No. 128841

In the Illinois Supreme Court

CHARLES MUHAMMAD and ANGIE MUHAMMAD, as parents of C.M., a minor, and C.M., individually,	)	
	)	On Appeal from the Appellate Court of Illinois, First Judicial District No. 1-21-0478
Plaintiff- Appellees,	)	
	)	
v.	)	On Appeal from the Circuit Court of Cook County, Illinois- Law Division Case No. 2019-L-6254 Hon. Brendan A. O'Brien
	)	
	)	
ABBOTT LABORATORIES INC. and ABBVIE INC.,	)	
	)	
Defendants-Appellants	)	

PLAINTIFF-APPELLEE'S BRIEF

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ARGUMENT

I. INTRODUCTION

C.M., the minor plaintiff in this case, suffered severe birth defects when he was exposed *in utero* to the drug Depakote that was manufactured and sold by Defendants Abbott Laboratories, Inc. and AbbVie, Inc. (hereinafter referred to collectively as "Abbott"). (R. C 631-636). C.M's parents Angie and Charles Muhammad filed suit on his behalf alleging that Depakote was defective and unreasonably dangerous on the ground that Abbott's warnings to physicians prescribing it were deficient because they did not disclose the true level of risk of teratogenic injury. *Muhammad v. Abbott Laboratories Inc.,* 2022 IL App 210478, ¶ 1. The relevant warnings stated that there was a 1% to 2% risk that a fetus exposed to Depakote might develop spina bifida, a severe birth defect. (R. C 634). Abbott also noted in its warnings that Depakote might pose unquantified risks of other birth defects. (R. C 634). C.M. alleges that Abbott knew but failed to warn that the risk of fetal injury from Depakote was much higher. Abbott had data from studies which it helped fund which indicated that the true risk of severe birth defects including cognitive deficits was as high as 17%. (R. C 634-635). C.M.'s mother, Angie Muhammad, was taking Depakote to treat a mental illness when she unexpectedly became pregnant while purportedly using a birth control patch. (R. C 633, 651). C.M. was born with multiple birth defects including spina bifida, major malformations and severe cognitive deficits. (R. C 633).

Abbott moved for summary judgment on two grounds. First, it claimed that the lawsuit was barred by the doctrine of judicial estoppel as a result of the lawsuit C.M. had prosecuted against Dr. Thomas Allen, one of Angie's physicians when she was

prescribed Depakote, and his employer Northwestern Memorial Hospital. (R. C 332-333). Second, Abbott contended that C.M. could not prove that the alleged deficiencies in its warnings were a proximate cause of his injuries because his mother's physicians, Dr. Christian Stepansky and Dr. Allen testified in their depositions that they would have prescribed Depakote to her even if the warnings had revealed the much higher risk of severe birth defects. (R. C 332-333). The trial court granted Abbott's motion on the ground of judicial estoppel. It made no ruling on the issue of proximate cause which it deemed moot. (R. C 354-367). The Muhammads appealed. (R. C 1148-1155),

The First District Appellate Court considered and ruled upon both issues raised in Abbott's motion for summary judgment. It found that the doctrine of judicial estoppel did not bar C.M.'s lawsuit against Abbott. . *Muhammad v. Abbott Laboratories Inc.,* 2022 IL App 210478, ¶ 40. And it found that the affidavit testimony submitted by C.M. of an expert in psychiatry, Dr. Suhayl Nasr, sufficiently contradicted the testimony of the two doctors to create a fact question that precluded summary judgment. *Id.* at ¶47. Accordingly, the court below vacated the summary judgment and remanded the case to the circuit court. *Id.* at 49. Abbott filed a Petition for Leave to Appeal with this Court. (A.083-109). Abbott's petition only seeks review of the proximate cause issue. (A. 083-109). Accordingly, the sole issue before this Court is whether the First District Appellate Court erred in finding that there are triable questions of fact that preclude summary judgment on the issue of proximate cause. Supreme Court Rule 315 (a); *Hansen v. Baxter Healthcare Corp.,* 198 Ill. 2d 420, 429 (2002).

II. THE EVIDENCE PLAINTIFFS ARE REQUIRED TO PROFFER TO CREATE A JURY QUESTION OF FACT ON THE ISSUE OF PROXIMATE CAUSE IN THEIR DRUG PRODUCT LIABILITY CLAIM BASED ON DEFECTIVE WARNINGS

Abbott did not contend in its motion for summary judgment that its warnings were adequate. (R. C 328-348). Nor did Abbott make the adequacy of its warnings an issue in its Petition to Appeal to this Court (A. 083-109). Therefore, Abbott cannot make the adequacy of its warnings an issue now. *Hansen v Baxter Healthcare Corp.,* 198 Ill. 2d 420, 429 (2002). By limiting its appeal to the issue of proximate cause, Abbott tacitly concedes that its warnings were inadequate. *Motus v. Pfizer, Inc.,* 196 F. Supp. 2d 984, 991 (C.D. CA. 2001). This concession is not surprising. At least two juries have found that the very same warnings at issue here were deficient and held Abbott liable to plaintiffs for *in vitro* injuries resulting from Depakote similar to those suffered by C.M. *Requel v. Abbott Laboratories, Inc., (In re Depakote:E.R.G.), 2017 U.S. Dist. S.D. Ill. LEXIS 112329; Barron v. Abbott Laboratories, Inc.,* 529 S.W. 3d 795 (S. Ct. Mo., 2017). So the issue before this Court is what evidence must a plaintiff proffer to defeat a motion for summary judgment based solely on the issue of proximate cause.

Abbott contends and plaintiffs do not dispute that its duty to warn is defined by the "learned intermediary" doctrine. Under this doctrine, the duty of a drug company to warn does not run to the patient who consumes a medication. Instead, as accurately stated by the court below, a drug company is obligated to "warn prescribing physicians of the drug's known dangerous propensities." *Muhammad v. Abbott Laboratories, Inc.,* 2022 IL App 210478, ¶ 43. The doctors are expected to use the information provided in the warnings to determine "which available drug best fits the patient's needs and chooses which facts from the various warnings should be conveyed to the patient." *Kirk v.*

Michael Reese Hospital & Medical Center, 117 Ill. 2d 507, 519 (1987). If adequate warnings of a drug's risks and side effects are given to prescribing physicians, the manufacturer is shielded from liability if a patient suffers injury from the adverse effects identified in its warnings. *Muhammad,* 2022 IL App 210478, ¶ 43.

In the instant case, the evidence is that Dr. Stepansky was a second year resident physician who prescribed Abbott's Depakote to Angie on May 24, 2005. (R. C 633). Dr. Allen was Dr. Stepansky's supervisor starting on July 1, 2005 and did not alter Dr. Stepansky's prescription for Depakote through September 9, 2005, the date on which Angie became pregnant. (R. C 633). Because Abbott concedes for purposes of their summary judgment motion that its warnings were inadequate, this Court must begin its analysis that from the premise that Dr. Stepansky and Dr. Allen were not learned intermediaries. *Hansen v. Baxter Healthcare Corp.,* 198 Ill. 2d 420, 432 (2002).

Some jurisdictions have found that if the doctrine of the learned intermediary does not apply, the logical extension is that a drug manufacturer cannot be insulated from liability for its defective warnings by the doctrine. *Giles v. Wyeth, Inc.,* 500 F. 2d 1063, 1068 (S.D. Ill. 2007). In other words, there is a presumption that the inadequate warnings caused the plaintiff's alleged injuries. *Id. (citing Seley v. G.D. Searle & Co.,* 67 Ohio St. 2d 192, 423 N.E. 2d 831, 839 (Ohio 1981). Under this theory, often referred to as the heeding presumption, the plaintiff does not have to prove what their prescribing physician might or might not have done if adequate warnings had been given to establish proximate cause. *Huskey v. Ethicon, Inc.,* 2015 U. Dist. LEXIS 109454, p. 25 (S.D. W.Va.). In jurisdictions that have adopted this theory, it is presumed that warnings, if given, will be heeded and followed and that medical practitioners will act competently."

Mahr v. G.D. Searle & Co., 72 Ill. App. 3d 540, 566 (1979) (applying Texas law). This presumption is rational because a prescribing doctor can only speculate retrospectively that their course of conduct would not have been influenced by an adequate warning. *Giles,* 500 F. Supp. at 1068.

States that have adopted the heeding presumption theory also hold that the presumption is rebuttable. *Eck v. Parke, Davis & Co.,* 256 F. 3d 1013, 1019 (10th Cir. 2001) (applying Oklahoma law). This rebuttal is usually through testimony of the prescribing physician that he or she would have not taken a different course of action even if there had been stronger warnings. *Id.* A successful rebuttal, however, does not end the analysis. In that instance, the burden shifts back to plaintiff to produce evidence to create a question of fact on the issue of proximate cause to get their case to a jury. *Id.* To create a triable issue, plaintiff "must either discredit the physician's testimony or call into question the substance of the testimony, or otherwise demonstrate that the alleged failure to worn was the proximate cause of their injuries." *Id.*

In contrast, states that have not adopted the heeding presumption, the plaintiff has the burden from the outset to prove that adequate warnings would have prevented plaintiff's injuries. *Motus v. Pfizer,* 196 F. Supp. 2d 984,982 (C.D. Ca. 2001).

This Court has not weighed in on the issue of what is required of plaintiff to prove proximate cause in a drug product liability claim based on an alleged failure to warn. *Giles v. Wyeth,* 500 F. Supp. 1063, 1068-1069 (S.D. Ill. 2007). Specifically, it has not adopted the heeding presumption theory. *Id.* There is, however, a basis for this Court to adopt the heeding presumption line of cases. In Illinois, manufacturers are entitled to assume that adequate warnings, if properly communicated to consumers, will be heeded.

Werckenthein v. Bucher Petrochemical Co., 248 Ill. App. 3d 282, 291 (1993). It is logically consistent for this Court to find a similar presumption that physicians likewise will heed and follow warnings when prescribing drugs. *Giles v. Wyeth,* 500 F. Supp. 1063, 1068 (S.D. Ill. 2007).

Abbott argues extensively that this Court should not endorse the heeding presumption theory. From the Muhammad's perspective, it is not essential for this Court to resolve this issue. Whether it is deemed that the heeding presumption applies or whether plaintiff bears the initial burden of proving causation the same result must be reached in this appeal. As correctly found by the court below, there are disputed questions of fact relative to proximate cause that preclude summary judgment on that issue.

III. THE TESTIMONY OF DR. STEPANSKY AND DR. ALLEN IS NOT INFALLIBLE AND DOES NOT CLOSE THE DOOR TO A FINDING THAT ABBOTT'S INADEQUATE WARNINGS CAUSED C.M.'S INJURIES

Abbott's argues it is entitled to summary judgment based on the testimony of Dr. Stepansky and Dr. Allen that they would have prescribed Depakote to C.M.'s mother Angie Muhammad, even if Abbott properly warned them of the true dangers of the drug. Abbott further contends that only the testimony of these doctors can be considered on the issue of proximate cause because they were the prescribing doctors. This argument that the testimony of treating physicians is supreme as compared to the expert testimony submitted by C.M. is echoed by the amicus briefs. In order for Abbott's arguments to prevail, however, this Court must find that the testimony of Dr. Stepansky and Dr. Allen given in response to hypothetical questions of what they would have done 15 years after

their treatment of Angie must be considered absolute even if there assertions are incredible as explained below.

This Court has stated that it is "unquestionably" the province of the jury "to pass upon the credibility of the witnesses, and to decide what weight should be given to the witnesses' testimony." *Maple v. Gustafson,* 151 Ill. 2d 445, 452 (1992). See also, *Watson v. West Suburban Medical Center,* 2018 IL App 162707, ¶ 239. This is particularly true in the context of a motion for summary judgment which is not intended to "try an issue of fact, but to determine whether any genuine issue of material fact exists." *Happel v. Wal-Mart Stores,* 199 Ill. 2d 179, 186 (2002). Moreover, the testimony of Dr. Stepansky and Dr. Allen must be construed strictly against Abbott, the moving party, and in the light most favorable to C.M., the nonmoving party. *Id.*

Other courts, when confronted with similar circumstances in which a prescribing doctor has testified that he would not have acted differently even if given a proper warning, have held such that such testimony in and of itself raises an issue of credibility that is a jury question precluding summary judgment. *Rush v. Wyeth,* 2006 U.S. Dist. LEXIS 47472 (E.D. Ark.); *Golod v. LaRoche,* 964 F. Supp. 841, 857 (S.D.N.Y. 1997); *Bravman v. Baxter Healthcare Corp.,* 984 F. 2d 71, 75 (2nd Cir. 1993). The rationale is that "a physician's testimony regarding what he or she would have done in 20/20 hindsight" should not be considered absolute. *Rush,* 2006 U.S. Dist. LEXIS 47472 at 8-9. That is, "unless a physician's claim that she would have prescribed a drug even if adequately warned is self-disserving, the credibility of such a claim is generally a jury question not to be resolved on a motion for summary judgment." *Golod v. LaRoche,* 964 F. Supp. 841, 857 (S.D.N.Y. 1997). Dr. Stepansky and Dr. Allen are not defendants in

this litigation and, therefore, their testimony that they would not have acted any differently is not self-disserving. *Id.* Moreover, based on the totality of the testimony of the two doctors and the circumstances in which they delivered psychiatric treatment to Angie Muhammad, a jury could conclude that their assertions are unbelievable.

The common theme in the arguments of Abbott and those of the Product Liability Council, Inc. (PLAC) in its *amicus curiae* brief is that Angie Muhammad's treating physicians are in a better position than a retained expert to say whether there would have been a different outcome had adequate warnings been given. This is allegedly due to their superior personal knowledge of their Angie's medical history, background and needs. PLAC Brief at 14-15. The testimony of Dr. Stepansky and Dr. Allen contradicts this hypothesis.

First, Dr. Allen played no role in the initial decision to prescribe Depakote to Angie Muhammad on May 24, 2005. On that date, Dr. Allen was still completing his residency training. It was not until July 1, 2005 that Dr. Allen began working in Northwestern Memorial Hospital's Psychiatric Rehabilitation Clinic. (R. C 764). By that date, Angie had already been taking Depakote for five weeks (R. C 652-653). Therefore, Dr. Allen's assertion in his deposition testimony on October 14, 2020, that he would have prescribed Depakote no matter what is neither relevant nor material to the issue of proximate cause because he did not participate in choosing Depakote for Angie. Had Dr. Stepansky, who was acting in conjunction with two other psychiatrists, Dr. Bronfman and Dr. Dago, chosen to start Angie on lithium, another drug recommended by Dr. Dago, on May 24, 2005 rather than Depakote, C.M.'s injury would have been avoided. (R. C 631-

636). This choice would have been made before Dr. Allen came into the picture making his conduct irrelevant.

On July 1, 2005, Dr. Allen became Dr. Stepansky's supervisor. As supervisor, Dr. Allen claims that he could have stopped Angie's prescription for Depakote if he thought the risk of her getting pregnant and giving birth to a deformed child outweighed the benefit of the drug. (R. C 775). There is no evidence, however, that Dr. Allen ever performed such a risk/benefit analysis before Angie became pregnant.

In the deposition Dr. Allen gave on January 9, 2017, he admitted that between July 1, 2005 and the date in October 2005 when he learned Angie was pregnant, he did not personally talk to her about the risks and benefits of Depakote. (R. C 778). The only interaction Dr. Allen had with Angie in that time frame was a vague recollection of seeing her in a hallway of the clinic or getting a brief introduction. (R. C 766, 773).

The medical chart corroborates that Dr. Allen did not evaluate Angie before she became pregnant. The records reflect that Dr. Allen did not write anything into Angie's chart until February 25, 2006. (R. C 785). This entry was designated as being a "Late Note" for events that occurred on October 20, 2005. (R. C 791). Dr. Allen's "Late Note" was written into the record after he knew an ultra-sound showed that C.M. had spina bifida. The timing of this note and its tardiness suggests it was written for posterior protection.

When Dr. Allen testified on January 9, 2017, he said he knew that Depakote could cause spina bifida and other neural cognitive defects. (R. C 768). He admitted, however, that he did not know exactly what his understanding was in 2005 as to the incidents of these birth defects. (R. C 768). Notwithstanding his prior lack of knowledge regarding the

level of risk Depakote posed in 2005, Dr. Allen claimed on October 14, 2020 that he would have approved giving Depakote to Angie even if there was a 100% probability that her baby would suffer severe birth defects if she got pregnant while taking the drug. (R. C 244, 249-250). This assertion is incredible in light of the fact that there were other less teratogenic drugs available, such as lithium, to treat Angie's mood disorder. (R. 768-770). In fact, Dr. Dago, an outside consultant who evaluated Angie in May 2005 recommended that she could be given either lithium or Depakote to stabilize her mood disorder. (R. C 750). After Depakote was stopped when Angie became pregnant in October she had a breakdown in December. Afterward she was give lithium as a substitute because of its lesser teratogenic effect and was successfully maintained on it until she gave birth to C.M. in May 2006. (R. C 633, 666-667).

Based on the inconsistencies in Dr. Allen's testimony, a jury could easily find that his testimony relating to the issue of proximate cause is simply unbelievable. Or it could find it is immaterial because he was not involved in prescribing Depakote in the first place. Under Illinois law, it is the task of the fact finder at trial to make that determination. *Maple v. Gustafson,* 151 Ill. 2d 445, 452 (1992).

Dr. Stepansky's testimony that he too would not have altered course if warned of Depakote's true risk of causing birth defects is similarly lacking in credibility. First, Dr. Stepansky testified on September 21, 2016 that he could not recall his rationale for prescribing Depakote to Angie. (R. C 654). Nor can he recall the substance of the discussions he would have had with his supervisor, Dr. Brontman, before starting the medication. (R. C 654). Also, Dr. Stepansky did not memorialize what he was thinking in the notes he wrote in Angie's medical records. (R. C 654).

Dr. Stepansky testified that he had no recollection of considering lithium as an alternative mood stabilizer even though Dr. Dago had sent him a report on May 19, 2005 in which he advised Dr. Stepansky to "consider Lithium, Depakote" as part of his treatment recommendations. (R. C750). In the same deposition, Dr. Stepansky testified that he likely would have considered lithium based on his custom and practice. (R C 654). But he could not recall his reasoning for ultimately choosing Depakote over lithium. (R. C 654).

Between September 21, 2016 and his second deposition on November 12, 2020 Dr. Stepansky had an amazing epiphany. In the later deposition, Dr. Stepansky testified that based on the risk analysis he employed in 2005, which he could not recall previously, he would have prescribed Depakote to Angie even if Abbott's warnings indicated that the risk of neurodevelopment delay to a fetus exposed to the drug *in vitro* was 20% or even greater. Dep. at 43-44.

Dr. Stepansky claimed in 2020 that his rationale for prescribing Depakote regardless of the risk, was based on his confidence that Angie would use birth control reliably and avoid becoming pregnant. (R. C 209-210). Dr. Stepansky testified further that if "there was some uncertainty about whether she could take appropriate steps or whether [he] was witnessing that she wasn't taking appropriate steps, then [he] would not have prescribed Depakote." (R. C 209).

This testimony of Dr. Stepansky is stunning in light of the knowledge he had in 2005 about Angie's ability to reliably use birth control. Dr. Stepansky knew Angie was using a patch for birth control when he prescribed Depakote to her on May 24, 2005. (R. C 651). He also knew that nine days earlier on May 15, 2005, Angie informed Dr.

Stepansky's treatment team that she did not have a gynecologist to renew her prescription for the patch and she was running out. *Id.* The records further reflect that Angie did not understand why she needed a new gynecologist. *Id.* The clinic's social worker scheduled Angie for a gynecological appointment on June 14, 2005 and arranged for a prescription to be placed immediately at an Osco drugstore to renew her patch for another two months. *Id.* Dr. Stepansky admitted that he was aware of these events when they happened. (R. C 652).

Angie's lack of basic understanding of birth control should not have reassured Dr.Stepansky that he could count on her to avoid getting pregnant. More significantly, it is another dagger through Dr. Stepansky's credibility. Based what he testified to in 2020, a jury could conclude that Dr. Stepansky would not have prescribed Depakote if he had been warned by Abbott of the increased risks due to Angie's inability to avoid getting pregnant which in the end was proven to be true. It is for a jury to decide this fact issue.

IV. THE COURT BELOW CORRECTLY FOUND THAT THE AFFIDAVIT TESTIMONY OF DR. NASR CREATES A TRIABLE QUESTION OF FACT ON THE ISSUE OF PROXIMATE CAUSE

Muhammad's expert, Dr. Nasr, opines that if Abbott had warned in 2005 that Depakote was known to cause serious congenital malformations in up to 17% of the fetuses exposed to the drug, then it would have been a deviation from the standard of care to have prescribed Depakote to Angie. (R. C631-636) Defendants argue that Dr. Nasr's opinions are not relevant because Dr. Stepansky and Dr. Allen testified that they "would not have done anything differently." Defendants argue further that this testimony is conclusive on the issue of proximate cause.

