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U.S. DISTRICT COURT
N.D. OF ALABAMA

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ALABAMA
SOUTHERN DIVISION

IN RE: CHANTIX (VARENICLINE) PRODUCTS LIABILITY LITIGATION This Order Relates To: ALL CASES	Master File No.: 2:09-CV-2039-IPJ MDL No. 2092

MEMORANDUM OPINION

Pending before the court is the defendant's motion for summary judgment and exhibits in support of said motion as to (1) the adequacy of the July 1, 2009, label, and (2) the running of the statutes of limitations based on the July 1, 2009, label (doc. 590); a memorandum in support of said motion (doc. 591); the plaintiffs' brief in opposition to said motion (doc. 602); exhibits in support of said opposition (docs. 609 and 610); and the defendant's reply (doc. 617). Having considered the foregoing, the court finds as follows:

FACTUAL BACKGROUND

This is a multidistrict product liability action concerning the drug Chantix,[1] touted by defendant as a medication to aid in smoking cessation. The Food and Drug Administration (FDA) approved Chantix for sale in the United States in May 2006. Master Consolidated Complaint (doc. 36), at ¶ 17. Greatly simplified, Chantix works

[1]The generic name of the drug is varenicline.

by reducing nicotine cravings in smokers trying to quit both by blocking nicotine from reaching receptors in the brain and also by causing a steady release of dopamine in the brain. *Id*., ¶ 26.

According to the plaintiffs, Chantix causes depression and other psychiatric disorders, some so severe that reports of suicide and attempted suicide from Chantix use have been made. Master Consolidated Complaint, ¶ 32. The plaintiffs allege defendant either knew or should have known about such side effects, but for defendant's intentional failure to design studies which were reflective of their targeted population. Master Consolidated Complaint, ¶¶ 27-31, 33-38. The defendant denies there is any merit to such allegations, and asserts that numerous studies show the side effects of Chantix to be in line with those of other nicotine replacement therapies (NRTs), such as nicotine patches.

Because of reports of suicidal thoughts and acts, as well as other neuropsychiatric disorders, the labeling of Chantix since May 2006 has been changed to strengthen the warnings on the package inserts, culminating in a "black box warning" being placed on the package insert in July 2009. *See* defendant ex. 1 (doc. 590-1). In November 2007 the "adverse reactions" section of the label was updated to reflect post-marketing reports of depression, agitation, changes in behavior,

suicidal ideation and suicide in patients taking Chantix.[2] *See* defendant ex. 2 (doc. 590-2). In January 2008 the label was again updated, this time adding a "warnings" section which reflected "[s]erious neuropsychiatric symptoms have occurred in patients being treated with Chantix." Defendant ex. 3 (doc. 590-3) at 10. The warning continued that people taking Chantix "should be observed for ... changes in behavior, agitation, depressed mood, suicidal ideation and suicidal behavior." *Id.* That label also warned that such symptoms had been reported in patients taking Chantix, that individuals with serious psychiatric illnesses were excluded from pre-marketing studies of Chantix, and that the safety of Chantix had not been established in individuals with such pre-existing illnesses. *Id.* The label was again strengthened in May 2008 to state that patients taking Chantix who develop neuropsychiatric symptoms should stop taking the drug and contact their health care provider immediately. Defendant ex. 4 (doc. 590-4).

In addition to the black box warning added in July 2009, a "Medication Guide" was added to the package inserts at the same time, to inform patients that "[s]ome

[2]The FDA's pre-market approval of a new drug application includes the approval of the exact text in the proposed label. *See* 21 U.S.C. § 355; 21 CFR § 314.105(b) and (c) (2008). Generally speaking, a manufacturer may only change a drug label after the FDA approves a supplemental application. However, a manufacturer may make certain changes to its label before receiving the agency's approval if a manufacturer is changing a label to "add or strengthen a contraindication, warning, precaution, or adverse reaction." Under these circumstances a manufacturer may make the labeling change upon filing its supplemental application with the FDA; it need not wait for FDA approval. §§ 314.70(b)(2)(v); 314.70(c)(6)(iii)(A).

people have had changes in behavior, hostility, agitation, depressed mood, and suicidal thoughts or actions while using CHANTIX ..." and that if "you [or] your family" notice such symptoms or changes in behavior, "stop taking CHANTIX and call your healthcare provider right away..." Defendant ex. 5 (doc. 590-5), at 1. The "black box warning" and the Medication Guide have remained unchanged since July 2009.

