UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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RONALD ALSTON,

Plaintiff,

-against-

CARACO PHARMACEUTICAL, INC. and
ORTHO-MCNEIL PHARMACEUTICAL, INC.,

Defendants.

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08 Civ. 2826

OPINION

A P P E A R A N C E S:

Pro Se

RONALD ALSTON
#00-A-3985
Great Meadow Correctional Facility
11789 State Route 22
Comstock, NY 12821

Attorneys for Defendant Ortho-McNeil Pharmaceutical, Inc.

PATTERSON BELKNAP WEBB & TYLER LLP
1133 Avenue of the Americas
New York, NY 10036-6710
By: John D. Winter, Esq.

Attorneys for Defendant Caraco Pharmaceutical Laboratories

REISS, EISENPRESSS AND EISENBERG
425 Madison Avenue
New York, NY 10017
By: Matthew Henry Sheppe, Esq.

Sweet, D.J.

Defendants Ortho-McNeil Pharmaceutical, Inc. ("Ortho") and Caraco Pharmaceutical Laboratories, Ltd. ("Caraco" or collectively, the "Defendants") have moved for summary judgment under Rule 56.1 Fed. R. Civ. P. to dismiss the amended complaint of plaintiff, pro se, Ronald Alston ("Alston" or the "Plaintiff"). Upon the findings and conclusions set forth below, the motion is granted, and judgment will be entered dismissing the complaint.

Prior Proceedings

The complaint was filed on March 18, 2008. It alleged that the failure of the Defendants to warn the New York Department of Corrections adequately of the risks and potential side effects of using Ultram, manufactured by Ortho, or its generic equivalent tramadol, manufactured by Caraco, Plaintiff became physically and psychologically addicted to tramadol. (Compl. at ¶¶ 30, 42-44, 47-50.) The Plaintiff has alleged that between June 2004 and June 2005 he became "a severe Ultram dependent person dependent upon Ultram physically and psychologically." (Id. at ¶ 44.)

According to the complaint, this physical and psychological addiction led the Plaintiff to engage in certain "drug-seeking" activities, including buying tramadol from other inmates and receiving tramadol from other inmate's mouths. (Id. at ¶¶ 32, 37, 40.) The Plaintiff claims that due to these actions, he was exposed to hepatitis B, although the medical records indicate that the Plaintiff does not currently have, and never has had, hepatitis B. (Id. at ¶¶ 39-40.) Interpreting the claims raised in the complaint as broadly as possible, the Plaintiff also asserts that his dependence was caused by the Defendants' failure to ensure that the Department of Corrections adhered to warnings provided to it regarding tramadol. (Id. at ¶¶ 47-50.)

The instant motions after extensions to oppose were granted to the Plaintiff were marked fully submitted on April 15, 2008.

The Facts

The facts were set forth in the Defendants' Local Rule 56.1 Statement and Supporting Affidavits and are not in dispute except as noted.

Ultram is the brand name for tramadol, an opioid analgesic pain medicine. It is a prescription medicine that is approved for use in the management of moderate to moderately severe pain in adults. Ortho first received approval from the United States Food and Drug Administration ("FDA") to market Ultram on March 3, 2995.

From 1995 until 2002 tramadol was marketed exclusively by Ortho as the brand name product Ultram. In June 2002 Caraco, as well as other companies, was granted approval by FDA to manufacture and market tramadol in its "generic" form. Once it received FDA approval, Caraco began manufacturing and distributing the generic form of tramadol.

The tramadol prescribing information in effect when the Plaintiff was prescribed the medicine detailed the symptoms he allegedly experienced. That prescribing information stated in relevant part:

WARNINGS

Withdrawal

Withdrawal symptoms may occur if ULTRAM is discontinued abruptly. (See DRUG ABUSE AND DEPENDENCE.) These symptoms may include: anxiety, sweating, insomnia, rigors, pain, nausea, tremors, diarrhea, upper respiratory symptoms, pilocerection, and rarely hallucinations. Other symptoms that have been seen less frequently with ULTRAM discontinuation include: panic attacks, severe anxiety, and paresthesias. Clinical experience suggests that withdrawal symptoms may be avoided by tapering ULTRAM at the time of discontinuation.

Physical Dependence and Abuse

ULTRAM may induce psychic and psychical dependence of the morphine-type (u-opioid) (see DRUG ABUSE AND DEPENDENCE). ULTRAM should not be used in opioid-dependent patients. ULTRAM has been shown to reinitiate physical dependence in some patients that have been previously dependent on other opioids. Dependence and abuse, including drug-seeking behavior and taking illicit actions to obtain the drug, are not limited to those patients with prior history of opioid dependence....

