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: Judy Ann Whitely, as trustee for the next-of-kin of Mark Alan Whitely, Plaintiff, v. Pfizer Inc., Defendant.	INGE P. JOHNSON U.S. DISTRICT JUDGE Civil Case No.: 2:10-cv-1463-IPJ

DEFENDANT PFIZER INC.'S MOTION FOR CONTINUANCE AND/OR STAY OF PROCEEDINGS

Defendant Pfizer Inc. respectfully requests that the Court continue the trial in *Whitely v. Pfizer* until January 22, 2013 to allow all parties to complete discovery and any pre-trial motion practice related to Pfizer's Clinical Trial A3051122. The trial, which was conducted at the request of the European Medicines Agency, evaluated Chantix safety in smokers with major depression. The results of the trial were announced today. Because the trial results go directly

to the heart of Plaintiff's medical causation and punitive damages claims in *Whitely* and in the litigation as a whole, the results should be part of the scientific record in the first bellwether case to go to trial.

If the Court is not inclined to grant a continuance at this time, Pfizer asks instead that proceedings in *Whitely* be stayed, pursuant to Fed. R. Civ. P. Rule 7(b) and Fed. R. App. P. Rule 8(a)(2), at least until such time as the Eleventh Circuit rules on Pfizer's petition for writ of mandamus concerning trial subpoenas issued to Pfizer's CEO and other employees.

INTRODUCTION

Nearly two decades ago, the breast implant MDL took place in this same District Court. Thousands of women filed lawsuits after anecdotal reports suggested that silicone breast implants may be linked to autoimmune disease. *See* Ex. 1, Goss et al., FOOD & DRUG L. J. 2001;227, at 7-8 ("Goss 2001"). While controlled studies were being conducted to evaluate the possibility of an association, cases went to trial and plaintiffs received large jury awards. *Id*. at 9. It was not until controlled studies were completed and Judge Sam Pointer appointed a Rule 706 National Science Panel to independently review the science, that it became clear that the breast implant litigation had gotten ahead of the science. *Id*. at 10-11. The studies showed, and the panel concluded, that there was

no scientific basis for plaintiffs' autoimmune claims.[1] *Id.* Absent a short continuance to allow both parties to review the new scientific evidence from Pfizer's Clinical Trial A3051122, there is a substantial risk that history will repeat itself here.

In 2006, Chantix entered the U.S. market as the first new smoking cessation medication in more than a decade. Chantix quickly became an important treatment option for millions of smokers struggling to break their addiction to nicotine. Shortly thereafter, independent scientists such as those from the U.S. Public Health Service concluded that Chantix is the single most effective smoking cessation therapy on the market.[2]

In late 2007, Pfizer received a number of anecdotal reports of patients experiencing neuropsychiatric events while taking Chantix.[3] Although the FDA-approved Chantix label was amended to include a boxed warning describing

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[1] The panel determined that the "preponderance of the data did not support claims that silicone gel breast implants altered the incidence or severity of autoimmune disease or that the implants precipitate novel immune responses or induce systemic inflammation." *Id.* A few years later, an independent review group appointed by the U.K.'s Department of Health and the U.S. Institute of Medicine confirmed the panel's conclusion. *Id.*

[2] *See* Ex. 2, Fiore et al., CLINICAL PRACTICE GUIDELINE: TREATING TOBACCO USE AND DEPENDENCE 109, 121 (May 2008).

[3] Anecdotal reports are "merely accounts of medical events [that] reflect only reported data, not scientific methodology." *McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1253-54 (11th Cir. 2005). Such reports "raise questions; they do not answer them." *Id.* at 1254.

those anecdotal reports, the label further states that they cannot "establish a causal relationship to drug exposure."[4] Ex. 3, Chantix Label, Nov. 9, 2011, at 4 ("Chantix Label").

In the wake of these anecdotal reports and the label change, plaintiffs started filing lawsuits alleging that Chantix causes serious neuropsychiatric events, including suicide and depression.

