# UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

MICHELE FECHO, et al, Plaintiffs,

v.

CIVIL ACTION NO. 11-10152-MBB

ELI LILLY AND COMPANY, et al, Defendants.

# MEMORANDUM AND ORDER RE: MOTION FOR PARTIAL SUMMARY JUDGMENT FOR FAILURE TO PROVE PROXIMATE CAUSATION (DOCKET ENTRY # 324); MOTION TO STRIKE EXHIBITS TO PLAINTIFFS' OPPOSITION TO MOTION FOR PARTIAL SUMMARY JUDGMENT FOR FAILURE TO PROVE PROXIMATE CAUSATION

December 21, 2012

(DOCKET ENTRY # 337)

#### BOWLER, U.S.M.J.

Defendant Eli Lilly and Company ("Lilly") moves for summary judgment on a negligent failure to warn claim in the second amended complaint (Count I). (Docket Entry # 324). Lilly submits there is an absence of admissible evidence that the breast cancer experienced by plaintiffs Andrea Andrews ("Andrews"), Michele Fecho ("Fecho"), Donna McNeely ("McNeely") and Francine Melnick (collectively: "plaintiffs") was proximately caused by Lilly's failure to warn that maternal ingestion of Diethylstilbestrol ("DES") increases the risk of breast cancer in the mother's female offspring. (Docket Entry # 324). Lilly separately moves to strike three affidavits (Docket

Entry ## 331-4, 331-5 & 331-6) filed by plaintiffs to support their opposition to the partial summary judgment motion (Docket Entry # 337). After conducting a hearing on November 19, 2012, this court took the motions (Docket Entry ## 324 & 337) under advisement. Because the content of the summary judgment record depends upon whether to include the three affidavits, this court initially turns to the motion to strike.

# I. MOTION TO STRIKE

Lilly seeks to strike the affidavits of: (1) Victor Greco, M.D. ("Dr. Greco"), a board certified physician in the specialty of general surgery; (2) Irene Makowiec ("Makowiec"), a former patient of the late Richard Bonacci, M.D. ("Dr. Bonacci"); and (3) Clare Ritz ("Ritz"), another former patient of Dr. Bonacci. Dr. Bonacci was a general practitioner with an office located in Tresckow, Pennsylvania. Plaintiffs' mother, the late Frances Melnick ("Melnick" or "plaintiffs' mother"), was under Dr. Bonacci's care during the pregnancies of her five children. For purposes of the partial summary judgment motion, Lilly acknowledges that Melnick ingested Lilly's DES. (Docket Entry # 325, n.2).

Plaintiffs offer the affidavits to show that Dr. Bonacci's routine prescribing practice was to read and heed warnings from drug manufacturers and to share the information with his patients. (Docket Entry ## 333 & 350). Lilly maintains that Dr.

Greco's testimony is hearsay because he lacks personal knowledge of Dr. Bonacci's practice and is not testifying as an expert.<sup>1</sup>

(Docket Entry # 325, n.9; Docket Entry # 338). Lilly further posits that the testimony is not admissible to show Dr. Bonacci's character or his "habit" of heeding drug manufacturers' warnings and advising his patients of such warnings.<sup>2</sup>

Lilly seeks to strike the remaining two affidavits as inadmissible habit evidence for the same reasons. As with Dr. Greco's testimony, Lilly argues that Ritz's and Makowiec's testimony constitutes inadmissible character evidence under Rule 404, F.R.E. ("Rule 404"). Lilly's additional argument that the

Plaintiffs' pretrial memorandum does not designate Dr. Greco as an expert witness. (Docket Entry # 350, p. 31). At the December 12 and 13, 2012 conferences, plaintiffs' counsel represented that Dr. Greco was a fact witness. This court stated its agreement from the bench during the December 13, 2012 conference.

Lilly's additional argument that the affidavit testimony (Docket Entry # 331-4) contradicts Dr. Greco's prior deposition testimony is not well taken. It is true that where a party gives "clear answers to unambiguous deposition questions, he or she cannot raise an issue of fact by submitting a subsequent affidavit that merely contradicts the deposition testimony." Lowery v. AIRCO, Inc., 725 F.Supp. 82, 85-86 (D.Mass. 1989); accord Colantuoni v. Alfred Calcagni & Sons, Inc., 44 F.3d 1, 4-5 (1st Cir. 1994); Chapman Ex Rel. Estate of Chapman v. Bernard's, Inc., 167 F.Supp.2d 406, 419 (D.Mass. 2001). "Variations in a witness's testimony and any failure of memory throughout the course of discovery create an issue of credibility" which is properly resolved by the finder of fact. <u>Tippens v. Celotex</u> <u>Corporation</u>, 805 F.2d 949, 954 (11<sup>th</sup> Cir. 1986) (reversing allowance of summary judgment and finding that affidavit was not inherently inconsistent with deposition testimony and should have been considered). Whereas certain portions of the deposition testimony (Docket Entry # 327-8, pp. 50-51 & 100-102) vary from the affidavit, other portions (Docket Entry # 327-8, pp. 103-108 & 131-133) coincide with the affidavit.

subject matter of the witnesses' testimony (Dr. Bonacci's practices regarding warnings) constitutes a new statement is unavailing. The identity of these individuals is not a surprise. Plaintiffs filed previous statements on July 6, 2012, identifying them as former patients of Dr. Bonacci.<sup>3</sup> The change in the import of their testimony does not warrant striking it from the summary judgment record.

#### BACKGROUND

As set forth in Dr. Greco's deposition, he graduated from Jefferson Medical College in Philadelphia, Pennsylvania in 1951. After graduation, he remained in Philadelphia where he served his surgical residency at the Jefferson Medical College Hospital.

After completing his residency, he moved to Drums, Pennsylvania in 1956. McNeely, Andrews, Fecho and Francine Melnick were born in 1952, 1953, 1955 and 1958. Dr. Greco therefore moved to the area after the births of three of the four plaintiffs.

Drums, Tresckow and Hazleton, Pennsylvania are located in the same general area.<sup>4</sup> Dr. Greco began practicing surgery in the Hazleton area in 1956. The nature of his practice covered

<sup>&</sup>lt;sup>3</sup> Moreover, during a December 13, 2012 conference, plaintiffs' counsel represented that she first disclosed these two individuals to Lilly in May or June 2012.

This court takes judicial notice of the locations of Drums, Tresckow and Hazleton, Pennsylvania. See <u>United States v. Bello</u>, 194 F.3d 18, 23 (1<sup>st</sup> Cir. 1999) ("[g]eography has long been peculiarly susceptible to judicial notice for the obvious reason that geographic locations are facts which are not generally controversial").

"everything from remov[ing] toenails to operating on hearts."

(Docket Entry # 327-8). At the outset of his practice, he had

"free time" and, in an attempt to build his practice, he made one

or two social visits to Dr. Bonacci's office in 1956 or 1957 to

introduce himself. (Docket Entry # 327-8). Dr. Greco did not

have the opportunity "to see" Dr. Bonacci during these social

visits because "he was always very busy." (Docket Entry # 327
8).