Abbott's position is contrary to Illinois law as it has been developed following this Court's opinion in *Snelson v. Kamm*, 204 Ill. 2d 1, 46 (2003). In *Snelson,* this Court endorsed the concept that when a doctor testifies that his course of action would not have changed even if he had been given additional information, a plaintiff can always challenge that assertion and create a question of fact on the issue of proximate cause by offering expert opinion as to what a reasonably well qualified physician would have done under the same or similar circumstances. *Id.* at 46. The genesis of this principle is Justice Frossard's dissent in *Seef v. Ingalls Memorial Hospital*, 311 Ill. App. 3d 7, 26-27 (1st Dist. 1999). *Id.* Subsequently, this principle has been applied in two appellate court decisions to reverse summary judgments granted in favor of defendants. *Buck v. Charletta,* 2013 IL App (1st) 122144, ¶¶69-72; *Shicheng Guko v. Kamel,* 2020 IL App (1st) 190090, ¶¶33-34.

In *Seef*, the defendant hospital's nurses failed to properly interpret a fetal monitor strip and timely inform the mother's obstetrician, Dr. Sutkus, that her unborn baby was in trouble. Dr. Sutkus, however, testified that even if he had been told about the abnormal strip earlier, he would not have taken any different action. *Id*. at 26. The plaintiff countered with the testimony of an expert obstetrician, Dr. Lilling, who contradicted the treater and opined that a reasonably qualified obstetrician would have delivered the baby sooner if informed of the abnormal strip. Notwithstanding this expert opinion testimony, the majority of the court in *Seef* upheld the judgment entered in favor of the hospital. In their opinion, the plaintiff could not establish proximate cause even with expert testimony in light of the obstetrician's testimony that he would have done nothing different. *Id.* at 12. Justice Frossard dissented. In the pertinent portion of his dissent, Justice Frossard

reasoned that "Dr. Sutkkus speculated about what he would have done had the nurse acted in accordance with the standard of care, whereas Dr. Lilling offered not speculation but an expert medical opinion as to how an obstetrician meeting the standards of care should have proceeded if properly notified." *Id.* at 27. Justice Frossard went on to say that "[t]he weight to be given Dr. Sutkus' and Dr. Liling's conflicting testimony was a matter for the jury to determine" *Id.* He further observed that "[a] trial court is not required to accept a defendant's hypothetical testimony as uncontroverted fact, particularly when the opposing party offers contradictory testimony." *Id*. at 27 (citing *Wodziak v. Kash*, 278 Ill. App. 3d 901 (1st Dist. 1996)).

In *Snelson,* the plaintiff contended that the defendant hospital's nurses failed to inform Snelson's physician, Dr. Kamm about his complaints of pain. *Snelson,* 204 Ill. 2d at 43-44. Dr. Kamm testified that even if the nurses told him about Snelson's complaints of pain, he would not have changed his course of treatment. *Id.* The plaintiff did not present an expert to contradict Dr. Kamm's testimony. *Id.* at 44. In Snelson's appeal to this Court, the judgment for the hospital was affirmed. In making this ruling this Court said: "Snelson's suggestion that it is impossible for a plaintiff to prove causation where the doctor testifies that he would not have acted differently regardless of what information could have been given [by the nurses] is a red herring for two reasons. First, Snelson mistakenly assumes that a doctor will not be willing to tell the truth about whether the conduct of the hospital nurses affected his decision making ability. Second, a plaintiff would always be free to present expert testimony as to what a reasonably qualified physician would do with the undisclosed information and whether the failure to disclose the information was a proximate cause of the plaintiff's injury in order to

discredit a doctor's assertion that the nurse's omission did not affect his decision making. *Id.* at 45-46. (citing *Seef v. Ingalls Memorial Hospital,* 311 Ill. App. 3d 7, 26-27 (1999) (O'Mara Frossard, P.J., dissenting).

Subsequent to *Snelson*, courts consistently have held that when a defendant moves for summary judgment on the issue of proximate cause based on the assertion of a treating doctor that he would not have done anything different, a plaintiff can defeat the motion with expert testimony regarding what a doctor should have done to comply with the standard of care. *Buck v. Charletta,* 2013 IL App (1st) 122144 ¶¶69-72; *Shicheng Guko v. Kamel,* 2020 IL App (1st) 190090 ¶¶33-34.

Here, the Muhammads' tendered to the trial court the affidavit of Dr. Suhayl Nasr, an expert in psychiatry. (R. C631-636). He testifies that if a reasonably qualified psychiatrist knew the information Abbott allegedly failed to disclose that the risk of major birth defects caused by Depakote was 10 to 17%, as opposed to the 1% to 2% as stated in its warnings, psychiatrists would not have prescribed Depakote to Angie under any circumstances. *Id.* To do so, in Dr. Nasr's opinion, would have violated the standard of care. *Id*. Dr. Nasr's expert testimony discredits the hypothetical testimony of Dr. Stepansky and Dr. Allen and offers an alternative course of action. A jury must decide which to believe. *Buck v. Charletta,* 2013 IL App (1st) 122144 ¶¶69-72.

Abbott argues that Justice Frossard's dissent in *Seef,* as endorsed by this Court in *Snelson* and followed in in *Buck* and *Shicheng* Guko is inapposite because the concept arose in medical malpractice cases rather than a case arising from a drug manufacturer's alleged failure to warn. The First District Appellate Court rejected this argument and correctly noted that "[w]hile that distinction is accurate, it makes no difference."

Muhammad v. Abbott Laboratories, Inc., 2022 IL App 210478, ¶45. In each instance, a treating doctor was deprived of information vital to the doctor's decision making. As pointed out by Justice Frossard, the treating doctor's testimony that he or she would not have done anything different is hypothetical speculation which may be tainted by bias. A plaintiff should be permitted to contest a treater's testimony by presenting expert opinion that provides an objective course of conduct required by the standard of care.

In this instance, the testimony of the treaters Dr. Stepansky and Dr. Allen is riddled with inconsistencies that make it incredible. Therefore, the expert testimony of Dr. Nasr is even more compellingly necessary to explain what should have happened during Angie's treatment.

The Illinois Chamber of Commerce, in its *amicus curiae* brief suggests that if the lower court's decision is upheld, it will invite plaintiffs to hire experts to contradict their own failure to read and follow warnings. Brief of Chamber of Commerce at 9-11. In each of the cases cited, the plaintiff admitted that he or she did not read the warnings that accompanied the product. Therefore, no connection could be made between the allegedly inadequate warnings and plaintiff's injury because the plaintiff did not read the warning. See, *Kane v. R.D.Werner Co., Inc.,* 275 Ill. App. 3d 1035 (1995); *Murray v. Chicago Youth Center,* 352 Ill. App. 3d 95 (2004); and, *Broussard v. Houdaille Industries, Inc.,* 183 Ill. App. 3d 739 (1989). This significant factual difference makes this argument specious.

Here, Dr. Stepansky and Dr. Allen were aware of the Abbott's warnings at the time Depakote was prescribed to Angie Muhammad in 2005. The problem was Abbott's warnings did not say what was needed to be said to provide them with the information

needed to make a proper risk verses benefit analysis when determining whether Depakote was the right medication for Angie.

The Chamber of Commerce also suggests that if upheld, the lower court's decision will impose vicarious liability on Abbott for the conduct of Dr. Stepansky and Dr. Allen. Brief of Chamber of Commerce at 16-20. This argument is nonsensical. Dr. Nasr's affidavit testimony was not offered to prove that the doctors were negligent. It was offered to contradict their assertions that they would have done nothing different with proper warnings. This Court has deemed such testimony appropriate in *Snelson.*

V. ABBOTT WAIVED AN APPEAL ON THE ISSUE OF JUDICIAL ESTOPPEL

Abbott moved for summary judgment in the trial court on the ground that under the judicial estoppel doctrine the Muhammads' case against it was barred by their prior lawsuit against Dr. Allen and Northwestern Memorial Hospital. This case went to trial in August 2018. *Muhammad v. Abbott Laboratories, Inc.,* 2022 IL App 210478.10-22. Abbott contended that the factual positions taken by the Muhammads in the Northwestern litigation were contrary to the factual positions they are advancing in this litigation. The trial court agreed with this argument of Abbott and granted summary judgment. (R. C 364-367). The trial court did not rule on Abbott's alternative argument based on proximate cause, the issue before this Court. (R. C 364-367).

The Muhammads appealed. The First District Appellate Court ruled that the trial court's ruling on the issue of judicial estoppel was erroneous and reversed this finding. *Id.* at ¶ 40. Abbott did not raise the issue of judicial estoppel in its Petition for Leave to Appeal. (A. 083-109. By not including the issue of judicial estoppel in its Petition, Abbott waived this issue. Supreme Court Rule 315 (a); *Hansen v. Baxter Healthcare Corp.,* 198 Ill. 2d 420, 429 (2002).

Nonetheless, Abbott, in section D of its argument contends that the lower court decision should be reversed on equitable grounds. Abbott's Brief at 36-39. This argument is nothing more than a re-hash of the arguments it made on the issue of judicial estoppel. Therefore, these arguments of Abbott should not be considered. *Hansen v. Baxter Healthcare Corp.,* 198 Ill. 2d 420, 429 (2002).

Moreover, the appellate court's decision on the issue of judicial estoppel was correct. As the lower court pointed out, there can be more than one proximate cause of a plaintiff's injury. *Muhammad v. Abbott Laboratories, Inc.,* 2022 IL App 210478, ¶ 31 (citing *Shicheng Guo v. Kamal,* 2020 IL App 190090, ¶ 23. Moreover, in a case involving alleged defective warnings for a drug or medical device, it is not inconsistent for the prescribing physicians to be found liable on theories of medical negligence and the manufacturers under theories of product liability. *Hansen v. Baxter Healthcare Corp.,* 198 Ill. 2d 420, 422 (2002); *Tongate v. Wyeth Laboratories,* 220 Ill. App. 3d 952 (1991). Therefore, this argument is without merit.

VI. CONSLUSION

For the reasons stated, Plaintiffs-Appellees Charles Muhammad and Angie Muhammad as parents of C.M., a minor, and C.M. individually pray for this Court to affirm the decision of the First District Appellate Court in *Muhammad v. Abbott Laboratories, Inc.,* 2022 IL App 210478, and further, remand this cause to the Circuit Court of Cook County for a trial on the merits.

Respectfully submitted,

By: */s/ Milo W. Lundblad*
Milo W. Lundblad

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CERTIFICATE OF COMPLIANCE

I, Milo W. Lundblad, an attorney for Appellees Charles Muhammad and Angie Muhammad as parents of C.M, a minor, and C.M., individually, hereby certify that this Brief conforms to the form and length requirements of Rule 341. The length of this Brief, excluding the pages containing the Rule 341(d) cover, the Rule 341(c) Certificate of Compliance, the Certificate of Service , and those matters to be appended to the brief under Rule 342(a), is 5,487 words.

/s/ Milo W. Lundblad
Milo W. Lundblad

NOTICE OF FILING/CERTIFICATE OF SERVICE

The undersigned hereby certifies that on the 17th day of May, 2023, I electronically submitted a true and correct copy of the foregoing *Appellee's Brief* and the following *Appendix to Appellee's Brief* to the Clerk of Court using the Court's approved electronic filing service provider.

The undersigned hereby further certifies that one copy of the *Appellee's Brief* and one copy of the *Appendix to Appellee's Brief* were served via electronic mail and U.S. Mail on the 17th day of May, 2023, to the following counsel/parties of record to this appeal:

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Under penalties as provided by law pursuant to Section 1-109 of the Code of Civil Procedure, the undersigned certifies that the statements set forth in this Notice of Filing/Certificate of Service are true and correct.

/s/ Milo W. Lundblad
Milo W. Lundblad

No. 128841

In the Illinois Supreme Court

CHARLES MUHAMMAD and ANGIE MUHAMMAD, as parents of C.M., a minor, and C.M., individually,	)	On Appeal from the Appellate Court of Illinois, First Judicial District
Plaintiff- Appellees,	)	No. 1-21-0478
v.	)	On Appeal from the Circuit Court of Cook County, Illinois- Law Division
ABBOTT LABORATORIES INC. and ABBVIE INC.,	)	Case No. 2019-L-6254 Hon. Brendan A. O'Brien
Defendants-Appellants	)	

APPENDIX TO PLAINTIFF-APPELLEE'S BRIEF

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3.	Excerpts from 01/09/2017 Deposition of Thomas Allen, MD	C 761-803	A040-82
4.	Defendants-Petitioners Petition for Leave To Appeal		A083-A109

IN THE CIRCUIT COURT OF COOK COUNTY, ILLINOIS
COUNTY DEPARTMENT, LAW DIVISION

CHARLES MUHAMMAD and ANGIE MUHAMMAD, As Parents of CHARLES MUHAMMAD, a minor, and CHARLES MUHAMMAD, Individually,	)	
Plaintiffs,	)	
vs.	)	Case No. 2019 L 6254 Calendar X Judge Brendan O'Brien
ABBOTT LABORATORIES, INC., and ABBVIE INC.	)	
Defendants.	)	

AFFIDAVIT SUHAYL JOSEPH NASR, M.D.

NOW COMES YOUR affiant, Suhayl Joseph Nasr, M.D., duly sworn upon oath, states that I am over the age of 18, have personal knowledge of and am competent to testify to the following:

1. I am a medical doctor licensed to practice medicine by the States of Indiana and Illinois. I am Board Certified by the American Board of Psychiatry and Neurology in general psychiatry and geriatric psychiatry. I earned my undergraduate degree in Biology/Chemistry and medical degree from American University of Beirut, Beirut, Lebanon. Thereafter, I did an internship in Medicine/Neurology at American University Medical Center, Beirut, Lebanon. I came the United States in 1974 and completed a residency and fellowship in psychiatry at Strong Memorial Hospital which is affiliated with The University of Rochester School of Medicine and Dentistry, Rochester, New York.
2. I have been in the private practice of psychiatry since 1986. As part of my practice, I am Medical Director of Behavioral Health Service Line for Beacon Health System and Consultant, Notre Dame University Counseling Center.
3. I am currently a Volunteer Clinical Professor with the Indiana University School of Medicine-South Bend and Adjunct Assistant Professor of Psychology at Notre Dame University. Earlier in my career, I held teaching appointments at the University of Chicago, The Pritzker School of Medicine and the University of Illinois at Chicago. While at the Illinois State Psychiatry Institute and University of Illinois at Chicago, I treated mentally ill patients as outpatients in clinics similar to the Stone Institute of Psychiatry where Angie Muhammad was treated starting in 2003. Attached hereto as Exhibit Q is my curriculum vitae which sets out in greater detail my education, training and experience in the field of psychiatry.
4. In the course of my professional career, I have treated many patients with bipolar and schizoaffective disorders similar to the mental illnesses diagnosed in Angie Muhammad. Through my education, training and experience, I am familiar with

medications used to treat patients with mental disorders similar those suffered by Mrs. Muhammad, including medications to modulate mood swings including Lithium and Depakote (also known as valproic acid).

5. Based on my education, training and experience, I am familiar with the standard of care required of psychiatrists and residents in psychiatry treating patients suffering mental disorders similar to those with which Angie Muhammad was diagnosed in 2005 under the same or similar circumstances.
6. At the request of counsel for the Muhammads, I have reviewed the medical records, documents, and other materials:
    a. Stepansky deposition transcript and exhibits-Northwestern
    b. Stepansky deposition transcript and exhibits-Abbott
    c. Allen deposition transcript and exhibits-Northwestern
    d. Allen deposition transcript and exhibit-Abbott
    e. Northwestern Hospital Records
    f. Dr. Channon Assessment
    g. MacNeal Hospital Records
    h. Riveredge Hospital Records
    i. Dr. Stepansky Letter to Dr. Dago
    j. Dr. Dago Reports (Typed and hand written.)
    k. Dr. Siegel evaluation
    l. Abbott Document 0000110
    m. Abbott Document 0000114
    n. Abbott Document 0000116
    o. Abbott Document 0000584
    p. 2005 PDR excerpt Re: Depakote

7. Following my review of the above materials, I find the following facts to be relevant:
    a. Angie Muhammad was born on March 22, 1978. At the relevant times she was married. She gave birth to her first son in 2001; her second son in 2004 and her third son, who is the plaintiff, on May 18, 2006.
    b. Angie had a history of a hospital admission for treatment of mental illness in Mexico in approximately 1997, her first admission. After moving to the Chicago area she had multiple additional admissions at Northwestern Memorial Hospital to treat acute psychotic events on April 28 through May 23, 2002; February 21 through March 6, 2003; and, December 10, 2003 through January 23, 2004. Following this admission, Angie began receiving treatment as an outpatient at the Rehabilitation Clinic of the Stone Institute of Psychiatry which is part of Northwestern Memorial Hospital.
    c. In January 2005, Dr. Christian Stepansky, a psychiatry resident became part of the team treating Angie at the Clinic. The team included an attending psychiatrist, Dr. Marcia Brontman; and Dr. Janet Peden, a psychologist. Dr. Stepansky saw patients, including Angie, on Tuesdays. Dr. Stepansky was responsible for managing Angie's medications. When Dr. Stepansky saw patients on Tuesdays, he would assess their symptoms, assess their medication regimen, adjust their medication regimen if necessary, and give them an appointment to return. Dr. Brontman, did not see patients with Dr. Stepansky.

d. From January 2005 through May 4, 2005, Angie had multiple hospital admissions to treat acute psychotic symptoms.
e. On or about May 16, 2005, Dr. Stepansky asked Dr. Pedro Dago, a Spanish speaking colleague, to evaluate Angie to determine in part whether her ability to speak English was an impediment to her treatment at the clinic.
f. Dr. Dago evaluated Angie on May 19, 2005 and prepared a report for Dr. Stepansky. He made a diagnosis of "most likely bipolar v. schizoaffective" and commented that "she can get very psychotic and very dangerous." Dr. Dago made treatment recommendations which included "[c]onsider Lithium, Depakote."
g. On May 24, 2005, Dr. Stepansky saw Angie and during this evaluation he prescribed Depakote. Dr. Stepansky's note does not state his reasons for prescribing Depakote. He believes it would have been to prevent further cycling of Angie's bipolar disorder. Although Dr. Dago's recommendation was for Lithium or Depakote, Dr. Stepansky cannot recall whether he considered prescribing Lithium. Dr. Stepansky knew both Lithium and Depakote could harm a fetus if Angie became pregnant. Dr. Stepansky does not recall why he chose Depakote over Lithium. His note does not refer to Lithium. Dr. Stepansky's note says: "Risks/benefits of med discussed. Written info given. Specifically informed patient of teratogenic potential. Liver, pancreatic, hemo effects." The doctor does not remember what he specifically told Angie about the risks and benefits of Depakote.
h. On May 31, 2005, Angie returned to the clinic. She told Dr. Stepansky that her menstrual period was late. A STAT pregnancy test was negative. Dr. Stepansky continued prescribing Depakote and increased the daily dose.
i. Dr. Stepansky continued prescribing Depakote and increasing Angie's daily dose through the summer of 2005. Dr. Allen replaced Dr. Brontman as Dr. Stepansky's supervisor on July 1, 2005. There are no notes in the medical chart documenting any contact between Dr. Allen and Angie before October 2005. In retrospect, we know Angie became pregnant on approximately September 8 or 9, 2005.
j. On October 11, 2005, Angie informed Dr. Stepansky that her menstrual period was late. She refused going the hospital's laboratory for a pregnancy test. Dr. Stepansky did not direct Angie to stop taking Depakote.
k. On October 20, 2005, Dr. Stepansky learned that a laboratory test confirmed Angie was pregnant and told Angie to stop taking Depakote.
l. At the end of November 2005, Angie was hospitalized to treat acute psychotic symptoms. After this episode, Angie was started on Lithium.
m. On May 18, 2006, Angie gave birth to her son, the plaintiff in this case, who was born with a neural tube defect. Dr. Siegel, a neurologist, is of the opinion that in addition to his neural tube defect, the child has severe cognitive impairment, jaw and teeth maldevelopment, and other malformations that were caused by his exposure to Depakote during the early period of embryogenesis. The conditions are permanent.
n. Abbott's product labeling for Depakote published in the 2005 Physician's Desk Reference provides a "Black Box" warning that "VALPROATE (THE

GENERIC NAME FOR DEPAKOTE) CAN PRODUCE TERATOGENIC EFFECTS (E.G. SPINA BIFIDA). ACCORDINGLY, THE USE OF DEPAKOTE TABLETS IN WOMEN OF CHILD BEARING POTENTIAL REQUIRES THAT THE BENEFITS OF ITS USE BE WEIGHED AGAINST THE RISK OF INJURY TO THE FETUS."

o. The 2005 labeling states that the estimated risk of a fetus exposed to valproic acid developing spina bifida is approximately 1 to 2%. The labeling further states that offspring of women receiving valproic acid during pregnancy have an increased incidence of birth defects. Abbott's drug information disclosure did not quantify the amount of increased risk.

p. In contrast to Abbott's 2005 labeling, an internal document produced by Abbott in discovery in this matter shows that in 2004, Abbott possessed a proposed unpblished abstract authored by researchers from the Antiepileptic Drug Pregnancy Registry which discussed its data from the study of teratogenic effects of valproic acid and other anti-seizure medications taken by pregnant women. The abstract was entitled: "Valproate Monotherapy is a Potent Teratogen in Humans." The data showed that 8.1% of babies born to women taking Depakote had major malformations. The researchers concluded that "Valproate is a potent teretogen in humans and its use should be reduced to the minimum or substituted by another safer AED." Abbott objected to the title of the abstract and conclusion. After the authors reviewed Abbott's comments, the objected to title and conclusion were revised.

q. Also, in May 2004, Abbott was aware of "two new data sets" that suggested a 10.7-17% risk of teratogenicity associated with Depakote use in women with epilepsy and the rate of risk was "significantly higher than the package insert."