In October 2011 the FDA released a Safety Announcement which reported that the FDA reviewed two FDA-sponsored studies evaluating the risk of neuropsychiatric injury from Chantix. Defendant ex. 6 (doc. 590-6). That Announcement states

> Neither study found a difference in risk of neuropsychiatric hospitalizations between Chantix and ...NRT.... However, both studies had a number of study design limitations, including only assessing neuropsychiatric events that resulted in hospitalization, and not having a large enough sample size to detect rare adverse events .... Although these two studies did not suggest an increased risk of neuropsychiatric events that result in hospitalization, they do not rule out an increased risk of other neuropsychiatric events with Chantix.

Id., at 1. That Announcement further states that "[o]verall, FDA has determined that the current warnings in the Chantix drug label, based on post-marketing surveillance reports, remain appropriate." *Id*., at 2.

The defendant asserts the July 2009 label change is sufficient as a matter of law, and thus should trigger the statute of limitations to run on all plaintiffs' failure

to warn claims based on neuropsychiatric injury. The plaintiffs disagree, asserting that the court cannot find the July 2009 warning sufficient as a matter of law.[3]

SUMMARY JUDGMENT STANDARD

A moving party is entitled to summary judgment if there is no genuine issue of material fact, leaving final judgment to be decided as a matter of law. *See* Federal Rule of Civil Procedure 56; *Matsushita Elec. Indus. Co. v. Zenith Radio Corp*., 475 U.S. 574, 587, 106 S.Ct. 1348, 1355-56 (1986); *Reeves v. C.H. Robinson Worldwide, Inc*., 525 F .3d 1139, 1143 (11th Cir.2008). The facts, and any reasonable inferences therefrom, are to be viewed in the light most favorable to the non-moving party, with any doubt resolved in the non-movant's favor. *See Adickes v. S.H. Kress & Co.*, 398 U.S. 144, 158, 90 S.Ct. 1598, 1609 (1970). All "reasonable doubts" about the facts and all justifiable inferences are resolved in favor of the non-movant. *Fitzpatrick v. City of Atlanta*, 2 F.3d 1112, 1115 (11th Cir.1993). However, all "doubts" need not be so resolved. *Barnes v. Southwest Forest Industries, Inc.,* 814 F.2d 607, 609 (11th Cir.1987). Once met by the moving party, the burden shifts to the non-moving party to come forward with evidence to establish each element essential to that party's case sufficient to sustain a jury verdict. *See Celotex Corp. v. Catrett*, 477 U.S. 317, 322,

[3]As pointed out in the plaintiffs' brief in opposition, the defendant's motion does not address non-neuropsychiatric injury, nor neuropsychiatric claims arising prior to July 2009. *See* doc. 602 at 1, n.1, and 2. Those issues are not before the court at this time.

106 S.Ct. 2548, 2552 (1986); *Earley v. Champion Int'l Corp*., 907 F.2d 1077, 1080 (11th Cir.1990).

A party opposing a properly submitted motion for summary judgment may not rest upon mere allegations or denials of his pleadings, but must set forth specific facts showing that there is a genuine issue for trial. *Eberhardt v. Waters*, 901 F.2d 1578, 1580 (11th Cir.1990). In addition, the non-moving party's evidence on rebuttal must be significantly probative and not based on mere assertion or be merely colorable. *See* Rule 56(e); *Anderson v. Liberty Lobby, Inc*., 477 U.S. 242, 249-50, 106 S.Ct. 2505, 2511 (1986). Speculation does not create a genuine issue of fact. *Cordoba v. Dillard's, Inc*., 419 F.3d 1169, 1181 (11th Cir.2005).

