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In re: PPA Litigation (phenylpropanolamine)	SUPERIOR COURT OF NEW JERSEY MIDDLESEX COUNTY DOCKET NO.: 264 HON. MARINA CORODEMUS **DRI BRIEF AS *AMICUS CURIAE* IN SUPPORT OF DEFENDANT'S MOTION FOR THE ENTRY OF AN ORDER AUTHORIZING *STEMPLER* INTERVIEWS CONSISTENT WITH THE HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT OF 1996.**

The Defense Research Institute ("DRI") is an organization with more than 21,000 individual lawyer and 400 corporate members throughout the United States. It seeks to ensure that issues important to the defense bar, its clients and to the preservation and enhancement of the judicial process are properly and adequately addressed.

These objectives are accomplished through scholarly publications, continuing legal education, testimony on legislation impacting the civil justice system, and by participation as amicus curiae on issues of significance to the defense bar and its clients. DRI provides a forum for the networking of state and local defense organizations who share a concern for the proper and efficient operation of the civil justice system.

INTRODUCTION

The plaintiffs are making an unprecedented argument that the Health Insurance Portability and Accountability Act of 1996, 42 U.S.C. §§1320-d, *et seq.* ("HIPAA" or "the Act")[1], broadly preempts all state-law litigation practices that provides equal access for all counsel in personal injury litigation to a plaintiff's treating physician – such as the informal interviews authorized by *Stempler v. Speidell*, 100 N.J. 368 (1985).

There is no extensive preemption as plaintiffs claim. The jurisprudential policies that support equal litigation access to treating physicians are entirely consistent with HIPAA, which was passed by Congress in 1996 in order to ensure the security of electronic health information while it is being stored or during the exchange of that information between entities. Express preemption under HIPAA is limited to "contrary state law." Such preemption clauses are interpreted narrowly. There is no conflict. HIPAA expressly preserves state litigation practices from preemption.

[1]Pub.L. No. 104-191, 110 Stat. 1936 (1936).

STEMPLER INTERVIEWS ARE RECOGNIZED UNDER HIPAA

There is no physician patient privilege in any litigation "in which the condition of the patient is an element or factor of the claim or defense of the patient." N.J.S.A. §2A:84A-22.4. Thus, in *Stempler* the New Jersey Supreme Court unanimously held that defense counsel in personal injury litigation had the right to seek informal interviews with physicians who had treated the plaintiff, if such treaters were willing, and provided that certain notifications were provided to opposing counsel. *See* 100 N.J. at 382-83.[2] The *Stempler* court approved this practice as an equitable compromise among the competing interests of all sides:

> The **defense** interest (1) not to "be restricted to the formality, expense, and inconvenience of depositions" in seeking relevant evidence, and (2) in seeking out "testimony that would be helpful to the defendant at trial" outside the presence of opposing counsel. 100 N.J. at 381.
>
> The **plaintiff's** interest (1) "to protect from disclosure by the physician confidential information not relevant to the litigation" and (2) "to preserve the physician's loyalty to the plaintiff" so that the treater "will not voluntarily provide evidence or testimony that will assist the defendant's cause." *Id.* at 381.
>
> The **treating physician's** interest in "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.

[2]The defense must notify the plaintiff of the intent to conduct such interviews, and the plaintiff must provide written authorization (which can be compelled if unreasonably refused) describing the scope of the interview and informing the treating physician that it is voluntary. Plaintiff must be notified of the time and place of each interview, and may communicate to the treater in advance of the interview any "appropriate concerns." In "specific" instances of "substantial prejudice," the plaintiff may seek a protective order. *See* 100 N.J. at 382-83.

The Civil Rules are not the exclusive means of discovery, and the Court expressly encouraged personal interviews and "other informal means of discovery that reduce the cost and time of trial preparation." *Id.* at 382.