8. Following my evaluation of the information reviewed, I formed the following conclusions and opinions which I hold to a reasonable degree of medical certainty based on my education, training and experience in the field of psychiatry:

a. If prior to May 24, 2005, Abbott's product labeling and warnings disclosed that there was a 10 to 17% or greater risk of birth defects in a fetus exposed *in utero* to Depakote (valproic acid), a reasonably careful psychiatrist possessing the knowledge, skill and care ordinarily used by a reasonably careful psychiatrist would not have prescribed Depakote to Angie Muhammad on May 24, 2005 or on any date thereafter. Or in other words, if a psychiatrist prescribed Depakote to Angie on or after May 24, 2005, that psychiatrist would have deviated from the standard of care.

b. Bases for my opinion:

i. Angie Muhammad was a fertile woman of child bearing age who was married and sexually active. Therefore, she was at risk for an unplanned pregnancy while taking Depakote.

ii. Other than sterilization, other methods of birth control are not 100% effective. Angie's mental illness and history of medication non-compliance increased her risk of getting pregnant inadvertently.

iii. Angie's risk of getting pregnant combined with the 10 to 17% risk of a birth defect in her child if she got pregnant while taking Depakote

outweighed the potential benefit Depakote might have had in treating her bipolar v. schizophrenic disorders.

iv. The 10 to 17% or greater risk of birth defects that Abbott failed to disclose in its 2005 product labeling significantly changed the risk/benefit analysis used in weighing whether it is appropriate to prescribe Depakote. This higher risk of birth defects, tips the balance against Depakote.

v. Another important factor that must be considered in the risk/benefit analysis for prescribing Depakote is whether there was any other effective and safer medication available. In this instance there was a better medication available in 2005. Dr. Dago recommended "Lithium, Depakote." Lithium has been used for decades to successfully treat bipolar/schizophrenic disorders. Lithium presents a small risk of causing heart defects that can be corrected through surgery. Lithium can be used during pregnancy. Attachment b, Stepansky transcript, Exhibit 1. Lithium was prescribed to Angie during her pregnancy in January 2006. When compared to the greater risk of birth defects for Depakote (10 to 17% or greater) of which Abbott was aware of but failed to disclose, Lithium clearly should have been the medication of choice for Angie had the increased risk been part of the equation.

c. Dr. Stepansky and Dr. Allen in depositions given in 2020 claim that even if they had been told by Abbott that the overall birth defect risk was 10% plus an added risk of neurodevelopmental delay of 20%, they would still have prescribed Depakote to Angie in 2005. Dr. Allen went further to claim he would have prescribed Depakote to Angie even if there was a 100% risk of birth defects if she got pregnant while taking the drug. This testimony of Dr. Stepansky and Dr. Allen is contrary to the standard of care and does not represent what a reasonably careful psychiatrist would have done in under the circumstances in 2005 for the reasons stated in paragraph (b) above.

d. If Abbott had disclosed the higher 10 to 17% risk of birth defects, plaintiff Charles Muhammad IV would not have been injured by his exposure to Depakote. That is, it is more likely than not, had Depakote not been prescribed, Charles IV would not have been born with spina bifida, congenital defects and other anomalies that he has.

e. Bases for opinion:

i. If Abbott disclosed and warned of the true risk of birth defects caused by *in utero* exposure to Depakote, the drug would not have been prescribed to Angie by psychiatrists adhering to the standard of care.

ii. Therefore, if Depakote had not been prescribed, Charles IV would not have been exposed and injured by the drug when Angie got pregnant in September 2005.

9. I base my opinions on the information provided and I reserve the right to revise and

supplement them as additional information becomes available.

Suhayl Nasr, M.D.

Date: 3/1/2021

VERIFICATION BY CERTIFICATION

Under penalties as provided by law pursuant to 735 ILCS 5/1-109, the undersigned certifies that the statements set forth in this instrument are true and correct, except as to matters therein stated to be on information and belief and as to such matters, the undersigned certifies that he/she verily believes the same to be true.

Signed on March 1, 2021.

Suhayl Nasr, M.D.

Muhammad vs Northwestern Memorial Hospital

12 L 12174

Deposition of: Christian F. Stepansky, M.D.

Taken on: September 21, 2016

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IN THE CIRCUIT COURT OF COOK COUNTY, ILLINOIS
COUNTY DEPARTMENT, LAW DIVISION

CHARLES MUHAMMAD and ANGIE MUHAMMAD, As Parents of CHARLES MUHAMMAD, a minor, and CHARLES MUHAMMAD, Individually,

Plaintiffs,

v.

No. 12 L 12174

NORTHWESTERN MEMORIAL HOSPITAL and MEDICAL CENTER, DANIEL YOHANNA, M.D., and THOMAS W. ALLEN, M.D.,

Defendants.

The discovery deposition of CHRISTIAN F. STEPANSKY, M.D., taken in the above-entitled cause, before Margaret A. Verhey, a notary public within and for the County of Cook and State of Illinois, and a Certified Shorthand Reporter of said state, at 70 West Madison Street, Chicago, Illinois, on the 21st day of September, 2016, at 2:12 o'clock p.m.

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REPORTED BY: MARGARET A. VERHEY, CSR
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I N D E X

WITNESS PAGE
CHRISTIAN F. STEPANSKY, M.D.
Examination By Mr. Lundblad 4
Examination By Ms. Kaner Socol 122

E X H I B I T S

Plaintiff's Deposition Exhibit REFERENCED
No. 2 13
MARKED
No. 12 41

(Witness sworn.)

CHRISTIAN F. STEPANSKY, M.D.,

called as a witness herein, having been first duly sworn, was examined and testified as follows:

EXAMINATION

BY MR. LUNDBLAD:

Q Good afternoon. Will you please state your name for the record and spell your names for our court reporter?

A Christian F. Stepansky. First name, C-h-r-i-s-t-i-a-n, middle initial F, last name, S-t-e-p-a-n-s-k-y.

Q What is your date of birth?

A October 2nd, 1976.

Q Have you given a deposition before?

A Yes. In some capacity, yes.

Q How many times?

A Twice.

Q Based on those experiences I'm sure you know a little bit about what to expect and I'm sure your attorney has advised you as to what will happen this afternoon. Let me just go over a couple of ground rules.

First of all, be sure that you understand

my question. If I in particular misuse a medical term, please let me know and/or if my question doesn't make any sense, let me know and I'll reword it or we'll have the court reporter read it back for you. Is that understood?

A Yes.

Q Second of all, we need all of your answers in words today. You can't nod your head, shake your head, and in particular we need to you say yes or no rather than uh-huh or uh-uh because later we may wonder what you meant. Is that also understand?

A Yes.

Q I'm sure if you forget one of us will correct you. The last thing would be that if you would let me finish asking my question before you start answering. I'll try to do the same for you. That way our court reporter will only have to take down one person at a time, we'll get a clearer record and a more readable record. Is that also understood?

A Yes.

Q Where do you live?

A My home address is 612 South East Avenue, E-a-s-t, Oak Park, Illinois 60304.

Q Are you married?

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A Yes.
Q **Your wife's name?**
A Mona, M-o-n-a, same last name.
Q **Is she in the medical field?**
A No.
Q **Where did you go to undergraduate school?**
A University of Chicago.
Q **And what did you major in?**
A Classical studies.
Q **What year did you graduate?**
A 1998.
Q **Where did you go to medical school?**
A Northwestern Feinberg School of Medicine.
Q **And when did you start medical school?**
A 1999.
Q **And graduated when?**
A 2003.
Q **How did you end up going from classical studies to medicine?**
A I was pre-med and classical studies major at the same time. I wanted to major in something that interested me in a unique way and also had visions of become a doctor, so I did both.
Q **All right. After you graduated in 2003,**

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what did you do next?
A I went straight to a residency program at Northwestern McGaw Medical Center.
Q **And what was the residency program in?**
A Psychiatry.
Q **And how long was the program?**
A A four-year program.
Q **So you finished it in 2007?**
A That is correct.
Q **At the relevant times with this case, we're talking about the year 2005, so you would have been in your residency program at that point?**
A That is correct.
Q **And you would have been what, in your third year of -- no, you would have been completing your second and starting your third?**
A The calendar year of 2005 began in the middle of my second year.
Q **Okay. The calendar year or the year for your residency go from what, July 1st --**
A July 1st, 2003 to July 1st, 2007.
Q **Okay. So you would have -- in the early months of 2005, you would have been in the middle of your second year?**

Page 8

A That is correct.
Q **Okay. Are you currently practicing psychiatry?**
A I am.
Q **Where?**
A The Jesse Brown VA Medical Center here in Chicago.
Q **How long have you been at Jesse Brown?**
A Since July of 2007.
Q **Have you practiced any other place in addition to Jesse Brown?**
A Briefly in the years immediately after the completion of residency I did some moonlighting overnight shifts at one of the Northwestern affiliated hospitals as a separate job.
Q **Would that have been in the emergency department or on consultation?**
A The overnight on-call psychiatrist doing admissions in the emergency room as well as covering the inpatient unit.
Q **At Jesse Brown are you employed by the federal government?**
A Yes.
Q **And during your years of residency starting**

Page 9

in 2003 through June 30th of 2007, who was your employer?
A Northwestern McGaw Medical Center.
Q **Do you have any personal memory of Angie Muhammad?**
A Yes.
Q **And can you tell me what is it that you remember about her?**
A I remember her at times dramatic clinical appearance, often overdressed for her appointments, expansive or exaggerated affect. I remember her frequent hospitalizations in the early months that I worked with her. I do remember the complexity of the case given her hospitalizations, her children at home. I do remember calling DCFS, which is something I very, very rarely did, so it stands out. I remember the complex medical decisions that needed to be made and I remember her pregnancy. Given the circumstances, that certainly stood out in my residency career.
Q **Now I take it as a resident you were working under the supervision of an attending physician?**
A Yes.

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Q And when you first started seeing Mrs. Muhammad, who were you working under?
A This was specifically in the rehabilitation program part of Stone Institute. That was the -- that was a half time rotation I was on beginning in January of 2005 and for the next six months I was under the supervision of a rehabilitation psychiatry attending named Dr. Marcia Brontman. I believe it was B-r-o-n-t-m-a-n.
Q First name Marshall?
A Marcia. I believe M-a r-c-i-a, I believe.
Q Okay. And when did her supervision end?
A I believe June 30th of that year when she left the rehabilitation program.
Q And who took over your supervision?
A Dr. Tom Allen.
Q A few moments ago you said that you recall that Mrs. Muhammad's case involved complex medical decisions. Can you expand on that? What do you mean by "complex medical decisions"?
A In the early months that I worked with her she was hospitalized I believe four times for very serious symptoms including suicidality and homicidality. It became increasingly clear that the

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medications she would be discharged from the hospitals on were not effective, that she was frequently going into another episode shortly after her discharge, she would need readmission and other medication considerations were going to need to be considered. And whenever I am considering a mood stabilizer in a young female, that becomes complex in and of itself.
Q And why is it a complex question in a young female?
A Well, the most effective medications for bipolar disorder, which is what it became clear that she had, are potentially teratogenic and that always has to be considered with young female patients.
Q Okay. When you say teratogenic, you mean those medications can cause harm to a fetus if the young woman becomes pregnant?
A That is correct. The risk is there for the medications that were being considered.
Q In prescribing mood stabilizers that have the potential for causing injury to a fetus to a young woman who is in the age of becoming pregnant, what are the considerations that you have to give to determine whether or not to prescribe such a

Page 12

medication?
MS. KANER SOCOL: Before you answer the question I'm going to object to the word "injury" because I don't think that was Dr. Stepansky's testimony.
MR. LUNDBLAD: All right.
MS. KANER SOCOL: If you don't mind rephrasing.
BY MR. LUNDBLAD:
Q All right. You told me that mood stabilizers have the risk of causing harm to a fetus, correct?
A Yes.
Q And so my question is, in deciding whether or not to give a mood stabilizer to a young female who potentially can become pregnant, what considerations do you have to give knowing that these medications have a risk of harming a fetus?
A The risks of treating versus non-treating need to be carefully considered. The risk of not prescribing a mood stabilizer in a clinical situation where further mood episodes could be life threatening to the patient or others has to be very carefully weighed against the potential risk of the side effects of the medication in the situation.
Q What are the potential mood stabilizers

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that can be used that were available back in 2005?
A Because she had already done poorly with typical and atypical psychotic medications, a mood stabilizer was considered namely Depakote or lithium.
Q And what medication was she on, not the mood stabilizer but the other, to treat her illness?
A At that time?
Q Right.
A I would have to consult the record.
Q All right. The record you're referring to is what has been marked previously as Plaintiff's Exhibit No. 2. It is a binder containing notes related to Angie Muhammad. And if you could advise me what page are you referring to and the page number is on the lower right-hand corner.
A At the time the mood stabilizer was begun she had already been on, on page 85, she had already been on Risperdal, Prozac and Cogentin.
MR. LUNDBLAD: I'm sorry. Could you read that answer back, please?
(Record read as requested.)
BY MR. LUNDBLAD:
Q Isn't it true that when you first started seeing Mrs. Muhammad she was on Haldol?

A When I first saw her in January she had just been discharged from a hospitalization on Haldol.

Q And how was the Haldol being administered to her?

A At that time it was given orally.

Q I thought I saw some references where she was given Haldol by injections.

A I believe she received Haldol Decanoate in one of her subsequent hospitalizations.

Q If I could refer you to page 48. Page 48 is entitled Treatment Plan Review. Are you familiar with this document?

A Yes.

Q And what is its purpose?

A This is completed as part of an interdisciplinary team meeting. I don't recall how often the team had to update them. That escapes my memory. But at various intervals a Treatment Plan Review would need to be completed and signed by all the people of the interdisciplinary team.

Q Okay. And I see your signature on the top line lower left-hand box; is that correct?

A That is correct.

Q And the attending physician, is that the Dr. Brontman?

A That is correct.

Q And it looks like the date of this team meeting was April 15th of 2005?

A That is correct.

Q And all the people who signed in were all part of the team that was attending to Mrs. Muhammad?

A That is correct.

Q All right. And one of the team members was Janet Peden, who is what, a Ph.D psychologist?

A That is correct.

Q If you look in the mid part of the sheet that has assessment of treatment since last review, it appears that this recites her past hospitalizations. It looks like she was -- in February she was at it looks like MacNeal Hospital; is that correct?

A Yes.

Q And then from 2-25 to 3-2-2005 she was at Lake Shore Hospital?

A Yes.

Q And where is Lake Shore Hospital located?

A I don't know.

Q Then if we go down to the fourth line, it says -- not sure what it says. It starts out, it says after and I can't make out the next word, patient more stable on IM Haldol and Prozac. Do you see that?

A Yes.

Q And was that the medication regimen she was on as of April 15th of 2005?

A That's what this Treatment Plan Review would indicate, yes.

Q All right. And the bottom line it describes that she was working at Marshall Field's, was very happy and currently stable on meds with mood; is that correct?

A Yes. I can't make out that last part. There is something before the word mood. But other than that, that is correct.

Q Okay. What was your role as a member of the team that was taking care of Mrs. Muhammad?

A I had a panel of patients called a medication group that I would see on Tuesday afternoons for I believe two hours weekly for the duration of the year 2005. That was my role on the team.

Q When you say medication group, what did you do? The medication group, are you talking about a group of patients?

A I have to be clear. It was referred to as a group because it used to be held as a group, but by the time I came on board in the rehabilitation program, all the medication management sessions were held individually. And I would see over the course of the two hours between four and eight patients in a room with my nurse on the team, who also signed this treatment plan, Judy Wilson.

Q What was your function in seeing these four to eight patients on Tuesday afternoons?

A I would assess their symptoms, assess their medication regimen, adjust their medication regimen if necessary, order laboratory tests if necessary and give them an appointment to return.

Q And I think you told us your assistant was Nurse Wilson?

A That is correct.

Q What role, if any, did your supervising attending physician play in your Tuesday evaluations of these patients?

A I would have weekly supervision with

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Dr. Brontman on a different -- at a different time. I don't know when, but it was a weekly one-hour supervision with Dr. Brontman. Dr. Brontman did not see the patients as I saw them.

Q All right. I got a little bit sidetracked here. You mention that two mood stabilizers are Depakote and lithium. Are there others in addition to that?

A Carbamazepine is a mood stabilizer.

Q Is there a generic name?

A Tegretol. Lamotrigine which is Lamictal. Those are the only other two. And for various reasons, those were not part of the consideration.

Q Depakote, what risk of injury does it pose to a fetus?

A In my training it was certainly clear that neural tube defects, spina bifida and neurocognitive effects are certainly a risk with this medication.

Q What about with lithium?

A Also has teratogenic effects particularly cardiac malformations.

Q After Mrs. Muhammad became pregnant, I believe it was in January 2006, she was placed on lithium, correct?

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A Correct.

Q The other drugs you mentioned, the Tegretol, what risk of fetus injury does that pose?

A It does have teratogenic effects. What I -- and I would have to -- I'm not able to elaborate further on that. It is a medication I don't use often in my current practice.

I do know that it is a medication that is known to increase the metabolism of contraceptives and would make hormonal contraceptives less effective which is why that was not an option.

Q What was the fourth one again?

A Lamotrigine which is Lamictal. It is also a medication I don't use frequently now in my training. I believe it was considered more useful in situations where mood stabilization was needed in a predominantly depressive patient and I also believe there are teratogenic effects, but I cannot speak to that at present.

Q Do you recall ever meeting Angie's husband Charles?

A He was never, as I recall, present within session at patient request, but I did meet him informally a number of times in the waiting area.

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Q And Angie requested that her husband not be present; is that what you're saying?

A I don't recall that specific conversation, but I do recall that his absence in sessions was noteworthy and I do recall at some point she actively not wanting him there.

Q Okay. First of all, why do you say it was his absence was noteworthy?

A For a complex case like this, you would want to enlist -- in my practice I would certainly want to enlist family members, spouses to get further support for the treatment plan. So that was certainly -- I presume that was considered. I don't specifically remember that conversation, but given my practice and how I was trained, a spouse's involvement in a case like this would be sought after.

Q And did you ever ask Angie why she didn't want her husband Charles present in these sessions?

A I believe I did. I do not recall the content of those conversations other than what has been documented, if anything.

Q I think you mentioned that you had several what you call informal conversations with Mr. Muhammad. Approximately how many times did you have an informal conversation with him?

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A Perhaps three times.

Q Do you recall what you and Mr. Muhammad discussed during those informal conversations?

A I don't know if I have an independent recollection of that. I believe I saw in a note of Dr. Peden an incident, which I can remember a bit of, when he brought her in for a session because he was concerned for her behavior and Ms. Muhammad had to be hospitalized at that point. So there was some interaction with him as far as why he brought her into the clinic then and what he had witnessed.

Q Do you recall when that was?

A Page 112, November 30th, 2005. This was a session with Dr. Peden in Dr. Peden's office that I believe Dr. Peden had called me to be a part of and it says Dr. Stepansky and writer met with patient and husband to discuss approaches to pregnancy. I can't read some of this. This session became a crisis episode which ended up in her rehospitalization.

Q Okay.

A I do remember seeing him in that encounter.

Q Do you have any recollection of any other

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discussions that you had with Mr. Muhammad?
A Nothing specific. It could have been as small as why they were late coming into their appointment and he would say some transportation issue or something like that, but nothing more than that.
Q The Cogentin, what is the purpose for giving that?
A Cogentin is used to treat the side effects of typical antipsychotics such as Haldol. Medications such as Haldol are known to cause Parkinsonian type side effects of tremors and the Cogentin is a medication that can counter that.
Q Okay. And what is the purpose of Haldol?
A Haldol is called a typical antipsychotic which would treat psychotic symptoms: auditory or visual hallucinations, delusions, paranoia.
Q Okay. Haldol, is that an appropriate medication to have been prescribed to treat Mrs. Muhammad's condition?
A Appropriate, yes, but as it became clear, inadequate.
Q And in addition to the Haldol, was she also being given Prozac?

