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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ALABAMA
SOUTHERN DIVISION

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

MEMORANDUM IN SUPPORT OF PFIZER INC.'S MOTION FOR SUMMARY JUDGMENT AS TO (1) THE ADEQUACY OF THE JULY 1, 2009 LABEL, AND (2) THE RUNNING OF STATUTES OF LIMITATIONS BASED ON THE JULY 1, 2009 LABEL

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PRELIMINARY STATEMENT

On July 1, 2009, Pfizer updated the Chantix label to add a boxed warning regarding reports of neuropsychiatric events in patients taking Chantix, a warning that Plaintiffs themselves describe as "the most serious warning in the FDA's arsenal." Master Compl. ¶ 84. Among other things, the boxed warning:

- advised physicians and patients of reports of "[s]erious neuropsychiatric events;"
- included the neuropsychiatric events at issue in this litigation – *e.g.*, depression, suicidal ideation, suicide attempt, and completed suicide – and the circumstances under which they had been reported;
- cautioned that patients taking Chantix should be observed for neuropsychiatric symptoms; and
- directed patients and caregivers that patients "**stop taking Chantix and contact a health care provider immediately**" if they underwent atypical changes in behavior or thinking or "develop[ed] suicidal ideation or suicidal behavior." Ex. 1 (July 2009 Package Insert) at 1.

This warning adequately informed physicians and patients, as a matter of law, about the potential for patients taking Chantix to experience neuropsychiatric events. Plaintiffs have not (and cannot) come forward with any admissible evidence, much less any admissible expert opinion evidence, sufficient to create a genuine issue of material fact on the adequacy of the July 2009 label. Plaintiffs' labeling and regulatory expert, Dr. Cheryl Blume, did not criticize the July 2009 label; indeed, she did not opine on it at all. Nor did any other of Plaintiffs' experts offer an admissible opinion on labeling. Only one of those experts – ***non-regulatory*** expert Dr. Joseph

Glenmullen – addressed the July 2009 label, and it is unclear whether his passing statements, which are based on a single adverse event table and flawed data produced by another expert designated by Plaintiffs, are intended to be opinions on labeling at all. If so, Dr. Glenmullen is not qualified to render labeling opinions, and his few statements fall short of even the lowest thresholds for admissibility and materiality. In any event, even were his statements about labeling admissible, no reasonable juror could find the label inadequate.

Because the July 2009 Chantix label is adequate as a matter of law, Pfizer requests that the Court enter summary judgment in favor of Pfizer in the following types of cases in which a plaintiff claims to have suffered a neuropsychiatric injury: (1) all cases in which Plaintiffs were prescribed Chantix after July 1, 2009; and (2) all cases in which a one-year limitations statute applies and that were filed after July 1, 2010; all cases in which a two-year limitations statute applies and that were filed after July 1, 2011; and all cases in which a three-year limitations statute applies and that have not been filed on or before July 1, 2012. At this point, Pfizer does not seek the entry of final judgment in any particular case in this MDL that falls within the above parameters; if the Court grants this motion, Pfizer will seek entry of judgment in such cases at an appropriate later time.

BACKGROUND

The Food and Drug Administration first approved Chantix, a prescription aid to smoking cessation, in May 2006. The FDA simultaneously approved the

Chantix label, which had been repeatedly reviewed and edited by doctors and scientists at the FDA to accurately reflect scientific information known at the time about Chantix, including information obtained from extensive clinical trials. *See* Introduction & Statement of Facts Relevant to All *Daubert* Motions, § I.C (filed May 18, 2012). After Chantix began to be sold in the United States, Pfizer updated the label, as appropriate; each update required review and approval of the FDA.

For example, with the FDA's approval, Pfizer updated the "**ADVERSE REACTIONS**" section of the Chantix label in November 2007 to reflect post-marketing reports of neuropsychiatric events such as "depressed mood, agitation, changes in behavior, suicidal ideation and suicide in patients attempting to quit smoking while taking Chantix." Ex. 2 (November 2007 Package Insert at 16).[1] Pfizer, again with the FDA's approval, added a "**WARNINGS**" section to the label in January 2008 regarding "[s]erious neuropsychiatric symptoms [that] have occurred in patients being treated with Chantix." Ex. 3 (January 2008 Package Insert) at 1. That Warning advised that "[p]atients attempting to quit smoking with CHANTIX and their families and caregivers should be alerted about the need to monitor for these symptoms and to report such symptoms immediately to the patient's healthcare provider." *Id.* at 9. And Pfizer, again with the FDA's approval, updated this

[1] Unless noted, all emphases in labeling text appears in the original. "Neuropsychiatric events" refers to symptoms of psychiatric and nervous system disorders, including but not limited to anxiety, depression, aggression, suicidal ideation, and suicidal behavior. *See* Medical Dictionary for Regulatory Activities ("MedDRA"), available at http://www.meddramsso.com.

"**WARNINGS"** section in May 2008 to further emphasize that "**patient[s] should stop taking CHANTIX and contact a health care provider immediately**" if they developed neuropsychiatric symptoms. Ex. 4 (May 2008 Package Insert) at 9.