Since the inception of the MDL, a growing number of controlled studies have evaluated the efficacy and safety of Chantix. As of early 2012, regulatory agencies across the world, as well as independent scientific bodies, had reviewed the results of those controlled studies and concluded as follows:

- **European Medicines Agency ("EMA") (2009):** "[T]he current evidence does not support a causal relationship between smoking cessation using [Chantix] and the occurrence of [suicide-related events] or other depressive disorders";[5]
- **U.K.'s Medicine and Healthcare Products Regulatory Agency ("MHRA") (2009):** MHRA-sponsored study found "no clear evidence that [Chantix] was associated with an increased risk" of self-harm and "no

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[4] The Eleventh Circuit recognizes that precautionary warnings on a product label do not "provide scientific proof of causation," *Rider v. Sandoz Pharms. Corp.*, 295 F.3d 1194, 1201 (11th Cir. 2002), because they are based "upon a lesser showing of harm to the public than the preponderance-of-the-evidence or more-likely-than-not standard used to assess tort liability." *McClain*, 401 F.3d at 1250.

[5] Ex. 55 to MDL Doc. 580 (filed under seal), CHMP Final Assessment Report, Jan. 22, 2009, at 11 ("CHMP Final Assessment"). The EMA is the European equivalent of the U.S. Food & Drug Administration.

evidence" that Chantix is associated with an increased risk of depression or suicidal thoughts;[6]

- **U.S. Food & Drug Administration ("FDA") (2011):** "Neither [of the two FDA-sponsored studies] found a difference in risk of neuropsychiatric hospitalizations between Chantix and nicotine replacement therapy";[7]

- **U.S. Department of Defense ("DOD") (2012):** "Our findings are largely consistent with results from randomized trials that found no significantly increased risk of neuropsychiatric events in [Chantix] users when compared to placebo or NRT [Nicotine Replacement Therapy] patch . . . Our findings were [also] consistent with an observational study of 63,265 NRT users and 10,973 [Chantix] users that showed no increased risk of self-harm, depression, or suicidal ideation for [Chantix] compared to NRT in patients with or without previous psychiatric history";[8] and,

- **Cochrane Collaboration (2012):** "There is little evidence from controlled studies of any link between [Chantix] and psychiatric adverse events."[9]

Against this backdrop, Pfizer consistently has maintained that these lawsuits are too far ahead of the emerging Chantix science. *See Rider*, 295 F.3d at 1202 ("Law lags science; it does not lead it.") (quoting *Rosen v. Ciba-Geigy Corp.*, 78 F.3d 316, 319 (7th Cir. 1996)); *Allison v. McGhan Med. Corp.*, 184 F.3d 1300,

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[6] Ex. 4, Gunnell et al., BRIT. MED. J. 2009;339:b3805, at 1 ("Gunnell 2009").

[7] Ex. 5, FDA Drug Safety Communication, Oct. 24, 2011, at 1 ("FDA Communication").

[8] Ex. 6, Meyer et al., accepted for publication, ADDICTION, doi: 10.1111/j.1360-0443.2012.04024.x, at 12-13. *See also* Ex. 7, Pharmacovigilance Center Report for FDA: Rate of Neuropsychiatric Events in Varenicline Users Compared to Nicotine Replacement Therapy Patch Users, May 2012.

[9] Ex. 8, Cahill et al., COCHRANE DATABASE SYS. REVS. 2012, Issue 4 at 14 ("Cochrane Analysis"). The Cochrane Collaboration is a highly respected, independent research group that holds a seat on the World Health Assembly.

1322 (11th Cir. 1999) (explaining that the federal courtroom is not the place for consideration of conjecture or unproven hypotheses). Now, however, without a short adjournment of the *Whitely* trial, it is virtually certain that the emerging Chantix science will lag the law and that the first bellwether trial will not be based on a complete scientific record.

Final results from Pfizer's Clinical Trial A3051122, which was designed to evaluate the effects of Chantix in smokers with major depression, were announced today. The trial results go to the heart of Plaintiff's medical causation and punitive damages claims, which are based on allegations that Pfizer did not adequately study patients with pre-existing psychiatric conditions such as depression, and that such patients are most "susceptible" to the alleged neuropsychiatric effects of Chantix.