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A At what time?
Q Well, when you first encountered -- why don't we start -- if you flip to page 58.
A Yes.
Q And it is a note dated January 25th, 2005. I take it this was one of your medication meetings that you had with Mrs. Muhammad?
A That is correct. This is my first interaction with her as part of the rehabilitation medication appointments. I did meet her once before in an emergency room setting earlier in that month, I believe, so this is not the first time I saw her, but it was the first medication appointment as part of the rehabilitation program.
Q And that would have been where? Where did you encounter her in the emergency situation?
A The emergency room of Northwestern Hospital.
Q Were you the on-call physician for that particular day?
A That is correct.
Q I believe you also saw her in the emergency department in April. We'll get to that.
A I believe you're correct, but I would have to check the date.
Q All right. Based on the notes, what was her medication regimen at that time, January 25th?
A This was shortly after she was discharged from this hospitalization of January 2005 and she was discharged apparently on Haldol and Cogentin and nothing else at this point.
Q On the right-hand side about middle of the page it says something about patient informed. Can you read that part of your note into the record?
A Patient informed of long term risk of TD, which is tardive dyskinesia, with being on Haldol and patient reported to eventually want to change antipsychotics but consented to continue Haldol for now.
Q And what is the last line?
A Patient complained of occasional headache in past week.
Q And the TD that you're referring to, is that tremors that you would treat with the Cogentin?
A Not exactly. There are multiple motor effects that could happen with Haldol. There are short term effects such as dystonias, akathisias, Parkinsonism. Some of those are treated with

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Cogentin. Tardive dyskinesia is a long term effect usually after someone is on Haldol for years.
Q Do you know how long she had been on Haldol at this point?
A I would have to check the record.
Q We jump ahead to page 61 of Exhibit 2. This is a visit of February 8th of 2005?
A Correct.
Q And another one of your medication monitoring visits?
A Correct.
Q What did you do on the rest of the days other than Tuesday afternoons?
A So in January through June of 2005, I was half time in the rehabilitation program, half time in the outpatient treatment center. And as part of the rehabilitation program rotation in addition to these medication visits, I would also do intake assessments. I would do clinic work at a satellite clinic that the rehabilitation clinic had at a local YMCA, I would attend the team meetings, some other various capacities in the rehabilitation rotation.
The other half time through June of 2005 was outpatient treatment center which was the general

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outpatient clinic for Stone which is part of the residency training program and I would see individual patients as part of that program as well.

Q What is the difference between the rehabilitation program and the outpatient clinic?

A The rehabilitation program is meant for lower functioning patients with chronic mental illness, as I recall. It offered interdisciplinary supportive programs, classes to help people with severe mental illness.

The outpatient treatment center was for higher functioning patients who essentially needed psychotherapy or medication management or both with limited other supports.

Q What is the distinction between lower functioning and higher functioning?

A Well, that would be a clinical matter. If a patient needed more than, say, a monthly medication appointment and twice monthly therapy appointment, if they needed more in terms of life skills training, coping skills, skills to -- basic living skills, then rehabilitation would be considered. Usually for certain diagnoses rehabilitation would be more for either chronic schizophrenia, severe bipolar

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disorder. And then the outpatient treatment center would be for more mild to moderate anxiety or mood disorders.

Q Okay. Who made the determination that Mrs. Muhammad needed to be in the rehabilitative section?

A Well, this was before my time in the rehabilitation program, but I believe when she was hospitalized at the end of '03, early '04 -- often it is from an inpatient hospitalization that it is determined what kind of outpatient treatment would be adequate for a particular patient. I believe it was when she was discharged from that hospitalization that the doctors taking care of her on the inpatient unit would say she probably needs a level of care that rehabilitation program would provide.

Q Did you ever have any contact with Mrs. Muhammad in the outpatient clinic?

A No.

Q Going down on page 61, it is your February 8 visit, under assessment and plan, what was your diagnosis?

A Schizoaffective disorder.

Q And what is the lettering after that?

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A The DO is disorder.

Q Disorder. Okay. All right. And you were continuing with the Haldol and the Cogentin at that time?

A Yes. Yes.

Q Haldol and Cogentin, do they pose any risk to a fetus, risk of injury?

MS. KANER SOCOL: Risk of harm?

MR. LUNDBLAD: Risk of harm.

MS. KANER SOCOL: Okay.

THE WITNESS: I would -- Haldol is not a medication I use often and I rarely work with females now, so I would defer answering that as far as my current knowledge base.

BY MR. LUNDBLAD:

Q What about Cogentin?

A The same thing.

Q When you were taking care of a patient like Mrs. Muhammad, one member of the team would note it, it was Janet Peden. Is it Peden or Peden?

A I don't remember.

Q Okay. And she was what, a psychologist?

A I believe so.

Q What interactions would you have or did you

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have with the psychologist with Ms. Peden or Dr. Peden, I should say?

A Certainly at the team meeting I would interact with her and we would share clinical data and perhaps make a clinical decision. And as needed, for example, the incident I already cited on page 112 when there was a crisis or some need where Dr. Peden needed assistance and I was available she could page me and I would if possible be present.

Q Did you have access to Dr. Peden's notes?

A They were part of the chart.

Q Would you review her notes relating to Mrs. Muhammad prior to your sessions with her when you reviewed her medications?

A That would be my customary practice, yes.

Q All right. Page 66 looks like another one of your medication reviews?

A Yes.

Q And this would have been about two weeks after the other one. Again, in the middle of the page, you have a note it starts out patient states she feels drowsy. Could you read that into the record, please?

A Patient states she feels drowsy. No other

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side effects. Patient willing to continue with medication although is concerned with sedation. Patient states she is able to ignore confrontations was her husband and avoid arguments.

Q Okay. The drowsiness to what medication was that being attributed, if any?

A I don't know what other medications she was on at the time. That's not on this page, but the Seroquel that she was on could certainly explain that.

Q Seroquel, was that a new medication?

A That is an atypical antipsychotic. The generic name is Quetiapine, Q-u-e-t-i-a-p-i-n-e. And I believe she was placed on that medication in the intervening hospitalization she had.

Q Going to the A and P, can you read that part of your note?

A Schizoaffective disorder. Continue Seroquel as dosed. Compliance encouraged. Return to clinic two weeks. Release signed to talk with inpatient psychiatrist doctor something. I cannot read that.

Q Okay. And why did you get authorization to speak to that unknown doctor?

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A I don't recall. In my usual practice I would try to have as much continuity of care between doctors as possible. I imagine it was for that purpose.

Q If you could turn to page 68. This was a note from March 8th of 2005. And, again, this was one of your medical management interactions with Mrs. Muhammad?

A That is correct.

Q Based on the note how was Mrs. Muhammad doing as of that day? Why don't you just read the note into the record. I'm not able to read this one.

A Patient reports continued increased stress, angry feelings toward husband especially when there are behavioral issues with children. Patient reports med compliance and pill bottle seems to indicate this. Patient denies auditory visual hallucinations, denies any suicidal-homicidal thoughts of any kind. Reports improved mood despite stress. Sleep, appetite within normal limits. Denies paranoia, racing thoughts. Objective assessment: Well groomed, cooperative, reduced eye contact. Speech, Spanish accent. Affect, euthymic. Mood, quote, okay. Thought process, somewhat vague but linear.

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Thought content, preoccupied with stresses with husband. No suicidal-homicidal ideation. No auditory visual hallucinations. Insight/judgment, fair to poor. Assessment, schizoaffective disorder.

Q As of that date what was your understanding as to what the conflict was between Angie and her husband Charles?

A I have no independent knowledge of that. Based on the note it appears that the children were a stress in the marriage.

Q Did you have any knowledge as to what impact the prior pregnancies had on Angie's mental health? Maybe let me ask a question.

What was your understanding as to how many children she and Charles had together at that point?

A This is not from an independent recollection but from my review of the chart. She had two children at the time is my understanding.

Q Okay. And what was your understanding in 2005 as to what effect, if any, the pregnancies had on Mrs. Muhammad with those two prior children?

A Again, I have no independent recollection, but in the chart review that I had done, she had presented for the very first hospitalization -- I'm

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sorry, for the hospitalization at the end of 2003 after which she was referred to rehabilitation clinic I believe she was pregnant at that time, so I knew she had an episode requiring hospitalization during that pregnancy. And I believe in further chart review going back to a prior hospitalization, there was other evidence of mood episode at some point during the course of her first pregnancy, but I don't recall offhand.

Q Okay. If you were aware of the impact of the pregnancies on Mrs. Muhammad of her prior children, is that something you would have noted when you were doing your medical management meetings with Mrs. Muhammad?

MS. KANER SOCOL: Objection. Calls for speculation. If you recall.

THE WITNESS: Can you repeat the question?

MR. LUNDBLAD: Can you read it back, please?

(Record read as requested.)

THE WITNESS: Well, at the time I believe I had access to the chart and I was aware of her prior history and that would have been a part of my medical decision making.

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BY MR. LUNDBLAD:

Q All right. But would it have been your custom and practice to make a notation of it in your note as part of your discussion of your treatment plan?

A Can you rephrase the question?

Q Sure. The fact that Mrs. Muhammad had an apparent adverse reaction to being pregnant, was that -- would that be something that would be significant in your evaluation of her mental status and your prescribing of medications to deal with her mental illness?

A Well, it would be my custom and practice to inform the patient that with bipolar illness pregnancy can exacerbate the illness, that pregnancy should be carefully considered and planned for this reason. So that would have been part of my discussion with her.

Q Well, when you would have a discussion with a patient about those issues, is that something you would document in your notes to record and document that you had had such a discussion with the patient?

A Not necessarily. I could have had those discussions and not had it documented.

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Q Now, were you aware of the conflict between -- well, strike that.

Were you aware of the, I guess, conflict between Angie and her husband where Charles wanted more children and Angie did not?

A I believe I was aware of that.

Q Is there any place in any of your notes where you document your awareness of that conflict?

A I don't recall offhand. I would have to review all my notes to be certain.

Q Now it appears as of March the method by which the Haldol was given had changed to where it was an injection. If you look on page 69.

A I believe that was to continue the plan from the hospitalization, her most recent hospitalization.

Q All right. Do you know why there was a change made from giving Haldol in the pill form to Haldol by injection? Do you know why that was done?

A This was the original decision of the inpatient psychiatrist, so I couldn't specifically state why.

Q And why did you continue using an injection rather than pills?

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A My main concern was to try to build an alliance with Ms. Muhammad which was exceedingly difficult in these early months because of her repetitive hospitalizations. She was hospitalized in between many of these sessions that I had with her. And it is my customary practice to if someone is doing well with whatever they're on and whoever started the plan, the treatment plan, in this case her inpatient psychiatrist, that I would continue it unless and until I have strong reason to believe a change needs to be made and I have an adequate alliance with the patient. So I didn't feel it was urgent enough at this point to make a change given her clinical status and how she did with that treatment regimen.

Q All right. One of the stressors that I believe you documented was having to deal with the two children that she had; is that correct?

A Yes.

Q And was it your opinion at that time that it would be contraindicated for her to have another child?

A Certainly I would expect that were she ever to wish to have another child it would have to be

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done in a planned way with foreknowledge with a discussion of medications, with a discussion of her living arrangement and status of her marriage. I mean, these are discussions that could be addressed in therapy and discussed in my sessions with her. So the theoretical question I don't think I could speak to of whether a pregnancy for all time for the rest of her life would be contraindicated.

Q Well, were you aware that a few days before you saw Mrs. Muhammad on March 8th that Dr. Peden was discussing tubal ligation with Mrs. Muhammad? Were you aware of that?

A I likely was at the time. I only recall it now in reading this note.

Q Okay. Did you ever discuss with Mrs. Muhammad the possibility of having tubal ligation in the same time frame in March of 2005?

A I don't have independent recollection of that either way.

Q If you had such a discussion, is that something that you would have documented in your note based on your custom and practice?

A Possibly but not definitely.

Q All right. I believe your next note is on

Page 38

page 72. Right. Page 72. Can you read into the record the top part of your note, please?

A Patient now working at Marshall Field's selling perfume as of today. Children with babysitter. Husband's friend found job for her. Patient compliant with Prozac every day. Reports missing no doses. Denies depression, feeling hopeless, suicidal-homicidal ideation. Patient denies any conflict with husband or arguments. Patient requests getting out of house to work helps with stresses around the home. No auditory visual hallucinations. Denies anxiety. Sleep within normal limits.

Q Okay. And at that point you continued with the injection of Haldol, correct?

A Correct.

Q And then you also continued with Prozac?

A Correct.

Q And who started the Prozac?

A She was on the Prozac on page 69.

Q I guess the question is, did you initiate the Prozac?

A She had a hospitalization apparently ending around March 2nd as denoted in page 67. I believe it

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was during that hospitalization that the Prozac was started.

Q What would be the purpose of giving both Haldol and the Prozac? What would be the function of the Prozac?

A Well, if her predominant mood state at the time was depression, then it can be argued that an antidepressant is warranted.

Q All right. If we jump then to page 74, it looks like this was around the time that Mrs. Muhammad had another hospitalization that started out at the Northwestern emergency room?

A Yes.

Q And I believe this is the one where you were on call and actually saw her in the emergency room?

A It appears that way, yes.

Q And I believe as a result of that she was involuntarily hospitalized?

A I don't have the emergency room records. I would have to find that. She was hospitalized, yes. Whether it was involuntary or not, I don't know.

Q I have an excerpt from another document. It might be easiest to give it to you and we can mark

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it.

MS. KANER SOCOL: Do you have a page number?

MR. LUNDBLAD: You know, it is from a different place. I have front to back marking or copying which I probably shouldn't do. Anyway, mark this as Exhibit 12. Plaintiff's Exhibit 12.

MS. KANER SOCOL: Should we make a copy of this?

MR. LUNDBLAD: Yeah, that might be easiest.

(Short break taken.)

BY MR. LUNDBLAD:

Q We're at page 74 of Exhibit No. 2 and this is where you made the notation. What was going on with Mrs. Muhammad as of that date? And it was April 19th, 2005. It might be easiest just read into the record your note from 11:00 a.m. on that date.

A Yes. I personally saw patient on presentation to Northwestern Memorial Hospital ER on the morning of April 17th while on call. Patient appeared greatly distressed. Tearful. Unable to respond to most questions appropriately. Apparently was upset that her boyfriend stole some money. Also endorsed anger at husband and thoughts of harming husband and children with a knife. Patient appeared grossly psychotic with thought blocking. Patient was

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transferred to outside hospital. Will follow.

(Plaintiff's Exhibit 12 marked.)

MS. KANER SOCOL: Can you read back what Dr. Stepansky was reading before?

(Record read as requested.)

BY MR. LUNDBLAD:

Q What was the outside hospital? It looks like River Edge?

A River Edge. Yes. In the next part of the note it does say River Edge.

Q You have now in front of you what has been marked as Exhibit 12. Is this a note that is in your handwriting?

A Yes.

Q And this appears to have been dated April 17, 2005, 7:30 a.m.; is that right?

A Yes.

Q And this was a certificate for an involuntary admission for Mrs. Muhammad?

A Yes.

Q And it appears you were the physician who completed the certificate?

A Yes.

Q And what is the reason that you stated that

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she needed to be kept in involuntarily?
A The patient has a history of schizoaffective disorder and presents complaining of depression and expressing thoughts of harming her husband and her two children with a knife. She appears acutely depressed, tearful, disorganized. Patient requires emergent psych hospitalization for safety.
Q Okay. And if you turn to the next page of Exhibit No. 12, again, is this in your handwriting?
A The next page, yes.
Q And in the middle it says mood/affect and what do you have there?
A Mood, depressed. Affect, congruent, tearful.
Q Is there an indication as to what medications that she was on at this time? If we go to the page it has page 10 at the bottom it has a fairly long list of medications.
A I believe this was a history taken from somebody else who signed this page and this is listing all previous medications going back to the past, not present medications.
Q Okay. And one of the medications listed

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there was Depakote?
A Yes.
Q Do you know where or who prescribed the Depakote?
A I don't have independent knowledge, but in some document I saw that that was in a 2002 hospitalization. I would have to find that though.
Q That was long prior to your involvement with Mrs. Muhammad?
A Yes.
Q All right. If we go to the next page, page 11, it has Haldol IM and Zoloft. Do you see that?
A Yes.
Q And that's the current medications. That's what she was on at the time she came to the hospital?
A That should be what is denoted there. Why it says Zoloft instead of Prozac, I do not know.
Q What is the difference between Zoloft or Prozac?
A They're both antidepressants but they're different medications. Prozac is fluoxetine. Zoloft is sertraline.
Q Is Zoloft a medication that can be used to treat the conditions that Mrs. Muhammad had?

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A Zoloft is an antidepressant that can be used for someone with depression.
Q All right. Is that something that can be used with the type of disorder that Mrs. Muhammad had in addition?
MS. KANER SOCOL: Objection as to what time frame I guess.
MR. LUNDBLAD: I'll withdraw it as I don't think it's important.
BY MR. LUNDBLAD:
Q So as a result of this it appears that you made a report to the Department of Children and Family Services. We're back on page 74 of Exhibit 2; is that correct?
A Correct.
Q And it looks like on page 75 you noted your conversations with someone from the department -- from DCFS, correct?
A Correct.
Q All right. And at the very bottom it says -- what is the last line on page 75?
A Discussed above with Dr. Brontman who agrees.
Q Okay. And what was your plan of action

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that she agreed with or is it just the reporting to DCFS?
A The reporting to DCFS and the plan to -- it says above that they reported investigation will proceed within 24 hours, so I was discussing all of the above with Dr. Brontman.
Q Okay. It looks like the next time that you saw her after this episode and hospitalization was not until it looks like May 2nd. We're on page -- I'm sorry. Your next note is page 78. It is an April 28th, 2005 note.
A Yes.
Q And it appears that as of that date Mrs. Muhammad was still at Glen Oaks Hospital?
A That she had been transferred there. Correct.
Q Okay. And then the next page, page 79, it looks like you were contacted by a psychiatrist from Glen Oaks?
A Yes.
Q And can you read your note on page 79 into the record, please?
A Contacted by Dr. Bowden, patient's psychiatrist at Glen Oaks Hospital. He had planned

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to discharge patient home April 30. He was evidently unaware of events that had transpired at River Edge especially at the ongoing concern for patient's children's safety, the need to have family meeting to discuss DCFS reporting or that she had received a Haldol Dec injection at River Edge. When informed that writer had reported case to DCFS and patient's children's safety was active issue, Dr. Bowden agreed to postpone discharge and recontact me prior to discharge. Dr. Bowden was reached at (847)975-7911.

Q Okay. Your next note underneath that is May 5th. Can you read that into the record, please? In the column at the left you have 5-5-05 late for 5-4-05. What do you mean by that entry where you say late?

A Well, the incident that I'm writing about happened on 5-4, but I could not document it until 5-5.

Q All right. And can you read into the record that note?

A Contacted by it looks like Barry Philips, social worker at Glen Oaks, who stated that patient will be discharged on May 4th, '05. Had Dr. Bowden call me. Per Dr. Bowden, DCFS assessed situation and

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no intervention was deemed necessary. Dr. Bowden stated that husband was involved in discharge planning. Dr. Bowden stated patient endorsed no acute homicidal suicidality and was stable for discharge. Home May 4th, '05.

Q And then it looks like she came in and saw you next on May, is that May 10th?

A Yes.

Q All right. Can you read where it says subjective objective into the record? What did you write?

A Quote, I'm happy. I was happy to leave hospital, end quote. Denies depression, anger, hopelessness. Complains of blurred vision and shaking. States that she was admitted to hospital after son stole things from store and this, quote, upset her. Less stress because of babysitter helping two to three times a week. No thoughts of harming children. No suicidal ideation. No auditory visual hallucinations. Patient quit job secondary to too much stress, in quotes. Denies any current stress with husband. Positive galactorrhea.

Q What did you mean by that?

A Galactorrhea is milk production of the

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breast which can be a side effect of Haldol.

Q What about blurred vision or the shakiness, are those also side effects of Haldol potentially?

A The shaking, yes. Blurred vision, I would rather not comment on.

Q All right. Under your assessment and plan what did you write there?

A Schizoaffective disorder. Discontinue PO Haldol. Start Risperdal taper to 3 milligrams PO QHS. Continue Prozac. Reduce Cogentin to one milligram PO QHS. Follow up with Dr. Peden. Gave appointment slip for PAC appointment June 14th, '05. Appointment with Dr. Dago May 19th, 8:00 a.m.

Q All right. Why did you discontinue Haldol on that date?

A It appears because of the side effects.

Q Okay. And why were you tapering the Cogentin then?

A I believe Cogentin could be associated with blurred vision.

Q And then you started the Risperdal in place of the Haldol?

A Correct.

Q And then you continued with Prozac?

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A Correct.

Q And then it says there at the bottom that you gave the order for PAC. Do you see that, the PAC appointment?

A Yes.

Q What does PAC stand for?

A I believe it is the obstetrics clinic or GYN clinic, but I'm not certain what PAC stands for.

Q Do you know why she was referred to the obstetric clinic or gynecology clinic?

A I have no independent recollection.

Q If you could turn back to page 76, this is a note by your colleague Dr. Peden. Do you see there about a little over halfway down the sentence starts out, patient still has not understood need for new gynecologist. Writer called PAC for her to looks like something appointment and explain need. Explain to patient she must stay on patch and is -- I'm not sure. Something about desperate to have more children. Also had husband come in and explained clearly and forcefully to him that patient is in danger of killing children when she is sick. And then it says told him that he must take her to PAC appointment.

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Were you aware of those events and conversations?

A Given my interaction with Dr. Peden and my reviewing of her detailed notes, I would have been aware. I have no independent knowledge of that.

Q All right. And right before that where I started reading, and I apologize, I should have started there, it says patient then something about the birth control patch had not been renewed. Do you see that?

A Where is that?

Q It is right before I started reading where it says patient still has not understood need for new gynecologist. The sentence immediately preceding that it says patient then something birth control patch not been or not being renewed. Do you see that?

A It appears to say that, yes.

Q All right. so you were aware then that as of May Mrs. Muhammad appeared not to have a gynecologist to be providing her with means of preventing another pregnancy, correct?

MS. KANER SOCOL: I'm going to object. Don't guess or speculate. If you know.

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BY MR. LUNDBLAD:

Q All right. You told us it was your custom and practice that you would review Dr. Peden's notes, correct?

A Yes.

Q And so based on your custom and practice you would have read her note from May 9th that we just went through on page 76, correct?