"The mere existence of some factual dispute will not defeat summary judgment unless that factual dispute is material to an issue affecting the outcome of the case .... A genuine issue of material fact does not exist unless there is sufficient evidence favoring the nonmoving party for a reasonable jury to return a verdict in its favor." *Chapman v. AI Transport*, 229 F.3d 1012, 1023 (11th Cir.2000), quoting *Haves v. City of Miami*, 52 F.3d 918, 921 (11th Cir. 1995). A factual dispute regarding a non-material issue will not preclude the defendant from succeeding on a motion for summary judgment. *Brown v. American Honda Motor Co.*, 939 F.2d 946, 953 (11th Cir.1991).

LEGAL ANALYSIS

A. Adequacy of 2009 Boxed Warning

While the elements of a failure to warn claim vary from state to state, the requirements of a such a claim generally include that "where the manufacturer ... of a product has actual or constructive knowledge of danger to users, the ... manufacturer has a duty to give warning of such dangers." *See e.g., PLIVA, Inc. v. Mensing,* 131 S.Ct. 2567, 2573 (2011), citing *Frey v. Montgomery Ward & Co.*, 258 N.W.2d 782, 788 (Minn.1977). *See also Stupak v. Hoffman-LaRoche, Inc*., 326 Fed.Appx. 553, 557-558 (11th Cir.2009) (discussing Wisconsin law and noting that "under both negligence and strict liability failure to warn claims, the duty to warn arises from the foreseeability of the harm encountered by the user. Hence, in order to maintain an action against a manufacturer for harm arising from the manufacturer's failure to warn of a danger ... the plaintiff must prove that the manufacturer knew or should have known of the danger which caused the harm at issue").[4]

Although such claims arise under the various laws of the fifty states, the content of the drug label itself is regulated by federal law. "Under the 1962 Drug Amendments to the Federal Food, Drug, and Cosmetic Act, 76 Stat. 780, 21 U.S.C.

[4]The variations in this standard among the 50 states are beyond the scope of this opinion and not necessary to the proposition raised by the plaintiffs' claims, namely that in any failure to warn action, the sufficiency of the warning given is at issue.

§ 301 *et seq*., a manufacturer seeking federal approval to market a new drug must prove that it is safe and effective and that the proposed label is accurate and adequate." *PLIVA*, 131 S.Ct. at 2574, citing 21 U.S.C. §§ 355(b)(1), (d); *Wyeth v. Levine*, 555 U.S. 555, 567, 129 S.Ct. 1187, 173 L.Ed.2d 51 (2009). Thereafter, a manufacturer bears responsibility for the content of its label at all times. "It is charged both with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market." *Wyeth v. Levine*, 555 U.S. at 570-571 (citing 21 CFR § 201.80(e) (requiring a manufacturer to revise its label "to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug");[5] § 314.80(b) (placing responsibility for post-marketing surveillance on the manufacturer); 73 Fed.Reg. 49605 ("Manufacturers continue to

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[5]With regard to "boxed warnings," that section of the Code of Federal Regulations states that

> Special problems, particularly those that may lead to death or serious injury, may be required by the Food and Drug Administration to be placed in a prominently displayed box. The boxed warning ordinarily shall be based on clinical data, but serious animal toxicity may also be the basis of a boxed warning in the absence of clinical data. If a boxed warning is required, its location will be specified by the Food and Drug Administration. The frequency of these serious adverse reactions and, if known, the approximate mortality and morbidity rates for patients sustaining the reaction, which are important to safe and effective use of the drug, shall be expressed as provided under the "Adverse Reactions" section of the labeling.

21 CFR § 201.80(e).

have a responsibility under Federal law ... to maintain their labeling and update the labeling with new safety information")).