Dr. Greco became more familiar with Dr. Bonacci during monthly staff meetings at the two local hospitals, "St. Joseph's and Hazleton General." (Docket Entry # 327-8). The discussion at these educational staff meetings among the small community of local doctors covered "anything and everything." (Docket Entry # 327-8). Dr. Greco remembers discussing "mutual problems" as well as advances in surgery, medical treatment for hypertension and antibiotics with Dr. Bonacci. (Docket Entry # 327-8).

In addition to seeing Dr. Bonacci twice a month at these staff meetings, Dr. Greco saw him at the hospitals. Dr. Greco customarily did his rounds at 6:00 a.m. and 6:00 p.m. A family physician such as Dr. Bonacci would also conduct rounds when he had patients at one of the hospitals. In addition, Dr. Greco estimated that he received "anywhere from one to four surgical referrals" from Dr. Bonacci per month. (Docket Entry # 327-8). Dr. Greco usually consulted with Dr. Bonacci about all of the

patients he referred. The two also discussed "advances in surgery" and in antibiotics. (Docket Entry # 327-8).

Dr. Greco did not treat patients in Dr. Bonacci's office.

He never attended any of the house calls Dr. Bonacci made and he never shared an office with Dr. Bonacci. Dr. Greco, a general surgeon, did not practice medicine with Dr. Bonacci, a family practitioner. The relevant portion of the deposition testimony reads:

- Q. . . Dr. Bonacci made house calls did he not?
- A. Yes he did.
- Q. Did you ever go on any house calls with him?
- A. No, I didn't. If you're going to ask me what is Dr. Bonacci's practice, I don't know, I didn't practice with him. I know the type of physician he was, if you want to ask me that.

(Docket Entry # 327-8, pp. 101-102). Dr. Greco is, however, familiar with Dr. Bonacci's character. He depicts:

Dr. Bonacci's character as being conservative, very compassionate and almost anal retentive as far as the care of his patients was concerned. And his patients always came first. And I am sure that if he read any warning on any drug, if he thought it was bad enough, he certainly would not dispense it, because that's the type of individual he was.

(Docket Entry # 327-8).

Dr. Greco does not recall talking to Dr. Bonacci about DES. He does remember seeing "a prescription" for DES written by Dr.

Bonacci.<sup>5</sup> In addition, he "would imagine" that Dr. Bonacci wrote prescriptions for antibiotics because "very few doctors stocked antibiotics in their office[s]."<sup>6</sup> (Docket Entry # 327-8).

"[T]he common drugs that most doctors stocked" in their offices included sedatives, sleeping capsules, aspirin and codeine because they "treat[ed] the most common complaints that people coming into a family doctor had." (Docket Entry # 331-7). Like Dr. Bonacci, Dr. Greco prescribed drugs from his office.

Consistent or, at a minimum, not inconsistent with Dr.

Greco's clear answers at the deposition, he attests to the

following in the subsequent affidavit: "[I]t was common for me

to discuss issues relating to the practice of medicine with Dr.

Bonacci half a dozen times a month, in either patient referrals,

<sup>&</sup>lt;sup>5</sup> The relevant portion of the deposition testimony reads:

Q. Do you know, as you sit here today, what specific medicines [Dr. Bonacci] dispensed?

A. I know one of the medicines he dispensed was DES, diethylstilbestrol, I know that as a matter of fact.(Docket Entry # 331-7, p. 110).

At a later point during the deposition, Dr. Greco testified as follows:

Q. Did you have the opportunity to ever actually see a prescription written by Dr. Bonacci for DES?

A. Yes, I testified to that. (Docket Entry # 327-8, p. 130).

<sup>&</sup>lt;sup>6</sup> In the 1950s, Pennsylvania law allowed licensed physicians to dispense medication. (Docket Entry # 327-8).

hospital rounds, or association meetings." (Docket Entry # 331-4). He describes his relationship with Dr. Bonacci as "both personal and professional." (Docket Entry # 331-4). The two "often discuss[ed] treatment options" for the patients Dr. Bonacci referred and whether "medication alone, or surgery, would be most beneficial, and what were the side effects and risks of the various modalities." (Docket Entry # 331-4). It was "impossible" for Dr. Greco to specify the number of conversations he had with Dr. Bonacci about "drug side effects" but he believed "it was enough" for him to know "the nature of [Dr. Bonacci's] practice." (Docket Entry # 331-4). Dr. Greco does recall discussing the risks and side effects of antibiotics with Dr. Bonacci and the information in the manufacturer's labeling.

Dr. Greco also averred that Dr. Bonacci's "custom and habit" was not to "prescribe any drug if it came with a warning similar to" the warning attached to the affidavit. (Docket Entry # 331-

<sup>&</sup>lt;sup>7</sup> The attached hypothetical warning reads:

The safety and efficacy of DES is still under investigation. Although there are reports that DES may be helpful in maintaining a pregnancy, other reports question its efficacy. Both human and animal studies report that natural as well as synthetic estrogens (1) cross the placenta, (2) cause anomalies in the sexual tissue of a developing fetus, [and] (3) affect the breast of the newborn, presenting an increased risk of vaginal or breast neoplasm. Synthetic and natural estrogens are a known cause of cancer. Further investigation is warranted. There are no controlled studies which support either efficacy or safety.

<sup>(</sup>Docket Entry # 331-4).

## 4, $\P$ 8). In the affidavit, he further states:

that the standard medical practice in Hazleton was, and is, to pass warnings on to our patients. In fact, to do any less would amount to a departure from accepted practice. Dr. Bonacci was regarded by myself, and other physicians, as one of the best and most caring doctors in the area. That he would prescribe DES, without discussing a warning like this with his patients, would be a departure from his routine and habitual practice. In the entire course of my familiarity with Dr. Bonacci, for him to ignore a manufacturer's warning would be unthinkable.

(Docket Entry # 331-4,  $\P$  9).

In sum, beginning in and around 1956 or 1957, Dr. Greco became acquainted with Dr. Bonacci. The two physicians developed a personal and professional relationship. Dr. Greco was not part of Dr. Bonacci's practice. They did not discuss DES although Dr. Greco does remember seeing a prescription for DES written by Dr. Bonacci. Dr. Greco never witnessed Dr. Bonacci warn a patient about side effects of a medication let alone the side effects of DES. He never saw Dr. Bonacci inform a patient of risks or side effects contained in a manufacturer's label for a drug. He therefore did not have first hand knowledge of Dr. Bonacci's prescribing practices of heeding a manufacturer's negative warnings and not prescribing a medication or informing a patient of side effects, if any, of a medication he was prescribing.