The bellwether process will not be served if neither the parties nor their experts get a full opportunity to analyze this new evidence prior to the first bellwether trial. If the trial results do not show that Chantix causes suicide-related events in this so-called "susceptible" population, it is hard to imagine how Chantix could cause such events in healthier populations or how Pfizer could be liable to Plaintiff for compensatory or punitive damages. If, on the other hand, the trial results support Plaintiff's claims, the results will promote the truth-seeking

function of the trial and help the parties evaluate the merits of subsequent cases. Either way, the *Whitely* trial should trail the emerging science, not lead it.

Accordingly, Pfizer respectfully requests the Court to continue trial until January 22, 2013 to allow all parties to complete discovery and any pre-trial motion practice related to the results of Clinical Trial A3051122. If the court is not inclined to grant a continuance, Pfizer requests a stay of proceedings at least until such time as the Eleventh Circuit has ruled on Pfizer's mandamus petition.

BACKGROUND

On October 10, 2012, Pfizer filed a petition for a writ of mandamus with the Eleventh Circuit seeking review of this Court's decision denying Pfizer's motion to quash trial subpoenas issued to Pfizer's Chief Executive Officer Ian Read and Pfizer employees Diana Hughes and Carl Wilbanks. *See* Ex. 9, Petition for Writ of Mandamus. The Eleventh Circuit has yet to issue a decision.

Today, the final results of Pfizer's Clinical Trial A3051122 were announced. Pfizer started the trial in March 2010 to evaluate the safety of Chantix use in smokers with major depression. The trial enrolled 525 participants who were then randomized to treatment with Chantix or placebo and followed for 52 weeks. Plaintiffs' counsel have long been aware that the trial was in progress and were informed last month that the final results would be available in October 2012, prior to the start of the *Whitely* trial. *See* Ex. 10, June 13, 2011, Letter from Matthew

Holian to Gary Wilson; Ex. 11, September 4, 2012 Letter from Matthew Holian to Gary Wilson. The results of this clinical trial will provide significant new evidence related to the central medical causation and punitive damages claims in this case.

While the Court is familiar with the history of this case and of this litigation, some background may help to contextualize the significance of these new clinical trial results. On September 3, 2007, a heavily intoxicated musician, Carter Albrecht, was shot and killed by a neighbor who believed the musician was burglarizing his home. Mr. Albrecht's girlfriend publicly blamed Chantix for his behavior and death. The incident sparked national media attention that led to anecdotal reports of patients experiencing neuropsychiatric events while taking Chantix.[10]

Although these anecdotal reports raised some questions about the mental health of patients taking Chantix, regulators in the United States and Europe recognized that anecdotal reports could not answer those questions.[11] They also

[10] *See* Ex. 52 to Doc. 580 (filed under seal), Pollock et al., FDA Office of Surveillance and Epidemiology, *Suicidality*, July 16, 2008, at 42-43 ("Pollock 2008") (stating that "[s]timulated reporting, on the basis of the publicity surrounding adverse effects of [Chantix], seems a likely explanation for the substantially increased reporting rate for suicidal events observed in the latter half of 2007").

[11] FDA has concluded that anecdotal reports are "uninterpretable" in assessing the relationship between medications and neuropsychiatric events. *See* Ex. 12, Test'y of Dr. Russell Katz, FDA Tr., July 10, 2008, at 103. *See also* Chantix

concluded that studies with a control group are required to determine whether smokers trying to quit with Chantix are at any greater risk of neuropsychiatric events than those trying to quit by other means.[12]

Accordingly, these regulators conducted a review of all controlled studies that existed at the time and found no reliable evidence that Chantix causes such events. In early 2009, for example, European regulators concluded that "the current evidence does not support a causal relationship between smoking cessation using [Chantix] and the occurrence of [suicide-related events] or other depressive disorders." CHMP Final Assessment, at 10. Although FDA still requested that the Chantix label include a boxed warning informing physicians about the anecdotal reports, FDA approved additional language noting that "[b]ecause these events are

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Label, at 4 ("Because these events are reported voluntarily from a population of uncertain size, it is not possible to reliably estimate their frequency or establish a causal relationship to drug exposure."); REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 218 (3d ed. 2011) (Both case reports and case series provide anecdotal evidence and are "not [] sufficient to show association, because there is no comparison group."); *McClain*, 401 F.3d at 1254 (anecdotal reports "raise questions; they do not answer them.").