The label at issue here has, since July 2009, included the warning that

> Serious neuropsychiatric events, including, but not limited to depression, suicidal ideation, suicide attempt and completed suicide have been reported in patients taking CHANTIX....
>
> All patients being treated with CHANTIX should be observed for neuropsychiatric symptoms including changes in behavior, hostility, agitation, depressed mood, and suicide-related events including ideation, behavior, and attempted suicide....
>
> These events have occurred in patients with and without pre-existing psychiatric disease. Patients with serious psychiatric illness such as schizophrenia, bipolar disorder, and major depressive disorder did not participate in the pre-marketing studies of CHANTIX and the safety and efficacy of CHANTIX in such patients has not been established.
>
> **Advise patients and caregivers that the patient should stop taking CHANTIX and contact a healthcare provider immediately if agitation, hostility, depressed mood, or changes in behavior or thinking that are not typical for the patient are observed, or if the patient develops suicidal ideation or suicidal behavior.**

Defendant ex. 1, at 1 (emphasis in original).[6]

The plaintiffs rely on the testimony and expert report of Joseph Glenmullen, M.D., for evidence that the current label on Chantix is insufficient. *See* plaintiffs' brief in opposition, at 4-8. In his expert report, Dr. Glenmullen states that "on July

[6]The plaintiffs assert this warning omits "feelings of hopelessness or symptoms of suicidality" as contraindications. Plaintiffs' brief in opposition, at 8. The court finds no merit in this contention, as "feelings of hopelessness" are within the definition of "depression," and "symptoms of suicidality" would include such things as "depressed mood," "suicidal ideation," and "suicidal behavior," all of which are clearly included in the defendant's warning label.

1, 2009 the FDA's Chantix warnings culminated in a black box, the highest level warning possible, prominently displayed at the beginning if a drug's official prescribing information." Report of Glenmullen, at 38, submitted as plaintiff ex. 016178. After setting forth the warning and the list of possible psychiatric side effects, Dr. Glenmullen states that this list "underscores the severity of Chantix's side effects." *Id*., at 39. Dr. Glenmullen adds that defendant resisted these FDA required changes as early as 2007 and that defendant resisted the addition of the black box warning, delaying its implementation by eight months. *Id*., at 40-41. Later in his report, Dr. Glenmullen discusses other medications which impact dopamine levels or uptake in regard to FDA required warnings, the conclusion being that dopamine-altering medications tend to have neuropsychiatric effects and thus have mandated warnings concerning those effects. *Id.*, at 52-53.

Conspicuously absent from Dr. Glenmullen's report is any discussion of the adequacy of the 2009 black box warning. Hence plaintiffs' arguments otherwise, based on Dr. Glenmullen's expert report, are unpersuasive. Perhaps recognizing this shortcoming, the plaintiffs rely instead on Dr. Glenmullen's deposition testimony, where he suggests that the Chantix label should reflect the Veteran's Administration prescribing guidelines. *See e.g.*, plaintiffs' brief in response at 7-8.

While plaintiffs suggest that the Chantix label should include a warning to prescribing doctors not to use Chantix as a first line treatment to assist in smoking cessation, in accordance with the Veteran's Administration (VA) guidelines, such a suggestion is not relevant to the issue of the sufficiency of the current label for purposes of a failure to warn claim. The issue for a failure to warn claim is whether the warning given was sufficient to alert to the possibility of the harm actually suffered.

Relevant to these arguments is whether the label sufficiently alerted medical professionals that their patients could suffer neuropsychiatric injuries from taking Chantix as prescribed. The parties agree that the vast majority of states apply the "learned intermediary doctrine" to failure to warn claims concerning prescription medications.[7] *See e.g., Toole v. Baxter Healthcare Corp*., 235 F.3d 1307, 1313 (11th Cir.2000); *Ellis v. C.R. Bard, Inc*., 311 F.3d 1272, 1279 (11th Cir.2002) ("the learned intermediary doctrine is nearly universal; where drugs or medical devices are only available to the public by prescription from a physician or dentist, the products manufacturer fulfills its duty to warn by advising the professional of the dangers of the product ...") (citations omitted); *Christopher v. Cutter Labs*., 53 F.3d 1184, 1192 (11th Cir.1995) (same); *Anderson v. Sandoz Pharma. Corp*., 77 F.Supp.2d 804, 808

[7]For a somewhat exhaustive listing of states and federal courts which have adopted the learned intermediary doctrine, see *Vitanza v. Upjohn Co.*, 778 A.2d 829, 838 n.11 (Conn.2001).