Dr. Greco has, however, spoken with Dr. Bonacci numerous times about patients that they shared. They saw each other frequently including at monthly staff meetings and during

hospital rounds. From 1956 until at least 1980,8 they both practiced medicine in the Hazleton community. They discussed inter alia advances in medicine and mutual problems. They also had conferences about a particular patient's concerns about drug side effects and that such side effects should be discussed with the patient.

Dr. Greco is also familiar with the standard medical practice in the Hazleton area. He moved to Drums in or around July 1956 and established a surgical practice covering a wide range of medical conditions. He retired in 1986. Monthly staff meetings at the two hospitals allowed Dr. Greco to "get[] the feel of what the practice was in the area." (Docket Entry # 327-8). The community of doctors in the area was small.9

#### DISCUSSION

Lilly maintains that Dr. Greco's testimony is hearsay, does not constitute a "habit" under Rule 406, F.R.E. ("Rule 406"), and is inadmissible character evidence under Rule 404. (Docket Entry # 338). Plaintiffs submit that Dr. Greco may testify about Dr. Bonacci's custom and prescribing practices under Rule 406.

According to plaintiffs, Dr. Greco's familiarity with Dr.

<sup>&</sup>lt;sup>8</sup> Dr. Bonacci died in the 1980s. Dr. Greco retired in 1986.

<sup>&</sup>lt;sup>9</sup> As discussed infra, such first hand knowledge about the practice of medicine in the Hazleton area provides an adequate foundation from which to provide a lay opinion about the standard medical practice in Hazleton in and around the mid to late 1950s.

Bonacci's practices allows him to testify about the latter's habit of passing manufacturer's warnings about the drugs he prescribed to his patients as well as his practice not to prescribe drugs that carry a warning such as the one attached to his affidavit. (Docket Entry ## 333 & 331-4). Dr. Greco's affidavit also opines about the standard medical practice in Hazleton. The standard practice encompassed passing warnings to patients.

The Federal Rules of Evidence distinguish between character evidence in Rule 404 and Rule 405, F.R.E., and habit evidence in Rule 406. Because different rules apply to each category, it is important to clarify the distinctions as applied to Dr. Greco's statements.

A habit "describes one's regular response to a repeated specific situation." Rule 406, F.R.E., Advisory Committee Notes; Weissenberger's Federal Evidence Courtroom Manual, § 406 (7th ed. 2011) ("concept" of a habit "is best understood as a person's regular practice of meeting a particular kind of situation with a specific type of responsive conduct"). Habit evidence "may be probative of '"the regular practice of meeting a particular kind of situation with a specific type of conduct, such as the habit of going down a particular stairway two stairs at a time, or of giving the hand-signal for a left turn."'" United States v.

Newman, 982 F.2d 665, 668 (1st Cir. 1992) (quoting Advisory

Committee Notes of Rule 406, quoting McCormick, <u>Evidence</u> § 195 at 826). In contrast, "Character is a generalized description of one's disposition, or of one's disposition in respect to a general trait, such as honesty, temperance, or peacefulness." Rule 406, F.R.E., Advisory Committee Notes.

Dr. Greco's statement that, "Dr. Bonacci was regarded by myself, and other physicians, as one of the best and most caring doctors in the area" (Docket Entry # 331-4,  $\P$  9, sent. 3-5) is a statement about his character. Likewise, Dr. Greco's deposition testimony describing "Dr. Bonacci's character as being conservative, very compassionate and almost anal retentive" or his dedication to his patients (Docket Entry # 327-8, pp. 132-133 & 135-136) constitutes character evidence. Insofar as plaintiffs seek to rely on this evidence to establish Dr. Bonacci's conduct on the particular occasions that he prescribed DES to plaintiffs' mother, Rule 404(a) does not permit it. Subject to certain exceptions that do not apply to Dr. Greco's statements, Rule 404(a) prohibits the admission into evidence "of a person's character or character trait . . . to prove that on a particular occasion the person acted in accordance with the character or trait."<sup>10</sup> Rule 404(a), F.R.E.

Dr. Greco's averment that "one of Dr. Bonacci's greatest concerns was ensuring that his patients and [Dr. Greco's] patients were well informed of the risks and benefits of their medications" (Docket Entry # 331-4, ¶ 5) falls into a grey area between character and habit evidence. If construed as character evidence, it is not admissible under Rule 404. It is likewise

Turning to the proposed habit evidence, Dr. Greco's statements fall into the following categories: (1) statements of specific conduct that Dr. Bonacci dispensed DES and that he saw a prescription for DES written by Dr. Bonacci (Docket Entry # 331-7, pp. 110 & 131); (2) statements about his discussions with Dr. Bonacci about the risks and side effects of antibiotics or advances in antibiotics (Docket Entry # 331-4, ¶ 7; Docket Entry # 327-8, p. 107, ln. 2-15); (3) statements about his discussions with Dr. Bonacci regarding unidentified patients' concerns about the risks and side effects of medication (Docket Entry # 331-4,  $\P\P$  4 & 6); (4) statements about his discussions with Dr. Bonacci concerning advances in medicine, "mutual problems," an unidentified shared patient or the practice of medicine in general (Docket Entry # 331-4, ¶ 3, sent. 1) (Docket Entry # 327-8, p. 104, ln. 3-7; p. 105, ln. 20-24; p. 106, ln. 20-24; p. 107, ln. 1 & 16-24; p. 108, ln. 1-18); and (5) opinions about Dr. Bonacci's prescribing practices (Docket Entry # 331-4,  $\P$  2 & 8; Docket Entry # 327-8, pp. 133-135) and the standard medical practice in Hazleton (Docket Entry # 331-4,  $\P$  9, sent. 1-2). These statements either attempt to provide evidence of Dr. Bonacci's prescribing habits, opinions about the practice of medicine in Hazleton or Dr. Bonacci's practices in particular and/or background or foundational evidence to support admission of such evidence. Plaintiffs also seek admission of the

inadmissible as habit evidence for reasons discussed infra.

aforementioned testimony by two of Dr. Bonacci's patients.

Plaintiffs, as the parties offering the Rule 406 evidence, bear the burden of establishing the habitual nature of the practice. See United States v. Newman, 982 F.2d at 668; Weil v. Seltzer, 873 F.2d 1453, 1461 (D.C.Cir. 1989). The two factors considered controlling in determining whether an individual's behavior pattern "has matured into a habit" are the "'adequacy of sampling and uniformity of response.'" <u>United States v. Newman</u>, 982 F.2d at 668 (quoting Rule 406 Advisory Committee Notes). Both "factors focus on whether the behavior at issue 'occurred with sufficient regularity making it more probable than not that it would be carried out in every instance or in most instances." Id. (quoting Weil v. Seltzer, 873 F.2d at 1460). "The requisite regularity is tested by the '"ratio of reaction to situations."'" Id. (quoting Wilson v. Volkswagen of America, Inc., 561 F.2d 494, 512 ( $4^{th}$  Cir. 1977), and citing Weil v. Seltzer, 873 F.2d at 1461). Plaintiffs must therefore provide a sufficient foundation to assess the adequacy of the sampling. See id. ("[a]ppellant's proffer failed to demonstrate the admissibility of the MacDonald testimony under Rule 406" and "provided no foundation for assessing the adequacy of the sampling"). "[T]he regularity of the conduct alleged to be habitual" or routine, here, Dr. Bonacci's prescribing practices or the standard medical practices in Hazleton of sharing warnings with patients, must "rest on an

analysis of instances numerous enough to support an inference of systematic conduct and to establish one's regular response to a repeated specific situation." <u>Id.</u> (internal quotation marks and brackets omitted).