A Yes.

Q Okay. And, in fact, in the second line it says that Mrs. Muhammad was going to see you on the following day, correct?

A Where does it say that?

Q It says appearance something mood elevated something and then will see Dr. Stepansky tomorrow.

A Yes. Yes.

Q And if you look on page 77, it says that PAC at the bottom there again another note by Dr. Peden, it says PAC called with appointment for June 14th, 2005 at 1:30. They also called Osco, renewed patch for two more months. And then it says writer left appointment slip with Dr. Stepansky, meaning you. And we note from the following note that you apparently saw what Dr. Peden had left you

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and you, in fact, then called PAC to set up and confirm the appointment, correct?

A Well, it says I gave the appointment slip for PAC, yes.

Q Okay. So based on your custom and practice, you would have been aware of the events that were documented by Dr. Peden?

A Yes.

Q Okay. Then if we move on, the next note I believe is page 81. Page 81 looks like a note from May, is that, 23rd?

A Yes.

Q And can you just read into the record what you note?

A Contacted Elysia Childs (773)866-5756, the DCFS investigator involved with the case. She stated that she did meet with patient while patient was still hospitalized. She has not yet successfully met with husband. She intends several more attempts at outreach and anticipates the evaluation, slash, recommendations will be complete in the next two weeks.

Q Okay. And on the next page it is the end of a note by your colleague Dr. Peden and her last

Page 53

line is advise Dr. Stepansky of all the above issues, correct?

A Correct.

Q Do you have any recollection of a conversation you had with Dr. Peden regarding her note?

A Not this particular conversation.

Q All right. Now the next note is page 85. This is another one of your medication review appointments with Mrs. Muhammad, correct?

A Yes.

Q The date was May 24th, 2005?

A Yes.

Q Can you read into the record what you wrote at the top?

A Patient reports return of tremor in last 24 hours. Yesterday had some difficulty getting out of bed. Today no problem getting out of bed. Had brief argument with husband in past week but now resolved and they have apologized. Sleep through night without problems. Appetite within normal limits. Eating something. That's cut off. Feels like she thinks clearly with Risperdal. No suicidal-homicidal ideation. Denies depression, anxiety, euphoria,

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irritability.
Q So this is now approximately -- well, it is 20 days after she was discharged from the hospital, correct? Your notes reflect she was discharged on May 4th.
A That's correct.
Q And so at this point she seemed to be stable?
A Yes.
Q Now, on the lower right hand part there when you're talking or evaluating formal thought disorder, what did you write? It looks like more?
A More organized, slash, coherent than last appointment but still somewhat disorganized.
Q Okay. And what do you mean by that evaluation?
A That there was some improvement in her thought process as I met with her.
Q All right. And at this evaluation this is when you started the Depakote; is that correct?
A Correct.
Q And why did you stop or -- Strike that.
Why did you start Depakote on this date? What was your reasoning?

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A I don't have independent knowledge of my discussions with Dr. Brontman, but there would have been discussions with Dr. Brontman, my supervisor, about starting a medication to prevent further episodes, a prophylactic medication. The nature of bipolar illness are periods of apparent stability, symptoms are minimal, but they can resurface and we know from the prior five months she had gone through quite a few such cycles and so Depakote would have been started at this point to prevent further cycling of her bipolar disorder.
Q Can you read into the record what you wrote under your A and P?
A Schizoaffective disorder. Start Depakote 500 BID. Check level. Return to clinic one week. Risks, slash, benefits of med discussed. Written info given. Specifically informed patient of teratogenic potential. Liver, pancreatic, hemo effects. Continue Risperdal, Prozac, Cogentin.
Q Now in that note is there any documentation of your rationale for giving the Depakote that you just explained to us?
A It is not clarified in the note.
Q And is there any documentation in your note

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that you discussed starting Mrs. Muhammad on Depakote with your supervising physician?
A That is not in the note.
Q And then it says that you advised Mrs. Muhammad of the potential teratogenic effects of Depakote; is that correct?
A It says specifically informed patient of teratogenic potential.
Q And do you recall what it was you would have told Mrs. Muhammad?
A I don't have an independent recollection. I have my custom and practice regarding Depakote which is to speak about neural tube defects and spina bifida and neurocognitive effects.
Q And according to your note when you were having this discussion you had that discussion with Mrs. Muhammad alone and not also with her husband, true?
A The note doesn't clarify that. My recollection would be all of these sessions were with Ms. Muhammad and Ms. Judy Wilson always.
Q And not Mr. Muhammad?
A And not Mr. Muhammad.
Q All right. You said you gave some

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literature or some paperwork. What was it that you would have given her?
A There was a sheet of information for all medications that were being discussed with patients that the rehabilitation clinic had and I would have given her the one for Depakote. And I believe I saw a copy of that as part of the record.
Q Now, in your note here do you have any notation -- Strike that.
As part of your discussion with Mrs. Muhammad, did you tell her that she should not get pregnant while taking Depakote?
A Yes. As part of teratogenic potential, I would say getting pregnant would equal high risk for teratogenic potential.
Q All right. Is there anything in your note documenting what means of birth control that Mrs. Muhammad was using as of that date?
A It is not specified in this note.
Q Is there anything in this note indicating whether or not Mrs. Muhammad and her husband were using condoms when they engaged in sex?
A There is nothing in this note about that.
Q Is there anything in your note recommending

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or advising the Muhammads to use condoms during sexual activity?

A There is nothing about that in this note.

Q And then when or -- Strike that.

Before you prescribed the Depakote, did you consider prescribing lithium as an alternative?

A I have no independent recollection of that, but it is my custom and practice of when considering a mood stabilizer to consider lithium.

Q And why did you choose Depakote over lithium?

A I have no independent recollection of this, but in my training and part of my studies in residency it was thought that Depakote is the medication of choice for bipolar disorder with rapid cycling. When there are more than four episodes, four mood episodes in a year, rapid cycling bipolar disorder, Depakote is thought to be more effective.

Q If you were to compare lithium versus Depakote, which of the two has the potential for greater teratogenic harm?

MS. KANER SOCOL: I'm going to object to the question. Lack of foundation. If you can answer it, if you think that you're an expert in

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pharmacological --

THE WITNESS: I would say that to my knowledge both are Category D pregnancy risk medications which means both -- in both medications risk to the fetus has been proven, but the benefits of such a medication could potentially outweigh such risk and they are both in that same category.

BY MR. LUNDBLAD:

Q Now based on the discussion we had a few minutes ago regarding notes of your colleague about Mrs. Muhammad not having a gynecologist, about needing a prescription to continue her patch for birth control -- let me strike that.

Obviously when you prescribed the Depakote you knew that Mrs. Muhammad was of an age that -- a childbearing age, correct?

A Correct.

Q And you knew that she had already had two children, true?

A Correct.

Q And one child was what, I think a little more than a year old at that point?

A I would have to confirm that, but about that age, yes.

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Q And to your knowledge Mrs. Muhammad and her husband were sexually active, correct?

MS. KANER SOCOL: I'm going to object. If you know. It calls for speculation. Lack of foundation.

THE WITNESS: No knowledge of that.

BY MR. LUNDBLAD:

Q Well, before prescribing Depakote wouldn't you inquire as to whether or not the Muhammads were sexually active?

A I would have confirmed that regardless of their sexual activity that she had a birth control method in place of some sort.

Q Okay. Now, when you're prescribing Depakote, I think you said, you told us as part of your custom and practice you would advise a female of childbearing age that they should not get pregnant while taking Depakote, correct?

A Can you rephrase the question?

Q Sure. You told us that as part of your custom and practice you would have advised Mrs. Muhammad not to get pregnant while she was on Depakote, true?

A Well, I would have been very clear about the risk to the pregnancy and therefore her need to

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not get pregnant to avoid the potential risks.

Q All right. So it would be your recommendation to your patient a female of childbearing age on Depakote to avoid getting pregnant?

A Yes.

Q And in order to avoid getting pregnant and if your patient, female patient is sexually active, that that patient would need to use some form of birth control to prevent pregnancy, correct?

A Yes.

Q And the person, the female patient would have to be capable, would she not, of being able to follow directions and use birth control as directed to prevent pregnancy?

A Yes.

Q And you knew from our prior discussions that a few weeks earlier Mrs. Muhammad did not have a gynecologist, right?

A As of that particular time, correct.

Q And the note from Dr. Peden indicated that Mrs. Muhammad did not understand that she needed a gynecologist. Isn't that what was written down?

MS. KANER SOCOL: I'm going to object.

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THE WITNESS: I think it was phrased differently in her note.
MS. KANER SOCOL: Lack of foundation. Misstates the record.
MR. LUNDBLAD: I'll withdraw the question.
BY MR. LUNDBLAD:
Q When you prescribed the Depakote on May 24th of 2005, did you inquire as to whether or not Mrs. Muhammad was using some form of birth control?
A It would be my custom and practice to do so.
Q Is there any place documented in your note your inquiry and her response as to whether or not she was using birth control?
A Not in this note.
Q Now from the prior notes you knew that she had been using a patch for birth control and that there was a note indicated that the PAC had issued a prescription for a two-month renewal of the patch. Did you -- when you were talking with Mrs. Muhammad, did you ask to see the patch and determine whether or not she, in fact, was using it?
A I do have independent recollection of asking to see her patch multiple occasions because

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that is something that I don't often do which is why I think I recall it.
Q And well your -- there's no documentation in your note that you looked and actually observed that she had a patch on as of May 24th, is there?
A On this note, it is not specified in the note.
Q Okay. Now, you described before how Mrs. Muhammad was in the rehabilitation section of the practice and that's because she had a more severe mental illness, correct?
A Yes.
Q And you told us about how she had had what, three or four hospitalizations in the year 2005 up until May; is that correct?
A Correct.
Q Was Mrs. Muhammad capable of properly using birth control preventing pregnancy at the time that you prescribed the Depakote?
A Well, the nature of bipolar illness is that if she is within an episode, a mood episode, her capacity could potentially be impaired to give consent. At this point she was out of the hospital and she was not in the midst of an acute episode and

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that capacity could very well be present and I would have in my custom and practice would have assessed for that.
Q All right. It's a little bit different question, but a question I was going to ask. And that -- the question is, was Mrs. Muhammad capable of understanding your warnings to her about the potential teratogenic effect of Depakote when you prescribed it on May 24th?
A I have no independent recollection, but given that I did prescribe it and I would have had to be comfortable with my clinical assessment that she did understand what I had to say.
Q But the question I asked previously, which you did not answer directly, and you may have misunderstood my question, and that is, based on the history that Mrs. Muhammad had with the degree of her mental illness, was she capable as of May 25th, 2005 of following direction and using birth control as directed to prevent pregnancy?
A I believe she was.
Q Isn't it true that during the time that you had been treating her or dealing with her there was issues as to whether or not she was compliant in

Page 65

taking her medications?
A Compliance was frequently assessed. I'm not sure which note you're referencing where compliance was an issue.
Q Okay. The fact the Haldol was given as a shot as opposed to a pill, was the reason for doing that because Mrs. Muhammad was not compliant in taking her Haldol as directed?
MS. KANER SOCOL: I'm going to object. Lack of foundation and calls for speculation unless you have an understanding.
THE WITNESS: That was started by another psychiatrist for any number of reasons.
BY MR. LUNDBLAD:
Q Okay. The cycling that you referred to and the fact that she had these episodes that required hospitalization, do you know if those episodes were the result of Mrs. Muhammad not taking her medications as directed?
A I would have to look at the timeline, but when she was on the Haldol injection, obviously her compliance was not a variable and yet she still required hospitalization, I believe. And at other times in my note I had documented that I had looked

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at her pill bottle and it appeared to reflect her compliance. So if you ask which particular -- at which particular point, it would be helpful.

Q Okay. If we could move on to page 87. Before we go to that, page 85 when you switched to Depakote, and I may have asked this already, why did you continue with the Cogentin?

A Some of the side effects of Haldol which Cogentin can help with Risperdal can also cause and I could presume that's why it was still present.

Q All right. Page 87. This is now your note from May 31st of 2005, correct?

A Correct.

Q And this is another one of your medication evaluation meetings with Mrs. Muhammad?

A Correct.

Q All right. Can you read into the record what you wrote?

A Denies depression, anxiety. Reduced stress due to babysitter taking care of kids two times per week. Sleep eight hours per night. Arguments with husband, quote, I ignore him, end quote. Feels, quote, more relaxed, end quote, with new medication. Positive weight gain, quote, 5 pounds in past week,

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end quote. Tremor has stopped. Galactorrhea is lessened. No suicidal-homicidal ideation endorsed. Patient concerned she may be pregnant, period two weeks late but has been wearing patch.

Q When Mrs. Muhammad expressed to you concern that she may be pregnant, did you advise her to stop taking the Depakote?

A At this point the note reflects that a STAT urine pregnancy test was ordered.

Q All right. She did say that her period was two weeks late, correct?

A Correct.

Q And did this cause you concern that the patch might not be effective in preventing pregnancy in Mrs. Muhammad?

A I was more concerned with getting that STAT urine test to see if this is something to be concerned about.

Q All right. How early in the pregnancy to your knowledge does Depakote potentially cause harm and cause these problems that we talked about, the spina bifida?

A I know the first trimester is the concerning -- most concerning time, but I wouldn't

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want to comment on any more specific than that.

Q Isn't it true that the first month is the most critical time?

A I can't comment on that.

Q Were you -- all right. So you ordered the STAT urine pregnancy test on that day, correct?

A Correct.

Q And where would the test have been done?

A I believe at Northwestern Hospital. I don't know specifically where the laboratory facility was.

Q All right. Now, there's no indication in your note from May 31st as to what the result of that test was, is there?

A On this note there is no result.

Q Okay. Did you advise Mrs. Muhammad to stop taking Depakote until you knew whether or not she was pregnant?

A I don't have any independent recollection of that.

Q If you as a psychiatrist having prescribed Depakote to a female of childbearing age for which there is a suspicion of pregnancy, under the standard of care, should you tell that patient to stop taking

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Depakote immediately until the pregnancy is confirmed or not confirmed?

A The negative urine test even though it wasn't noted on May 31st it was resulted on May 31st. It was noted in my note page 89. So the result was already back as of May 31st.

Q That wasn't my question though. My question was that under the standard of care for a psychiatrist if you're treating a female of childbearing age and the treatment is Depakote and there is a suspicion of the female being pregnant, to meet the standard of care, should the psychiatrist order the patient to immediately stop taking Depakote until the results of the pregnancy test are known?

MS. KANER SOCOL: Object to lack of foundation.

THE WITNESS: It is a theoretical question because there are, I suppose, clinical situations where suddenly stopping Depakote could have its own risks which could potentially outweigh the risks of continuing the Depakote.

BY MR. LUNDBLAD:

Q All right. In this instance Mrs. Muhammad had been on the Depakote a week, correct?

A Correct.

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Q And I guess or my question still is under the standard of care, under those circumstances where Depakote has been given a week and there is a suspicion of pregnancy, should the Depakote be stopped until a pregnancy test and result is obtained?

MS. KANER SOCOL: I believe that has been asked and answered.

THE WITNESS: I don't see the difference in the question I've already answered.

MS. KANER SOCOL: Okay. Can we take a short break?

MR. LUNDBLAD: Uh-huh.

(Short break taken.)

BY MR. LUNDBLAD:

Q Okay. Still on the note of May 31st, 2005, page 87 of Exhibit 2 toward the right side of the page two-thirds of way down you have VPA 5-31-05, 19.4 circled. Do you see that?

A Yes.

Q As I understand it in order to determine whether or not you have a therapeutic level of Depakote you have to measure the amount in the blood?

A That's correct.

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Q And you had labs drawn -- blood drawn on May 31st, correct?

A Correct.

Q And the finding was 19.4, right?

A Correct.

Q Is that a therapeutic level?

A I don't know what the range is for that laboratory at that time, but that would usually be low.

Q Okay. It appears that you had that value on May 31st and put it in your note, correct?

A Sure.

Q But you do not have any notation regarding the result of the pregnancy test, do you?

A Not on this note.

Q All right. Going to the bottom A and P, it looks like you increase the amount of Depakote. Why did you do that? You increase it from 500 milligrams to 1,000?

A Because of the low blood level.

Q All right. And then it says continue other meds, true?

A Correct.

Q And then it stays STAT urine. What is

Page 72

that, MCG?

A HCG.

Q H. That's the pregnancy test?

A Correct.

Q And then what is the next sentence you wrote?

A Patient informed again about VPA teratogenic effect.

Q And why did you repeat your warnings?

A To be certain that I was clear with her that Depakote has risks when used in pregnancy.

Q Then your last line under A and P, what did you have there?

A Recheck VPA and return to clinic one week.

Q Okay. Now, after the episode where Mrs. Muhammad was concerned that she might be pregnant on that day, did you consider at all switching from Depakote to another medication -- Strike that.

Did you -- after the episode where Mrs. Muhammad was concerned that she was pregnant did you have -- did you consider stopping the Depakote because of the risk of her getting pregnant and the potential harm from that Depakote?

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A I'm sorry. Can you repeat the question?

Q Sure. We talked about how Mrs. Muhammad came in and said she thought she might be pregnant because she was two weeks late with her period and as a result of that you ordered a pregnancy test, correct?

A Correct.

Q And the fact that there was a possibility that she was pregnant, did you at that point consider stopping the Depakote because of the potential risk of harm that might occur if she got pregnant?

A I don't --

Q It is a bad -- what I'm driving at is based on this sort of pregnancy scare, did you think at all about reconsidering your decision to give Depakote and to withdraw it because of the risk that Mrs. Muhammad might get pregnant?

A I don't know what I considered. My priority was to check an immediate pregnancy test.

Q Okay. On this date when there was this scare, pregnancy scare, did you consider switching Mrs. Muhammad to a different mood stabilizer such as lithium?

A I don't recall considering a change.

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Q Did you discuss with Dr. Brontman the pregnancy scare and whether or not there should be any change in the medications for Mrs. Muhammad?
A That certainly is a question appropriate for supervision. I have no recollection of that.
Q And there is no documentation in your note indicating that you discussed the issue with Dr. Brontman, correct?
A There is no clarification of that in this note.
Q All right. Moving on then to page 89. It looks like the next time you saw Mrs. Muhammad was June 7th of 2005, correct?
A Correct.
Q Can you just read into the record quickly what you wrote?
A Patient reports increased appetite with some weight gain. Sleep eight hours per night and feels increased fatigue during the day. Patient reports med compliant, continued conflict with husband but denies any major arguments or homicidal ideation toward him. No suicidal ideation, hopelessness or depression. No anger. Homicidal ideation towards children endorsed. No crying

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spells. No tremor. Galactorrhea nearly resolved. Patient not currently working.
Q All right. And then you document that the pregnancy test from May 31st was negative, correct?
A Correct.
Q But I take it you again checked the Depakote level; is that right?
A Correct.
Q And you did not get the test result while or on June 7th, correct?
A When I wrote this note. That's correct.
Q Okay. And so what was your assessment and plan?
A Schizoaffective disorder. Continue VPA, Risperdal, Prozac. Await labs. Recheck VPA. Return to clinic two weeks.
Q The recheck was that -- when you say await labs, what labs were you waiting for?
A I believe it is a recheck of the Depakote level.
Q Going to page 90, this is a note by your colleague Dr. Peden and on the note for June 16th about halfway down it says Dr. Stepansky is concerned re her Depakote level. Do you recall what your

Page 76

concern was?
A I don't know what Depakote level that is referring to.
Q All right. Same page, page 90, the next note down which is it looks like a June 20th note by Dr. Peden. At about halfway down it says writer told Ms. Childs patient is and I'm not sure what JP stands for.
A I don't know where you're at.
Q It is the next -- no. It is where your thumb is.
A Okay.
Q It talks about a conversation with it looks like with Elysia Childs and it says told Ms. Childs patient looks like is JP -- well, looks like it is struck out.
A That is her initials.
Q Right. All right. Patient, I'm not sure, talks something about children when she is symptomatic which occurs when she is off meds. Do you see that?
A Yes.
Q Did Ms. Peden ever advise you that she thought Mrs. Muhammad was not taking her medications

Page 77

as prescribed?
A I don't recall that.
Q All right. Page 92. This is your note from June 21st of 2005. Can you again just read into the record what you wrote?
A No complaints. Busy, quote, busy with children. No stress reported. Denies any conflicts with husband, children. Increased appetite. 20 pounds gain reportedly. Denies depression, sadness, anxiety. Sleeping eight to ten hours nightly. Good energy. Endorses med compliance. Denies any thoughts of harming self, husband or children. No other side effects reported.
Q The increase appetite and weight gain, did you attribute that to any of her medications?
A Yes. I certainly considered that.
Q And what medication would have that effect?
A Certainly Depakote can cause that but as well Risperdal and Prozac could do that as well.
Q All right. In the left hand margin it looks like you have a lab result for VPA, the Depakote, 29.5. Is that a therapeutic level?
A Again, I don't know what the laboratory range -- every laboratory is a little bit different,

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but I believe in most cases that would be still considered low.

Q And underneath it looks like CBC and what else, within normal limits?

A Correct.

Q What is the last one?

A U preg, urine pregnancy. Negative.

Q Did you -- does this refer to another testing?

A I believe so because we're now one month -- we're now three weeks on from the last test, so I would believe that's another test.

Q All right. And was that a test you ordered?