Although Plaintiffs and their experts dispute the adequacy of these various FDA-approved labels and/or the timing of their implementation, they have offered no legitimate dispute about the adequacy of the July 2009 label, discussed below, which instituted a boxed warning concerning reports of neuropsychiatric events.

STATEMENT OF UNDISPUTED FACTS

The Chantix boxed warning appears on the first page of the July 2009 Chantix label. It is set apart from other text by its appearance inside a (bolded) box. It provides, in full, as follows:

> **WARNING:**
>
> Serious neuropsychiatric events, including, but not limited to depression, suicidal ideation, suicide attempt and completed suicide have been reported in patients taking CHANTIX. Some reported cases may have been complicated by the symptoms of nicotine withdrawal in patients who stopped smoking. Depressed mood may be a symptom of nicotine withdrawal. Depression, rarely including suicidal ideation, has been reported in smokers undergoing a smoking cessation attempt without medication. However, some of these symptoms have occurred in patients taking CHANTIX who continued to smoke.
>
> 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 symptoms, as well as worsening of pre-existing psychiatric illness and completed suicide have been reported in some patients attempting to quit smoking while taking CHANTIX in the post-marketing experience. When symptoms were reported, most were during CHANTIX treatment, but some were following discontinuation of CHANTIX therapy.

> 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.** In many post-marketing cases, resolution of symptoms after discontinuation of CHANTIX was reported, although in some cases the symptoms persisted; therefore, ongoing monitoring and supportive care should be provided until symptoms resolve.
>
> The risks of CHANTIX should be weighed against the benefits of its use. CHANTIX has been demonstrated to increase the likelihood of abstinence from smoking for as long as one year compared to treatment with placebo. The health benefits of quitting smoking are immediate and substantial.
>
> (See **WARNINGS/Neuropsychiatric Symptoms and Suicidality, PRECAUTIONS/Information for Patients, and ADVERSE REACTIONS/ Post-Marketing Experience**)

Ex. 1 at 1.

This information is further addressed in other sections of the label. The "**WARNINGS**" section, beneath the heading "**Neuropsychiatric Symptoms and Suicidality**," repeats that "[s]erious neuropsychiatric symptoms have been reported in patients being treated with Chantix" and that those "reports have included changes in mood (including depression and mania), psychosis, hallucinations, paranoia, delusions, homicidal ideation, hostility, aggression, anxiety, and panic, as well as suicidal ideation, suicide attempt, and completed suicide." *Id.* at 9. The

"**PRECAUTIONS**" section, beneath the heading "**Information for Patients**," provides that "some patients have experienced changes in mood (including depression and mania), psychosis, hallucinations, paranoia, delusions, homicidal ideation, aggression, anxiety, and panic, as well as suicidal ideation and suicide when attempting to quit smoking while taking Chantix." *Id.* at 13.

Chantix also comes with a "**MEDICATION GUIDE**" written specifically for patients. Ex. 5 (July 2009 Medication Guide). Like all Chantix labels, the FDA reviews and approves all Chantix Medication Guides. The first page of the July 2009 Medication Guide that was instituted in conjunction with the boxed warning describes – as "the most important information" patients should know about Chantix – reported neuropsychiatric events and what patients should do if they experience such events:

> **What is the most important information I should know about CHANTIX?**
>
> Some people have had changes in behavior, hostility, agitation, depressed mood, and suicidal thoughts or actions while using CHANTIX to help them quit smoking. Some people had these symptoms when they began taking CHANTIX, and others developed them after several weeks of treatment or after stopping CHANTIX.
>
> If you, your family, or caregiver notice agitation, hostility, depression or changes in behavior or thinking that are not typical for you, or you develop any of the following symptoms, stop taking CHANTIX and call your healthcare provider right away:
>
> - thoughts about suicide or dying, or attempts to commit suicide
> - new or worse depression, anxiety or panic attacks
> - feeling very agitated or restless
> - acting aggressive, being angry, or violent
> - acting on dangerous impulses

- an extreme increase in activity and talking (mania)
- abnormal thoughts or sensations
- seeing or hearing things that are not there (hallucinations)
- feeling people are against you (paranoia)
- feeling confused
- other unusual changes in behavior or mood

Id. at 1.

The "**MEDICATION GUIDE**" further cautions patients as to the potential for new or worsening mental health problems:

What are the possible side effects of CHANTIX?

- **Some patients have had new or worse mental health problems.**

Id. at 4.

With respect to neuropsychiatric events, the Chantix label and Medication Guide have remained unchanged since July 2009. The FDA confirmed in a Drug Safety Communication issued on October 24, 2011, over two years after the boxed warning was instituted, its continuing belief "that the drug's benefits outweigh the risks ***and [that] the current warnings in the Chantix drug label are appropriate***." Ex. 6 (FDA Drug Safety Communication, Oct. 24, 2011) at 1 (emphasis added).