The testimony of two of Dr. Bonacci's former patients (Docket Entry ## 331-5 & 331-6) falls significantly short of the requisite number of instances and uniformity of response from which to establish Dr. Bonacci's prescribing practices. Ritz and Makowiec were Dr. Bonacci's patients for a lengthy period of time. Dr. Bonacci, who was too busy to see Dr. Greco during the latter's social visit[s] to his office, had significantly more than two patients to whom he prescribed medication. instances of prescribing medications to Ritz and Makowiec are therefore not numerous enough to support a finding of habitual conduct. See id. at 669 (quoting G.M. Brod & Co. v. U.S. Home <u>Corporation</u>, 759 F.2d 1526, 1533 (11<sup>th</sup> Cir. 1985), rejecting Rule 406 evidence because the "specific instances within experience of witness, when considered in light of thousands of unobserved similar instances, 'falls far short of the adequacy of sampling and uniformity of response which are the controlling considerations governing admissibility'").

Turning to Dr. Greco's testimony, plaintiffs wish to use his testimony to show that Dr. Bonacci would have heeded a manufacturer's warning and not prescribed DES if the drug carried

a warning similar to the one attached to Dr. Greco's affidavit. According to plaintiffs, when faced with the situation of prescribing medication to his patients, Dr. Bonacci had a regular practice or habit of heeding a manufacturer's warnings and either not prescribing the medication or sharing the negative warnings with his patients. Dr. Greco, however, has never seen or observed Dr. Bonacci prescribe medication. He lacks personal knowledge of Dr. Bonacci's particular prescribing behavior of heeding a manufacturer's negative warning. Dr. Greco never saw or witnessed Dr. Bonacci prescribe medication to a patient let alone see him prescribe DES. Dr. Greco is not a member of Dr. Bonacci's staff and was not in a position to observe Dr. Bonacci prescribe medication.

The statements in categories two through four do not adequately or sufficiently show similar instances of the behavior or practice at issue. Discussions about medical advances or the side effects of antibiotics between two physicians (as opposed to a physician and a patient) or about a shared patient are not evidence of similar instances let alone instances numerous enough to warrant the inference of Dr. Bonacci's habitual conduct of not prescribing medications that carried negative warnings. See also G.M. Brod & Co., Inc. v. U.S. Home Corporation, 759 F.2d at 1533 ("Sierra's testimony of specific instances of Home's operation within his personal experience, when considered in the light of .

. . the significant differences between the types of contracts involved" and course of dealing "falls short of the adequacy of sampling and uniformity of response"); <a href="mailto:accord\_United States v.">accord\_United States v.</a>
<a href="Mailto:Newman">Newman</a>, 982 F.2d at 669 (quoting G.M. Brod & Co., Inc. v. U.S.
<a href="Mailto:Home Corporation">Home Corporation</a>, 759 F.2d at 1533). As direct instances of habit evidence, the testimony in categories two through four does not constitute part of the summary judgment record.

The statements in category one that Dr. Greco saw "a prescription written by Dr. Bonacci for DES" and his professed knowledge that Dr. Bonacci dispensed DES (Docket Entry # 331-7, pp. 110 & 131) also fail to establish that the behavior occurred with sufficient regularity. As specific instances of conduct, these instances are not numerous enough, even including the two affidavits from Dr. Bonacci's former patients, to support an inference of systemic conduct on the part of Dr. Bonacci in not prescribing medication with negative warnings. See United States v. Newman, 982 F.2d at 668.

Lilly also argues that Dr. Greco's testimony amounts to hearsay. The argument is well taken insofar as it applies to Dr. Greco's testimony about Dr. Bonacci's prescribing practices. Dr. Greco's recitations of what Dr. Bonacci said to him are hearsay. Dr. Bonacci is not a party and, accordingly, his statements to Dr. Greco do not constitute party admissions. Dr. Greco has no firsthand knowledge of the prescribing practices of Dr. Bonacci. See, e.g., Weil v. Seltzer, 873 F.2d at 1461. Categories one and

four, however, provide a foundational basis to support admissible evidence in the form of Dr. Greco's lay opinion on the standard medical practice in Hazleton.

Rule 406 is silent with respect to the method of proof to establish habit. The rule simply states that:

Evidence of a person's habit or an organization's routine practice may be admitted to prove that on a particular occasion the person or organization acted in accordance with the habit or routine practice. The court may admit this evidence regardless of whether it is corroborated or whether there was an evewitness. 11

Rule 406, F.R.E.

Here, the proponents of the evidence do not rely on expert testimony as a means to prove habit. They do, however, proffer Dr. Greco's lay opinions subdivided as: (1) statements of his opinion that Dr. Bonacci would not have prescribed DES or any medication if it contained certain negative warnings (Docket Entry # 331-4,  $\P\P$  2 & 8) (Docket Entry # 327-8, pp. 133-135); and (2) statements of Dr. Greco's opinion about "the standard medical practice" in Hazleton (Docket Entry # 331-4,  $\P$  9, sent. 1-2).

The latter sentence specifies that admissibility does not require corroborating evidence or an eyewitness. Rule 406 therefore "abrogated older authority that habit evidence was not admissible in certain cases if there was an eyewitness to the event." 2 J. Weinstein & M. Berger, Weinstein's Federal Evidence § 406.05 (2<sup>nd</sup> ed. 2012).

Dr. Greco provides additional descriptions of the medical practice in the Hazleton area (Docket Entry # 327-8, pp. 103 & 106) which, together with other evidence in the record, provides sufficient foundation for the aforementioned lay opinion regarding standard medical practice of local doctors practising in the Hazleton area.

Rule 406 case law exemplifies a preference for proof of specific instances of conduct based on the witnesses direct observations. See Hall v. Arthur, 141 F.3d 844, 849 (8th Cir. 1998) (affirming Rule 406 admission of testimony from dentist's other patients who had personal knowledge of what the dentist told or did not tell them about risks for the same procedure the dentist performed on the plaintiff); Meyer v. United States, 638 F.2d 155, 156 (10th Cir. 1980) (affirming Rule 406 admission of dentist's own testimony of what he did to advise patients of risk); Weil v. Seltzer, 873 F.2d at 1460-1461 (unsuccessful attempt to introduce testimony of five former patients who had personal knowledge of how the defendant treated their allergies but no personal knowledge of how the defendant treated other patients).

Rule 406 does not, however, exclude lay opinion evidence.