* * *

DRUG ABUSE AND DEPENDENCE

ULTRAM may induce psychic and physical dependence of the morphine-type (u-opioid). (See WARNINGS.) Dependence and abuse, including drug-seeking behavior and taking illicit actions to obtain the drug are not limited to those patients with prior history of opioid dependence. The risk in patients with substance abuse has been observed to be higher. ULTRAM is associated with craving and tolerance development. Withdrawal symptoms may occur if ULTRAM is discontinued abruptly. These symptoms may include: anxiety, sweating, insomnia, rigors, pain, nausea, tremors, diarrhea, upper respiratory symptoms,

> piloerection, and rarely hallucinations. Other symptoms that have been seen less frequently with ULTRAM discontinuation include: panic attacks, severe anxiety, and parasthesias. Clinical experience suggests that withdrawal symptoms may be relieved by reinstitution of opioid therapy followed by a gradual, tapered dose reduction of the medication combined with symptomatic support.

The Plaintiff is a forty-five year old male with a self-reported history of opioid abuse and a resident of Southport Correctional Facility, a prison in Pine City, New York. (Compl. T ¶¶ 6, 22.) The Plaintiff has suffered from asthma as well as chronic back and knee pain for a number of years. The Plaintiff also has a history of disc herniation and related back problems. As part of the treatment for his back and knee pain, the Plaintiff has been prescribed a number of medications, including a 100 mg dosage of tramadol. The Plaintiff was first prescribed tramadol on June 9, 2004. (Compl. at ¶ 23.)

Since this initial prescription for tramadol, the Plaintiff's physicians have continued to prescribe the medicine for his back and knee pain. On April 19, 2007, more than two years after the Plaintiff claims to have: (i) become addicted to tramadol; (ii) experienced withdrawal symptoms; and (iii) been placed in a Department

of Corrections detoxification treatment program, the Plaintiff's physician renewed his tramadol prescription.

The Plaintiff's physician decided to discontinue his prescription for tramadol on September 21, 2007. After this date, the Plaintiff was given Tylenol for his back and knee pain. The Plaintiff's prescription for tramadol was not discontinued due to side effects, or because of a reduction in his back or knee pain but because the Plaintiff repeatedly had been caught trying to hoard tramadol pills. The Plaintiff had been warned by prison staff and his physicians that hoarding and stealing of tramadol pills would lead to the discontinuation of his medications. (September 21, 2007 letter describing reason for discontinuation of tramadol prescription and August 16, 2007 physician's note describing Plaintiff's history of attempts at hiding medications.)

As an inmate at a correctional facility, the Plaintiff has been regularly tested for diseases such as HIV/AIDS, tuberculosis, and hepatitis B. On May 3, the Plaintiff was given a blood test for hepatitis B, and tested negative for the virus. One year later, the Plaintiff was vaccinated against the hepatitis B virus.

This vaccination process is specifically indicated only for individuals who do not have markers for hepatitis B. Prison staff have stated to the Plaintiff, as recently as October 2008, that he does not have hepatitis B.

According to Ortho the tramadol ingested by the Plaintiff was manufactured by Caraco. According to Caraco the evidence as to the source of the tramadol is not clear. On this record the factual dispute is unresolved.

The Summary Judgment Standard

Summary judgment is granted only where there exists no genuine issue of material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c); see Celotex Corp. v. Catrett, 477 U.S. 317, 322-23 (1986); SCS Commc'ns, Inc. v. Herrick Co., 360 F.3d 329, 338 (2d Cir. 2004). The courts do not try issues of fact on a motion for summary judgment, but, rather, determine "whether the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 251-52 (1986).

"The party seeking summary judgment bears the burden of establishing that no genuine issue of material fact exists and that the undisputed facts establish [its] right to judgment as a matter of law." Rodriguez v. City of New York, 72 F.3d 1051, 1060-61 (2d Cir. 1995). In determining whether a genuine issue of material fact exists, a court must resolve all ambiguities and draw all reasonable inferences against the moving party. See Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 587 (1986); Gibbs-Alfano v. Burton, 281 F.3d 12, 18 (2d Cir. 2002). However, "the non-moving party may not rely simply on conclusory allegations or speculation to avoid summary judgment, but instead must offer evidence to show that its version of the events is not wholly fanciful." Morris v. Lindau, 196 F.3d 102, 109 (2d Cir. 1999) (internal quotes omitted). Summary judgment is appropriate where the moving party has shown that "little or no evidence may be found in support of the nonmoving party's case. When no rational jury could find in favor of the nonmoving party because the evidence to support its case is so slight, there is no genuine issue of material fact and a grant of summary judgment is proper." Gallo v.