(S.D.Tex.1999) ("If [the doctor] was aware of the possible risks involved in the use of the drug, yet chose to use it regardless of the adequacy of the warning, then, as a matter of law, the adequacy of the warning was not a producing cause of the plaintiff's injury.") (internal quotations and citations omitted). *See also Timmons v. Purdue Pharma. Co.*, No. 8:04-CV-1479-T-26MAP, 2006 WL 263602 (M.D.Fla. Feb. 2, 2006) (unpublished) (where doctor's decision to prescribe OxyContin was made independent of any alleged misrepresentations by the manufacturer, the court found that "the learned intermediary doctrine precludes a finding of causation" between the faulty warnings and the injury of addiction). Thus the court must consider the failure to warn claim in light of the warning's intended audience, medical doctors. Yet surely the decision as to use a medication as a first-line treatment is uniquely up to the prescribing medical professional and based on a decision concerning his or her individual patient.

With this backdrop, the court has considered the plaintiffs' new proposition on label inadequacy – that a warning not to use Chantix as a first-line treatment should have been included.[8] The plaintiffs have pointed to no evidence from Dr. Glenmullen concerning the sufficiency of the current black box warning other than his opinion that the VA recommendation should have been included. However, in making this

[8]The plaintiffs do not suggest that such a statement should have been included on the Medication Guide required to be given to patients upon receiving a prescription for the same.

argument, the plaintiffs mix apples and oranges. The fact that the VA recommends to its doctors that Chantix not be a first line treatment does not impact the veracity of the 2009 black box warning. In also noting that the VA has advised not to use Chantix as a first line treatment, plaintiffs' expert Cheryl Blume eloquently states that:

> In October 2006, a monograph prepared for the VA for consideration of addition of Chantix to its formulary, noted that "Varenicline should not be used as a first-line therapy. ***It is effective in young healthy patients but there is few data in patients like those we serve***. It should be restricted to use in patients who have failed on NRT and/or buproprion or in whom buproprion is contraindicated".

See expert report of Blume (submitted as plaintiff ex. 016164), at 39-40 (emphasis added).

To survive a motion for summary judgment, a party must do more than make conclusory allegations. The Eleventh Circuit has "consistently held that conclusory allegations without specific supporting facts have no probative value.... One who resists summary judgment must meet the movant's affidavits with opposing affidavits setting forth specific facts to show why there is an issue for trial." *Leigh v. Warner Bros., Inc*., 212 F.3d 1210, 1217 (11th Cir.2000) (internal citation omitted). Similarly, the district court has no obligation to parse a summary judgment record to search out facts or evidence not brought to the court's attention." *Atlanta Gas Light*

Co. v. UGI Utilities, Inc., 463 F.3d 1201, 1208 n. 11 (11th Cir.2006). Dr. Glenmullen provides no assistance to the plaintiffs in this regard.

Dr. J. Wesley Boyd, M.D., another of plaintiffs' experts, does state that in his opinion, Chantix should not be used as a first line treatment. Expert report of Boyd, submitted as plaintiff ex. 016165, at 17. However, at no time did he opine that the 2009 warning contained in the Chantix label was inadequate. The plaintiffs attempt to dodge this problem by arguing, "[a]s with other aspects of the VA guidelines, noted above, this opinion of Dr. Boyd – that Chantix is not a first line therapy – is not contained in the July 2009 label."[9] Plaintiffs' brief in opposition, at 8-9. However, not to confuse the issue, Dr. Boyd's opinion is that Chantix should not be used as a first line therapy. His opinion does not include a statement that the lack of the same on the label constitutes a failure to adequately warn that this medication may cause neuropsychiatric side effects.[10] The plaintiffs' assertions that "Pfizer's counsel chose

[9]As made obvious by Dr. Blume, the VA's opinion as to the use of Chantix is limited based solely on the population the VA serves. Its opinion does not, and cannot, extend beyond its realm of patients.