[12] *See, e.g.*, Gunnell 2009, at 1 ("Although clinician and patient reports of adverse events associated with [Chantix] suggest the possibility of serious side effects, controlled studies are required to quantify the degree of risk, distinguish the side effects of [Chantix] from the effects of smoking cessation, and take account of the characteristics of people who decide to stop smoking (confounding by indication)."). *See also, Allison*, 184 F.3d at 1316 ("While we acknowledge the importance of anecdotal studies for raising questions and comparing clinicians' findings, in the face of controlled, population-based epidemiological studies which find otherwise, these case studies pale in comparison.").

reported voluntarily from a population of uncertain size, it is not possible to reliably estimate their frequency or establish a causal relationship to drug exposure." Chantix Label, at 4. The FDA-approved label never has stated or suggested that Chantix is capable of causing neuropsychiatric events such as suicide and depression.

After completing their initial evaluation, regulators asked Pfizer to conduct additional controlled trials that included patients with pre-existing psychiatric conditions. For example, FDA requested that Pfizer conduct a large-scale clinical trial in smokers with a history of neuropsychiatric illness. *See* Pollock 2008, at 7. That trial, which is ongoing, would be unethical if there was any reliable scientific evidence that Chantix can cause suicide or other neuropsychiatric events.[13]

The EMA also asked Pfizer to conduct a controlled trial in smokers with major depression. *See* CHMP Final Assessment, at 11. In addition, FDA and the MHRA sponsored three large-scale observational studies designed to evaluate whether Chantix increases the risk of serious neuropsychiatric events.

Before these studies were completed, and even though no regulatory agency had concluded that Chantix causes suicide or depression, Plaintiffs filed numerous

[13] *See* Ex. 13, FRIEDMAN & FURBERG ET AL., FUNDAMENTALS OF CLINICAL TRIALS 20-22 (4th ed. 2010) ("[D]esigning a trial specifically to prove harm, especially serious harm, would be unethical . . . the presence of uncertainty as to the benefits or harm from an intervention among the expert medical community . . . is a justification for a clinical trial.").

lawsuits alleging a causal link. Plaintiffs further alleged that Pfizer's pre-approval Chantix studies were not adequately designed to evaluate the mental health of patients taking Chantix, that smokers with pre-existing psychiatric conditions are most "susceptible" to the neuropsychiatric effects of Chantix, and that Pfizer is liable for punitive damages because it did not include such patients in its studies.[14] Plaintiffs' punitive damages claims are premised on the assumption that Chantix can, in fact, cause these so-called "susceptible" patients to commit suicide.

After this MDL was up and running, the medical, scientific and regulatory communities began to receive results from FDA and other government-sponsored studies designed to evaluate the mental health of patients taking Chantix. For example, in the fall of 2009, researchers published results of the U.K.'s MHRA study in the prestigious *British Medical Journal*. After studying more than 80,000 patients, those researchers found "no clear evidence that [Chantix] was associated with an increased risk" of self-harm and "no evidence" that Chantix is associated with an increased risk of depression or suicidal thoughts. *See* Gunnell 2009, at 1.

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[14] *See, e.g.*, Ex. 11 to MDL Doc. 580 (filed under seal), Expert Rep. of Shira Kramer, Ph.D., M.H.S., Dec. 6, 2011, at 20-22; MDL Doc. 607, Pls.' Mem. of Facts & Law in Opp'n to Def.'s Mot. to Exclude Opinions Offered by Dr. Shira Kramer, at 17-18; MDL Doc. 642, *Daubert* Order, at 32, 34 n.20, 24; Doc. 32-1, Mem. In Support of Pl.'s Mot. to Amend Compl. to Add Claim for Punitive Damages, at 10-11 (stating that Pfizer failed to study "patients[] most likely susceptible to psychiatric adverse reactions: those with a psychiatric illness or [who] had received psychiatric treatment in the past twelve months").