Prudential Residential Servs., L.P., 22 F.3d 1219, 1223-24 (2d Cir. 1994) (citations omitted).

The Claim Against Ortho For Failure To Warn Is Dismissed

The essence of the Plaintiff's claim against Ortho is that Ortho failed to warn that the use of Ultram, particularly by individuals with a history of prior opioid abuse, may lead to addiction as well as to withdrawal side effects such as diarrhea, insomnia, headaches and anxiety. (Compl. ¶¶ 37-41.) However, all of these alleged injuries are addressed in the prescribing information for Ultram.

A memorandum the Plaintiff filed with the Court stated that Ortho failed to warn users that Ultram is "not recommended for patients who have a history of substance abuse with opioid and that Ultram may induce psychic and psychical dependence including drug-seeking behavior and taking illicit actions to obtain the drug are not limited to those patients that have a prior history of opioid dependence. The drug re-initiate[s] substance abuse, and drug craving." Plaintiff's Memorandum of Law in Support of Application for the Appointment of Counsel (dated January

22, 2008). This language is copied word-for-word from the warnings contained in Ultram's labeling.

To succeed on his failure-to-warn claim, a plaintiff must prove that: (1) Ortho did not provide his physicians with adequate warnings about risks that it knew or should have known Ultram cause; and (2) the inadequacy of those warnings was the proximate cause of his injuries. Figueroa v. Boston Scientific Corp., 254 F. Supp.2d 361, 369-70 (S.D.N.Y. 2003); Glucksman v. Halsey Drug Co., Inc., 160 A.D.2d 305, 307, 553 N.Y.S.2d 724, 726 (1st Dep't. 1990). For prescription medications such as Ultram, the duty to warn is met by providing information to the prescribing physician, not to the patient directly. Figueroa, 254 F. Supp.2d at 370. As the learned intermediary, it is the role of the physician to "balance the risks against the benefits of various drugs and treatments and to prescribe them and supervise their effects." Martin v. Hacker, 83 N.Y.2d 1, 9, 628 N.E.2d 1308, 1311, 607 N.Y.S.2d 598, 601 (N.Y. 1993).

It has long been the law in New York that prescription medicine warnings are adequate when, as here, information regarding "the precise malady incurred" was

communicated in the prescribing information. Wolfgruber v. Upjohn Co., 72 A.D.2d 59, 60, 62, 423 N.Y.S.2d 95, 96-97 (4th Dep't. 1979), aff'd, 52 N.Y.2d 768, 417 N.E.2d 1002, 436 N.Y.S.2d 614 (1980); Fane v. Zimmer, 927 F.2d 124, 129 (2d Cir. 1991). In such instances, when a plaintiff claims to be injured in a manner that is addressed by warnings provided to his physician, summary judgment is granted on failure to warn claims. See, e.g., Sita v. Danek Medical, Inc., 43 F. Supp.2d 245, 260 (E.D.N.Y. 1999) (summary judgment grated because defendant warned physician "against the precise usage and injuries in question").

The FDA-approved label for Ultram is unequivocal in warning about the injuries allegedly sustained by Plaintiff and by providing Plaintiff's physician with "specific detailed information on the risks of the [product], the manufacturer has been held absolved from liability as a matter of law." Fane, 927 F.2d at 129 (quoting Wolfburger, 72 A.D.2d at 61-62) (brackets in original).

The labeling for Ultram available in 2004 stated that "ULTRAM may induce psychic and psychical dependence of the morphine-type (u-opioid)," that "ULTRAM should not be

used in opioid-dependent patients," and that "ULTRAM has been shown to reinitiate physical dependence in some patients that have been previously dependent on other opioids." The symptoms of withdrawal allegedly experienced by Plaintiff, including diarrheas, insomnia, headaches and anxiety, also are addressed in the FDA-approved warning label. Id. Finally, the labeling explicitly warns of the possibility of "[d]ependence and abuse, including drug-seeking behavior and taking illicit actions to obtain the drug." (Id.)

Ortho discharged its duty to warn here by providing express warnings about the injuries allegedly sustained by Plaintiff. "If the doctor is sufficiently warned, the product is not defective" and summary judgment is appropriate. Fane, 927 F.2d at 129 (citing Lindsay v. Ortho Pharmaceutical Corp., 637 F.2d 87, 91 (2d Cir. 1980)); Krasnopolsky v. Warner-Lambert Co., 799 F. Supp. 1342, 1346-47 (E.D.N.Y. 1992) (granting summary judgment when learned intermediary was sufficiently warned of risks of drug and finding that "speculative and conclusory claims of possible inadequacies in the warning without any evidentiary backup does not create a genuine factual issue so as to preclude summary judgment").