As explained by one commentator:

Rules 602 and 701 in combination provide that an opinion of a nonexpert witness is admissible if based upon personal knowledge and helpful to the trier of fact in determining a fact of consequence. Opinions of witnesses as to the routine practice of an organization or habit of an individual based upon personal knowledge of the witness should normally be permitted on such grounds. If undisputed, opinion testimony would avoid wasting time. Where in controversy, specific instances of conduct may in the discretion of the court be required to be disclosed as part of development of the witness' basis for his opinion.

Although the testimony of the habit bearer would also suffice, <u>see</u>, <u>e.g.</u>, <u>United States v. Arredondo</u>, 349 F.3d 310, 315 (6<sup>th</sup> Cir. 2003), Dr. Bonacci died in the mid-1980s.

Specific instances forming the basis of the witness' opinion may of course be developed on cross-examination.

Michael H. Graham, <u>Handbook of Federal Evidence</u> § 406:4 (6<sup>th</sup> ed. 2006). Exercising this court's discretion, <u>see generally</u> 2 J. Weinstein & M. Berger, <u>Weinstein's Federal Evidence</u> § 406.06[2] (2<sup>nd</sup> ed. 2012), Dr. Greco's lay opinions may provide a proper means to establish habit or routine practice if they satisfy the requirements of Rule 701.<sup>14</sup>

Rule 701 governs the admission into evidence of a lay opinion. The lay opinion witness remains a fact witness as

With respect to the lay opinion of the standard medical practice in Hazleton (Docket Entry # 331-4, ¶ 9), the Hazleton community of doctors must constitute an organization or group within the meaning of Rule 406. See 2 J. Weinstein & M. Berger, Weinstein's Federal Evidence § 406.03[2] (2nd ed. 2012) (entity must be cohesive organization to admit routine practice under Rule 406); Rule 406, F.R.E., Advisory Committee Notes ("[e]quivalent behavior on the part of a group is designated 'routine practice of an organization' in the rule"); see also <u>United States v. Rangel-Arreola</u>, 991 F.2d 1519, 1523 (10th Cir. 1993) ("loose-knit group" of truck drivers "with no apparent structure or routine" was not an organization or group within the meaning of Rule 406). More specifically, the entity in question "must be a cohesive organization marked by structure and routine." 2 J. Weinstein & M. Berger, Weinstein's Federal Evidence § 406.03[2] (2nd ed. 2012) (citing United States v. Rangel-Arreola, 991 F.2d at 1523); see generally Elias v. Suran, 616 N.E.2d 134, 137 (Mass.App.Ct. 1993) (applying Massachusetts law). Here, the practice in the Hazleton community of local doctors differed from the practice in "big cities." (Docket Entry # 327-8, p. 103). Doctors followed their patients in the hospital. It was a rule in the two local hospitals to attend monthly staff meetings. (Docket Entry # 327-8, p. 105). Dr. Greco and Dr. Bonacci were members of that group inasmuch as they saw each other at these meetings. "It was a small community." (Docket Entry # 327-8, pp. 106-107). For purposes of summary judgment only, this court finds that the group qualifies as an organization.

opposed to an expert witness. See Weissenberger's Federal Evidence Courtroom Manual, § 701 (7th ed. 2011) ("Rule 701 governs the admissibility of opinion testimony by lay witnesses, more commonly referred to as 'fact' witnesses"). Unlike an expert's opinion, a layman's opinion must be "rationally based on the witness's perception." Rule 701(a), F.R.E.; see Rule 602, F.R.E.; 23 Charles Alan Wright & Kenneth W. Graham, Jr. Federal Practice and Procedure § 5276 (1980) (noting need to "show that his opinion or generalization is based on his personal knowledge"). The rule imposes additional conditions that the opinion testimony is helpful to determine a fact or clearly understand the witness's testimony and is not based on scientific, technical or other specialized knowledge under Rule 702. 15 Under the rule, courts allow "lay witnesses to express opinions about a business 'based on the witness's own perceptions and "knowledge and participation in the day-to-day affairs of the

<sup>&</sup>lt;sup>15</sup> The rule reads as follows:

Opinion Testimony by Lay Witnesses

If a witness is not testifying as an expert, testimony in the form of an opinion is limited to one that is:

<sup>(</sup>a) rationally based on the witness's perception;

<sup>(</sup>b) helpful to clearly understanding the witness's testimony or to determining a fact in issue; and

<sup>(</sup>c) not based on scientific, technical, or other specialized knowledge within the scope of Rule 702.

Rule 701, F.R.E.

business."'" <u>United States v. Munoz-Franco</u>, 487 F.3d 25, 35-36 (1st Cir. 2007) (quoting <u>United States v. Polishan</u>, 336 F.3d 234, 242 (3rd Cir. 2003), with internal brackets omitted); <u>see United States v. Valdivia</u>, 680 F.3d 33, 50-51 (1st Cir. 2012) (drug enforcement agent allowed to give lay opinion about telephone account at issue based on his prior drug investigations and experience "that traffickers often list unrelated third parties as their telephones' subscribers").

For previously stated reasons, Dr. Greco lacks firsthand knowledge of Dr. Bonacci's prescribing practices. Accordingly, there is an inadequate foundation under Rule 701(a) to consider Dr. Greco's opinion that Dr. Bonacci would not have prescribed DES if it contained a warning similar to the one attached to Dr. Greco's affidavit. (Docket Entry # 331-4, ¶ 2).

Turning to the existence of the requisite knowledge under Rule 701(a) as a basis to consider Dr. Greco's opinion about standard medical practice in the Hazleton area, he practiced medicine as a surgeon in the area from 1956 to 1986. He is intimately familiar with the small community of doctors having attended monthly staff meetings and conducted rounds at the two hospitals. He therefore has the requisite knowledge within the meaning of Rule 701(a). The opinion is helpful to determine the proximate cause issue in Count I. Routine medical practice in the mid to late 1950s in Hazleton is decidedly less complex than

it is today. (Docket Entry # 327-8, p. 103). As such, it is not based on knowledge within the scope of Rule 702.

As evidence of habit, although a patient's medical history is not routine, a manufacturer's warnings about a medication are established by product literature disclosed and communicated by the manufacturer or contained in established authorities such as the Physicians' Desk Reference to Pharmaceutical Specialities and Biologicals (1952) (Docket Entry # 331-3) or the American Druggist Blue Book (1952) (Docket Entry # 327-4). The opinion could therefore be admissible to show the practice of the small group of doctors in the local community allowing the jury to infer the practice of Dr. Bonacci.