A I believe so.

Q And why did you order a repeat pregnancy test?

A I don't recall.

Q All right. Under your assessment and plan, what did you write?

A Schizoaffective disorder versus bipolar affective disorder. One, increased VPA to 1,000 BID given subtherapeutic level. Two, continue Prozac, Risperdal, Cogentin. Three, recheck VPA chem panel.

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Four, return to clinic two weeks.

Q All right. Now the next page, page 93, it looks like you made a note on July 5th, 2005. And can you read into the record what you wrote?

A Patient without complaints. Compliant with meds. Only adverse effects are slight fatigue, minimal breast discharge. Patient denies any stresses in home, any suicidal ideation, homicidal ideation. Mood, good, stable. Enjoys caring for children. Sleep, well. Denies anxiety, slash, mood swings. No psychotic symptoms endorsed.

Q All right. Your assessment and plan again?

A Bipolar disorder versus schizoaffective disorder. One, continue meds. Two, recheck VPA. Three, return to clinic two weeks.

Q All right. On the right side it looks like you have the results of blood work?

A Yes.

Q And why did you order a CBC?

A With Depakote you also need to get periodic CBCs to look at platelet count.

Q And it looks like you pulled out the values for liver ALT and AST?

A Correct.

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Q Is liver another potential problem?

A Exactly.

Q And the level was now 88.8. Is that a therapeutic level?

A By most laboratories I believe that would be considered therapeutic.

Q Okay. It looks like the next note, page 96 --

A 95.

Q One second here. You're right. 95 is now July 14. Can you write in -- read in what you wrote?

A No complaints. Patient described incident in which she fell asleep and awoke to find 14 month old had something, soap on his face and eyes, had to be taken to hospital but was okay. No depression, irritability, suicidal or homicidal ideation. No auditory or visual hallucinations. Minimal stress, slash, conflict in the home reported.

Q All right. In your objective it looks like you say patient difficult to follow but?

A Mostly linear.

Q What did you mean by that observation?

A That her thought process was mostly linear, mostly able to be followed and at times she was more

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difficult to follow.

Q Okay. Then page 96, that's your August 2nd, 2005 visit, correct?

A Correct.

Q And it looks like the Depakote level had dropped. It went from 88 to 29.3?

A Correct.

Q And how did you account for the drop?

A Sometimes there are fluctuations based on patient's diet or metabolism that could account for some fluctuation.

Q Can a reduction in level also be the result of a patient not taking the medication?

A It could be. Obviously she -- it wouldn't be a complete noncompliance because 29.3 is still present in her bloodstream.

Q Right. But it could reflect the patient not taking all of the Depakote as prescribed, correct?

A Potentially.

MS. KANER SOCOL: What was the date again, August?

MR. LUNDBLAD: 2nd.

MS. KANER SOCOL: Okay.

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BY MR. LUNDBLAD:
Q And it looks like now you increase the Depakote dosage from 1,000 milligrams to 1500?
A To 1,000 in the morning and 1500 in the evening.
Q Okay. And then you ask her to check -- recheck the level in five days?
A Correct.
Q Do you know if she came back to have her level checked as directed?
A I don't know. The next level is marked here as August 19th it appears.
Q What page is that on?
A 98.
Q All right. Is that August -- I have -- it says August 23rd in mine.
A That is the date of the note. The date of the blood level denoting there is 8-19.
Q And it was 54.2?
A Correct.
Q So it was higher but it had not returned to the level of 88, correct?
A Correct. But this could be within the therapeutic range. I don't know.

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Q All right. All right. Can you read into the record what you wrote on that date, August 23rd?
A Surprised by husband who bought a house on short -- a house on south side rather unexpectedly. Excited about move but concerned about transportation issues. Denies depression, anxiety, psychotic symptoms. Careful about diet, slash, exercise. Sleeping well through the night. Tolerating well meds.
Q And your objective observations?
A Smiling, cheerful, pleasant, speech. Thought process, linear. Thought content, no suicidal-homicidal ideation or auditory visual hallucinations. Insight/judgment, limited.
Q Now, again, you continued the same medications and this time you did not change the Depakote, right?
A Correct.
Q The next visit, page 99, and this is now September 13th of 2005, correct?
A Yes.
Q And it is another one of your regular medication evaluation meetings, correct?
A Correct.

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Q Can you read into the record what you wrote?
A Has recently moved to new house on south side. Has been tired recently, secondary to move. Sleep nine hours. Denies depression, anxiety, psychotic symptoms. Compliant with medications. No adverse effects. Denies anger, homicidal ideation, conflict with husband or kids.
Q Your objective observations?
A Well dressed, groomed. Speech, slash, motor within normal limits. Mood, good. Affect, overly bright. Thought process, limited. Thought content, no suicidal-homicidal ideation or auditory or visual hallucinations.
Q And it looks like the Depakote level was 60.2?
A Correct.
Q Moving forward then now we're at page 101. And now we're at -- all right. Page 101 now we're October 11th of 2005, correct?
A Yes.
Q Can you read into the record what you wrote?
A Quote, okay, unquote. No problems. Likes

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new house. Less stress. Misses downtown. Denies depression. Increased sleep to ten hours a night. Denies any thoughts of harming self or others. Appetite within normal limits. Denies any side effects. Tolerating without side effects.
Q Your observations?
A Well groomed, excessively smiling, at times incongruent with content. No suicidal or homicidal ideations. No auditory or visual hallucinations. Linear coherent thought process. Insight/judgment, fair.
Q Okay. It looks like again you had labs drawn?
A Yes.
Q And underneath where it starts with ALT, what do those abbreviations reflect?
A These are all liver tests.
Q Okay. Were her liver functions within normal limits?
A I believe so.
Q All right. Now you have the Depakote is at 120.1; is that correct?
A Yes.
Q And you circled it. Is that value high?

A It depends on the range of the laboratory. I couldn't say.

Q Okay. And what was your assessment and plan?

A Assessment, bipolar disorder I. One, continue Risperdal, Prozac, Depakote. Two, reduce Cogentin to .5 QHS given increased sleep. Three, patient reports missed period. Resistant to lab pregnancy test but agreed to take home pregnancy test and inform me of result ASAP. Patient using OCP patch.

Q And why did you want to do the pregnancy test?

A To see if she was pregnant because of her missed period.

Q Okay. And from your note you did not tell Mrs. Muhammad to stop taking Depakote on that day even though she reported having a missed period, correct?

A That's correct.

Q Now going to the next page, your colleague Dr. Peden on the 13th of October it appears that she saw Mrs. Muhammad on that day, correct?

A Yes.

Q And looks like on the first note fourth line down it says discussed missing period and confused re results of home pregnancy test. Do you see that?

A Yes.

Q Writer repeatedly urged her to go get test from doctor which patient something Dr. Stepansky?

A SS, slash, T is stated that, I believe.

Q Also what?

A Dr. Stepansky also urged.

Q Okay. Patient understood concern in taking meds if pregnant and patient agreed to call Dr. Stepansky and request referral for pregnancy test.

Did Mrs. Muhammad call you for the referral and did you provide the referral?

A Yes.

Q All right. Having referred Mrs. Muhammad for a pregnancy test, when you gave the referral, did you at that time tell Mrs. Muhammad to stop taking Depakote?

A No.

Q Now if we turn to page 103, this is another note by your colleague Dr. Peden, correct?

A Yes.

Q And it looks on the fourth line down it says patient asks re pregnancy test outcome. Do you see that?

A Yes.

Q And it says stated she went on Tuesday. And it says writer and something unable to find online. Dr. Stepansky when paged stated test positive and he had been trying to reach patient. Do you see that?

A Yes.

Q When did you become aware of the positive pregnancy test result?

A The note for me on the following page 104 says received result from lab 10-20 that patient's urinary pregnancy test was positive.

Q Okay.

A So 10-20.

Q And on 10-20 you told Mrs. Muhammad to stop taking the Depakote, correct?

A Can I read my note? Received result from lab 10-20 that patient's urine pregnancy test positive, contacted patient 10-20 and informed patient to stop Depakote and Cogentin. Patient to

increase Risperdal to 4Q daily. Will call in 1-milligram tabs for patient to take with 3-milligram tabs. Continue Prozac. Return to clinic Tuesday 10-25, 3:30 p.m.

Q How quickly is the hospital able to do a pregnancy test? Immediately? What is the turnaround?

A As I recall, it would be same day.

Q Okay. Now, again, under the standard of care for a psychiatrist, if you knew that Mrs. Muhammad had missed a period, should you have told her to stop taking the Depakote until there was a pregnancy test completed to determine whether or not she was pregnant?

A That's not the standard of care.

Q And why not? I mean, so you're saying that even if you suspect that a female patient is pregnant that it is okay to continue on the Depakote until you know one way or the other on the pregnancy?

A It could be the standard of care to maintain the Depakote.

Q Well, my question is, under the standard of care, would you agree that as soon as a psychiatrist knows that a patient is pregnant that Depakote should

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be stopped immediately?
A No. I don't believe that's the standard of care.
Q Well, in the case of Mrs. Muhammad, the moment you knew that she was pregnant in October you told her to stop taking Depakote?
A I did tell her to stop Depakote at that time, yes.
Q And you told her that -- on your note on page 104 you said that you received the result from the lab on October 20th that she was pregnant or had a positive test and on the same day, October 20th, you informed her to stop the Depakote, correct?
A Correct.
Q And you stopped the Depakote because of the potential for harm that the Depakote could cause to the fetus, correct?
A I stopped it out of an abundance of caution and until further discussion with supervisor or what have you until a final decision could be made.
Q Is there any notation by you that you spoke to any supervisor about this situation?
A I would have to review the record. I don't see that in this note.

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Q Now by this point in time you had a new supervisor, Dr. Allen?
A That's correct.
Q Is there any indication here that you spoke to Dr. Allen about the potential that Mrs. Muhammad was pregnant as of the time you knew she missed her period on October 11, 2005? Is there anything in your note from that date on page 101 indicating that you discussed the situation with Dr. Allen?
A It is not in the note. In Dr. Peden's note --
MR. LUNDBLAD: I object to the coaching here. What page are you looking at?
MS. KANER SOCOL: It is not coaching. We're just trying to get a clear record.
MR. LUNDBLAD: What page are you looking at?
MS. KANER SOCOL: My records are different.
THE WITNESS: On my note it is --
BY MR. LUNDBLAD:
Q What date?
A -- 104. Page 104 October 21st note from Dr. Peden.
Q All right. And that's a note from October 21st, correct?

Page 92

A Correct.
Q And that's already after you had Mrs. Muhammad stop the Depakote, right?
A That's correct.
Q And if we go down on page 104, you did not make a note on October 20th about the events. You again entered a late note five days after the fact on October 25th, correct?
A Correct. I should say that in the last six months of 2005 I was no longer working half time in the rehabilitation clinic. I was spending half my time at the Evanston Hospital child psychiatry program and so I was on site much less often to write notes.
Q All right. Now, in your note that you wrote on the 25th, you said contacted patient 10-20 and informed patient to stop Depakote and Cogentin, correct?
A Correct.
Q And then you say patient to increase Risperdal. Was that direction given to Mrs. Muhammad on the 20th during that same conversation?
A It appears from my note that's the case.
Q All right. And then you also told her to

Page 93

continue the Cogentin?
A The Prozac.
Q The Prozac?
A Yes.
Q And then she was to return to see you on the 25th; is that correct?
A Correct.
Q It says in the note of Dr. Peden that Dr. Allen to discuss the situation with Dr. Stepansky and try to what, change meds today over phone? Do you recall having a discussion with Dr. Allen?
A I don't independently recall that discussion.
Q And it says Dr. Stepansky may try to contact gynecologist. Is it Dr. Plower?
A It appears that.
Q Did you speak to Dr. Plower?
A I don't recall that.
Q All right. Now going to page 105, this is a note from October 25th of 2005. Can you read into the record what you wrote?
A Reports increased anxiety due to pregnancy. Six to seven hours nightly. Reports a.m. nausea, slash, vomiting. Denies depression, slash, racing

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thoughts. Compliant with Risperdal 4 milligrams and Prozac 20 milligrams. No adverse effects. Husband and patient have not yet decided how to respond to pregnancy issue. Denies suicidal-homicidal ideation or auditory visual hallucinations.

Q If a female patient becomes pregnant who is on Depakote should the Depakote be stopped immediately to prevent the potential of harm to the fetus caused by the Depakote?

A Not necessarily.

Q Why not?

A Again, it is a clinical issue as to the risks and benefits which need to be weighed and considered. And there are risks to stopping the Depakote as there is to continuing it.

Q What are the risks?

A The risks to stopping the Depakote is that another mood episode could occur which could be life threatening to herself or others.

Q Well, did you discuss the on -- when Mrs. Muhammad reported to you on the 11th that she had missed her period and you wanted her to get a pregnancy test, did you give her the option of stopping the Depakote?

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MS. KANER SOCOL: Could you read the question back?

(Record read as requested.)

THE WITNESS: I don't recall giving her the option.

BY MR. LUNDBLAD:

Q Now, would you agree that it would be the patient's choice as to whether they were going to stop the Depakote to prevent harm to their fetus knowing that it might cause an adverse relapse of her mental illness? Isn't it the patient's choice?

MS. KANER SOCOL: I'm going to object to that. Calls for speculation, lack of foundation. If you can answer.

THE WITNESS: Can you repeat the question?

BY MR. LUNDBLAD:

Q Sure. You told us that whether or not you stopped Depakote if a patient is suspected of being pregnant, a female patient, that it depends on a balancing of the risks and benefits, risk of injury to the fetus versus the benefit to the mother to control her mental illness. My question is, isn't that decision one that has to be made by the patient whether she wants to take the risk of getting sicker for the benefit of protecting her fetus?

Page 96

A It would be my custom and practice to have that discussion.

Q Now you in your other notes when you talked about the potential for teratogenic harm you noted that in your record; did you not?

A I did.

Q And in the note from October 11th of 2005, there is no mention again about discussion of the potential teratogenic harm to the fetus, is there?

A Not in this note, no.

Q Going back to page 105, your note from October 25th, you indicate there that you made an appointment with Dr. Emily Su. Dr. Su is an obstetrician who deals in high risk deliveries?

A That's what this note seems to denote. I don't know Dr. Su.

Q All right. And why did you make the appointment with Dr. Su?

A I don't know specifically why.

Q Okay. Plan No. 2 is continue what?

A Risperdal 4 milligrams QHS, Prozac 20 milligrams QAM.

Q If we look in the left-hand column there it has the date 10-18-05. Do you see that?

Page 97

A Yes.

Q And then underneath it says urine pregnancy test and it has a positive with a circle?

A Yes.

Q And does that indicate the date that the pregnancy test was done?

A It appears so.

Q All right. Plan No. 3 is will see?

A Dr. Peden, 10-27-05.

Q Plan No. 4?

A Check quant HCG.

Q What is that?

A That is a blood test to see the amount of HCG in the bloodstream which can denote how far along in the pregnancy.

Q And why did you want to determine that?

A For more information.

Q Do you know if there is any medication that can be given to counteract the potential harmful effects of Depakote on a fetus?

A I believe folic acid.

Q Did you prescribe folic acid to Mrs. Muhammad?

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A I don't know.
Q Is there any order or any note indicating that you prescribed folic acid?
A I would have to review the full record.
Q All right. But in your notes from the 11th, the 25th, and the small 25th note and the large 25th note, there is no mention made of prescribing folic acid, is there?
A I don't see that.
Q All right. Plan No. 5, what did you have there?
A Reemphasized risk of teratogenicity with VPA, parentheses, birth defects including NTD, closed parentheses. Patient expressed understanding.
Q What does NTD stand for?
A Neural tube defects.
Q And why did you repeat this or why did you reexplain the risks to Mrs. Muhammad after you had stopped the Depakote?
A Well, again, to remind her that Depakote in pregnancy can cause birth defects.
Q If we could turn to page 106, this is a note again of your colleague Dr. Peden from October 27th. And in the first line it says eager to

Page 99

know results of second pregnancy test. Writer paged Dr. Stepansky, no results --
A Yet.
Q -- yet. Dr. Stepansky will call patient by end of day tomorrow. So on the 25th did you order a repeat of the pregnancy test?
A This may be the quantitative HCG, No. 4 in the plan.
Q Okay. And would that test -- Strike that. Isn't it true that sometimes there are false positives with pregnancy tests?
A Yes.
Q The quantitative HCG test you ordered was that in part to also confirm that Mrs. Muhammad was pregnant?
A Yes.
Q All right. Page 108. November 8th of 2005. Can you read into the record what you wrote?
A Reports increased fatigue secondary to pregnancy. Had headaches previously but resolved. Some increased frustration with her children. Sons are constantly fighting. Denies depression, anxiety. Endorses that she is looking forward to new baby. Reports mild tremor last week now resolved. No

Page 100

dystonia. Increased appetite. Sleep 11:00 p.m. to 11:00 a.m.
Q All right. And your objective observations?
A Well groomed, euthymic, bright affect. Thought process, organized, slash, linear. No suicidal-homicidal ideation. No auditory visual hallucinations. Insight/judgment, fair.
Q When you say euthymic, what is that?
A Feeling good. Good mood.
Q Okay. Your plan?
A One, continue Risperdal. Given patient's prior decompensation when treated with typical antipsychotic, benefit of using atypical likely high. Patient explained of no proven risk of Risperdal in pregnancy despite limited data in literature. Patient agreed to continue with Risperdal. Patient informed again of risk of teratogenicity of VPA.
Q Okay. When you say typical medication, what do you mean by that?
A That refers to older antipsychotic medication such as Haldol.
Q Okay. And why did you think that she would benefit more from Risperdal?

Page 101

A The atypical antipsychotics do have some mood stabilization effects which the typical antipsychotics do not.
Q As of this date when you saw her was her condition stable, her mental condition?
A At this point it appears she is -- her symptoms are controlled.
Q Now, under Plan No. 1, why did you again inform Mrs. Muhammad of the risks of teratogenic harm from the Depakote?
A Well, again, to remind her that even though she was no longer on it that she was pregnant while taking it and therefore the risk is there.
Q Did you ever counsel Mrs. Muhammad to abort the fetus?
A I have no recollection of that.
Q No. 2 under your plan?
A Continue Prozac. Patient informed of known safety of Prozac in pregnancy.
Q No. 3?
A Obstetric high risk appointment November 10, 12:30 p.m.
Q And then she was to return to see you in what, two weeks?

A Two weeks.
Q It looks like the two week visit occurred on November 22nd. It is page 110.
A Yes.
Q Can you again read into the record what you wrote?
A Quote, I'm okay. Reports headache times one hour after taking Risperdal doses. Reports fatigue. Increase sleep. Sleep 10:00 p.m. to 11:00 a.m. Denies depression, anxiety, irritability. Appetite decreased since DC Depakote, discontinuing Depakote. Upcoming OB appointment 12-7. No pregnancy complications. No suicidal-homicidal ideation. No symptoms of mania or psychosis.
Q Your objective finding?
A Well dressed, slash, groomed. Mood, good. Affect, somewhat inappropriately elevated. Thought process, linear. Thought content, no suicidal or homicidal ideation. No auditory visual hallucinations. Insight/judgment, fair.
Q And your assessment?
A Bipolar disorder I. Stable. One, continue Risperdal. Two --
Q If I can interrupt. On your assessment,

stable, that meant based on your observations and her report to you subjective you found her to be stable, correct?
A Correct.
Q So your Plan No. 1 was?
A Continue Risperdal. Two, BID. Patient advised to split tabs to make dose one QID if helps with headache.
Q And so the Risperdal at least to this point was maintaining her stability?
A At this point.
Q No. 2?
A Continue Prozac 20.
Q No. 3?
A Patient informed once again of the following risks, colon, one, pregnancy is high risk time for precipitating episodes of depression, mania, psychosis in patients with bipolar disorder. Two, fetus has been exposed to Depakote prior to DC of VPA. Three, Risperdal has limited data demonstrating safety in pregnancy. Patient aware and acknowledged understanding.
Q And, again, why were you repeating the information regarding the Depakote and the

teratogenic effect?
A To remind her that she was taking Depakote at the time of pregnancy and that there are risks of using Depakote in pregnancy.
Q All right. And the last sentence you wrote?
A Return to clinic four weeks.
Q Okay. What, the patient aware and --
A Acknowledged understanding.
Q Going back to the first one you said, pregnancy is a high risk time for repeating episodes?
A Precipitating episodes.
Q Okay. Why is that? Why does it happen -- what -- why is there an association between pregnancy and repeating episodes or precipitating episodes?
A The hormonal changes in pregnancy are -- both in pregnancy and in the peripartum and postpartum periods the hormonal changes are thought to contribute to mood episode onset.
Q The precipitating episodes caused by hormones, is that something that likely is to occur later in the pregnancy or does it not -- does it matter?
A I can't comment on that.

Q If we can go to page 111. It is a note by your colleague Dr. Peden from November 28th of 2005. It says patient and husband here to meet it looks like with writer and Dr. Stepansky. Do you recall participating in such a meeting?
A I referenced earlier that November 30th episode which is written about on page 112. I didn't know there was a separate meeting on the 28th. I didn't recall that. I do remember meeting with them with Dr. Peden.
Q Okay. All right. So on November 30th you had a meeting with Dr. Stepansky -- I am sorry. You, Dr. Peden and both Mr. and Mrs. Muhammad, correct?
A Yes.
Q And there is a note written by Dr. Peden on page 112. What went down at this meeting? What happened?
A I don't remember apart from what is written in this note. I would have to read it.
Q Okay. As a result of this session Mrs. Muhammad went to the emergency department?
A That is correct.
Q I believe she was, in fact, admitted and treated at Northwestern?