In a failure-to-warn action, a plaintiff "bears the burden to prove that defendant's failure to warn was a proximate cause of his injury and this burden includes adducing proof that the user of a product would have read and heeded a warning had one been given." Sosna v. American Home Products, 298 A.D.2d 158, 158, 748 N.Y.S.2d 548, 548 (1st Dep't. 2002); see also Smallwood v. Clairol, Inc., No. 03 Civ. 8394 SWK, 2005 WL 425491, at *2 n.5 (S.D.N.Y. Feb. 18, 2005). In the case of prescription medications, where warnings are directed to prescribing physicians, a plaintiff must demonstrate that had a different, more accurate warnings been given, his physician would not have prescribed the drug in the same manner. See, Mulhall v. Hannafin, 45 A.D.3d 55, 61; 841 N.Y.S.2d 282, 287 (1st Dep't. 2007); see Krasnopolsky, 799 F. Supp. at 1347. Plaintiff cannot meet this burden of demonstrating that an alleged failure to warn was the proximate cause of his injuries.

As the Plaintiff's medical records show, his physicians knew that Ultram could cause addiction, yet continued to prescribe tramadol to treat Plaintiff's back and knee pain. The Plaintiff claims to have become

addicted to tramadol in January 2005, and to have gone through detoxification in a Department of Corrections facility in February 2006. (Compl. at ¶¶ 30-31.) The Plaintiff's allegations of addiction to tramadol are documented in his medical records. Yet despite this evidence that the Plaintiff was reportedly addicted to tramadol in early 2005, his physician continued to prescribe the medicine for two more years. This decision by the Plaintiff's physicians to not alter their conduct, despite being apprised of the possible risks associated with tramadol, demonstrates that a more stringent warning would have had no practical effect on the physicians' actions.

Exercising their clinical judgment, the Plaintiff's physicians made the decision to prescribe and continue to prescribe tramadol for the Plaintiff's back and knee pain. Given the express language of Ultram labeling, this practice establishes the high likelihood that additional warnings would have no impact on the prescribing decisions at issue here. See Erony v. Alza Corp., 913 F. Supp. 195, 200 (S.D.N.Y. 1995) ("[a]n act cannot be the 'substantial cause' if the injury would have occurred regardless of the content of defendant's warning").

The Plaintiff has not shown that a failure to warn on the part of Ortho was the proximate cause of his injuries, as his physicians were aware of the risks of addiction and exercised their own clinical judgment in deciding to continue to prescribe tramadol to Plaintiff. Plaintiff's medical records show that he is not infected with hepatitis B.

On the specific date that the Plaintiff contends that his blood tested positive for hepatitis B, he was found to have "no markers" for the virus. Even more recently, the Plaintiff was told by medical staff at his correctional facility: "Mr. Alston . . . [y]ou do not have hepatitis B so do not worry about this." Notwithstanding the fact that the Plaintiff does not have hepatitis B, even if he did have hepatitis B, and even if the Plaintiff could demonstrate that he contracted the virus due to the mouth-to-mouth sharing of tramadol pills, this injury would be well-beyond the farthest reaches of Ortho's duty to warn.

Manufacturers have a duty to warn of the foreseeable risks posed by their products, but they are under no duty to anticipate or prevent criminal or quasi-

criminal conduct. Elsroth v. Johnson & Johnson, 700 F. Supp. 151, 163 (S.D.N.Y. 1988); Fagan v. AmerisourceBergen Corp., 356 F. Supp.2d 198, 207 (E.D.N.Y. 2004); Mulhall, 45 A.D.3d at 58, 841 N.Y.S.2d at 285 ("manufacturer's duty is to warn only of those dangers it knows of or are reasonably foreseeable"); Liriano v. Hobart Corp., 132 F.3d 124, 126 (2d Cir. 1998) ("[I]n New York that manufacturers have a duty to warn users of foreseeable dangers inherent in their products."). "Likewise, a manufacturer does not have a duty to warn that its product is susceptible to criminal misuse." Fagan, 356 F. Supp.2d at 207. Along these same lines, "[a]n inadequate warning cannot be the substantial cause of an injury if an intervening act occurs that is of 'such an extraordinary nature or so attenuates defendant's negligence from the ultimate injury that responsibility for the injury may not be reasonably attributed to the defendant.'" Erony, 913 F. Supp. at 200 (quoting Kush v. City of Buffalo, 59 N.Y.2d 26, 33,499 N.E.2d 725, 729, 462 N.Y.S.2d 831, 835 (1983)).