Eleven years after *Stempler*, HIPAA was enacted by Congress in part to require the Department of Health and Human Services ("HHS") to create national standards for the electronic transmission of health care information. *See* 42 U.S.C. §1320d-2. Congress recognized in HIPAA that the increased use of electronic data management technology in the medical area, while efficient, could threaten patient privacy. As a consequence, Congress included in the Act a mandate that the HHS adopt federal privacy protections for individually identifiable health information. *See* Pub.L. 104-191 §264 (uncodified).[3]

In response, HHS published a series of regulations, effective April 14, 2003, known collectively as the HIPAA Privacy Rule ("Privacy Rule" or "the Rule"). The Privacy Rule enforces Congress' directive by providing comprehensive standards and procedures for the electronic collection and disclosure of individually identifiable health information. *See* 68 Fed. Reg. 8334 (HHS Feb. 20, 2003).

As a general proposition, the Privacy Rule requires covered entities, (health care providers, health plans and health care clearinghouses[4]) to follow specified procedures to prevent improper or inappropriate disclosure of a patient's individually identifiable health

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[3]*See* Section 264(a) (requiring the Secretary of HHS to submit to Congress "detailed recommendations on standards with respect to the privacy of individually identifiable health information" no later than a year after enactment of the Act"); §264(c) (providing that if Congress does not enact privacy legislation within three years after enactment of the Act HHS shall "promulgate final regulations containing such standards").

[4]*See* Executive Order No. 13181, 65 Fed. Reg. 81321 (EOP Dec. 20, 2001).

information. There are exceptions to these procedures – and one of these exceptions (not mentioned by plaintiffs) is directly applicable to the present litigation.

The HIPAA Privacy Rule does not provide personal injury plaintiffs with absolute privacy of health care. Instead health care providers "may disclose protected health information in the course of any judicial. . .proceeding." 45 C.F.R. §164.512(e). This regulation states, in pertinent part:

> (e) Standard: Disclosures for judicial. . .proceedings.
>
> (1) Permitted disclosures. A covered entity *may disclose protected health information in the course of any judicial. . .proceeding*:. . . .
>
> (ii) In response to a subpoena, discovery request, *or other lawful process*, that is not accompanied by an order of a court. . .if:
>
> > (A) The covered entity receives satisfactory assurance. . .from the party seeking the information that reasonable efforts have been made by such party to ensure that the individual who is the subject of the protected health information that has been requested has been *given notice* of the request. . . .
>
> (iii) . . .[A] covered entity receives satisfactory assurances. . .if the covered entity receives from such party a written statement. . .that:
>
> > (A) The party requesting such information has made a good faith attempt to provide written notice to the individual. . .
> >
> > (B) The notice included sufficient information about the litigation. . .to *permit the individual to raise an objection to the court*. . ., and. . . .
> >
> > (1) No objections were filed; or
> >
> > (2) All objections filed by the individual have been resolved by the court. . . .

(Emphasis added.)

Thus, under the applicable HIPAA regulation any "lawful process that is not accompanied by an order of a court" simply requires "notice" and "satisfactory assurance" prior to production of individual medical information *Id.* §164.512(e)(ii)(A).

The *Stempler* procedures provide for notice. *See* 100 N.J. at 382-83. The federal regulation does not prohibit informal physician interviews or any other form of litigation-related information gathering permitted by state law. The regulation simply provides for resolution of "objections. . .by the court." *Id.* §164.512(e)(iii)(C)(2). Here, under *Stempler*, there is no valid bases for plaintiff's blanket objection to informal physician interviews. Plaintiffs do not dispute that *Stempler* specifically authorizes such interviews in personal injury litigation.[5]

In light of the applicable HIPAA regulation, plaintiffs' preemption argument makes no sense. Nothing in HIPAA purports to prohibit any method of gathering personal medical information about a personal injury plaintiff in the context of litigation initiated by that plaintiff. To the contrary, the language of §164.512(e) demonstrates that the HIPAA Privacy Rule contemplated and specifically addressed the issue of discovery in civil litigation-- and preserved state law practice.

In promulgating the Rule HHS itself confirmed that HIPAA was not intended to interfere with litigation discovery as permitted by state law. In its Final Rule promulgating 45 C.F.R. §164.512(e), HHS directly addressed the issue of state litigation practice.

