

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA**

**IN RE: ZOLOFT (SERTRALINE
HYDROCHLORIDE) PRODUCTS
LIABILITY LITIGATION**

***THIS DOCUMENT RELATES TO:
ALL ACTIONS***

§
§
§
§
§
§

MDL NO. 2342

12-MD-2342

HON. CYNTHIA M. RUFÉ

**DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF THEIR
MOTION FOR SUMMARY JUDGMENT**

TABLE OF CONTENTS

	<u>Page</u>
TABLE OF AUTHORITIES	ii
PRELIMINARY STATEMENT	1
ARGUMENT	2
I. SUMMARY JUDGMENT IS REQUIRED BECAUSE PLAINTIFFS LACK ADMISSIBLE AND SUFFICIENT EVIDENCE OF GENERAL CAUSATION	2
CONCLUSION.....	4

TABLE OF AUTHORITIES

<u>Cases</u>	<u>Page</u>
<i>Amorgianos v. National Railroad Passenger Corp.</i> , 137 F. Supp. 2d 147 (E.D.N.Y. 2001), <i>aff'd</i> , 303 F.3d 256 (2d Cir. 2002).....	3
<i>In re Bausch & Lomb Inc. Contacts Lens Solution Prods. Liab. Litig.</i> , 2010 WL 1727807 (D.S.C. April 26, 2010)	3
<i>Celotex Corp. v. Catrett</i> , 477 U.S. 317 (1986).....	2
<i>Daubert v. Merrell Dow Pharmaceuticals, Inc.</i> , 509 U.S. 579 (1993)	<i>passim</i>
<i>Goldstein v. Centocor, Inc.</i> , 310 F. App'x 331 (11th Cir. 2009)	3
<i>In re Human Tissue Prods. Liab. Litig.</i> , 582 F. Supp. 2d 644 (D.N.J. 2008).....	3
<i>Knight v. Kirby Inland Marine Inc.</i> , 482 F.3d 347 (5th Cir. 2007)	3
<i>Miller v. Pfizer, Inc.</i> , 356 F.3d 1326 (10th Cir. 2004)	3
<i>In re Nexium (Esomeprazole) Prods. Liab. Litig.</i> , 2014 WL 5313871 (C.D. Cal. Sept. 30, 2014)	3
<i>Norris v. Baxter Healthcare Corp.</i> , 397 F.3d 878 (10th Cir. 2005)	3
<i>Raskin v. Wyatt Co.</i> , 125 F.3d 55 (2nd Cir. 1997).....	2
<i>In re Rezulin Prods. Liab. Litig.</i> , 441 F. Supp. 2d 567 (S.D.N.Y. 2006).....	3
<i>Ruggiero v. Warner-Lambert Co.</i> , 424 F.3d 249 (2d Cir. 2005).....	3
<i>Rutigliano v. Valley Bus. Forms</i> , 929 F. Supp. 779 (D.N.J. 1996), <i>aff'd</i> , 118 F.3d 1577 (3d Cir. 1997).....	2, 4
<i>Siharath v. Sandoz Pharm. Corp.</i> , 131 F. Supp. 2d 1347 (N.D. Ga. 2001), <i>aff'd</i> , <i>Rider v. Sandoz Pharm. Corp.</i> , 295 F.3d 1194 (11th Cir. 2002).....	3

Soldo v. Sandoz Pharmaceuticals Corp.,
244 F. Supp. 2d 434 (W.D. Pa. 2003).....3

In re Viagra Prods. Liab. Litig.,
658 F. Supp. 2d 950 (D. Minn. 2009)..... 2-3

Wade-Greaux v. Whitehall Labs., Inc.,
874 F. Supp. 1441 (D.V.I. 1994),
aff'd, 1994 WL 16973481 (3d Cir. Dec. 15, 1994)..... 2-4

Wells v. SmithKline Beecham Corp.,
601 F.3d 375 (5th Cir. 2010)3

In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig.,
26 F. Supp. 3d 449 (E.D. Pa. 2014),
reconsid. denied, 2015 WL 314149 (E.D. Pa. Jan. 23, 2015)..... 1

In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig.,
26 F. Supp. 3d 466 (E.D. Pa. 2014)1

Rules / Statutes

Fed. R. Civ. P. 56.....2

Fed. R. Evid. 403 1

Fed. R. Evid. 7021

Defendants respectfully submit this memorandum of law in support of their motion for summary judgment under the traditional method.