The July 2009 label change was communicated to doctors and patients and extensively publicized. On July 1, 2009, Pfizer held a press conference and issued a press release regarding the boxed warning, *see* Exs. 7, 8, and sent a Dear Healthcare Provider Letter to prescribers, *see* Ex. 9. Pfizer's press release announced that the "updated label highlights safety information about reports of serious neuropsychiatric

events in a boxed warning" and contains updated "warnings about reports of neuropsychiatric symptoms and suicidality." Ex. 8 at 1. The press release incorporated and summarized the label changes regarding neuropsychiatric events, *id.* at 2-3, and cautioned under an "**IMPORTANT SAFETY INFORMATION**" heading that "[s]ome people have had changes in behavior, hostility, agitation, depressed mood, suicidal thoughts or actions while using Chantix," *id.* at 4. The Dear Healthcare Provider Letter "inform[ed] [doctors] of important changes to the Chantix package insert and patient Medication Guide," Ex. 9 at 1; it reproduced the boxed warning in full along with the updated Warnings and Precautions, *id.* at 1-2.

The FDA issued a press release and held a media briefing that same day. Exs. 10, 11. Both in its press release and media briefing, FDA summarized the substance of the boxed warning and other labeling updates, and stated that the boxed warning would "highlight the risk of serious mental health events including changes in behavior, depressed mood, hostility, and suicidal thoughts when taking these drugs [Chantix and Zyban]." Ex. 10 at 1; *see* Ex. 11 at 1-4.

In addition to these announcements and media events, local and national newspapers, radio shows, and television programs reported the label change warning of neuropsychiatric events reported in Chantix users.[2] This widespread publicity itself had been preceded by almost two years of extensive, nationwide publicity concerning

[2] *See* Ex. 12 (compiling media reports regarding institution of boxed warning and other label updates of July 1, 2009).

reports of neuropsychiatric adverse events in Chantix patients. *See* Master Compl. at 6-35 & notes 2-42 (discussing multiple news accounts, regulatory announcements and press conferences, and Pfizer statements publicizing neuropsychiatric reports starting in 2007 and continuing through July 1, 2009); *see* materials cited *infra* in notes 9-15.

SUMMARY JUDGMENT STANDARD

Summary judgment is warranted where "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(a). A dispute as to a material fact is "genuine" only "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248, 251-52 (1986). A non-moving party cannot create a "genuine issue of material fact" through speculation, conjecture, or evidence that is "merely colorable" or "not significantly probative." *Id.* at 249-50.

ARGUMENT

I. THE JULY 2009 CHANTIX LABEL PROVIDES ADEQUATE WARNINGS REGARDING NEUROPSYCHIATRIC EVENTS.

When a plaintiff brings a products liability action alleging injury based on a failure to warn, "the liability test . . . , regardless of the theory of liability, is adequacy." David G. Owen, *Products Liability Law* § 9.2, at 593 (2d ed. 2008).[3] Under the learned intermediary doctrine, adequacy is judged from the perspective of a

[3] Plaintiffs' claims all are based on an alleged failure to warn, *see, e.g.*, Master Compl. ¶¶ 90, 98, 112, 118, 131, 147, 214, 236, 258, 268, 289, and necessarily fail given the adequacy of the July 2009 label. *Cf. In re Norplant Contraceptive Prods. Liab. Litig.*, 215 F. Supp. 2d 795, 802 (E.D. Tex. 2002).

physician. *See Ellis v. C.R. Bard, Inc.*, 311 F.3d 1272, 1279 (11th Cir. 2002) ("[I]n the case of prescription drugs, a warning as to possible danger in its use to the prescribing physician is sufficient.").[4] In West Virginia, the lone jurisdiction that expressly has rejected the learned intermediary doctrine, the adequacy of a warning is judged from the perspective of a patient. Accordingly, to prevail on a failure-to-warn claim a plaintiff must demonstrate the inadequacy of the warnings provided to physicians (in learned intermediary jurisdictions) or patients (in West Virginia).

A "'mere allegation of inadequacy'" – and there is nothing more here, *see, e..g.*, Master Compl. ¶ 87 – "is insufficient for [a] Plaintiff to survive summary judgment on a failure-to-warn claim." *Sheridan v. Merck & Co.*, 2003 WL 22902622, at *3 (E.D. La. 2003). The record is bereft of any genuine, material factual dispute that would preclude the entry of summary judgment – not only are the precise neuropsychiatric injuries complained of unambiguously and specifically addressed in the July 2009 label and Medication Guide, Plaintiffs have not come forward with any admissible expert opinions that even arguably could support a finding of inadequacy of these warnings.