> [T]he provisions in this paragraph *are not intended to disrupt current practice whereby an individual who is a party to a proceeding and has put his or her medical condition at issue* will not prevail without consenting to the production of his or her protected health information. In such cases,

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[5]Plaintiffs are not disputing that the *Stempler* interviews concern information that is relevant to this litigation. The Federal Register makes clear that "a covered entity making a disclosure under [§164.512(e)] may of course disclose only that protected health information that is within the scope of the permitted disclosure." 65 Fed. Reg. 82462, 82530. *Stempler* itself limits informal physician interviews to information that is relevant to litigation. *See* 100 N.J. at 383.

> we presume that parties will have ample notice and an opportunity to object in the context of the proceeding in which the individual is a party.

65 Fed. Reg. 82462, 82530 (emphasis added). This Federal Register notice is subject to mandatory judicial notice. *See* 44 U.S.C. §1507 ("[t]he contents of the Federal Register shall be judicially noticed"). Plainly, informal physician interviews in litigation such as this, where a plaintiff-patient has voluntarily placed his or her medical condition at issue by filing suit, are not merely contemplated, but expressly provided for, in the HIPAA Privacy Rule.

Courts defer to agency constructions of the statutes and regulations that they administer. *See E.g., Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842-843 (1984); *R & R Marketing, L.L.C. v. Brown-Forman Corp.*, 158 N.J. 170, 175 (1999). The Federal Register Final Rule confirms that HHS took particular care to recognize that, in the context of judicial proceedings such as the present litigation, health care providers such as treating physicians are called upon to disclose patient-plaintiffs' health care information as a matter of course. For this reason, in the litigation context, notice is "presumed" for purposes of §164.512(e)(ii) based upon "ample notice and the opportunity to object" in the lawsuit "in which the individual is a party." *See* 65 Fed. Reg. 82462, 82530. Thus HHS has made clear that the HIPAA Privacy Rule is not intended to affect current state-law litigation practice in any way.

Thus plaintiffs' contentions fail without any need even to consider preemption doctrine. The applicable regulations just do not operate in the fashion that plaintiffs claim. Recognizing that medical information is essential to litigation of personal injury matters, the Act permits disclosures in response to discovery requests or other lawful process and specifically preserves all "lawful process" (whether or not by court order) not

objectionable under state law. 45 C.F.R. §164.512(e). There is no conflict between HIPAA and New Jersey state law as exemplified by the *Stempler* decision. Thus, there cannot be preemption. There is no basis for Plaintiffs' contention that *Stempler* conflicts with HIPAA.

HIPAA DOES NOT PREEMPT NEW JERSEY STATE PRACTICE ALLOWING INFORMAL INTERVIEWS OF TREATING PHYSICIANS

I. Preemption Under HIPAA Is Expressly Limited To "Contrary" State Law.

HIPAA contains an express preemption clause that limits preemption to situations involving direct conflict between the Act and state law. Any federal standard resulting from HIPAA's implementation "shall supersede any *contrary* provision of State law." 42 U.S.C. §1320d-7(a)(1) (emphasis added). A "contrary" state law is defined as one that would make it "impossible [for a covered entity] to comply with both the State and federal requirements," or that would stand "as an obstacle to the accomplishment and execution of the full purposes and objectives of [the Act]." 45 C.F.R. §160.202.[6]

As already demonstrated, *Stempler*-type interviews are preserved in 45 C.F.R. §164.512(e), and HHS has explicitly stated its intention "not. . .to disrupt current practice" concerning "a party to a proceeding [who] has put his or her medical condition at issue." 65 Fed. Reg. at 82530. Thus, compliance with both *Stempler* and the HIPAA Privacy Rule is neither impossible, nor do informal *Stempler* interviews stand as an obstacle to the accomplishment of HIPAA's objectives. To the contrary, HIPAA is diametrically the opposite of plaintiff's arguments. *Stempler* and the Privacy Rule are

[6]Unless prohibited by statute, administrative agencies may delineate the preemptive scope of the statutes they administer. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 496 (1996).

completely harmonious because HHS expressly carves out from the Privacy Rule the free flow of information in judicial settings. Plaintiffs are attempting to manufacture a conflict between state and federal law where none exists.