Finally, this determination to include Dr. Greco's lay opinion on the standard medical practice in Hazleton as habit evidence under Rule 406 as part of the summary judgment record or that such a practice in the Hazleton community exists and qualifies as Rule 406 habit evidence is not the law of this case with respect to the proceedings at trial based on a different record. See Fisher v. Trainor, 242 F.3d 24, 29 n.4 (1st Cir. 2001) ("'initial denial of summary judgment does not foreclose, as the law of the case, a subsequent grant of summary judgment on an amplified record'"). The ruling also does not foreclose the possibility of admitting Dr. Greco's lay opinion testimony for purposes other than to show the routine practice of medicine in

the Hazleton under Rule 406. <u>See generally United States v.</u>

<u>Valdivia</u>, 680 F.3d at 50-51 (discussing lay opinion of drug enforcement agent without referring to Rule 406).

As a final matter, at the November 2012 hearing, plaintiffs opposed the motion to strike as outside the parameters of a procedural order. The order limited the number of pages of the memorandum in support of summary judgment, the LR. 56.1 statement and the "[s]upporting exhibits and affidavits." (Docket Entry # 319). It did not limit Lilly's ability to file a motion to strike exhibits filed by plaintiffs to support their opposition.

See generally Iacobucci v. Boulter, 193 F.3d 14, 19 (1st Cir. 1999) ("[a] trial court ordinarily is the best expositor of its own orders").

## II. MOTION FOR PARTIAL SUMMARY JUDGMENT

Lilly seeks partial summary judgment on the duty to warn negligence count due to the absence of evidence that Lilly's failure to warn that DES increases the risk of breast cancer in a patient's female offspring proximately caused plaintiffs' breast cancer. Under the "learned intermediary" rule, plaintiffs must show "that if Lilly had warned Dr. Bonacci that DES increased the risk of breast cancer in a patient's female offspring, then Dr. Bonacci would not have prescribed the drug," according to Lilly. (Docket Entry # 325).

Plaintiffs assert that Pennsylvania law<sup>16</sup> applies a rebuttable "heeding presumption" because they were exposed to DES without their consent, there is no evidence that Dr. Bonacci ignored Lilly's warnings and there is evidence that he deferred to manufacturers' warnings. Plaintiffs submit it is a question for the jury as to whether Dr. Bonacci had a habit, custom or practice of reading and heeding warnings for drugs he prescribed and whether Dr. Bonacci would not have prescribed DES to plaintiffs' mother if he was given a proper warning. It is also a jury question whether, if Dr. Bonacci shared an adequate warning with plaintiffs' mother, she would have refused to take the drug, according to plaintiffs. (Docket Entry # 333).

# STANDARD OF REVIEW

Summary judgment is designed "'to pierce the boilerplate of the pleadings and assay the parties' proof in order to determine whether trial is actually required.'" <u>Davila v. Corporacion De Puerto Rico Para La Difusion Publica</u>, 498 F.3d 9, 12 (1st Cir. 2007). It is appropriate when the summary judgment record shows "there is no genuine issue of material fact, and the moving party is entitled to judgment as a matter of law." Rule 56(a), Fed. R. Civ. P. "A dispute is genuine if the evidence about the fact is such that a reasonable jury could resolve the point in the favor of the non-moving party." American Steel Erectors, Inc. v. Local

The parties correctly agree that Pennsylvania law applies to Count I.

Union No. 7, International Association of Bridge, Structural,

Ornamental & Reinforcing Iron Workers, 536 F.3d 68, 75 (1st Cir.

2008). "'A fact is material if it carries with it the potential to affect the outcome of the suit under the applicable law.'"

OneBeacon America Insurance Co. v. Commercial Union Assurance Co.

of Canada, 684 F.3d 237, 241 (1st Cir. 2012).

Facts are viewed in favor of the non-movants, i.e., plaintiffs. Noonan v. Staples, Inc., 556 F.3d 20, 23 (1st Cir. 2009). "Where, as here, the nonmovant has the burden of proof and the evidence on one or more of the critical issues in the case is not significantly probative, summary judgment may be granted." Davila v. Corporacion De Puerto Rico Para La Difusion Publica, 498 F.3d at 12 (internal quotation marks, citation and ellipses omitted); accord OneBeacon America Insurance Co. v. Commercial Union Assurance Co. of Canada, 684 F.3d at 241 (on issues where movant does not have burden of proof, movant can obtain summary judgment by showing "'an absence of evidence to support the nonmoving party's case'"); Clifford v. Barnhart, 449 F.3d~276, 280 (1st Cir. 2006) (if moving party makes preliminary showing, nonmoving party must "produce specific facts, in suitable evidentiary form, to establish the presence of a trialworthy issue" with respect to each element on which he "would bear the burden of proof at trial") (internal quotation marks and citations omitted).

Nonmovants such as plaintiffs "'may defeat a summary judgment motion by demonstrating, through submissions of evidentiary quality, that a trialworthy issue persists." Rockwood v. SKF USA Inc., 687 F.3d 1, 9 (1st Cir. 2012). "[C]onclusory allegations, improbable inferences, and unsupported speculation" however are "insufficient to discharge the nonmovant's burden." Id. (internal brackets supplied and internal quotation marks omitted)); see Chiang v. Verizon New England Inc., 595 F.3d 26, 30 (1st Cir. 2010) (noting requirement to ignore "'conclusory allegations, improbable inferences, and unsupported speculation'" on summary judgment). Finally, uncontroverted statements of fact in a LR. 56.1 statement comprise part of the summary judgment record. See Cochran v. Quest Software, Inc., 328 F.3d 1, 12 (1st Cir. 2003) (the plaintiff's failure to contest date in LR. 56.1 statement of material facts caused date to be admitted on summary judgment).

#### FACTUAL BACKGROUND

In addition to Dr. Greco's lay opinion, the summary judgment record shows the following. Plaintiffs' mother suffered a miscarriage in 1949. She gave birth to Mary Ann Killian ("Killian") in 1950. In 1951, she experienced a second miscarriage. Thereafter, she gave birth to McNeely, Andrews, Fecho and Francine Melnick in 1952, 1953, 1955 and 1958. Plaintiffs' mother was a patient of Dr. Bonacci's throughout this time period. Dr. Bonacci did not prescribe DES to plaintiffs'

mother during her first pregnancy. For purposes of the present motion, she did ingest Lilly's DES during the pregnancies of each of the four plaintiffs. Dr. Bonacci is deceased and has not provided any testimony or documentation relative to his treatment of plaintiffs' mother.

During the 1950s, Lilly recommended DES treatment for threatened abortion as well as repeated or habitual abortion.

(Docket Entry # 327-6). The phrase "habitual abortion" denotes three or more consecutive abortions. Lilly also recommended DES therapy "to prevent accidents of pregnancy." (Docket Entry # 331-3). Lilly's literature supplied to physicians did not include any warning about the risk that DES could cross the placenta and affect a baby in utero. (Docket Entry ## 331-2, 327-5 & 327-6). Lilly's literature provided to physicians also noted that, "In the absence of hypothyroidism, probably the most effective agent" for treating habitual abortion is DES. (Docket Entry # 331-2).