Page 106

A That's what it says, yes.
Q Did you participate at all in her treatment at Northwestern?
A Usually I did not have care of a patient on the inpatient unit. That was left for the inpatient team.
Q All right. Going ahead, page 114. We have a note December 13, 2005. Again, this is your note from one of your regular meetings?
A Yes.
Q And, again, can you read into the record what you wrote?
A Patient discharged from 8 West on Friday 12-9-05. Patient able to describe reason for admission, colon, anger towards her husband over babysitting coverage and resultant suicidal ideation in reaction to this anger. Patient currently denies any depression, slash, anger, slash, irritability. No suicidal ideation. Patient reports she is excited to be pregnant and does not want to learn sex of baby until delivery. She wants to have this baby and wants tubal ligation after delivery. She reports sleeping well. Patient expressed interest in getting Risperdal Consta injection.

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Q All right. What is the injection?
A That is a long acting formulation of the Risperdal medication.
Q And why was that being offered?
A I don't know specifically why other than to reduce the need to remember to take a daily medication.
Q Do you recall if there was indication that she was not being compliant with her medication?
A I don't see evidence of that.
Q All right. Your observation?
A Well dressed, slash, groomed. Spanish accented, poor grammar. Mood, okay. Quote, okay. Affect, ebullient. Thought process, linear. Thought content no suicidal-homicidal ideation or auditory visual hallucinations. Insight/judgment, limited.
Q Your observation -- your plan?
A One, continue oral Risperdal 2 milligrams PO BID. Two, patient agreed to Consta, will give first IM, intramuscular, injection today 25 milligrams. Three, high risk OB clinic appointment 12-14-05. Four, Dr. Peden appointment 12-19-05.
Q All right. So on that day she was given an injection of the Risperdal?
A According to the note from my nurse Judy Wilson.
Q Why were you doing both by mouth and the injection?
A When you begin the IM injection, you need to remain on the oral medication for a period of time for the blood level to get to the appropriate level before you taper off the oral medication.
Q The next thing of consequence, page 116. It is a typewritten form dated January 3rd of 2006, correct?
A Yes.
Q And it looks like basically a letter addressed to Ms. Angie Muhammad?
A Yes.
Q And on that date you were recommending that she start taking lithium; is that correct?
A That is correct.
Q And why was lithium being recommended?
A Again, I believe it was because a mood stabilizer was still warranted to prevent further mood episodes. Risperdal is not a mood stabilizer with the effectiveness of lithium.

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Page 109

Q Okay. And in this letter there was a paragraph that talks about the potential adverse reactions, correct?
A Correct.
Q And it lists a long litany of things that can happen. Then it talks about more serious adverse reactions including kidney toxicity, thyroid disorders and cardiac arrhythmias, correct?
A Correct.
Q And then it talks about how you would be monitoring blood levels with lithium with frequent blood tests. Lithium toxicity could result in kidney failure and seizures. And then the last paragraph it says that lithium is known to increase the risk of congenital malformations in a fetus when taken by pregnant patients. In particular, lithium is known to increase the risk of cardiac malformations. These risks are thought to be greater when it is administered in the first trimester. You must be aware of these potential risks to the fetus. By this time had -- Mrs. Muhammad had passed through the fist trimester; had she not?
A I believe so.
Q So as stated here the risks of

Page 110

malformations is lower as the pregnancy progresses?
A Correct.
Q Do you recall why you created this document and had Mrs. Muhammad sign off on it?
A I believe it was at the instigation of Dr. Allen who wanted this document.
Q Okay. Do you know if doctor -- Strike that.
Who made the decision to recommend the lithium?
A I believe that was in my discussions with Dr. Allen, who I believe also had discussions with other colleagues about the case.
Q Okay. Do you know where -- Strike that.
I guess I can answer my own question. On page 117 it looks like you saw Mrs. Muhammad on January 3rd, 2006?
A I believe this was my final meeting with her.
Q All right. Did you present the document we just went through to have her sign it?
A Yes.
Q Do you know was Mr. Muhammad present when you went through this document and had her sign off

Page 111

on it, the acknowledgment about the risks of lithium?
A I don't recall that.
Q All right. Going to page 117, can you read into the record what you wrote?
A Quote, I'm fine, end quote. New babysitter something helped alleviate stresses of babysitting. Compliant with PO Risperdal. Able to sleep through the night. Reports no mood swings, depression, anger, irritability. No suicidal or homicidal ideation. Denies racing thoughts. Reports having felt better with husband's friend having moved out of the house. No adverse effects.
Q Your observation or did you complete --
A Well groomed. Talkative but not pressured. Mood, okay. Affect, bright. Thought process, linear. Thought content, no suicidal or homicidal ideation. No auditory visual hallucinations. Insight, fair. Judgment, fair.
Q Your assessment?
A Bipolar disorder I. Most recent mixed. Plan --
Q Before you get there, what do you mean when you say "most recent mixed"?
A Mixed episode. A mixed episode has

Page 112

characteristics of both a depressive episode and a manic episode.
Q All right. Your Plan No. 1?
A One, continue Consta 25 milligrams intramuscular Q 2 weeks. Two, continue Risperdal 2 milligrams PO BID will begin to taper after next week. Three, discussed risks, benefits, side effects, profile of lithium. In particular discussed teratogenic potential. Patient signed consent to trial. I believe patient currently has capacity to give consent. Four, check lithium level 1-9 or 1-10. Five, return to clinic 1-10. Six, aware of change of M.D. Seven, will discuss with Dr. Jill Guelich, OB/GYN 5-6427.
Q And what was the reason for the discussion with Dr. Guelich?
A It would likely be about the fact that we were starting lithium so that she was aware of that.
Q Now, when you started Mrs. Muhammad on Depakote, you did not create a similar document to have her sign off on as you did with the lithium; is that correct?
A That's correct. Dr. Brontman did not instigate such a document more than the written

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information that the rehabilitation program had supplied.
Q So your short answer is no, no such document was created and signed?
A That is correct.
Q Now, it says No. 6, aware of change of M.D. What does that refer to?
A So the end of this calendar year brought an end to my involvement with the rehabilitation medication panel and a new resident one year behind me would be picking up my caseload for that program.
Q Okay. Going to page 119, it appears that you did sort of a summation?
A Correct.
Q Is this something that was typically done by residents?
A Yes.
Q Going to the middle, you did some labs?
A Yes.
Q And what was the purpose for doing the labs?
A Well, the second set of labs is -- I'm sorry. This is from November 30th. So given that she is on lithium -- I'm sorry, on Risperdal, we like

to monitor blood sugar and lipid panel. So that's why an A1C, which is a blood sugar laboratory. And presumably knowing that she would be put on lithium, we wanted to get a creatinine to see how her kidney function was and her thyroid to see how that was.

Q Was there any test result as of that date regarding the lithium level?

MS. KANER SOCOL: Which date?

MR. LUNDBLAD: The date of this report of January 10, 2006.

THE WITNESS: No. The labs that are referenced are from November 30th and June 7th. There are no January 2006 labs.

BY MR. LUNDBLAD:

Q All right. Then underneath there you have your diagnoses?

A Yes.

Q And when you say possible cluster B traits, what do you mean by that?

A Well, that is in reference to -- cluster B is a group of personality disorders. Axis II used to be used in the previous DSM to denote personality disorder diagnosis. So when you say traits, it does not imply that she has a personality disorder

diagnosis but she may have had traits of such.

Q And under Axis IV you have chronic illness H, slash, O stands for history of?

A Yes.

Q And it says history of med noncompliance, correct?

A Yes.

Q And that would mean noncompliance with taking medications?

A Yes.

Q And then childcare stressors. And then Axis V you have 45. What does that mean?

A So in the previous DSM Axis V was a global assessment of functioning which was a number from 0 to 100 to summarize a patient's overall psychosocial functioning. Typically less than 30 implies need for hospitalization. Less than 50 means unable to work. And every number has sort of a place along that spectrum of functioning.

Q And what would be the average or cutoff for someone who is functioning in society, holding a job?

A Well, if you're holding a job you would have to be at least in the 50s.

Q And if you're free of mental illness, where would you score then?

A 60s and higher. This is a parameter that is not used anymore in the current DSM though to be clear.

Q All right. And then your plan?

A Begin taper off of oral Risperdal as she continues Consta injections. Two, monitor lithium levels closely and adjust dose as needed. Follow labs per protocol. Three, patient's OB/GYN is Dr. Komal, K-o-m-a-l, Bajaj, B-a-j-a-j, pager 5-0838. I have spoken with her regarding lithium administration. She advises that a document be placed in power chart detailing our recommendations for lithium discontinuation during peripartum period to prevent neonatal lithium toxicity. Discussed with Tom Allen.

Q All right. The last part where it says placed in a power chart detailing recommendations for lithium discontinuation, was such a document created?

A I don't remember.

Q When it says discuss with Dr. Allen, what were you going to talk to him about?

A Talk to him on my liaison with the OB/GYN.

Q Do you know who it was that took over for you after you left?

A I believe it was Dr. Jeffrey Mudrick, M-u-d-r-i-c-k.

Q Did you know that Mrs. Muhammad was diagnosed as having a congenitally deformed fetus during the course of her pregnancy?

A Yes. When she had her ultrasound.

Q Okay. And when did that ultrasound take place? Is that prior to January?

A I believe it was after that point. I would have to check the record.

Q How did you learn about the ultrasound results?

A It was -- I don't remember. It was likely from either Dr. Peden or Dr. Mudrick or Dr. Allen.

Q Were you later aware of the birth of Charles Muhammad IV in May of 2006?

A I was informed. I don't know when or by who.

Q Did you know that Charles IV had spina bifida?

A I was informed, but I don't know when I found that out.

Q Okay. Did you have any later discussions

with Dr. Allen or anyone else regarding -- and Dr. Peden regarding what had happened to Mrs. Muhammad and the fact that her child was born with spina bifida?

A I do recall being part of an interdisciplinary meeting at some point with Dr. Allen, I believe Dr. Krasner was present, to discuss how we can be of --

MS. KANER SOCOL: Okay. Stop right there. It is privileged under the Medical Studies Act. That's that. I'm instructing you not to answer.

BY MR. LUNDBLAD:

Q You said that a Dr. Krasner was involved in the meeting?

A I shouldn't answer that.

Q I think I can know who is present.

MS. KANER SOCOL: If you recall who was present.

BY MR. LUNDBLAD:

Q You said Dr. Krasner?

A Dr. Krasner. Yes.

Q Is he in the psychiatric department?

A He was the interim chair at the time.

Q Was there anyone present in addition to the three of you, Dr. Allen, Krasner and yourself?

A There were others I don't recall.

Q Do you recall when the meeting took place?

A I don't recall.

Q You mentioned at the very beginning that you have given depositions previously. In what context?

A When I was -- let's see. When I was 18 years old I was a plaintiff in a motor vehicle collision case. That was in 1995. The incident was in 1992.

Q It must have been a bad experience if you can remember the year.

A It was. It was. And then in approximately 2009 I was asked to be deposed at the VA I believe as an expert witness of some sort. I don't recall the details.

Q Okay. Did that relate to a commitment of a patient or --

A It had to do with a former patient's attempts at getting service-connected compensation, I believe.

Q Okay. In that case were you giving testimony and opinions on behalf of the patient or the VA or for whom?

A Gosh, I don't remember.

Q Have you ever been involved in the role of an expert witness or consultant in litigation?

A No.

Q Do you have any other lawsuits pending against you?

A No.

Q Have you been sued on other cases?

A No.

Q At the VA hospital can you describe for me what kind of practice do you have?

A I'm full time in the posttraumatic stress disorder clinic seeing patients for medication management who have a diagnosis of posttraumatic stress disorder. All veterans.

Q You indicated that you moonlighted some before. Do you currently do that?

A No. I did that just a few times after residency was over in 2008 and 2009.

Q Do you have any administrative positions at the VA?

A No.

Q Have you gone through the process to become board certified?

A I am board certified.

Q And when were you boarded?

A September 2009.

Q Do you do any research?

A I do not.

Q Have you written any articles, abstracts that have been published?

A Not since residency.

Q Okay. How many articles were you involved with in your residency?

A Just one article.

Q What was the topic?

A How residents handle patient suicide.

Q Who were your coauthors?

A My coresidents. There were eight total residents in my class and we did a grand rounds presentation and it was published in -- I forget the name of the journal.

Q Any other publications?

A No.

Q Have you been a presenter at any professional meetings?

A No.

Q What did you review today to prepare for

the deposition?

A The chart documents.

Q The documents that are in Exhibit 2?

A That's correct.

Q Did you review any other documents?

A No.

Q Did you review any depositions?

A No.

Q Did you do any research in the medical literature prior to the deposition to prepare for the deposition?

A No.

MR. LUNDBLAD: Okay. I believe that's all the questions I have for now.

MS. KANER SOCOL: Okay. Let's take a minute break and then I probably have just one or two.

THE WITNESS: Okay.

(Short break taken.)

EXAMINATION

BY MS. KANER SOCOL:

Q Dr. Stepansky, did you conform to the standard of care as a reasonably careful psychiatrist in your care and treatment of Angie Muhammad?

A Yes.

MS. KANER SOCOL: Okay. That's all the questions I have. Signature is reserved. So you can read it over. Okay?

THE WITNESS: Okay.

FURTHER DEPONENT SAITH NOT

IN THE CIRCUIT COURT OF COOK COUNTY, ILLINOIS
COUNTY DEPARTMENT, LAW DIVISION

CHARLES MUHAMMAD and ANGIE MUHAMMAD, As Parents of CHARLES MUHAMMAD, a minor, and CHARLES MUHAMMAD, Individually,

Plaintiffs,

v. No. 12 L 12174

NORTHWESTERN MEMORIAL HOSPITAL and MEDICAL CENTER, DANIEL YOHANNA, M.D., and THOMAS W. ALLEN, M.D.,

Defendants.

This is to certify that I have read the transcript of my deposition taken in the above-entitled cause by Margaret A. Verhey, Certified Shorthand Reporter, on the 21st day of September, 2016, and that the foregoing transcript accurately states the questions asked and the answers given by me as they now appear.

_____
CHRISTIAN F. STEPANSKY, M.D.

No corrections (Please initial)_____.
Number of errata sheets submitted_____(pgs).
SUBSCRIBED AND SWORN TO
before me this _____ day
of _____ , A.D. 2016.

_____
Notary Public

STATE OF ILLINOIS)
) SS:
COUNTY OF C O O K)

I, MARGARET A. VERHEY, a Certified Shorthand Reporter within and for the State of Illinois, do hereby certify:
That previous to the commencement of the examination of the witness, the witness was duly sworn to testify the whole truth concerning the matters herein;
That the foregoing deposition was reported stenographically by me, was thereafter reduced to a printed transcript by me, and constitutes a true record of the testimony given and the proceedings had;
That the said deposition was taken before me at the time and place specified;

That the reading and signing by the witness of the deposition transcript was agreed upon as stated herein;

That I am not a relative or employee or attorney or counsel, nor a relative or employee of such attorney or counsel for any of the parties hereto, nor interested directly or indirectly in the outcome of this action.

IN WITNESS WHEREOF, I do hereunto set my hand at Chicago, Illinois, this 3rd day of October, 2016.

Margaret A. Verhey
Certified Shorthand Reporter
State of Illinois
CSR License No. 084-003368

Muhammad vs. Northwestern Memorial Hospital

12 L 12174

Deposition of: Thomas W. Allen, M.D.

Taken on: January 09, 2017

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Page 1

STATE OF ILLINOIS)
) SS.
COUNTY OF COOK)

IN THE CIRCUIT COURT OF COOK COUNTY, ILLINOIS
COUNTY DEPARTMENT, LAW DIVISION

CHARLES MUHAMMAD and ANGIE MUHAMMAD, As Parents of CHARLES MUHAMMAD, a minor, and CHARLES MUHAMMAD, Individually,

Plaintiffs,

vs. No. 12 L 12174

NORTHWESTERN MEMORIAL HOSPITAL and MEDICAL CENTER, DANIEL YOHANNA, M.D., and THOMAS W. ALLEN, M.D.,

Defendants.

The deposition of THOMAS W. ALLEN, M.D., taken before Kim Kocimski, Certified Shorthand Reporter, taken pursuant to the provisions of the Illinois Code of Civil Procedure and the Rules of the Supreme Court thereof pertaining to the taking of depositions for the purpose of discovery at 70 West Madison Street, Suite 4000, Chicago, Illinois, commencing at 3:09 p.m. on January 9, 2017.

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* * * * * *

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(EXHIB ITNOS. 2 AND 22 RETAINED B YMR. LUNDB LA D)

CERTIFIED QUESTIONS

PAGE LINE
So was -- In light of the fact that you had alternatives that were of lesser teratogenicity, how was Depakote essential to Mrs. Muhammad's treatment? 137 22

In your evaluation of Mrs. Muhammad, in whether or not Depakote was appropriate for her when you took over in July, did you make a determination as to whether or not the use of Depakote was essential to the care and treatment of Mrs. Muhammad? 138 22

(Witness sworn.)

WHEREUPON:

THOMAS W. ALLEN, M.D.,

called as a witness herein, having been first duly sworn, was examined and testified as follows:

EXAMINATION

BY MR. LUNDBLAD:

Q. Would you please state your name for the record?

A. Thomas Allen.

Q. How do you spell your last name?

A. A L L E N.

Q. What is your date of birth?

A. June 2nd, 1970.

Q. Where do you live?

A. 431 West Oakdale, O A K D A L E, Avenue, Apartment No. 8 and then the letter C, Chicago, Illinois 60657.

Q. Okay. Have you given a deposition before?

A. Yes.

Q. All right. I'm sure that counsel has also told you what to expect. Let me just go over a couple of ground rules to remember.

First of all, if you do not understand my

question, if I misuse a medical term, or you just don't understand what I'm getting at, please let me know so I can reword the question or have the court reporter read it back for us. Is that understood?

A. Yes.

Q. Second, we need all of your answers in words today. You can't nod your head, you can't shake head. We also need an yes and no rather than an uh-huh or an uh-uh.

Is that also understood?

A. Yes.

Q. And finally, if you'd let me finish asking my question before you start answering, that way our court reporter will only have to take down one person at the time. We'll get a clearer record and a more accurate record.

Is that understood?

A. Yes.

Q. All right. You are physician?

A. Yes.

Q. Licensed by the State of Illinois?

A. Yes.

Q. When did you get your Illinois license?

A. I got my Illinois license in 2004.

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Q. Where did you go to medical school?
A. Northwestern University Feinberg School of Medicine.
Q. What year did you graduate?
A. Actually, I'm sorry. My medical license I received -- Let's see, I graduated in 2001. So I received my medical license in -- it would have been after 2001.
Q. Okay.
A. Yeah.
Q. All right. Has your Illinois license ever been subjected to any disciplinary proceedings?
A. No.
Q. So it's never been suspended, revoked, or put on probation at any time; is that correct?
A. That's correct.
Q. Have you been licensed to practice medicine in any other state?
A. Yes. Washington.
Q. When did you get your Washington license?
A. 2014.
Q. And why did you get a Washington license?
A. I had a temporary job there.
Q. Where?

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A. It was group health outpatient psychiatry clinic from January of 2014 to May of 2014.
Q. Okay. And why did you take this temporary job?
A. It was a period of time between closing my psychiatry practice in December of 2013 and starting a clinical fellowship in hospice and palliative medicine in July of 2014.
Q. Okay. Do you still hold your Washington license?
A. No.
Q. You let it just expire?
A. Yes.
Q. And when did it lapse?
A. I believe it lapsed I believe it lapsed in 2015.
Q. Okay. Was your Washington license ever subjected to any disciplinary proceedings?
A. No.
Q. All right. After graduating from medical school, I take it you did an internship?
A. Yes, I did. I did a six-month medical internship.
Q. Where?

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A. That was also at Northwestern.
Q. And thereafter you went on for more postgraduate training?
A. Yes.
Q. In what field?
A. Psychiatry.
Q. And where?
A. At Northwestern.
Q. How many years?
A. So the six month internship and then it's three-and-a-half-year psychiatry residency; so a total of four years.
Q. When did you complete your residency?
A. I completed that in 2005.
Q. And what date would have been the completion date?
A. My completion date was July of 2005.
Q. July 1st?
A. I believe so, yes.
Q. What did you do after July 1st, 2005?
A. I had my first job working at Northwestern Memorial Hospital in their psychiatric rehabilitation clinic.
Q. How long did you work at the rehab clinic?