The Plaintiff claims that he was exposed to hepatitis B in the course of an illegal exchange of prescription tramadol pills from another prisoner's mouth to his own. This extraordinary action is well-beyond the

scope of the foreseeable use of tramadol and, therefore, is well-beyond the scope of Ortho's duty to warn. See e.g., Elsroth, 700 F. Supp. at 163, 164. This type of action is precisely the kind of "intervening act" that breaks the causal nexus between a manufacturer and a plaintiff; few actions could be more attenuated from the allegedly insufficient warnings in Ortho's labeling than the passing of the pills from one inmate's mouth to another.

The extraordinary facts alleged by the Plaintiff also defeat any causal nexus that could exist between his alleged injury and Ortho's conduct. See Kush, 59 N.Y.2d at 33, 499 N.E.2d at 729, 462 N.Y.S.2d at 835. Thus, the Plaintiff is precluded from asserting that Ortho caused his alleged, but non-existent, hepatitis B infection.

The Caraco Warnings Were Adequate

Courts have routinely held as a matter of law that a drug manufacturer will not be liable if there is evidence showing that the warning specifically warned of the side effects which occurred. Wolfsgruber, 72 A.D.2d at 61; Lindsay, 637 F.2d at 91; Martin v. Hacker, et al., 83 N.Y.2d 1, 9, 628 N.E.2d 1308, 1312 (N.Y. 1993).

In this case, the Plaintiff has alleged that his prescription use of Ultram/Tramadol caused diarrhea, insomnia, headaches, addiction and drug seeking behavior (Compl. ¶¶ 29, 30, 37.) Each alleged side effect was clearly described in Caraco's package insert:

> **DRUG ABUSE AND DEPENDENCE**
>
> Tramadol hydrochloride tablets may induce psychic and physical dependence of the morphine-type (u-opioid). (See WARNINGS.) Dependence and abuse, including drug-seeking behavior and taking illicit actions to obtain the drug are not limited to those patients with prior history of opioid dependence. The risk in patients with substance abuse has been observed to be higher. Tramadol hydrochloride tablets is associated with craving and tolerance development. Withdrawal symptoms may occur if tramadol hydrochloride tablets are discontinued abruptly. These symptoms may include: anxiety, sweating, insomnia, rigors, pain, nausea, tremors, diarrhea, upper respiratory symptoms, pilocerection, and rarely hallucinations. Clinical experience suggests that withdrawal symptoms may be relieved by reinstitution of opioid therapy followed by a gradual, tapered does reduction of the medication combined with symptomatic support.

Kurkiewicz Aff. ¶ 6, Ex. B.

Because all of the alleged side effects described by Alston are specifically indicated as potential side effects in tramadol's package insert, the warning is

adequate as a matter of law. Wolfsgruber, 72 A.D.2d at 61; Lindsay, 637 F.2d at 91, Martin, 83 N.Y.2d at 9, 628 N.E.2d at 1312.

Illegal Use Bars Recovery

The Plaintiff is also precluded from alleging failure to warn when he procured and used tramadol illegally. For Alston's negligence claim to survive a motion for summary judgment, the Plaintiff must establish "(1) a duty owed him by the manufacturer; (2) a breach thereof; and (3) injury proximately resulting therefrom." Solomon by Solomon v. City of New York, 66 N.Y.2d 1026, 1027, 489 N.E.2d 1294, 1294, 499 N.Y.S.2d 392, 392 (1985). The performance of an illegal act acts as a bar to any recovery for negligence. Manning v. Brown, 91 N.Y.2d 116, 120-21, 667 N.Y.S.2d 336, 338, 689 N.E.2d 1382, 1384 (N.Y. 1997) (unlicensed driver who was injured while joy-riding precluded from recovery); Barker v. Kallash, 63 N.Y.2d 19, 26, 479 N.Y.S.2d 201, 204, 468 N.E.2d 39, 42 (N.Y. 1984)) (plaintiff injured while constructing pipe bomb barred from recovery). Here, Alston has admitted that he obtained pills from other prisoners who had "mouthed" drugs in the medical center. Compl. ¶¶ 32, 37, 40 (Quasarano Aff. Ex.

A). Alston also admits deliberately exceeding the recommended dosage. Id. ¶ 33. Because Alston obtained and used Ultram/tramadol illegally, the Complaint against the Defendants is dismissed.

Conclusion

Upon the findings and conclusions set forth above, the complaint is dismissed with prejudice.

It is so ordered.

New York, NY
November 20 , 2009

ROBERT W. SWEET
U.S.D.J.