A. The July 2009 Chantix Label Is Adequate as a Matter of Law.

To be adequate, a warning "need not be perfect, only 'reasonable.'" Owen,

[4] *See Meridia Prods. Liab. Litig. v. Abbott Labs.*, 447 F.3d 861, 867 (6th Cir. 2006) ("vast majority of jurisdictions" apply doctrine); *Ehlis v. Shire Richwood, Inc.*, 367 F.3d 1013, 1017 (8th Cir. 2004) (same). The doctrine provides that a pharmaceutical company's duty to warn "runs to the physician rather than the patient." *Garside v. Osco Drug, Inc.*, 976 F.2d 77, 80 (1st Cir. 1992).

supra, § 9.2, at 593; *see In re Rezulin Prods. Liab. Litig.*, 331 F. Supp. 2d 196, 202 (S.D.N.Y. 2004) ("crux of the inquiry is whether the warning is reasonable under the circumstances"). If a warning is "accurate, clear, and unambiguous" its adequacy may be determined as a matter of law. *Rounds v. Genzyme Corp.*, 440 F. App'x 753, 756 (11th Cir. 2011); *see Meridia Prods. Liab. Litig. v. Abbott Labs.*, 447 F.3d 861, 867 (6th Cir. 2006). "If a warning specifically mentions the circumstances complained of, the warning ***is*** adequate as a matter of law." *Gerber v. Hoffmann-LaRoche Inc.*, 392 F. Supp. 2d 907, 916 (S.D. Tex. 2005) (emphasis added); *see Cather v. Catheter Tech. Corp.*, 753 F. Supp. 634, 640 (S.D. Miss. 1991) ("warning may be held adequate as a matter of law where the adverse effect that was ultimately visited upon the patient was . . . specifically warned against").

1. Pfizer Adequately Warned Physicians of Reports of Neuropsychiatric Events.

The July 2009 label prominently warned physicians about reports of neuropsychiatric events in Chantix users. The boxed warning, in plain, unmistakable terms, advises physicians that "serious neuropsychiatric events" have been reported; that the reported events include but are not limited to "depression, suicidal ideation, suicide attempt and completed suicide;" and that all patients "should be observed for neuropsychiatric symptoms, including changes in behavior, hostility, agitation, depressed mood, and suicide related events, including ideation, behavior, and attempted suicide." Ex. 1 at 1. These warnings are the first thing that any physician

sees when reviewing the July 2009 label, and they address ***precisely*** the neuropsychiatric injuries alleged by Plaintiffs in this MDL. Indeed, the injuries alleged in the Master Complaint parrot the reports of neuropsychiatric injuries set forth in the boxed warning: "neuropsychiatric injuries" including "behavioral changes, depression, aggression, agitation, hostility, rage, suicidal ideation, suicide attempts, and . . . successful suicide." Master Compl. ¶ 2.

It is inconceivable that this label, with this boxed warning and along with the information and admonitions also contained in the "Warnings" and "Precautions" sections, does not, as a matter of law, satisfy any duty Pfizer had to warn of neuropsychiatric events. (In other words, given this record, no reasonable juror could find this July 2009 label to be inadequate.) In fact, courts around the country have found labels similar to, and certainly no stronger than, the July 2009 label adequate as a matter of law.[5] In *Aaron v. Wyeth*, 2010 WL 653984 (W.D. Pa. 2010), for example, the court ruled that the label for Effexor, a prescription antidepressant, was adequate as a matter of law to the extent it advised physicians, in the "Warnings" section of the label, that among other things "[p]atients with major depressive disorder (MDD), both adult and pediatric, may experience worsening of their depression and/or the emergence of suicidal ideation and behavior (suicidality)." *Id.* at *8. "The plain

[5] *See Rounds v. Genzyme Corp.*, 440 F. App'x 753, 755 (11th Cir. 2011) ("[B]ecause Genzyme expressly and clearly warned . . . about the risk of the exact injury of which the [plaintiffs] now complain, the warnings were adequate as a matter of law."); *Ralston v. Smith & Nephew Richards, Inc.*, 275 F.3d 965, 976 (10th Cir. 2001).

language of the warning" thus "appear[ed] to advise physicians of the specific risk at issue," *i.e.*, the possibility that decedent, an adult patient with MDD, could engage in suicide-related behavior after initiating treatment with Effexor. *Id.* at *9.

Likewise, in *Snyder v. Hoffman-LaRoche, Inc.*, 2008 WL 4790666 (M.D. Fla. 2008), the court ruled the label for Accutane adequately warned physicians of the medication's "potential to cause certain psychiatric side effects (including suicide, suicidal ideation and suicide attempts)." *Id.* at *1. The label provided in the "Warnings" section that "Accutane may cause depression, psychosis, and, rarely, suicidal ideation, suicide attempts, and suicide," and provided in the "Adverse Reactions" section that "a number of patients treated with Accutane have reported depression, psychosis, and, rarely, suicidal ideation, suicide attempts and suicide." *Id.* The court disagreed with plaintiffs that the warnings "equivocate[d] in stating that Accutane 'may' cause depression and suicidal ideation, that emotional instability 'may bear no relation to therapy,' and that the side effect of suicide is 'uncommon' and/or 'rarely' occurs," and that the warnings were diluted by the defendant's statement that "'no one knows if Accutane caused these suicidal behaviors.'" *Id.* at *6. The warnings, "[t]aken as a whole, . . . clearly, accurately, and consistently conveyed" "that Accutane might cause suicide." *Id.*