#### DISCUSSION

Count I raises a negligent duty to warn claim against Lilly as the manufacturer of DES. As a federal court sitting in diversity and adjudicating a state law claim, this court is bound by the state's substantive law as pronounced by the state's highest court. See Barton v. Clancy, 632 F.3d 9, 17 (1st Cir. 2011). Turning to the pronouncements of the Pennsylvania Supreme Court, section 388 of the Restatement (Second) of Torts ("the Restatement") provides the applicable standard of care in a

negligent failure to warn claim against the manufacturer of a prescription drug. Hahn v. Richter, 673 A.2d 888, 890 (Pa. 1996) (product liability action against manufacturer of prescription drug); accord Incollingo v. Ewing, 282 A.2d 206, 220 n.8 (Pa. 1971) (action against pediatrician and osteopath for negligently prescribing drug and against manufacturer for negligent failure to warn). Under section 388, "the supplier has a duty to exercise reasonable care to inform those for whose use the article is supplied of the facts which make it likely to be dangerous." Incollingo v. Ewing, 282 A.2d at 220 n.8.

Lilly seeks to apply the learned intermediary doctrine first adopted in <a href="Incollingo v. Ewing">Incollingo v. Ewing</a>, 282 A.2d at 206. <a href="See Mazur v.">See Mazur v.</a>
<a href="Merck & Co.">Merck & Co.</a>, Inc.</a>, 964 F.2d 1348, 1356 (3rd Cir. 1992) ("learned intermediary rule was first adopted by the Pennsylvania Supreme Court in <a href="Incollingo v. Ewing">Incollingo v. Ewing</a>, 282 A.2d at 206"). As set forth in <a href="Incollingo">Incollingo</a>, the rule instructs that when a drug is "available only upon prescription of a duly licensed physician, the warning required is not to the general public or to the patient, but to the prescribing doctor." <a href="Incollingo v. Ewing">Incollingo v. Ewing</a>, 282 A.2d at 220. Two decades after <a href="Incollingo">Incollingo</a>, the Pennsylvania Supreme Court reiterated the rule that a manufacturer's warning for a prescription drug runs to the prescribing doctor as opposed to the patient. <a href="Coyle by Coyle v. Richardson-Merrell">Coyle by Coyle v. Richardson-Merrell</a>, Inc., 584 A.2d 1383, 1385-1386 (Pa. 1991) (citing <a href="Incollingo v. Ewing">Incollingo v. Ewing</a>, 282

A.2d at 220). The <u>Coyle</u> court elaborated upon the rule in the following manner:

"it is the duty of the prescribing physician to be fully aware of (1) the characteristics of the drug he is prescribing, (2) the amount of the drug which can be safely administered, and (3) the different medications the patient is taking. It is also the duty of the physician to advise the patient of any dangers or side effects associated with the use of the drug as well as how and when to take the drug. The warnings which must accompany such drugs are directed to the physician rather than to the patient-consumer as '[i]t is for the prescribing physician to use his independent medical judgment, taking into account the data supplied to him by the manufacturer, other medical literature, and any other source available to him, and weighing that knowledge against the personal medical history of his patient, whether to prescribe a given drug.'"

Id. at 1385-1386 (quoting with approval Makripodis v. Merrell Dow Pharmaceuticals, Inc., 523 A.2d 374, 378 (Pa.Super. 1987), quoting Leibowitz v. Ortho Pharmaceutical Corporation, 307 A.2d 449, 457 (Pa.Super. 1973)).

The learned intermediary doctrine undeniably poses an obstacle to plaintiffs in establishing causation. Plaintiffs do not dispute that proximate cause is a required element in a negligent failure to warn claim against a manufacturer. See Simon v. Wyeth Pharmaceuticals, Inc., 989 A.2d 356, 368

(Pa.Super. 2009) ("[p]roximate cause is an essential element in failure-to-warn cases involving prescription medications"); accord Cochran v. Wyeth, Inc., 3 A.3d 673, 676 (Pa.Super. 2010) (same); Owens v. Wyeth, 2010 WL 2965014, at \*2 (Pa.Super. July 26, 2010) (same) (unpublished); Lineberger v. Wyeth, 894 A.2d

The <u>Coyle</u> court refused to extend strict liability under section 402A of the Restatement to pharmacists dispensing prescription drugs. <u>Id.</u> at 1386 n.1 & 1387.

141, 150 (Pa.Super. 2006) (same). Instead, they seek to impose the rebuttable heeding presumption primarily based on a number of asbestos cases. These cases do not involve a manufacturer's alleged failure to issue proper warnings for prescription drugs. Rather, they involve strict liability causes of action under section 402A of the Restatement against manufacturers based on an inadequate warning.

The leading asbestos case plaintiffs cite that applies the rebuttable heeding presumption, <u>Coward</u>, 729 A.2d at 621, holds that:

[I]n cases where warnings or instructions are required to make a product non-defective and a warning has not been given, the plaintiff should be afforded the use of the presumption that he or she would have followed an adequate warning, and that the defendant, in order to rebut that presumption, must produce evidence that such a warning would not have been heeded.

Id. Because the plaintiffs in <u>Coward</u> had little choice but to confront the known risk of asbestos exposure in their places of employment, the court imposed a rebuttable presumption that they would have followed an adequate warning. <u>Id.</u> at 620-621. The other asbestos cases plaintiffs cite, all decisions by lower courts, adhere to <u>Coward</u> and apply the rebuttable heeding preemption in strict liability failure to warn cases against the manufacturer. <u>See Lonasco v. A-Best Products Co.</u>, 757 A.2d at 377 (quoting and applying holding in <u>Coward</u>, 729 A.2d at 621, in

Coward v. Owens-Corning Fiberglas Corporation, 729 A.2d 614 (Pa.Super. 1999); Lonasco v. A-Best Products Co., 757 A.2d 367 (Pa.Super. 2000); Chicano v. General Electric Co., 2004 WL 2250990 (E.D.Pa. Oct. 5, 2004).

strict liability asbestos failure to warn case against manufacturer); Chicano v. General Electric Co., 2004 WL 2250990, at \*5-6 & \*11 (quoting and applying holding in Coward, 729 A.2d at 621, in asbestos strict liability case against manufacturer).

Plaintiffs reason that the lack of choice that applied to the toxic, asbestos exposures to the plaintiffs in <a href="Coward">Coward</a>, <a href="Chicano">Chicano</a> and <a href="Lonasco">Lonasco</a> applies to plaintiffs' involuntary exposure to DES in utero. (Docket Entry # 333, pp. 5-8). Plaintiffs also rely on <a href="Viguers v. Philip Morris USA">Viguers v. Philip Morris USA</a>, <a href="Inc.">Inc.</a>, 837 A.2d 534 (Pa.Super. 2003). <a href="Viguers">Viguers</a> holds "that the heeding presumption does not apply" where the plaintiff, a smoker, made "the <a href="Voluntary">voluntary</a> choice . . . to begin and continue smoking tobacco" despite the existence of federally-mandated warnings on cigarette packages. <a href="Id">Id</a>, at 538 (emphasis added).

