

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

IN RE: ZOLOFT (SERTRALINE	§	MDL NO. 2342
HYDROCHLORIDE) PRODUCTS	§	
LIABILITY LITIGATION	§	12-MD-2342
<hr/>		
<i>THIS DOCUMENT RELATES TO:</i>	§	HON. CYNTHIA M. RUFÉ
<i>ALL ACTIONS</i>	§	
	§	

DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

Defendants Pfizer Inc., including its former division J.B. Roerig & Company, Pfizer International LLC, and Greenstone LLC respectfully move, pursuant to Fed. R. Civ. P. 56, for summary judgment under the Court's "traditional method" for summary judgment (Hon. Cynthia Rufe's Policies & Procedure, at 4). This Court has ruled that the testimony of Plaintiffs' final general causation expert Nicholas Jewell, Ph.D., is inadmissible. (Dkt. Nos. [1519], [1520].) Therefore, as set forth in the accompanying memorandum of law, incorporated herein, all Plaintiffs lack admissible and sufficient evidence necessary to establish causation, an essential element of their claims.

WHEREFORE, Defendants respectfully request that this Court grant Defendants' motion for summary judgment.

Dated: New York, New York
December 3, 2015

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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 shall send 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

**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**

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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

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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

EXHIBIT 1

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

MEMORANDUM

Case No. ML 12-2404 DSF (SSx)

Date 10/1/14

Title In re Nexium (Esomeprazole) Products Liability Litigation

Present: The Honorable DALE S. FISCHER, United States District Judge

Debra Plato

Not Present

Deputy Clerk

Court Reporter

Attorneys Present for Plaintiffs:

Attorneys Present for Defendants:

Not Present

Not Present

Proceedings: (In Chambers) Order GRANTING Motion for Summary Judgment (Dkt. No. 256)

In a separate order, the Court has granted Defendants' motion to exclude Plaintiffs' offered expert testimony on general causation. There is no dispute that Plaintiffs cannot establish their prima facie cases without that evidence. Therefore, Defendants' motion for summary judgment is GRANTED. Defendants are to lodge a proposed judgment no later than October 9, 2014.

IT IS SO ORDERED.

EXHIBIT 2

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UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

In Re: NEXIUM
(ESOMEPRAZOLE) PRODUCTS
LIABILITY LITIGATION

Case No.: 12-ml-2404 DSF (SSx)

JUDGMENT

This document relates to:

ALL CASES

The Court having entered its Order GRANTING Motion to Exclude Testimony of B. Sonny Bal (see Master Dkt. 255, 337) and Order GRANTING Motion for Summary Judgment (see Master Dkt. 256, 339), now enters final judgment as follows:

IT IS ORDERED, ADJUDGED, AND DECREED that judgment is entered in favor of Defendants AstraZeneca Pharmaceuticals LP, AstraZeneca LP, and McKesson Corporation, and against all Plaintiffs, on all claims asserted by Plaintiffs, whether in their individual complaints or by way of the First Amended Master Complaint. Plaintiffs, and each of them, shall recover nothing.

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IT IS FURTHER ORDERED that Defendants shall recover their costs of suit pursuant to a bill of costs filed in accordance with 28 U.S.C. § 1920 and Rule 54(d)(1) of the Federal Rules of Civil Procedure.

10/8/14

Dated: _____



Dale S. Fischer
United States District Judge

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

IN RE: ZOLOFT (SERTRALINE	§	MDL NO. 2342
HYDROCHLORIDE) PRODUCTS	§	
LIABILITY LITIGATION	§	12-MD-2342
_____	§	
<i>THIS DOCUMENT RELATES TO:</i>	§	HON. CYNTHIA M. RUFÉ
<i>ALL ACTIONS</i>	§	

[PROPOSED]
ORDER GRANTING
DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

In view of the Court's decision excluding the testimony of Plaintiffs' general causation expert Nicholas Jewell, Ph.D., under Federal Rules of Evidence 702 and 403 and the principles outlined in *Daubert v. Merrell Dow Pharmaceuticals, Inc.* (Dkt. Nos. [1519], [1520]), and having duly considered the briefing and arguments of the parties on summary judgment, the Court hereby ORDERS that Defendants' Motion for Summary Judgment is GRANTED.

Dated: _____, 2015

SO ORDERED

Hon. Cynthia M. Rufe

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 shall send electronic notification of such filing to all CM/ECF participants.

Dated: New York, New York
December 3, 2015

/s/ Mark S. Cheffo
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