Courts have found warnings significantly less descriptive, comprehensive, and prominent than those in the July 2009 Chantix label adequate as a matter of law as well. *See Salvio v. Amgen Inc*, 2012 WL 517446, at *4-6 (W.D. Pa. 2012) (dismissing

case where "Warnings" section disclosed "reports" of "serious infections . . . including fatalities," but did not warn specifically of infection type that caused death); *Saraney v. TAP Pharm. Prods., Inc.*, 2007 WL 148845, at *6 (N.D. Ohio 2007) (label that "repeatedly warn[ed] of the risk of loss of bone density warnings in "precautions" and "adverse reactions" sections adequate as a matter of law). In another MDL – *In re Rezulin Prods. Liab. Litig.*, 331 F. Supp. 2d at 200 – for example, the court found reference to a "clear and conspicuous table" in the adverse reactions section" of the label, was, for "the maladies complained of . . . adequate as a matter of law." And in *Broderick v. Sofamor Danek Group, Inc.*, 1999 WL 1062135 (S.D. Fla. 1999), the court ruled adequate as a matter of law a warning that "clearly and unambiguously identified the types of possible adverse affects a patient could suffer." *Id.* at *5.

The July 2009 label warns physicians of the specific risks at issue here, neuropsychiatric events in Chantix users, and thus is adequate as a matter of law.

2. Pfizer Adequately Warned Patients of Reports of Neuropsychiatric Events.

The warnings provided to patients regarding neuropsychiatric events are every bit as adequate as those provided to physicians, and thus satisfy the standard in West Virginia – the only outlier state that rejects the learned intermediary doctrine.

When a Chantix patient fills a prescription that patient receives a Chantix Medication Guide. The Medication Guide advises patients in plain language that neuropsychiatric events have been reported in Chantix users. *In re Meridia Products*

Liability Litigation, 328 F. Supp. 2d 791 (N.D. Ohio 2004), is instructive. There, the court ruled that a warning provided to patients was adequate as a matter of law. *Id.* at 811-12. It did so because "[t]he product insert provided to patients offer[ed] information in a Q & A format," *id.* at 810, and "include[d] the same warning, in the same capital boldface type, as the physicians' insert," *id.* at 814. That "warning adequately indicate[d] the scope of the danger, and its physical aspects and placement [were] adequate to sufficiently warn consumers." *Id.*

The same is true here – the Chantix Medication Guide offers information to patients in a Q & A format, and prominently warns of the same reports of neuropsychiatric events as the label itself. Echoing the warnings found in the label, the Medication Guide, in easy-to-understand language, specifically informs patients that "**the most important information**" they should know about Chantix is that "[s]ome people have had changes in behavior, hostility, agitation, depressed mood, and suicidal thoughts or actions while using CHANTIX to help them quit smoking" and that the "**possible side effects of CHANTIX**" include "new or worse mental health problems." Ex. 5 at 1, 4. The Medication Guide instructs patients to "stop taking CHANTIX and call [their] healthcare provider right away" if they begin to experience neuropsychiatric symptoms. *Id.*

The Medication Guide clearly warned Plaintiffs about the exact injuries of which they complain; those warnings are therefore adequate as a matter of law.

B. Plaintiffs Have No Admissible Expert Opinion Evidence that the July 2009 Chantix Label Is Inadequate.

Pfizer is entitled to summary judgment on the adequacy of the July 2009 Chantix warnings for another reason: Plaintiffs have not proffered admissible expert opinion evidence on the issue of adequacy. "When a plaintiff alleges that the warning given to a prescribing physician is inadequate, the plaintiff must prove his claim through expert medical testimony." *Graham v. Am. Cyanamid Co.*, 350 F.3d 496, 514 (6th Cir. 2003); *see Rice v. Genetech, Inc.*, 2012 WL 205886, at *2 (N.D. Ga. 2012) ("Plaintiff offers no expert opinion concluding" the label "was inadequate.").[6]

Plaintiffs disclosed one regulatory and labeling expert witness, Dr. Cheryl Blume. Although she was asked to address the adequacy and timeliness of Pfizer's labels regarding reports of neuropsychiatric events, *see* Ex. 3 (Blume Rpt. at 2) to Omnibus Set of Exs. In Supp. Of Def. Pfizer Inc.'s Mot. to Exclude Certain Op. Offered By Various Pls.' Experts (filed May 18, 2008) ("Omnibus Daubert Exs."), Dr. Blume did not offer in her 42-page report – or her deposition – any opinions regarding the adequacy of the July 2009 label, but rather limited her opinions to the earlier labels. It is telling that Dr. Blume, who repeatedly testifies against pharmaceutical companies in this type of litigation, does not opine the July 2009 label is inadequate.

