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SHORT FORM ORDER mg

SUPREME COURT - STATE OF NEW YORK
COUNTY OF NASSAU - PART 4

Present: HON. UTE WOLFF LALLY
Justice

MICHAEL KUPERSTEIN, ELAINE KUPERSTEIN, and STEVEN KUPERSTEIN,

Plaintiffs,

-against-

DONALD LAWRENCE, M.D., DOCTORS 4 KIDS, BARR LABORATORIES, INC. and BARR PHARMACEUTICALS, INC.,

Defendants.

Motion Sequence #3
Submitted July 21, 2010

INDEX NO: 21071/07

The following papers were read on this motion for summary judgment:

Notice of Motion and Affs.....1-5
Affs in Support.....6&7
Affs in Opposition.....8-14
Memoranda of Law.....15-17a

Upon the foregoing papers, it is ordered that this motion by defendants Barr Laboratories, Inc. and Barr Pharmaceuticals, Inc. for an order pursuant to CPLR 3212 granting summary judgment in their favor dismissing the plaintiffs' complaint against them is granted.

The plaintiffs in this action seek to recover damages for injuries the infant plaintiff Michael Kuperstein allegedly suffered as a result of taking the generic drug mefloquinel

mefloquine hydrochloride, also known as Lariam, prophylactically to prevent malaria when he traveled to China with his parents, the plaintiffs Elaine and Steven Kuperstein in 2004. The drug allegedly caused Michael cognitive deficits as well as psychotic and personality changes, memory loss and depression. The defendants Barr Laboratories, Inc. and Barr Pharmaceuticals, Inc. allegedly manufactured the drug and the defendant Donald Lawrence, M.D., of the defendant Doctors 4 Kids, allegedly prescribed it for Michael.

The plaintiffs have advanced nine causes of action against the Barr defendants: (1) negligent design; (2) breach of implied warranty; (3) breach of express warranty; (4) defective design-strict liability; (5) failure to warn-strict liability; (6) fraud; (7) violation of General Business Law § 350 (false advertising); (8) violation of General Business Law § 349 (deceptive act); (9) punitive damages; and, (10) parent's loss of services.

The plaintiffs seek to recover money damages from the defendants Dr. Lawrence and Doctors 4 Kids alleging medical malpractice, negligence and lack of informed consent and Michael's parents seek to recover for the alleged loss of his services.

The Barr defendants herein seek summary judgment dismissing the complaint against them. Dr. Lawrence and Doctors 4 Kids have requested that this Court search the record and dismiss the complaint against them pursuant to CPLR 3212(b).

The pertinent facts are as follows:

The plaintiff, Elaine Kuperstein, testified at her examination-before-trial that she learned about mefloquine from Dr. Kopeck who was an infectious disease doctor at Maimonides Memorial Medical Center where she worked as a registered dietician. She testified that Dr. Kopeck advised her to take mefloquine prophylactically before going to China because malaria was a very serious disease there. She obtained a prescription for

herself from Dr. Kopeck and filled it at the hospital's pharmacy. Her husband obtained a prescription for the drug from his internist, Dr. Kahn. Upon his father Steven Kuperstein's request via telephone, Michael's doctor defendant Dr. Lawrence called in a prescription for mefloquine for Michael who was then 15 years old to the Pathmark Pharmacy in East Rockaway. Steven Kuperstein testified at his examination-before-trial that he asked for Lariam, the reference listed drug for which Barr's mefloquine product is the generic equivalent. He also testified that after obtaining the prescription, he read the guide that came with it and concluded that the drug was safe for him, his wife and his son Michael. He further testified that had Dr. Lawrence discussed the risks and benefits of mefloquine with him as well as alternate options, they would not have taken it. Mrs. Kuperstein testified at her examination-before-trial that after taking six weekly doses of mefloquine before, during and after their trip, Michael began displaying symptoms and that when his doctor Dr. Lalia was so advised, she told them that his symptoms might be attributed to mefloquine and that he should discontinue taking it.

At his examination-before-trial, Dr. Lawrence testified that he spoke with one of Michael's parents on the telephone (he believed his father) and was told that the family was traveling to China and that they wanted a prescription for an antimalaria drug for Michael. Dr. Lawrence could not recall whether they asked for the drug by name. Dr. Lawrence testified that he consulted the "Red Book" which is published by the American Academy of Pediatrics to determine the proper dose for Michael of 250 milligrams. The Red Book indicated that the drug was contraindicated for anyone with depression, seizure disorder or psychosis. He testified that he also discussed the prescription with the pharmacist. He admitted that although he had the Physician's Desk Reference in his

office, he did not consult it before prescribing it for Michael, nor did he recall reading any other literature about mefloquine, including that written, published or disseminated by Barr.