As plaintiffs point out, Pl. br. at 7, Congress provided three exceptions to the Act's conflict-based preemption clause. These exceptions provide that even state law which is contrary to HIPAA escapes preemption if the state law: (1) is designed to prevent fraud and abuse in insurance; (2) concerns controlled substances; or (3) more stringently protects patient privacy than HIPAA. *See* 42 U.S.C. §1320d-7(a)(1). Plaintiffs' contention that *Stempler* is preempted because informal interviews do not fall under these three exceptions is fallacious. In their haste to reach the exceptions to §1320d-7, plaintiffs overlook the general preemption standard – that preemption is limited to "contrary" state law. The exceptions are irrelevant here. There is no preemption, because there is nothing "contrary" to state law. As demonstrated, HIPAA does not restrict state-law litigation practice in personal injury litigation in any way.

II. <u>A Presumption Against Preemption Precludes Any Broad Reading Of §1320d-7.</u>

Analysis of express federal preemption of state law begins with a strong presumption against preemption that requires the narrow construction of all ambiguities in preemption clauses in favor of the continued validity of state law. *See Medtronic v. Lohr*, 518 U.S. 470, 485 (1996). This presumption, driven by principles of comity and federalism, requires that:

> in all preemption cases, and particularly in those in which Congress has legislated. . .in a field which the States have traditionally occupied, we 'start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act.'

Medtronic, 518 U.S. at 485 (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). There is no federal physician/patient privilege. *Whalen v. Roe*, 429 U.S. 589, 602, n. 28 (1977). Privilege issues, even in federal litigation, are matters of state law. Fed. R. Evid. 501. The presumption against preemption thus applies with full force in this case.

Thus, even if Plaintiffs were correct (which they are not) that "the legislative history of HIPAA supports a strict reading of the express preemption clause," Pl. br. at 6, any such reading is defeated by the presumption against preemption. In *Medtronic* the Supreme Court acknowledged congressional concern with "interfere[nce] by "competing state requirements," 518 U.S. at 491 n.12, yet nevertheless applied the presumption against preemption to restrict the preemptive scope of a much broader preemption clause than 42 U.S.C. §1320d-7.[7] *Medtronic* makes clear that preemption clauses – where, as here, they impact matters historically governed by state law – are interpreted as narrowly as possible. Plaintiffs' reliance upon purported legislative history, Pl. br. at 6-7, to expand §1320d-7 beyond its express terms is defeated by the presumption against preemption.

III. Congress Did Not Intend HIPAA To Preempt State Discovery Practice In Personal Injury Litigation.

"[T]he purpose of Congress is the ultimate touchstone in every preemption case." *Medtronic*, 518 U.S. at 485 (quotations omitted). To determine "Congress' intent," courts "primarily" look to the language of the statute itself:

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[7] *Medtronic* involved preemption of state law by the Medical Device Amendments to the Food, Drug & Cosmetic Act. The relevant provision, 21 U.S.C. §360k(a) preempted any state law that was "different from or in addition to" federal medical device requirements. Here, by contrast HIPAA preempts only "contrary" state law. 42 U.S.C. §1320d-7.

> Congress' intent, of course, primarily is discerned from the language of the preemption statute and the statutory framework surrounding it. Also relevant, however, 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.

Id. at 486 (quotations omitted).

The HIPAA preemption clause does not permit – let alone mandate – preemption here. On its face, §1320d-7 demands that state law be *contrary* to the Act. Since, as demonstrated previously, the Privacy Rule contains a specific exemption for litigation-related discovery, *Stempler* cannot possibly be contrary to the terms of HIPAA. The HHS regulations define "contrary" to include anything that is "an obstacle to the accomplishment and execution of the full purposes and objectives of [the Act]" before there can be preemption. 45 C.F.R. §160.202.

Informal physician interviews cannot be an obstacle to HIPAA's purposes or objectives. As stated by Congress, HIPAA's purpose is to balance patients' need for the privacy of their health care information while promoting the use of efficient technology in the health care industry. *See South Carolina Medical Ass'n v. Thompson*, 327 F.3d 346, 348-49 (4th Cir. 2003). The Act's primary focus is the regulation of commercial behavior and to ensure the security of electronic health information while it is being stored or during the exchange of that information between entities. *Id.* at 348. It was neither HIPAA's intent, nor its purpose, to supercede state rules of civil procedure on a nationwide basis. *See* 65 Fed. Reg. at 82530.