Only one expert currently designated by Plaintiffs – Dr. Joseph Glenmullen, a

[6] *Accord Koncz v. Burroughs Wellcome Co.*, 1994 WL 178320, at *4 (N.D. Ill. 1994) (Plaintiff "offered no expert testimony . . . that the warning . . . which expressly indicates the potential side effects experienced" is "inadequate").

psychiatrist – has commented on the July 2009 label.[7] In a brief portion of his 79-page report, Dr. Glenmullen takes issue with the manner in which a particular table in the label (and every prior Chantix label) portrays certain clinical trial events, and takes issue with the fact that Pfizer has not provided "doctors and patients" (flawed) data prepared by Richard Olmstead, another Plaintiffs' expert, that allegedly show a "doubling of the risk" of depression events in Chantix users. *See* Omnibus Daubert Ex. 8 (Glenmullen Rpt.) at 11-12. These comments, to the extent they are intended to constitute labeling opinions (they are not identified as labeling opinions in Dr. Glenmullen's report and are not shared by Dr. Blume), are of no import.

To begin with, there is no reliable evidence of a "doubling" of the risk. *See* Mem. of P. & A. in Supp. of Mot. to Exclude Op. Offered By Richard Olmstead, Argument § I.A.2 (filed May 18, 2012) (alleged "doubling" based on methodologically flawed analysis). But even if such evidence existed, Dr. Glenmullen would not be qualified to testify that it belongs in the Chantix label, or that its absence from the July 2009 label renders that label inadequate. Dr. Glenmullen is a psychiatrist; he has never worked for a pharmaceutical company or FDA, and does not have any education, training, or experience in pharmaceutical regulations or product labeling. *See* Mem. of P. & A. in Supp. of Mot. to Exclude Op.

[7] Dr. William Wirshing, an expert Plaintiffs previously designated, also referenced in his report (but later contradicted at deposition) what may have been intended as a criticism of the July 2009 label. It is Pfizer's understanding that Plaintiffs have withdrawn Dr. Wirshing as an expert witness.

Offered By Pls.' Expert Dr. Joseph Glenmullen at 15-16, 33 (filed May 18, 2012); Omnibus Daubert Ex. 40 (Glenmullen Dep.) at 321-24. Dr. Glenmullen's views on the Chantix label do not constitute expert opinion evidence, are inconsistent with those of Plaintiffs' regulatory expert, and are not admissible. Nor in any event could Dr. Glenmullen's views create a genuine dispute as to whether the warnings provided by Pfizer to physicians and patients in the July 2009 label are adequate – under the case law cited above, those warnings reasonably advised of reports of neuropsychiatric events, the injuries at issue in this litigation. Whatever Dr. Glenmullen's views, Pfizer is entitled to summary judgment.

II. AS A MATTER OF LAW, THE JULY 1, 2009 BOXED WARNING STARTED THE RUNNING OF ALL STATUTES OF LIMITATIONS REGARDING CLAIMS FOR NEUROPSYCHIATRIC INJURY.

Not only is the boxed warning adequate as a matter of law, but also the date of its institution – July 1, 2009 – is the latest possible date on which all statutes of limitations began to run for any person alleging that Chantix caused him or her neuropsychiatric injuries. The July 2009 label was provided to doctors prescribing Chantix and the July 2009 Medication Guide was provided to patients taking Chantix; the warnings contained in those documents were, moreover, the subject of extensive publicity, which followed almost two years of national publicity about reports of neuropsychiatric events in Chantix patients. Thus, by July 1, 2009, at the latest, all Chantix patients were on notice sufficient to trigger the running of all statutes of limitations applicable to claims of neuropsychiatric injury.

Accordingly, the Court should issue an order providing: (1) that any statute of limitations for any claim that Chantix caused or contributed to a neuropsychiatric injury began to run, at the latest, by July 1, 2009, and therefore (2) Pfizer is entitled to summary judgment in cases in which plaintiffs are subject to a one-year limitations statute and which were filed after July 1, 2010; cases in which plaintiffs are subject to a two-year limitations statute and which were filed after July 1, 2011; and cases in which plaintiffs are subject to a three-year limitations statute and which are not filed on or before July 1, 2012. *See* Appendix A.

A. Limitations Periods Begin To Run When a Plaintiff Knows or Should Have Known of His or Her Claims.

Generally, the statute of limitations for a tort or products liability claim begins to run when the injury occurs, subject to any potentially applicable tolling and discovery-rule doctrines. *See Piazza v. Ebsco Indus.*, 273 F.3d 1341, 1347-49 (11th Cir. 2001); *M.H.D. v. Westminster Sch.*, 172 F.3d 797, 803 (11th Cir. 1999). Regardless of such individual state doctrines, however, it is settled that, ***at the latest***, a limitations statute is triggered, and begins running, when a plaintiff knows or ***by an exercise of reasonable diligence and intelligence should have discovered*** that the plaintiff's injury may have been caused by the defendant's allegedly defective product. *See Rodriguez v. Bayer Corp.*, 440 F. App'x 813, 815 (11th Cir. 2011); *Michals v. Baxter Healthcare Corp.*, 289 F.3d 402, 407 (6th Cir. 2002).

The inquiry is an "objective" one, based on objective facts, and not on a

particular plaintiff's subjective belief. *Ferguson v. Bayer Cropscience LP*, 2012 WL 767305, at *1 (4th Cir. 2012). Indeed, "[t]he plaintiff's actual knowledge need not be proved." *Hunt v. Am. Bank & Trust Co.*, 606 F. Supp. 1348, 1354 (N.D. Ala. 1985).[8]

B. Label Updates and Widespread Publicity Alerted or Reasonably Should Have Alerted Prescribers and Patients to Reports of Neuropsychiatric Events By July 1, 2009 At the Latest.