Barr received approval for its generic mefloquine hydrochloride product from the FDA on December 29, 2003. As a requirement for FDA approval, Barr was required to demonstrate that the package insert for its generic product was the same as the package insert for the reference listed drug, Lariam. *See* 21 CFR 314.9(a)(8). Like the package insert under "WARNINGS," the Physician's Desk Reference provides:

> "Mefloquine may cause psychiatric symptoms in a number of patients, ranging from anxiety, paranoia, and depression to hallucinations and psychotic behavior. On occasions, these symptoms have been reported to continue long after mefloquine has been stopped. Rare cases of suicidal ideation and suicide have been reported though no relationship to drug administration has been confirmed. To minimize the chances of these adverse events, mefloquine should not be taken for prophylaxis in patients with active depression or with a recent history of depression, generalized anxiety disorder, psychosis, or schizophrenia or other major psychiatric disorders. Lariam should be used with caution in patients with a previous history of depression. During prophylactic use, if psychiatric symptoms such as acute anxiety, depression, restlessness or confusion occur, these may be considered prodromal to a more serious event. In these cases ,the drug must be discontinued and an alternative medication should be substituted."

Barr did not receive any complaints or reports of adverse events from when it obtained FDA approval until Michael stopped taking its drug.

The defendants Dr. Lawrence and Doctors 4 Kids' request that this court search the record and dismiss the complaint as against them pursuant to CPLR 3212(b) is denied. "The 'court may search the record and grant summary judgment in favor of a nonmoving party only with respect to a cause of action or issue that is the subject of the motions before the court.' " (*East End Cement & Stone, Inc. v Carnevale*, 73 AD3d 974, quoting

Dunham v Hilco Const. Co., 89 NY2d 425, 429-430 , citing *Whitman Realty Group, Inc. v Galano*, 52 AD3d 505, 506; *Netjets Inc. v Signature Flight Support, Inc.*, 43 AD3d 1014, 1016; *Ey v Mecca*, 41 AD3d 534). The issues presented on the Barr defendants' motion differ significantly from the issues presented with respect to Dr. Lawrence and Doctors 4 Kids' liability, to wit: The Barr defendants are alleged to have manufactured the mefloquine while Dr. Lawrence is alleged to have negligently prescribed it. Contrary to what Dr. Lawrence and Doctors 4 Kids allege, dismissal as against Barr Laboratories does not *ipso facto* require dismissal as against them. Dismissal against Barr Laboratories lies, *inter alia,* for lack of proximate cause since Dr. Lawrence never read the drug warning in the Physician's Desk Reference or the accompanying package insert and lack of reliance since none of the plaintiffs' read their literature prior to purchasing their product.

Dr. Lawrence and Doctors 4 Kids' request that it be given permission to make an application for summary judgment despite its untimeliness is also denied. The relief was not requested in the proper form [CPLR 2214; *Myung Chun v North American Mortgage Co.*, 285 AD2d 42, nor has grounds for that relief, i.e., "good cause" for the delay, been demonstrated. CPLR 3212(a); *Brill v City of New York*, 2 NY3d 648].

"On a motion for summary judgment pursuant to CPLR 3212, the proponent must make a *prima facie* showing of entitlement to judgment as a matter of law, tendering sufficient evidence to demonstrate the absence of any material issues of fact." (*Sheppard-Mobley v King*, 10 AD3d 70, 74, *aff'd. as mod.*, 4 NY3d 627, *citing Alvarez v Prospect Hosp.*, 68 NY2d 320, 324; *Winegrad v New York Univ. Med. Ctr.*, 64 NY2d 851, 853). "Failure to make such *prima facie* showing requires a denial of the motion, regardless of