[10]Where the manufacturer warns of the injury the plaintiff suffered, other courts have found a manufacturer's warnings adequate as a matter of law. *See, e.g.,Stahl v. Novartis Pharmaceuticals Corp.,* 283 F.3d 254, 266 (5th Cir.2002) ("a drug warning is adequate as a matter of law if it clearly and unambiguously notifies the prescribing physician of the particular adverse reaction that forms the basis of the plaintiff's complaint."); *Anderson v. McNeilab, Inc*., 831 F.2d 92, 93 (5th Cir.1987); *Frazier v. Wyeth,* – F.Supp.2d –. 2012 WL 826987, 7 (D.Conn.2012); *Snyder v. Hoffman-LaRoche, Inc*., 2008 WL 4790666, 6 (M.D.Fla.2008) (stating that in evaluating warnings, death from suicide requires a warning of the most serious degree, but defendants' warning were sufficient in stating medication "may" cause suicide "rarely"); *Caveny v. Ciba–Geigy Corp*., 818 F.Supp. 1404, 1406 (D.Col.1992); *Cather v. Catheter Tech.*

not to inquire of Dr. Boyd concerning this opinion" and that "Dr. Boyd ... is a well-qualified psychiatrist who could offer expert testimony at trial about the lack of "completeness" and "accuracy" and thus the inadequacy, of the July 2009 label," (plaintiffs' brief in opposition, at 9), do not rise to the level of evidence the court can consider on the pending motion for summary judgment. Argument concerning what an expert witness "could" testify at trial is no more than rank speculation, not evidence.

The plaintiffs next argue that in an article co-authored by Dr. Glenmullen and Dr. Carl Furberg, another of plaintiffs' experts, the suggestion is made that "the FDA should consider revising the suicidal behavior and depression language in the Boxed Warning and Highlights of Prescribing Information to state clearly that the risks of suicidal behavior and depression are higher with varenicline than with other smoking cessation treatments." Plaintiffs' ex. 016092, plaintiffs' brief in opposition at 9-10. This statement is really indistinguishable from plaintiffs' argument that Chantix is so dangerous, it should not be used as a first-line treatment, as discussed above.

Corp., 753 F.Supp. 634, 640 (S.D.Miss.1991); *Bealer v. Hoffman–LaRoche, Inc*., 729 F.Supp. 43, 45 (E.D.La.1990); *Jones v. Lederle Labs*., 695 F.Supp. 700, 708 (E.D.N.Y.1988); *Upjohn Co. v. MacMurdo*, 562 So.2d 680, 683 (Fla.1990).

In fact, one court ruled that if a warning label clearly and unambiguously states the particular ailment suffered by the plaintiff, summary judgment on a failure-to-warn claim is appropriate despite the prescribing physician's testimony that the warning did not adequately inform him of the risk involved. *Calhoun v. Hoffman-La Roche, Inc.*, 98-2770, (La.App. 1 Cir.2000), 768 So.2d 57, 62.

However, the plaintiffs again do not suggest that the failure to include this language renders the warnings inadequate. Nowhere in their complaint do they suggest either this, or that the warnings should have stated that varenicline should not be used as a first line treatment, rendered the 2009 label changes insufficient.[11]

Rather, as other courts have recognized, it is the responsibility of the physician as a learned intermediary to assess the risks and benefits of a particular course of treatment. *Caveny v. CIBA-GEIGY Corp*., 818 F.Supp. 1404, 1406 (D.Colo.1992); *Ferrara v. Berlex Laboratories, Inc*., 732 F.Supp. 552 (E.D.Pa.1990); *Wooten v. Johnson & Johnson, Products, Inc*., 635 F.Supp. 799 (N.D.Ill.1986).

> [O]nly health-care professionals are in a position to understand the significance of the risks involved and to assess the relative advantages and disadvantages of a given form of prescription-based therapy. The duty then devolves on the health-care provider to supply to the patient such information as is deemed appropriate under the circumstances so that the patient can make an informed choice as to therapy.

The Restatement (Third) of Torts: Products Liability § 6(d) (1998), comment b. Similarly, as recognized by other courts, whether physicians choose to follow the warnings is a matter of medical judgment. *See e.g., Estate of LaMontagne v. Bristol-Myers Squibb*, 111 P.3d 857 (Wash.App.Div. 1, 2005), citing *Adams v. Synthes Spine Co.*, 298 F.3d 1114 (9th Cir.2002).