PRELIMINARY STATEMENT

Defendants are entitled to summary judgment because Plaintiffs lack admissible and sufficient evidence of general causation. The Court previously excluded the human causation opinions of Plaintiffs' initial batch of experts: Anick Bérard, Ph.D., Robert Cabrera, Ph.D., Michael Levin, Ph.D., and Thomas Sadler, Ph.D. *In re Zolof (Sertraline Hydrochloride) Prods. Liab. Litig.*, 26 F. Supp. 3d 449 (E.D. Pa. 2014), *reconsid. denied*, 2015 WL 314149 (E.D. Pa. Jan. 23, 2015); *In re Zolof (Sertraline Hydrochloride) Prods. Liab. Litig.*, 26 F. Supp. 3d 466 (E.D. Pa. 2014). The Court then allowed Plaintiffs to replace the excluded Dr. Bérard with Nicholas Jewell, Ph.D., as to alleged cardiac defects. After extensive briefing by both parties and a four-day *Daubert* hearing concerning Dr. Jewell's causation opinions as to alleged cardiac defects, the Court excluded Dr. Jewell's opinions under Federal Rules of Evidence 702 and 403 and the principles outlined in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). (Dkts. [1519] & [1520].) All of the remaining cases in this MDL allege cardiac defects. To the extent they may also allege non-cardiac injuries – *i.e.*, “injuries not included in the PSC's general causation expert reports,” Pretrial Order No. 84 (Dkt. [1175]) – no such plaintiff has filed a general causation expert report, let alone a general causation expert report by the June 15, 2015 deadline set by PTO 84. Plaintiffs thus lack admissible and sufficient evidence necessary to establish an essential element of their claims: causation. Plaintiffs admit that “[p]roof of general causation – that exposure to Zolof was capable of causing plaintiffs' injuries – is a prerequisite to recovery by every plaintiff herein.” Pls.' Br. (Dkt. [1054-1]) at 13. Without admissible and sufficient evidence to establish this essential element of their claims, all of Plaintiffs' claims fail as a matter of law. The Court should therefore enter summary judgment in favor of Defendants.

ARGUMENT

I. SUMMARY JUDGMENT IS REQUIRED BECAUSE PLAINTIFFS LACK ADMISSIBLE AND SUFFICIENT EVIDENCE OF GENERAL CAUSATION

“The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56. The “plain language” of Rule 56 “mandates the entry of summary judgment ... against a party who fails to make a showing sufficient to establish the existence of an element essential to that party’s case, and on which that party will bear the burden of proof at trial.” *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). A “failure of proof concerning an essential element of the nonmoving party’s case necessarily renders all other facts immaterial.” *Id.* at 323.¹

Here, Plaintiffs cannot establish general causation because this Court has excluded all of their experts as to general causation under the Federal Rules of Evidence and *Daubert*. Plaintiffs, therefore, lack admissible and sufficient expert testimony on general causation. General causation “is a fundamental element of each” of Plaintiffs’ claims. *Rutigliano v. Valley Bus. Forms*, 929 F. Supp. 779, 783 (D.N.J. 1996), *aff’d*, 118 F.3d 1577 (3d Cir. 1997); *see also Wade-Greaux v. Whitehall Labs., Inc.*, 874 F. Supp. 1441, 1475 (D.V.I. 1994), *aff’d*, 1994 WL 16973481 (3d Cir. Dec. 15, 1994). Expert testimony is required to establish general causation. *Rutigliano*, 929 F. Supp. at 783; *Wade-Greaux*, 874 F. Supp. at 1475. Where, as here, “expert opinion evidence regarding causation is inadmissible ... summary judgment must be granted to defendants.” *Rutigliano*, 929 F. Supp. at 783; *accord Wade-Greaux*, 874 F. Supp. at 1475. “[A]bsent an admissible general causation opinion, Plaintiffs’ claims necessarily fail and Pfizer’s motion for summary judgment must be granted.” *In re Viagra Prods. Liab. Litig.*, 658 F. Supp. 2d 950, 956 (D. Minn. 2009); *see also Raskin v. Wyatt Co.*, 125 F.3d 55, 65-67 (2d Cir. 1997).

¹ Defendants incorporate by reference their October 21, 2014, Motion for Leave to File a Motion for Summary Judgment Under the Standard Approach (Dkt. [1065]), and their November 4, 2014, Motion for Summary Judgment Under the Standard Approach, Memorandum of Law in Support, and Reply in Support. (Dkts. [1086], [1086-1], [1101]).

Indeed, Plaintiffs concede that “[p]roof of general causation – that exposure to Zolofit was capable of causing plaintiffs’ injuries – is a prerequisite to recovery by every plaintiff herein.” Pls.’ Br. (Dkt. [1054-1]) at 13.