The undisputed facts demonstrate that by July 1, 2009, at the latest, the information available to prospective plaintiffs was more than sufficient to put them on constructive notice, as a matter of law, of claims that Chantix allegedly caused their neuropsychiatric injuries. Tellingly, dozens of Plaintiffs filed complaints on or before July 1, 2009, and hundreds of Plaintiffs filed complaints within one year after the boxed warning was announced, including the Master Complaint itself, filed on March 23, 2010. On July 1, 2009:

- Pfizer issued a press release and held a press conference announcing the labeling change warning of neuropsychiatric events reported in Chantix users. *See supra* pp. 7-8.

- Pfizer sent a Dear Healthcare Provider Letter to prescribers alerting them of the label change warning of neuropsychiatric events reported in Chantix users. *See id.*

- The FDA issued a press release and held a press conference announcing the labeling change warning of neuropsychiatric events reported in Chantix users. *See supra* p. 8.

- Multiple local and national newspapers, radio shows, and television

[8] The discovery rule has "become the near unanimous rule" nationwide. 4 Louis R. Frumer & Melvin. I. Friedman, *Products Liability* § 26.04[2][a] (2012); *see Merck & Co. v. Reynolds*, 130 S. Ct. 1784, 1794 (2010) (discussing "the discovery rule").

programs reported the label change warning of neuropsychiatric events reported in Chantix users. *See supra* p. 8-9 & n. 2.

Warnings like those set forth in the July 2009 label, as well as warnings less prominent than those, constitute sufficient notice for statute of limitations purposes as a matter of law. *See Bunting v. Bristol-Myers Squibb Co.*, 2011 WL 2784101, at *3 (D.N.J. 2011) (claim time-barred because plaintiffs "should have been on inquiry notice of the connection between Plavix ingestion and stomach bleeding" given "warning label"); *Burrell v. Astrazeneca LP*, 2010 WL 3706584, at *6 (Del. Super. Ct. 2010) (plaintiffs "'chargeable' with knowledge of their claims" where "scientific community [had] discovered a possible link" and defendant "had specifically warned of the potential risk in its new label and in its 'Dear Doctor' letters").

In *Thompson v. Abbott Laboratories, Inc.*, 2011 WL 2937290, at *3 (E.D. La. 2011), for example, the Court ruled that claims arising out of birth defects allegedly caused by Depakote were time barred because the plaintiffs "could have discovered that Depakote caused their minor son's health issues and the stillbirth of their second child, had they used reasonable diligence following the births of both of their children. . . . [S]cientific articles from the mid-1990s ***and the 'black box warning' on the Depakote label*** revealed the possible birth defects resulting from Depakote use during pregnancy." *Id.* at *3 (emphasis added). In another MDL – *In re Zyprexa Products Liability Litigation*, 489 F. Supp. 2d 230, 278 (E.D.N.Y. 2007) – the court ruled a plaintiff's claim was time-barred because a label change warning about a risk of

diabetes, along with a Dear Healthcare Provider Letter regarding the label, "placed [the plaintiff] on notice that use of Zyprexa might have worsened his diabetes." *Id.*

The case for constructive notice is even stronger here, because, as Plaintiffs themselves affirmatively plead, some two years of protracted nationwide publicity regarding reports of neuropsychiatric events in Chantix patients ***preceded*** the boxed warning. Courts have widely recognized that such extensive publicity puts plaintiffs on inquiry notice of their claims as a matter of law. In the Vioxx MDL, *In re Vioxx Prods. Liab. Litig.*, 522 F. Supp. 2d 799 (E.D. La. 2007), the court ruled that the "media blitz" surrounding the withdrawal of Vioxx – preceded by media accounts reporting on the medicine's alleged risks and resulting lawsuits – "put the plaintiffs on notice of a potential link between their alleged injuries and the use of Vioxx." *Id.* at 801-02, 808. Other, similar rulings abound in pharmaceutical MDLs and cases. *See, e.g., In re Trasylol Prods. Liab. Litig.*, 2011 WL 5417173, at *3 (S.D. Fla. 2011) (granting summary judgment given "extensive selection of national and local news outlets, including major television programs and newspapers, providing coverage of a study … published in *The New England Journal of Medicine*" describing risks associated with Trasylol); *Adkins v. Duff*, 2004 WL 3103775, at *5-6 (E.D. Ky. 2004) (plaintiffs on inquiry notice based on publicity and class action settlement).

Such inquiry notice does not require definitive conclusions on causation. To the contrary, knowledge of a "possible link" in the medical community suffices to trigger the statute of limitations. *Buttice v. G.D. Searle & Co.*, 938 F. Supp. 561, 567

(E.D. Mo. 1996); *see Miller v. A.H. Robins Co.*, 766 F.2d 1102, 1105 (7th Cir. 1985) (rejecting notion that "limitations period begins to run only when a plaintiff knows or should have discovered that the defendant's product was the actual cause"); *In re Mirapex Prods. Liab. Litig.*, 735 F. Supp. 2d 1113, 1120 (D. Minn. 2010) (rejecting claim that limitations statute tolled until scientific study established causation and noting "[n]o court" has accepted that argument).