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[11]The plaintiffs' complaint does assert that the 2009 label remains inadequate. Master Complaint (doc. 36) at ¶ 87.

Unlike the majority cases reviewed by this court, the plaintiffs seek to pursue their failure to warn claims post the 2009 black box warning, not for failing to warn of possible complications from Chantix, but for failing to tell physicians when to prescribe it.[12] The plaintiffs amended complaint simply does not stretch far enough to include such a claim. Indeed, in their complaint, the plaintiffs recognize that a black box warning is "the most serious warning in the FDA's arsenal..." Master Complaint (doc. 36), ¶ 84.

Additionally, plaintiffs argue both that "hundreds of serious psychiatric adverse event reports that had been originated by Pfizer as far back as 2006 had not been properly submitted to the FDA," and that "many of the aforementioned adverse events occurred before July 2009..." Plaintiffs' brief in opposition, at 10. In no way does this assist plaintiffs' argument that the July 2009 label contained an inadequate warning. Thus, plaintiffs' next statement that "this is another respect in which expert testimony ***could be*** presented at trial concerning an issue of material fact as to the adequacy of the July 2009 Chantix label" neither follows from the preceding assertions, and nor assists plaintiffs' in surviving summary judgment on this narrow

[12]In other words, the label clearly sets forth potential side effects of Chantix. The decision to prescribe the medication anyway, given the severity of those side effects, is solely within the realm of medical judgment. An abuse or misuse of that judgment by a physician is far outside the scope of this action.

claim. *See* plaintiffs' brief in opposition, at 11 (emphasis added). The time to present evidence concerning an issue of material fact is now.[13]

For the foregoing reasons, the court finds the 2009 black box warning adequate as a matter of law on the issue of sufficiency of warnings for purposes of neuropsychiatric injuries. The court shall grant the pending motion on the same.

B. Statute of Limitations

Based on the foregoing, the defendant seeks to have this court rule that the statute of limitations started running on all neuropsychiatric claims on July 1, 2009. The plaintiffs respond that even if the July 2009 label is found adequate as a matter of law, such an ruling cannot be tantamount to a blanket summary judgment ruling on the statute of limitations in neuropsychiatric cases. Plaintiffs' brief in opposition, at 14. The court agrees. The issue of the running and/or expiration of the statute of limitations must be considered on a case by case basis, even given that the court has determined the July 2009 label adequate as a warning as a matter of law.

Rather than the method suggested by the defendant, namely that plaintiffs whose prescriptions were filled after July 1, 2009, should be free to present

[13]In fact, the plaintiffs openly admit that while "in the FDA's view there were at least some cases of serious neuropsychiatric symptoms that 'appeared to be clearly related to use of Chantix and not to nicotine withdrawal or some other factor'" that information "was not included in the Warnings ... in the July 2009 label. Although none of Plaintiffs' experts opined on this absence in their reports ... or was asked about it at deposition, expert testimony to the effect that this represents yet another way in which the July 2009 label is inadequate ***could be*** elicited at trial." Plaintiffs' brief in opposition, at 13 (emphasis added).

arguments opposing summary judgment, the court believes the proper course of action is to allow defendant leave to file motions for summary judgment in individual cases alleging neuropsychiatric injury, wherein the individual plaintiffs had prescriptions filled for the first time after the July 1, 2009, FDA mandated strengthening of the warnings for Chantix.

CONCLUSION

In consideration of the foregoing, the court shall rule by separate order that the July 1, 2009, black box warning is adequate as a matter of law to warn of the risk of neuropsychiatric complications in patients taking Chantix, and the court shall grant the defendant's motion for summary judgment (doc. 590) to this extent. For the reasons set out herein, the court shall also rule by separate order that the remainder of the defendant's motion for summary judgment is denied.

DONE and **ORDERED** this the 23rd day of July, 2012.

INGE PRYTZ JOHNSON
U.S. DISTRICT JUDGE