Tellingly, plaintiffs cite nothing in the Act or its legislative history supporting preemption in a civil litigation context.[8] The express references to civil litigation, in both the regulations and the Federal Register demonstrate precisely the opposite intent. The decision of the HHS to include §164.512(e) of the Privacy Rule establishes that the *Stempler* rule allowing informal interviews of treating physicians is wholly congruent with what Congress intended to accomplish when it enacted HIPAA.

Congressional reluctance to upset widespread state-law litigation practice was wise. "[A] party's right to interview witnesses is a valuable right. Witness interviews are one of the primary investigative techniques." *Wharton v. Calderon*, 127 F.3d 1201, 1204 (9th Cir. 1997). States that continue the "time-honored and decision-honored principle[], namely, that counsel for all parties have a right to interview an adverse party's witnesses (the witness willing) in private,"[9] do so for sound jurisprudential reasons. "Once a patient places his care and treatment at issue in a civil proceeding, there no longer remains any restraint upon a doctor in the release of medical information concerning the patient within the parameters of the complaint." *Orr v. Sievert*, 292 S.E.2d 548, 550 (Ga. App. 1982). Informal interviews are:

> less costly and less likely to entail logistical or scheduling problems; it is conducive to spontaneity and candor in a way depositions can never be; and it is a cost-efficient means of eliminating non-essential witnesses from the list completely.

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[8]The utter lack of support for plaintiffs' position is underscored by their reliance upon two advocacy articles written by other plaintiffs' lawyers in bar journals (one not even published). The only case they cite, *United States v. Louisiana Clinic*, 2002 WL 31819130 (E.D. La. Dec. 12, 2002), involved "disclosure of **nonparty** patient billing and medical records," *id.* at *1 (emphasis added), not information involving a personal injury plaintiff who had voluntarily placed his own medical condition at issue.

[9]*Williams v. Rene*, 72 F.3d 1096, 1103 (3d Cir. 1995) (quoting *International Business Machine Corp. v. Edelstein*, 526 F.2d 37, 42 (2d Cir. 1975)).

Romine v. Medicenters, Inc., 476 So. 2d 51, 55 (Ala. 1985). Restricting informal physician depositions "hinders settlement negotiations and trial preparation by restricting the gathering of relevant evidence in an informal fashion, thus requiring the more expensive and time-consuming procedures of a formal deposition." *Williams v. Rene*, 72 F.3d 1096, 1103 (3d Cir. 1995). Many other jurisdictions likewise recognize the benefits of informal interviews. [10]