In October 2011, FDA announced the results from its two observational studies, one conducted by the U.S. Department of Veterans Affairs and the other by the U.S. Department of Defense. *See* FDA Communication, at 1. The two studies, together comprising more than 64,000 patients, found no increase in the rate of neuropsychiatric events in Chantix users compared to patients trying to quit using the nicotine patch. *Id*.

Since this litigation began, dozens of controlled studies have evaluated the safety and efficacy of Chantix use in more than 150,000 patients.[15] In April 2012, a highly-respected research group known as the Cochrane Collaboration completed a comprehensive, independent review of the available Chantix evidence. These independent scientists concluded that "[t]here is little evidence from controlled studies of any link between [Chantix] and psychiatric adverse events." Cochrane Analysis, at 14.

In light of mounting and voluminous evidence from these controlled studies, Pfizer filed *Daubert* motions seeking to exclude Plaintiffs' experts' opinions that Chantix causes suicide-related events. The Court denied those motions, repeatedly referencing Plaintiffs' and their experts' claims that Pfizer did not study "susceptible" patients with "pre-existing major psychiatric disorders." *See* MDL Doc. 642, *Daubert* Order, at 32, 34 n.20, 24. In its Order denying Pfizer's

[15] MDL Doc. 582, Pfizer's Intro. & Statement of Facts Relevant to All *Daubert* Motions, at 67-68.

motions, the Court also relied on the fact that the EMA asked Pfizer to conduct a clinical trial in smokers with major depression. *See id*. at 20. Significantly, results from that trial were not available when discovery closed in July or when the Court issued its Order.

Now that the results of Clinical Trial A3051122 are available, those results can be considered by the experts, the Court, and jurors in *Whitely* and in any future trials.

ARGUMENT

Pfizer respectfully requests that the Court continue trial until January 22, 2013. A short continuance will allow all parties and their experts sufficient time to perform a thorough review of Pfizer's Clinical Trial A3051122, including analysis of the underlying study data, and conduct any necessary pre-trial motion practice.[16] While Pfizer recognizes that this Motion is being filed shortly before the scheduled start of the *Whitely* trial, the importance of ensuring that these new results are part of the record in the first bellwether trial far outweighs any inconvenience that may result from a short continuance.

While the decision to grant a continuance is within the sound discretion of the trial court, such discretion is not without limits. *See Gastaldi v. Sunvest Resort*

[16] In the event that the Court denies the motion for continuation, both parties' experts would be forced to try to conduct an accelerated review of the clinical trial results and forego discovery in order to testify about the current state of the science at the *Whitely* trial. A short adjournment will alleviate that problem.

Cmtys., LC, 709 F. Supp. 2d 1284, 1291 (S.D. Fla. 2010). A court may not deny a continuance when the need for one is warranted. *Id*. The Eleventh Circuit considers a number of factors in determining whether a request for continuation was warranted. *See Quiet Tech. DC-8, Inc. v. Hurel-Dubois UK Ltd.*, 326 F.3d 1333, 1350-51 (11th Cir. 2003). These include: (1) whether the party seeking the continuance was diligent in its efforts to ready its defense prior to the date set for the proceeding; (2) the likelihood that granting the continuance will address the stated need; (3) the extent to which the continuance would have inconvenienced the court and the opposing party; (4) the extent to which the moving party would be harmed by a denial of continuance; and (5) whether the court had previously granted a continuance in the case. *Id*. at 1351-52.

Here, all five factors weigh in favor of a continuance. As to the first factor, Pfizer was diligent in conducting discovery and preparing for trial. Pfizer adhered to the deadlines set by this Court and was prepared to begin trial as scheduled. Expert discovery related to the new trial results could not have occurred earlier because the results were not available until today. As to the second factor, a continuance until January 22, 2013 will permit both parties to review the new results, conduct relevant discovery, and file any necessary pre-trial motions. And, with respect to the fifth factor, this is the first time Pfizer has asked for a continuance.

The remaining two factors are perhaps the most critical and require the district court to balance the moving party's need for a continuance against the inconvenience that such continuance may cause the other party and the Court. As discussed below, those factors also weigh in favor of a continuance.