the sufficiency of the opposing papers." (*Sheppard-Mobley v King*, *supra*, at p. 74; *Alvarez v Prospect Hosp.*, *supra*; *Winegrad v New York Univ. Med. Ctr.*, *supra*). Once the movant's burden is met, the burden shifts to the opposing party to establish the existence of a material issue of fact. (*Alvarez v Prospect Hosp.*, *supra*, at p. 324). The evidence presented by the opponents of summary judgment must be accepted as true and they must be given the benefit of every reasonable inference. (*See*, *Demishick v Community Housing Management Corp.*, 34 AD3d 518, 521, *citing Secof v Greens Condominium*, 158 AD2d 591). The defendant Barr Pharmaceuticals has established that it did not manufacture or market mefloquine; Barr Laboratories did. Thus, Barr Pharmaceuticals has established its entitlement to summary judgment dismissing the complaint against it, thereby shifting the burden to the plaintiffs to establish the existence of a material issue of fact. (*Healy v Firestone Tire & Rubber Co.*, 87 NY2d 596, 601; *King v Greguss Management Corp.*, 57 AD3d 851, 853, *lv den.*, 13 NY3d 707; *Ito v Marvin Windows of New York, Inc.*, 54 AD3d 1002, 1003; *Jiminez v Iron Master Corp.*, 292 AD2d 426; *Amaris v Sharp Electronics Corp.*, 304 AD2d 457, *lv den.*, 1 NY3d 507 (2004).

"The manufacturer of a prescription drug has a duty to warn of all potential dangers which it knows or should know, and must take such steps as are reasonably necessary to bring that knowledge to the attention of the medical profession." *Glucksman v Halsey Drug Co., Inc.*, 160 AD2d 305, 307, *citing Baker v St. Agnes Hosp.*, 70 AD2d 400; see also, *Mulhall v Hannafin*, 45 AD3d 55). "Manufacturers apprise physicians of dangerous side effects in various ways. The most common are: (1) the inclusion in the Physicians Desk Reference, the annually updated encyclopedia of medications, of a normal description of

each of a manufacturer's drugs; and (2) the manufacturer's formal warning in the package insert of a prescription drug." *Martin v Hacker*, 83 NY2d 1, 9, *citing Baker v St. Agnes Hosp.*, *supra*; *Glucksman v Halsey Drug Co., Inc.*, *supra*). The Red Book expressly states that it does not contain all of the information in the Physicians' Desk Reference, including information concerning contraindications and adverse events, and it is not written by the manufacturer as are the warnings reprinted in the Physicians' Desk Reference. "Inserts must be written in accordance with the Food and Drug Administration's recommendation for the proper labeling of prescription drugs." [*Martin v Hacker*, *supra*, at p. 9, citing 21 CFR 201.56, 201.57; 21 USC § 355(e)].

"Whether the cause of action for failure to warn is based on negligence or strict liability, the courts of this state have consistently held that a manufacturer's duty is to warn only of those dangers it knows of or are reasonably foreseeable." (*Mulhall v Hannafin*, *supra*, at p. 58, citing *Rastelli v Goodyear Tire & Rubber Co.*, 79 NY2d 289, 297). "Knowledge, actual or constructive, of a danger inherent in a product is an essential factor in determining whether a manufacturer is liable." (*Mulhall v Hannafin*, *supra*, at p. 58, *citing Goldberg v Union Hardware Co.*, 162 AD2d 658, 659). "The lack of such knowledge is fatal to a failure-to-warn claim, and in the absence thereof, summary judgment is warranted. (*Mulhall v Hannafin*, *supra*, at p. 58, citing *Daley v McNeil Consumer Products. Co., a Div. of McNeil-PPC, Inc.*, 164 F Supp 2d 367, 373).

"However, the manufacturer's duty is owed to the medical community, and not to the patient. The doctor acts as an 'informed intermediary' between the manufacturer and the patient, evaluating the patient's needs, assessing the risks and benefits of available drugs,

and prescribing and supervising their use.' " (*Glucksman v Halsey Drug Co., Inc.*, *supra* at p. 307, quoting *Wolfgruber v Upjohn Co.*, 72 AD2d 59, *aff'd.* 52 NY2d 768, *citing Lindsay v Ortho Pharm Corp.*, 637 F2d 87; see also, *Mulhall v Hannafin*, *supra*). "Where the warning given to the physician, through the Physician's Desk Reference, and through package inserts and/or other literature, gives specific detailed information on the risks of the drug, the manufacturer may be absolved from liability." (*Glucksman v Halsey Drug Co., Inc.*, *supra*, at p. 307, *citing Wolfgruber v Upjohn, Co.*, *supra*; see also, *Mulhall v Hannafin*, *supra*).