As documented in the Master Complaint, starting in around September 2007 and continuing up to (and, for that matter, beyond) July 1, 2009, there was a steady stream of publicity about reports of neuropsychiatric events in patients taking Chantix. The publicity was spurred by a September 3, 2007, incident involving a Texas musician, Carter Albrecht, who reportedly had been taking Chantix. *See* Master Compl. at 18 n.23. After a night of drinking, Mr. Albrecht wandered into a neighbor's yard and began pounding on the neighbor's door; the neighbor mistook Mr. Albrecht for an intruder and accidentally shot and killed him. Although an autopsy reportedly revealed that Mr. Albrecht had a blood alcohol level more than three times the legal limit, his family and friends blamed Chantix for his behavior. There then ensued a whirlwind of publicity, as print and broadcast media outlets reported on this episode, focusing on Chantix and its alleged role in Mr. Albrecht's death.[9]

The FDA repeatedly noted the "publicity surrounding adverse effects of varenicline" and the "widespread publicity regarding varenicline and adverse

[9] Master Compl. ¶ 19 nn.24, 25, 26, ¶ 30 n.10 (citing media reports).

psychiatric events" as reported in the media.[10] Spurred by these reports, the FDA undertook a number of regulatory actions, which FDA – and Pfizer – publicized, generating yet more media attention. These pre-boxed warning actions included label changes in November 2007, January 2008, and May 2008, each of which was accompanied by press releases and Dear Healthcare Provider Letters sent to prescribers nationwide.[11] These and other regulatory events reinvigorated media attention and triggered a new avalanche of media reports.[12]

Further, following the Albrecht incident and before the boxed warning was instituted, the Institute of Safe Medication Practices ("ISMP"), an organization associated with several of Plaintiffs' litigation experts, issued four reports, on May 21, 2008, October 23, 2008, January 15, 2009, and May 7, 2009.[13] The first of these reports purported to find – based on post-marketing adverse event reports – a "strong signal of multiple safety problems" with Chantix and neuropsychiatric events.[14] The publicity impact of the first ISMP report was so far-reaching that the day after its publication, one of Plaintiffs' attorneys announced that his firm had "received 1,300

[10] Ex. 13 (FDA Office of Surveillance and Epidemiology ("OSE") Report at 42 (July 17, 2008), *id.* at 8); Ex. 14 (FDA OSE Report at 6 (Dec. 8, 2008); *id.* at 8, 13).

[11] Ex. 15 (Dear Healthcare Provider Letters dated Dec. 2007, Jan. 2008, and May 2008); *see* Master Compl. ¶¶ 43, 55, 62, 70-71, 74-78, 79-82 (discussing label changes, press releases and advisories, and related activity, and attendant publicity).

[12] Master Compl. ¶¶ 19 n.2, 35 n.12, 61 nn.35 & 36, 63 n.38 (citing media reports).

[13] Master Compl. ¶¶ 57 n.30, 63 (citing 2008 ISMP reports).

[14] Master Compl. ¶ 57 & n.30 (quoting May 21, 2008 ISMP report).

inquiries from concerned Chantix users since the release of the [ISMP] report late Wednesday [May 21, 2008]."[15] About two months later, that same firm filed one of the first Chantix lawsuits – and the news media published accounts of the suit.

For these reasons, all statutes of limitations for all claims that Chantix caused or contributed to neuropsychiatric injuries began to run by July 1, 2009, at the latest.

CONCLUSION

For the foregoing reasons, Pfizer respectfully requests that the Court enter a general summary judgment ruling that:

(1) the July 1, 2009 boxed warning is adequate as a matter of law to warn of the risk of neuropsychiatric events in patients taking Chantix;

(2) Pfizer is entitled to summary judgment in all cases in which plaintiffs alleging neuropsychiatric injuries were prescribed Chantix ***after*** July 1, 2009;[16] and

(3) Pfizer is entitled to summary judgment in all cases alleging neuropsychiatric injuries in which (a) a one-year limitations statute applies and that were filed after July 1, 2010, (b) a two-year limitations statute applies and that were filed after July 1, 2011, and (c) a three-year limitations statute applies and that have not been filed on or before July 1, 2012.

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[15] Ex. 16 (HealthandSurvival.com, *Latest Chantix Safety Concerns Add to Pfizer's Aches, Pains*, May 22, 2008).

[16] If Pfizer seeks entry of judgment based on this ruling in any particular case, and the Plaintiff has admissible evidence that he or she believes should not result in the granting of summary judgment notwithstanding the ruling, the Plaintiff will be free to make those arguments at that time.

Dated: May 18, 2012

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on May 18, 2012, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system which will send notification to the attorneys of record.

s/ Andrew B. Johnson
OF COUNSEL