Pfizer's request for a short continuance is based on critical new evidence and a number of exceptional circumstances. First, the data from Clinical Trial A3051122 goes to the heart of Plaintiffs' medical causation and punitive damages claims in *Whitely* and every other case. The trial was designed to evaluate the effects of Chantix in smokers with major depression—a population that Plaintiffs claim is most "susceptible" to the alleged suicide-related effects of Chantix. If, in fact, the clinical trial finds no evidence that Chantix causes suicide-related events in this so-called "susceptible" population, it is hard to imagine how Chantix could cause such events in any healthier population or how Pfizer could be liable to Plaintiff for compensatory or punitive damages in any case. If, however, the trial supports Plaintiff's claims, the results would be equally informative and should be a part of the record in the first bellwether case.

Second, as the initial bellwether trial, the *Whitely* case is supposed to help "facilitate resolution of the MDL by testing essential elements of each side's litigation strategy and establishing representative settlement values." *See* Ex. 14, Managing Multidistrict Litigation in Products Liability Cases: A Pocket Guide for

Transferee Judges, at 44. As the Fifth Circuit explained in *In re Chevron U.S.A., Inc.*, "[t]he term bellwether is derived from the ancient practice of belling a wether (a male sheep) selected to lead his flock. The ultimate success of the wether selected to wear the bell was determined by whether the flock had confidence that the wether would not lead them astray, and so it is in the mass tort context." 109 F.3d 1016, 1019 (5th Cir. 1997). In order to ensure that the parties and the Court are not led astray here, any verdict in the *Whitely* case should be based on all relevant science that exists at the time of the *Whitely* trial.

Third, a short continuance also may help avoid the exact type of law-leading-the-science problem that arose in the breast implant MDL. The breast implant litigation also began with a series of anecdotal reports. *See* Goss 2001, at 7-8. Controlled studies were conducted to evaluate whether breast implants cause autoimmune disease. *Id*. at 9. While those studies were still underway, cases went to trial, and plaintiffs received large awards. *Id*. Eventually, the controlled studies were completed, and the scientific community concluded that there was no scientific basis for plaintiffs' autoimmune claims. *Id*. at 10-11; *see also Bushore v. Dow Corning-Wright Corp.*, No. 92-344-CIV-T-26C, 1999 WL 1116920, at *5 (M.D. Fla. Nov. 15, 1999). A short adjournment will ensure that the most current science is part of the record in the *Whitely* trial and will minimize the likelihood of history repeating itself here.

Although Plaintiff has long been aware that the results of Clinical Trial A3051122 will be available around this time, Pfizer acknowledges that a short adjournment may cause some inconvenience to the Plaintiff. Plaintiff and her counsel will need to reshuffle their schedules and arrange for their witnesses to be available on different days, but any inconvenience resulting from a short adjournment likely will be minimal. Furthermore, given the importance of this new evidence to the entire docket and the appellate record in the first bellwether case, any inconvenience is clearly outweighed by the need to ensure that the first bellwether trial includes a full and fair presentation of the most up-to-date scientific record.

In the event that the Court is not inclined to grant a continuance at this time, Pfizer respectfully requests that the Court at least stay proceedings in *Whitely*, pursuant to Fed. R. Civ. P. Rule 7(b) and Fed. R. App. P. Rule 8(a)(2), until the Eleventh Circuit rules on Pfizer's mandamus petition. The Circuit's decision will determine what live witness testimony will be heard at the *Whitely* trial and will have a material impact on the trial preparation of both parties. A stay of proceedings will give time for the Eleventh Circuit to consider Pfizer's petition and ensure a "fair and efficient" adjudication of the *Whitely* case. *See Republic of Venezuela ex rel Garrido v. Philip Morris Cos.*, No. 99–0586–Civ, 1999 WL 33911677, *1 (S.D. Fla. April 28, 1999).

CONCLUSION

For the above stated reasons, Pfizer respectfully asks that the Court continue trial in *Whitely v. Pfizer* until January 22, 2013. In the alternative, Pfizer asks that the Court stay proceedings until such time as the Eleventh Circuit has ruled on Pfizer's mandamus petition.

Dated: October 16, 2012

Respectfully submitted,

/s/ Andrew B. Johnson
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CERTIFICATE OF SERVICE

I hereby certify that on October 16, 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