To prevail, "[a] plaintiff must demonstrate [both] that the warning was inadequate and that the failure to adequately warn of the dangers of the drug was a proximate cause of his or her injuries." (*Glucksman v Halsey Drug Co., Inc.*, *supra*, at p. 307). Where the prescribing doctor does not read the manufacturer's warnings, their adequacy or lack thereof cannot be the proximate cause of the plaintiff's injuries. (*Haggerty v Wyeth Aysert Pharmaceuticals*, 11 AD3d 511, *citing Sosna v American Home Products Co.*, 298 AD3d 158; *Guadalupe v Dracket Products Co.*, 253 AD2d 378; *Glucksman v Halsey Drug Co.*, *supra*).

"Regardless of the descriptive terminology used to denominate the cause of action (*viz.* 'strict liability' or 'negligence'), where the theory of liability is failure to warn, negligence and strict liability are equivalent." (*Wolfgruber v Upjohn, Co.*, *supra* at p. 67, *citing Bolm v Triumph Corp.*, 71 AD2d 429, *app dism.*, 50 NY2d 801, *lv dism.*, 50 NY2d 928; *Biss v Tenneco, Inc.*, 64 AD2d 204, *app den.*, 46 NY2d 711; *Rainbow v Albert Elia Bldg. Co., Inc.*, 49 AD2d 250; *Micallef v Miehle Co., Division of Miehle-Goss Dexter, Inc.*, 39 NY2d 376).

The plaintiffs' causes of action sounding in negligence, defective design-strict liability, breach of implied warranty of fitness, failure to warn–strict liability are dismissed. Since Dr. Lawrence never reviewed the warnings, their adequacy or lack thereof could not have caused the plaintiffs' injuries. (*Haggerty v Wyeth Aysert Pharmaceuticals*, *supra*; *Sosna v American Home Products*, *supra*; *Guadalupe v Dracket Products Co.*, *supra*).

In light of the fact that Barr Laboratories' warning was not read by the plaintiffs prior to their purchase of the product, reliance is lacking and therefore the claim for breach of express warranty must also be dismissed. (*Friedman v Medtronic, Inc.*, 42 AD2d 185, 190 *citing Crocker-Wheeler Elec. Co. v Johns-Pratt Co.*, 29 AppDiv 300, *aff'd.* 164 NY 193; 47 NY Jur Products Liability § 69; see also, *Schimmenti v PlyGem Industries, Inc.*, 156 AD2d 658, 659; *Schneidman v Whitaker Co.*, 304 AD2d 642, 643). Similarly, absent reliance, the plaintiffs' claim sounding in fraud fails. (*Spector v Wendy*, 63 AD3d 820). And, the plaintiff's claim under General Business Law § 350 fails for that reason as well. (*Gale International Business Machines Corp.*, 9 AD3d 446, *citing Murrin v Ford Motor Co.*, 303 AD2d 475; *Andre Strishak & Associates v Hewlett Packard Co.*, 300 AD2d 608; *McGill v General Motors Corp.*, 231 AD2d 449). As for the plaintiffs' claims pursuant to General Business Law § § 349, while reliance is not required (*Small v Lorillard Tobacco Co.*, 94 NY2d 43, 55; *Stutman v Chemical Bank*, 95 NY2d 24, 29; *Oswego Laborers Local 214 Pension Fund v Marine Midland Bank, N.A.*, 85 NY2d 20; *Singh v Queens Ledger Newspaper Group*, 2 AD3d 703; *Hazelhurst v Brita Prods. Co.*, 295 AD2d 240), absent reviewing the allegedly inadequate warning before purchasing the product which is clearly absent here, the plaintiffs simply cannot allege causation by a misleading act or practice or

deceptive or misleading advertisement. (*Gale v International Business Machines Corporation*, *supra*).

Because Michael's claims fail, the ninth cause of action maintained by his parents does, too.

The defendant Barr Pharmaceutics and Barr Laboratories' motion is granted and the complaint against them is dismissed.

Dated: August 16, 2010

UTE WOLFF LALLY, J.S.C.

TO: Langsam Law, LLP
Attorney for Plaintiffs
7 Dey Street, Suite 500
New York, NY 10007

Porzio, Bromberg & Newman, PC
Attorneys for Defendants Barr Laboratories Inc and Barr Pharmaceuticals, Inc.
156 West 56th Street, Suite 803
New York, NY 10019

Callan, Koster, Brady & Brennan, LLP
Attorneys for Defendants Donald Lawrence, MD and Doctors 4 Kids
One Whitehall Street, 10th Floor
New York, NY 10004

kuperstein-lawrence,etal,#3/sumjudg