Plaintiffs' reasoning is misplaced because in prescription drug cases the manufacturer's duty to warn goes to the learned intermediary, the physician, not to the patient. The physician has the choice of whether to prescribe a drug after weighing the data and warnings supplied by the manufacturer against his patient's medical history and taking into account other relevant concerns. See Simon v. Wyeth Pharmaceuticals, Inc., 989 A.2d at 368-369. In asbestos failure to warn cases, there is no learned intermediary exercising his independent medical judgment.

Furthermore, strict liability applies as opposed to negligence under section 388. See Anderson v. Wyeth, 2005 WL 1383174, at \*4 (Pa.Com.Pl. June 7, 2005).

Plaintiffs also point out that the Third Circuit in Pavlik

v. Lane Ltd./Tobacco Exporters International, 135 F.3d 876 (3<sup>rd</sup>

Cir. 1998), "predict[s] that Pennsylvania would adopt a

rebuttable heeding presumption as a logical corollary to comment
j" to section 402A of the Restatement. Id. at 883. Comment j

states that, "Where warning is given, the seller may reasonably

assume that it will be read and heeded; and a product bearing

such a warning, which is safe for use if it is followed, is not
in defective condition, nor is it unreasonably dangerous."

Restatement (Second) of Torts, § 402A, cmt. j. The corollary to
this rule "presume[s] that, when no warning or an inadequate

warning is provided, the end-user would have read and heeded an
adequate warning had one been given by the manufacturer." Pavlik

v. Lane Ltd./Tobacco Exporters International, 135 F.3d at 883.

Pavlik does not require applying a heeding presumption in the case at bar because the court made a prediction in a strict liability case against a distributer and manufacturer of a brand of butane fuel. Here again, this case involves a negligent failure to warn claim under section 388 against the manufacturer of a prescription drug in which the learned intermediary customarily exercises "'independent medical judgment,'" Coyle by Coyle v. Richardson-Merrell, Inc., 584 A.2d at 1386.

Plaintiffs additionally discount the reach of a series of cases cited by Lilly. See Gronniger v. American Home Products Corporation, 2005 WL 3766685, at \*5 (Pa.Com.Pl. Oct. 21, 2005) (rejecting heeding presumption as applied to manufacturer of

prescription diet drugs in negligent failure to warn action); <u>Leffler v. American Home Products</u>, 2005 WL 2999712, at \*5 (Pa.Com.Pl. Oct. 20, 2005) (same); Adams v. Wyeth, 2005 WL 1528656, at \*1 (Pa.Com.Pl. June 13, 2005) (rejecting heeding preemption in negligent failure to warn claim against manufacturer of prescription diet drug, Pondimin); Anderson v. Wyeth, 2005 WL 1383174, at \*6 (Pa.Com.Pl. June 7, 2005) (rejecting application of heeding presumption to negligent failure to warn claim against manufacturer of Redux and other diet drugs). Leffler as well as Gronniger accurately explain that, "Pennsylvania courts have consistently declined to apply any heeding presumption in pharmaceutical and most other product liability cases, strictly limiting the application of any such presumption to claims arising from involuntary workplace exposure to asbestos." Leffler v. American Home Products, 2005 WL 2999712, at \*5 (emphasis omitted); accord Gronniger v. American Home Products Corporation, 2005 WL 3766685, at \*5 (same).

Plaintiffs correctly point out that the same judge decided all four cases in the course of a six month time period involving the same or similar prescription diet drugs. Accepting the resulting limitation on the precedential reach of these decisions, proximate cause remains "an essential element in failure to warn cases involving prescription medications."

Daniel v. Wyeth Pharmaceuticals, Inc., 15 A.3d 909, 923

(Pa.Super. 2011); 19 Simon v. Wyeth Pharmaceuticals, Inc., 989 A.2d at 368. As stated in both these Pennsylvania appellate court cases adjudicating negligent failure to warn cases against prescription drug manufacturers, "Pennsylvania law requires that 'there must be some reasonable connection between the act or omission of the defendant and the injury suffered by the plaintiff.'" Daniel v. Wyeth Pharmaceuticals, Inc., 15 A.3d at 924 (quoting Demmler v. SmithKline Beecham Corp., 671 A.2d 1151, 1155 (Pa.Super. 1996), which involved strict liability defective warning claim against prescription drug manufacturer); Simon v. Wyeth Pharmaceuticals, Inc., 989 A.2d at 368 (same). More specifically, in the context of a negligence duty to warn claim, "'plaintiffs must further establish proximate causation by showing that had defendant issued a proper warning to the learned intermediary, he would have altered his behavior and the injury would have been avoided.'" Simon v. Wyeth Pharmaceuticals, Inc., 989 A.2d at 368 (quoting <u>Demmler</u>, 671 A.2d at 1155); <u>accord</u> Daniel v. Wyeth Pharmaceuticals, Inc., 15 A.3d at 924 ("the plaintiff must establish that if defendant 'had issued a proper warning to the learned intermediary, he would have altered his behavior and the injury would have been avoided'") (quoting Demmler, 671 A.2d at 1155); Cochran v. Wyeth, Inc., 3 A.3d at 676-677.

The Pennsylvania Supreme Court granted an appeal in part in <u>Daniel</u> limited to a separate issue. <u>Daniel v. Wyeth</u>

<u>Pharmaceuticals, Inc.</u>, 32 A.3d 1260 (Pa. 2011) (Nos. 318 EAL 2011, 319 EAL 2011).

In the case at bar, plaintiffs must provide sufficient facts in suitable evidentiary form with respect to proximate causation to allow a jury to find in their favor. Construing the record in plaintiffs' favor, including reasonable inferences, Dr. Greco, a lay witness, opines that the standard medical practice in Hazleton in and around the mid to late 1950s was for doctors to pass warnings from manufacturers of prescription drugs to their patients. Drawing reasonable inferences, Dr. Bonacci, a busy and therefore well known family physician in the area, adhered to this standard medical practice in Hazleton.

Plaintiffs' mother, having experienced two miscarriages, sought therapeutic treatment from Dr. Bonacci. Again drawing reasonable inferences in plaintiffs' favor, Dr. Bonacci prescribed Lilly's DES which plaintiffs' mother ingested.

Lacking information about DES, Dr. Bonacci did not warn plaintiffs' mother of the risk. In accordance with the standard medical practice in Hazleton, the jury can reasonably infer that Dr. Bonacci would have shared the warning with plaintiffs' mother. It is also reasonable to infer that plaintiffs' mother would have deferred to the warning Dr. Bonacci presented and, having successfully conceived Killian, would not have ingested the DES.

#### CONCLUSION

In accordance with the foregoing discussion, the motion to strike (Docket Entry # 337) is **ALLOWED** in part and **DENIED** in part. The motion for partial summary judgment (Docket Entry #

324) is **DENIED**.

/s/ Marianne B. Bowler

MARIANNE B. BOWLER

United States Magistrate Judge