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[10] *See, e.g., Samms v. District Court*, 908 P.2d 520, 525-26 (Colo. 1995) ("Informal methods of discovery not only effectuate the goals of the discovery process but tend to reduce the litigation costs and simplify the flow of information."); *Green v. Bloodsworth*, 501 A.2d 1257, 1258-59 (Del. Super. Ct. 1985) ("This Court will not condone the use of the formal discovery rules as a shield against defense counsel's informal access to a witness when these rules were intended to simplify trials by expediting the flow of litigation and to encourage the production of evidence."); *Street v. Hedgepath*, 607 A.2d 1238, 1247 (D.C. 1992) (informal interviews with treating physicians are permissible means of discovery); *Morris v. Thomsen*, 937 P.2d 1212, 1217-18 (Idaho 1987) (if plaintiff has not retained the treating physician as an expert witness, discovery rules...do not limit defense counsel's access); *Bryant v. Hilst*, 136 F.R.D. 487, 491 (D. Kan. 1991) (a patient who places his or her medical condition at issue forgoes right to preclude treating physicians from disclosing relevant information; interested parties should not be given complete control over categories of fact witnesses); *Butler-Tulio v. Scroggins*, 774 A.2d 1209, 1216-17, 150 (Md. App.) (refusing to create extra-statutory prohibition against informal interviews of treating physicians where patients have placed their medical conditions in issue), *cert. denied*, 783 A.2d 221 (Md. 2001); *Domako v. Rowe*, 475 N.W.2d 30, 33 (Mich. 1991) (encouraging open discovery to which both parties have a right); Minn. Stat. §595.02, subd. 5 (1988) (if the treating doctor consents and if 15 days notice and an opportunity to attend is given plaintiff, defense counsel may informally discuss case with doctor); *Filz v. Mayo Foundation*, 136 F.R.D. 165, 169-74 (D. Minn. 1991) (informal interviews with treaters are a valuable component of discovery); *Brandt v. Pelican*, 856 S.W.2d 667, 673 (Mo. 1993) (recognizing implied waiver of confidentiality when plaintiff places physical condition at issue); *In re Orthopedic Bone Screw Products Liability Litigation*, 1996 WL 530107, at *2 (E.D. Pa. Sep. 16, 1996) (allowing informal physician interviews in mass tort litigation "[b]ecause many states grant defendants the right to conduct informal discovery"); *Lewis v. Roderick*, 617 A.2d 119, 122 (R.I. 1992) (informal interviews are beneficial by reducing trial preparation time and expense of litigation); *Hogue v. Kroger Store No. 107*, 875 S.W.2d 477, 481 (Tex. App. 1994) (physician-patient privilege waived when plaintiff brings suit.), *writ denied* (Tex. Sep. 15, 1994); *Steinberg v. Jensen*, 534 N.W.2d 361, 371-72 (Wis. 1995) (allowing informal interviews with treating physicians to afford a wide latitude of cost-efficient discovery).

For all of these reasons, "to disallow a viable, efficient, cost effective method of ascertaining the truth because of the mere possibility of abuse, smacks too much of throwing out the baby with the bath water." *Langdon v. Champion*, 745 P.2d 1371, 1374 (Alaska 1987). Likewise, in *Stempler* the New Jersey Supreme Court has recognized that personal interviews are "an accepted, informal method of assembling facts and documents in preparation for trial" and that "[t]heir use should be encouraged... [to] reduce the cost and time of trial preparation." 100 N.J. at 382. Plainly, the *Stempler* rule reflects a balanced approach founded in sound and widely-recognized policy concerns.[11]

As have many states, HHS concluded in adopting the Privacy Rule that, once plaintiffs put their medical condition at issue by bringing personal injury law suit, their interest in the privacy of their medical information is no longer a matter for HIPAA, but is rather a matter to be determined in accordance with the law of whatever jurisdiction in which suit was filed. *See* 65 Fed. Reg. at 82530. Plaintiffs' contention that *Stempler* is preempted by HIPAA is without support in law, fact, or policy.

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[11] As the above discussion demonstrates, plaintiffs are thus incorrect in claiming, Pl. br. at fn.1, that informal treating physician interviews as in *Stempler* are prohibited in most jurisdictions. In addition to the sixteen or so jurisdictions that explicitly permit such interviews, another ten states have never restricted them – Hawaii, Kentucky, Maine, Nevada. North Dakota, Oregon, South Dakota, Utah, Vermont, and Wyoming.

Conclusion

For all of the above reasons, *amicus curiae* the Defense Research Institute respectfully urges the Court to find that *Stempler* is not preempted by HIPAA.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on August 1, 2003 I caused a true and complete copy of the Defense Research Institute's Brief As *Amicus Curiae* in Support of Defendant's Motion for the Entry of an Order Authorizing *Stempler* Interviews Consistent With the Health Insurance Portability and Accountability Act Of 1996 to be served via hand delivery upon the following:

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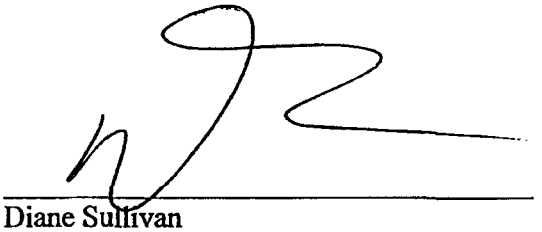

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