available as an informal discovery tool for mass tort cases. Rather, given the complexity of such cases, special hearings early during case management for the design of HIPAA-compliant authorization forms may become the custom for the conduct of *Stempler* interviews in future mass tort litigation.

Id. at 136 (footnote omitted). The Court agrees with Judge Corodemus that mass tort cases are "extreme" cases, requiring special management.

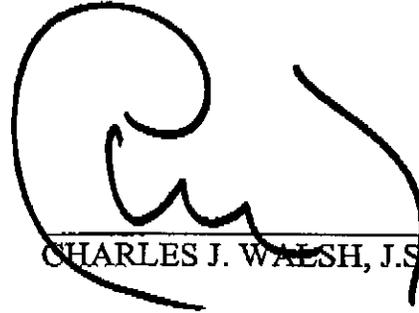
In these thirteen (13) cases, the Court recently ruled that the plaintiffs may avail themselves of the heeding presumption where a prescription drug product is involved. *In re Diet Drug Litigation*, BER-L-13379-04MT slip op. 11-22 (April 7, 2005); *Coffman v. Keene Corp.*, 133 N.J. 581 (1993); *Theer v. Philip Casey Co.*, 133 N.J. 610 (1993). This ruling has shifted the burden of going forward with evidence on proximate cause issues to Wyeth. Under these circumstances, Wyeth should be given appropriate formal and informal discovery tools to seek to accomplish its litigation tasks. Moreover, unlike the *Smith* court, this Court is not required to completely revamp discovery schedules on the eve of trial. This decision also is confined to the thirteen (13) plaintiffs scheduled for trial on May

cases without interfering unnecessarily with the use of personal interviews in routine cases." *Stempler*, 100 N.J. at 383.

31, 2005. Here, the litigants clearly have the resources to accomplish these limited discovery objectives while at the same time preparing for trial.

V.

For the reasons set forth in this Opinion, Wyeth's motion is granted in part. Wyeth may conduct *ex parte* interviews of the physicians for these thirteen (13) plaintiffs, employing the procedural safeguards detailed in the Authorization, a copy of which is attached as Appendix A, and the enclosed Order.

A handwritten signature in black ink, appearing to read 'CJ Walsh', is written over a horizontal line. The signature is stylized and cursive.

CHARLES J. WALSH, J.S.C.