Where, as here, plaintiffs have failed to pass the *Daubert* threshold on general causation, courts routinely grant summary judgment for defendants. This is because “[w]ithout the expert testimony,” a plaintiff “cannot prove general causation – and judgment *must* be entered for” the defendant. *Wells v. SmithKline Beecham Corp.*, 601 F.3d 375, 381 (5th Cir. 2010) (emphasis added). *E.g.*, *Goldstein v. Centocor, Inc.*, 310 F. App’x 331, 332-33 (11th Cir. 2009); *Knight v. Kirby Inland Marine Inc.*, 482 F.3d 347, 351-52 (5th Cir. 2007); *Ruggiero v. Warner-Lambert Co.*, 424 F.3d 249, 254-55 (2d Cir. 2005); *Norris v. Baxter Healthcare Corp.*, 397 F.3d 878, 884-86 (10th Cir. 2005); *Miller v. Pfizer, Inc.*, 356 F.3d 1326, 1335-36 (10th Cir. 2004); *Amorgianos v. National R.R. Passenger Corp.*, 137 F. Supp. 2d 147 (E.D.N.Y. 2001), *aff’d*, 303 F.3d 256, 270-71 (2d Cir. 2002); *In re Nexium (Esomeprazole) Prods. Liab. Litig.*, 2014 WL 5313871, at *1, *4 (C.D. Cal. Sept. 30, 2014); *id.*, MDL No. 12-2404 DSF, Dkt. [339] at 1 (Ex. 1); *id.*, Dkt. [347] at 1 (Ex. 2); *In re Bausch & Lomb Inc. Contacts Lens Solution Prods. Liab. Litig.*, 2010 WL 1727807, at *1-2 (D.S.C. April 26, 2010); *In re Viagra Prods. Liab. Litig.*, 658 F. Supp. 2d 950, 956 (D. Minn. 2009); *In re Human Tissue Prods. Liab. Litig.*, 582 F. Supp. 2d 644, 690-91 (D.N.J. 2008); *In re Rezulin Prods. Liab. Litig.*, 441 F. Supp. 2d 567, 579 (S.D.N.Y. 2006); *Soldo v. Sandoz Pharmaceuticals Corp.*, 244 F. Supp. 2d 434, 577 (W.D. Pa. 2003); *Siharath v. Sandoz Pharm. Corp.*, 131 F. Supp. 2d 1347, 1370-71, 1374 (N.D. Ga. 2001), *aff’d*, *Rider v. Sandoz Pharm. Corp.*, 295 F.3d 1194 (11th Cir. 2002).²

Third Circuit law is clear that Defendants here are entitled to summary judgment. For example, in *Wade-Greaux*, the plaintiff alleged that her use of a pharmaceutical product caused her child to be born with birth defects. 874 F. Supp. at 1447-48. The plaintiff’s experts proffered general causation opinions. *Id.* at 1448. Judge Giles “concluded that the opinions of

² Defendants previously discussed some of these cases in their prior briefing addressing summary judgment, *e.g.*, Dkt. [1065] at 5-9, [1086] at 5-10.

each of plaintiff's expert witnesses are inadmissible I am constrained to conclude that plaintiff has not met her burden ... to produce evidence sufficient to raise a genuine issue of material fact." *Id.* at 1485. Judge Giles thus granted summary judgment to the defendant. *Id.* at 1485-86. The Third Circuit affirmed, holding that "[w]e are satisfied that the district court properly exercised its discretion" under *Daubert* "and we will affirm the order ... which granted summary judgment." *Wade-Greaux*, 1994 WL 16973481, at *1.

In *Rutigliano*, a case also affirmed by the Third Circuit, the plaintiff claimed that exposure to the defendants' products caused her to develop a severe permanent disability. 929 F. Supp. at 782. The court concluded that the plaintiff's expert "failed to demonstrate" her general causation opinion was "supported by 'good science'" as required by *Daubert* and, thus, precluded the testimony. *Id.* "As this leaves plaintiff without admissible evidence that her alleged injury was caused by defendants' products, the Court will also grant summary judgment in favor of defendants." *Id.*

CONCLUSION

For the foregoing reasons, this Court should grant Defendants' motion for summary judgment under the traditional method.

Dated: New York, New York
December 3, 2015

QUINN EMANUEL URQUHART &
SULLIVAN, LLP

By : /s/ Sheila L. Birnbaum
Sheila L. Birnbaum
Mark S. Cheffo
Bert L. Wolff
Jonathan S. Tam

51 Madison Avenue, 22nd Floor
New York, New York 10010-1601
(212) 849-7000

KAYE SCHOLER LLP

Pamela J. Yates
Bert L. Slonim
Aaron H. Levine
250 West 55th Street
New York, New York 10019-9710
(212) 836-8000

WHEELER TRIGG O'DONNELL LLP

James E. Hooper, Jr.
Andrew H. Myers
370 Seventeenth Street, Suite 4500
Denver, Colorado 80202-5647
(303) 244-1800

DECHERT LLP

Robert C. Heim
Judy L. Leone
2929 Arch Street
Philadelphia, Pennsylvania 19104-2808
(215) 994-4000

*Attorneys for Defendants Pfizer Inc., including
its former division J.B. Roerig & Co., Pfizer
International LLC, and Greenstone LLC*

CERTIFICATE OF SERVICE

I hereby certify that on December 3, 2015, I electronically filed the foregoing with the Clerk of Court using the CM/ECF system, which sends electronic notification of such filing to all CM/ECF participants.

Dated: New York, New York
December 3, 2015

/s/ Mark S. Cheffo
Mark S. Cheffo