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A. I worked there for about three years.
Q. Then what did you do?
A. So then I worked -- I joined a group practice, private practice.
Q. What was the name of the group?
A. It was called Meridian Psychiatric Partners.
Q. Where was it located?
A. Downtown Chicago on Ontario.
Q. And how long did you stay with Meridian?
A. For about one year.
Q. Where did you go next?
A. I opened up my own practice.
Q. Why did you leave Meridian?
A. Excuse me. I wanted a chance to work for myself.
Q. Where did you open your practice?
A. 333 North Michigan Avenue.
Q. Did you have any partners?
A. No.
Q. So it was just yourself?
A. Just myself, yes.
Q. How long were you in private practice?
A. I was in private practice about five years.
Q. All right. And that would have taken us to,

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what, December of 2013?
A. Yes.
May I correct something?
MS. SOCOL: Sure.
BY THE WITNESS:
A. I got my medical degree in 2001 but I don't believe I got my license until 2004.
Q. Okay.
A. I'm sorry about that.
Q. Why did you terminate your practice?
A. I wanted to make a career change to hospice and palliative medicine.
Q. And what motivated you to make the career change?
A. I was interested in end-of-life care.
Q. Did you have to go back for more training?
A. I did, yes.
Q. And where did you go for training?
A. I went to Northwestern, did a fellowship -- a yearlong fellowship.
Q. And that started in July of 2014?
A. Exactly.
Q. And then you concluded in July of 2015?
A. Yes.

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Q. Where you do practice now?
A. I'm no longer in practice. I work as a medical director at Blue Cross/Blue Shield Insurance Company.
Q. When did you take that position?
A. That was in July of 2016 -- I apologize -- 2015.
Q. Did you ever engage in the practice of hospice and palliative care medicine?
A. No.
Q. So you finished your fellowship and then directly to Blue Cross/Blue Shield?
A. Yes.
Q. All right. When you were working for the rehabilitation clinic, you were employed then by Northwestern Memorial Hospital?
A. Technically, I was employed by Northwestern University Feinberg School of Medicine but I worked on staff at Northwestern Memorial Hospital. My paycheck came from the medical school.
Q. All right. And while you were working with the rehabilitation clinic, did you have hospital privileges?
A. Yes.

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Q. Where?
A. Northwestern Memorial Hospital.
Q. When you were at Meridian, did you have hospital privileges?
A. Yes.
Q. Where?
A. Northwestern Memorial Hospital.
Q. And likewise, when you were in private practice, did you have hospital privileges?
A. Yes.
Q. Again, at Northwestern?
A. Yes.
Q. Did you have privileges at any other hospital in addition to Northwestern?
A. Briefly from 2004 to 2005, while I was in my last year of residency, I had hospital privileges at Evanston Hospital. And I -- Yes.
Q. Any other hospital?
A. Un-uh.
Q. Is that a no?
A. I'm sorry. No, no other hospital.
Q. All right. Your privileges at Northwestern were they ever suspended, reduced, put on probation for any reason?

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A. No.
Q. Same question for Evanston?
A. No.
Q. Did you ever reach the point where you were board-certified?
A. Yes.
Q. And in what -- by what board?
A. I'm board-certified in psychiatry.
Q. And when did you get certified?
A. 2007.
Q. Did you pass on your first attempt?
A. Yes.
Q. Both written and oral?
A. Yes.
Q. Is your Illinois license still current and active?
A. Yes.
Q. Can you tell us, what do you do as a medical director for Blue Cross/Blue Shield?
A. Medical necessity reviews for behavioral health cases, let's see, clinical leadership, programming.
Q. Do you see any patients?
A. No.

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Q. Do you treat any patients?
A. No.
Q. Do you have any recollection of Angie Muhammad?
A. Yes.
Q. Tell me what you remember about her.
A. I remember -- I remember she was a challenging case. I remember her as a person, meeting her in the hallway. She seemed pleasant, pretty well-organized, fairly well-dressed.
I remember she had frequent periods of exacerbations of her illness that would require her to be in the hospital.
Q. Anything else?
A. I mean, I remember -- I mean, obviously I know what happened in terms of this case.
Q. Okay. You know that she had a child in May of 2006 that had birth abnormalities, correct?
A. Yes.
Q. Do you recall when it was you first encountered Ms. Muhammad?
A. Well, I started the job in July of 2005, and I have a vague recollection of meeting her either in the hallway or seeing her in the clinic, being introduced to

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her probably around that time.
Q. Do you recall who it was that introduced you to Angie?
A. It was either Judy Wilson, the nurse, or Chris Stepansky, the resident.
Q. What was your title with the clinic?
A. I was an attending psychiatrist.
Q. What were your duties as an attending psychiatrist?
A. So in this clinic, I -- half my time was in the rehab- - rehabilitation clinic supervising residents and half my time was in the -- what was called the satellite clinic at the Lawson YMCA for homeless, severely mentally ill patients. I saw patients there on my own but I also supervised residents.
Q. All right. What was the function of the rehabilitation clinic?
A. It was a clinic for severely, persistently mentally ill patients, frequent hospitalizations, difficult to treat psychiatric disorders. They needed higher intensity of services including group therapy, skill-building therapy, case management, medication management, occupational therapy.
Q. And your duty was to supervise the residents?

Page 16

A. One of my duties was, yes.
Q. Okay. How many were -- How many residents were assigned to the clinic?
A. So in one year -- Well, under me, there was one in that one year. There were other doctors who supervised other residents.
Q. Okay. All right. So you worked at the rehabilitation clinic from around July 1st, 2005 through July of 2008?
A. Yes.
Q. All right. And so if we could just focus then on when you started, in the summer of 2005, you said that you had one resident that you were supervising?
A. Yes.
Q. Okay. And that would have been Dr. Stepansky?
A. Correct.
Q. All right. And what else would you be doing at the clinic?
A. I also had a team. I was part of an interdisciplinary team consisting of a nurse, psychologist, occupational therapist. The resident was part of the team and then also social workers.
Q. Okay. And what was the function of the interdisciplinary team?

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A. So the team was a -- I believe, there were three teams in the clinic and each team had a -- that was over -- was responsible for overseeing the treatment of patients, so approximately a third of the clinic.
So we -- we talked interdisciplinary about what the treatment needs of the patients were -- recommend, what groups they should be in, clinically monitor them, talk about their progress, think if there's a treatment approach that maybe could help them better than what's already being done.
Q. Okay. Were you the only attending physician supervising these three teams?
A. No. I was supervising my own team. There were two other psychiatrics supervising the other two teams.
Q. Who were the other two psychiatrists?
A. At that time, it was Dr. Karen Breen, B R E E N, and Dr. Ken Cohen, C O H E N.
Q. Do you remember a physician named Marcia Brontman?
A. I do.
Q. And who was she?
A. She was the attending psychiatrist who preceded me in this -- on this team.

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Q. Okay. Do you know what level of experience she had?
A. Attending psychiatrist.
Q. Right.
I mean, do you know how many years beyond residency she was?
A. Good question. I don't know.
Q. All right. So you had one team. And how many patiens would you have been responsible for through this team?
A. I don't know. I would have to guess.
MS. SOCOL: Don't guess.
BY MR. LUNDBLAD:
Q. Can you give any ballpark estimate?
A. Hundreds.
Q. How often would the team meet?
A. We met weekly.
Q. And how often would each individual patient be reviewed by the team?
A. Technically, we had -- we were required to do a treatment plan every three months. However, we would review them as frequently as necessary, based on clinical conditions; so ad hoc, pretty often.
Q. All right. Can you tell me, how did you

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supervise your resident back then, Dr. Stepansky?
A. So we had a formal supervision session once a week for an hour where we talked about cases, talked about patients. I believe -- Yes.
And -- But we frequently talked every day. I was available by page. He also was coming to the satellite clinic to see patients. So I remember working with him very closely.
Q. All right. The once-a-week meeting, what day was it held?
A. I don't remember.
Q. How long did the meeting last, typically?
A. One to two hours.
Q. And how many patients would you discuss in one meeting, on average?
A. I don't remember.
Q. How would the patients be chosen, the ones that were going to be discussed at this weekly meeting?
A. We decided -- Well, we chose to staff them based on when they needed their treatment plan done, which was every three months. It was -- I believe it was a Medicare requirement. But we also chose to talk about them based on their clinical acuity or ad hoc.
Q. All right. I'm not sure I understood your

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prior answer.
Did you have a regular rotation of when you would discuss a patient during this weekly meeting?
A. We had a few patients we had to discuss in that hour, hour and a half just to get the paperwork done; but then the rest of the time we would talk about cases as they came up. So they weren't scheduled, they were just routine.
Q. The ones you had to do the paperwork for, which type of patients were those?
A. Those were clinic patients.
Q. And what was the reason or -- that you had to complete this paperwork?
A. I believe it was a Medicare requirement that the actual paperwork is done every three months.
Q. Now, is this different than the team meeting that you're talking about?
A. This is the same thing.
Q. The same thing.
All right. What I'm really -- What I'm asking about now is just, from my understanding, is that you and Dr. Stepansky would have one-on-one meeting per -- one time per week?
A. Yes.

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Q. And my question was: Did you schedule to review in rotation the patients that Dr. Stepansky was treating so that on such and such date you would come in and say, All right. We're going to talk about these ten patients?
A. Oh, I get your question.
So in the supervision, we talked about the patients he would have seen that week and then anybody else who was important to talk about.
Q. All right. When you were conducting these meetings with Dr. Stepansky, did you take down notes? Did you make anything in writing, a report, memorandum, anything to document your discussion with Dr. Stepansky?
A. I believe I jotted notes, yes.
Q. All right. Were those notes that were formally entered into the patient's chart?
A. No.
Q. Okay. What would you do with your notes?
A. I know when I left the clinic, I shredded my notes.
Q. Do you have, from memory, any recollection of discussing Angie Muhammad during your one-on-one meetings with Dr. Stepansky?
A. Yes.

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Q. And do you recall any estimate as to how many time you had discussed her one-on-one with Dr. Stepansky?
A. I don't remember exact number. I know it was frequent.
Q. What were the topics that you were discussing with Dr. Stepansky?
A. I believe she was seen in the clinic weekly, every other week, either by multiple -- sometimes multiple times a week either by Dr. Stepansky or Dr. Peden, the psychologist; and we would all talk interdisciplinary about how the patient is doing.
So during our supervision, I remember that topics would come up, How is Angie doing this week? And we would discuss, Do we need to make a medication change, are we worried about her getting sicker, et cetera.
Q. If you had a question about a patient, was there any resource, any physician you could go to to talk about a patient or a certain situation?
A. Multiple, yes.
Q. And who would those doctors be?
A. Well, the other two psychiatrists in the clinic -- the other two attending psychiatrists,

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Dr. Breen or Dr. Cohen were two examples.
Q. Okay. Do you recall ever going to Dr. Breen or Dr. Cohen to discuss Angie Muhammad?
A. I believe so, yes.
Q. Do you recall when Well, first of all, who did you go to?
A. I cannot recall specifically.
Q. And do you recall when you would have gone to talk about Angie Muhammad?
A. I don't remember.
Q. Do you recall what topic you discussed with either Dr. Breen or Dr. Cohen?
A. I don't remember.
Q. All right. When you took over the position in July of 2005, do you recall when you would have first talked about Angie Muhammad with Dr. Stepansky?
A. Excuse me. I think it was -- I believe it was right away after starting, during our first -- possibly during our first or second supervision.
Q. Okay. And do you remember the topic?
A. I don't remember.
Q. I take it you're familiar with the drug, Depakote?
A. Yes.

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Q. And what's the purpose or what use is Depakote in the area of psychiatric medicine?
A. It's primarily used as a mood stabilizer for people with bipolar order or for schizoaffective disorder bipolar-type.
Q. When did you first learn of Depakote? Is that something you learned about in your residency?
A. I believe so, yes.
Q. And what do you recall being taught about Depakote and its use in psychiatry?
A. That Depakote is one of the most effective medicines for treating bipolar disorder, specifically Bipolar Disorder Type I.
Q. Are you also -- Did you also know that Depakote is a teratogen meaning it can cause harm to a fetus?
A. Yes.
Q. All right. In July of 2005, what did you know about the potential teratogenic effect of Depakote?
A. I knew that it can cause neural tube defects in women who are exposed to Depakote during pregnancy.
Q. What else were you aware of?
A. That it -- That's basically it.
Q. Were you aware of whether or not Depakote can

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cause fetal defects in addition to the neural tube defects?
A. Yeah. Yes, it can cause neural cognitive defects as well.
Q. What other -- Anything else?
A. In pregnant women?
Q. Right.
A. Those are the main two I remember.
Q. Okay. During your training, were you exposed to the medical literature as it relates to the use of Depakote to treat mood disorders or as a mood stabilizer?
A. Yes.
Q. And based on the literature, what was your understanding as to the incidents of birth defects at -- related to the use of Depakote?
A. I don't know exactly.
MS. SOCOL: Don't guess if you don't know.
BY MR. LUNDBLAD:
Q. Did you -- Are there other medications that are used for mood stabilization in bipolar patients?
A. Yes.
Q. What others ones?
A. So Tegretol is one, lithium. Often the

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typical antipsychotics, for example, Risperdal or Zyprexa are used; and often the typical antipsychotics like Haldol or Prolixin are also used.
Q. Okay. Tegretol, another name for that, is that carbamazepine?
A. Yes.
Q. Compared to Depakote, how effective are Tegretol and lithium in treating bipolar disorder patients?
A. Specifically for patients who have rapid cycling bipolar disorder, which means more than four episodes in a year, they go in and out of a manic episode, the treatment of choice is Depakote. Also, for patients who are in mixed mood episode, for example, when they have depression and mania at the same time, the treatment of choice is Depakote.
Angie had both of those features. But you had asked ...
Q. Are -- Well, for example is Tegretol, is that effective in treating what -- was the first called, frequent cycling?
A. Rapid cycling.
Q. Rapid cycling.
A. It's not -- My understanding is it's not as

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effective as Depakote because one reason is it can lower the blood levels of other medications that people are on.
Q. And what was the second type of bipolar disorder Angie had?
A. She had rapid cycling with mixed mood features.
Q. All right. Tegretol, is that effective in treating bipolar disorders where there's a mixed mood disorder?
A. I believe it can be. My understanding is that Depakote has shown more efficacy in that population.
Q. All right. Is that the same -- Is it also true with Tegretol, that it can be effective in treating the rapid mood disorder? I'm sorry. I got to -- What's it called again, rapid --
MS. SOCOL: Cycling.
BY THE WITNESS:
A. Rapid cycling.
Q. Rapid cycling.
Is Tegretol -- can it be effective in treating rapid cycling mood disorder?
A. My understanding, from my training, was that Depakote is the preferred medicine for rapid cycling.

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Q. Right. My question is: Can Tegretol be effective in treating rapid cycling?
A. I believe it can.
Q. And how does lithium compare to Depakote as -- in treating bipolar disorder?
A. Lithium is best for pure mania not rapid cycling and not mixed. It's also good for bipolar depression.
Q. All right. Can you lithium be used to treat rapid cycling mood disorder?
A. Possibly.
Q. And what about the mixed mood disorder?
A. Possibly.
Q. After -- Well, later on, isn't it true that Mrs. Muhammad was given lithium?
A. Yes.
Q. And was the lithium effective in treating her rapid cycling mood disorder?
MS. SOCOL: I object. I think your question is vague as stated.
BY THE WITNESS:
A. If you could re- -- ask it differently.
Q. Sure.
Starting at about January of 2006,

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Mrs. Muhammad was put on lithium, correct?
A. Yes.
Q. And she was kept on lithium up through and until the time that she delivered her son Charles, IV, correct?
A. I believe so.
No. I think -- I believe she remained on it longer than that.
Q. Okay. During her -- the end of her pregnancy, did the lithium achieve its intended purpose of controlling her -- of stabilizing her mood?
A. Not fully.
Q. And in what way was it deficient?
A. I believe even though she was taking it, she still had exacerbations of the -- for illness.
Q. Now, going back to those three mood stabilizers -- Depakote, Tegretol, and lithium -- among those three, to your knowledge in 2005, which of them had the greatest propensity for causing at teratogenic injury?
MS. SOCOL: I'm going to object, lack of foundation, calls for speculation.
BY MR. LUNDBLAD:
Q. Well, let me ask the question this way.

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You told us that you had been exposed to medical literature regarding the teratogenic effect of Depakote, correct?
A. Correct. Yes.
Q. And I take it you have also been exposed to same type of literature relating to Tegretol and lithium?
A. Right.
Q. And were you aware of literature that indicated, that among those three -- Depakote, Tegretol, and, lithium -- that Depakote had the highest likelihood of causing an injury to a fetus?
MS. SOCOL: Objection, lack of foundation.
If you can answer, if you know, but don't guess.
BY THE WITNESS:
A. I know they all that had risks. I don't know the relative likelihood.
Q. All right. So are you saying then that in 2005 when you were treating Angie Muhammad that you did not know which of those three had the greater risk of harm to a fetus?
A. My understanding, Tegretol and Depakote had a higher risk of neural tube defects; and lithium had a

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risk of cardiac malformations.
I believe the risk of cardiac malformations was not as likely as the risk of neural tube defects.
Q. All right. In 2005, were you aware that Depakote could cause other fetal malformations in addition to Spina Bifida?
A. Yes.
Q. Were you aware of the frequency of other fetal malformations that were caused by Depakote?
A. Not the specific frequency.
Q. Back in 2005, did you know whether Depakote had a higher propensity to cause fetal malformation of all types than Tegretol?
A. I didn't have that knowledge, and I don't know that that's the case.
Q. Were you aware of medical literature that found an association between a higher incidence of fetal malformation based on the dosage of Depakote?
A. I'm not aware of that.
Q. So in 2005, you were not -- Well, strike that.
In 2005, were you aware of medical literature that indicated or suggested that there was a higher rate of fetal malformations, as high as 30.2 percent in patients receiving dosages of more than 1000 milligrams

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of Depakote per day? Were you aware of that?
MS. SOCOL: I'm going to object to foundation, to form.
You're reading from something without identifying it.
BY MR. LUNDBLAD:
Q. Okay. As part of your practice, did you read medical literature to keep up-to-date with the signs?
A. Yes.
Q. Were you familiar at all with a publication called Journal of Clinical Neuroscience?
A. I don't believe so.
MS. SOCOL: Of Clinical, what? I'm sorry.
MR. LUNDBLAD: Neuroscience.
MS. SOCOL: Is there a specific publication or year --
MR. LUNDBLAD: Yes. It's --
MS. SOCOL: -- of reference?
MR. LUNDBLAD: November of 2004. It looks like 11 (8:854 to 858.) The author -- The lead author is somebody named Dr. Vajda, V A J D A, and ...
BY MR. LUNDBLAD:
Q. All right. Were you aware of an article published in December of 2005 in something called

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Epilepsy -- Current Epilepsy?
A. No.
Q. Were you aware of information in that publication that indicated the fetal malformation rate for Depakote in the first trimester was higher than all other anti-epileptic drugs?
MS. SOCOL: I'm going to object to relevancy.
This has nothing to do with epilepsy.
Go ahead.
BY MR. LUNDBLAD:
Q. And that included Tegretol.
Was Tegretol also at times used to treat epilepsy?
A. Yes.
Q. Were you aware that Depakote had a higher level of fetal malformations than the other drugs including Tegretol and lithium?
A. I believe -- My understanding was that Depakote had a higher risk of neural tube defects than Tegretol. That was my understanding, but I can't quote the numbers.
Q. Okay. Were you aware of the relationship between dosage, that the incidence of fetal malformation with Depakote at levels greater than 1,100 milligrams

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was much higher than dosage rates of 600 milligrams or less?
MS. SOCOL: I'm going to object, form, foundation. He already has told you he's not familiar with the article.
BY MR. LUNDBLAD:
Q. Well, in July of 2005, were you aware that the risk of fetal malformation of patient taking Depakote at a dosage rate of 600 milligrams or less was lower than the rate with -- a dosage rate of 1000 milligrams or higher?
MS. SOCOL: I'm going to object, again, as to lack of foundation.
BY MR. LUNDBLAD:
Q. Were you aware of that information?
A. I don't know -- I'm not aware of those numbers.
Q. Okay. Now, were you familiar at all in 2005 -- Well, strike that.
I take it you're familiar with the publication known as Physicians' Desk Reference?
A. Yes.
Q. And the Physicians' Desk Reference, that contains information relating to medications that one

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can use as a resource, correct?
A. Yes.
Q. And the things that are listed in the Physicians' Desk Reference would be indications as to when a drug is appropriate to use; is that correct?
A. Yes.
Q. And on the other side, it would also indicate when drugs should not be used, true -- contraindications for using medications?
A. It will list contraindications for medications, yes.
Q. And the Physicians' Desk Reference is essentially a compilation of the -- what drug companies are required to put out in package inserts with their drugs?
A. Rephrase the question.
Q. Sure.
You're familiar with what are known as package inserts?
A. Yes.
Q. And package insert is what the drug company puts out listing indications, uses for its drugs as well as warnings on contraindications and side effects, true?
A. Yes.

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Q. And the Physicians' Desk Reference book that ess- -- it contains essentially the same information that's in a package insert, true?
MS. SOCOL: Objection, calls for speculation, lack of foundation.
Go ahead.
BY MR. LUNDBLAD:
Q. To your knowledge?
A. I don't know.
Q. Okay. The Physicians' Desk Reference book is something a physician, such as yourself, can look at to learn more about when a specific drug should be used or when it should not be used, correct?
A. It says what the indications for certain medications are and the contraindications.
Q. Okay. Now, are you aware then that in these Physicians' Desk Reference for Depakote, it did provide a warning that Depakote has a propensity of being teratogenic medicine?
A. Yes.
Q. Were you also aware of the warning put out by the drug company that made Depakote, Abbott Laboratories, that Depakote should only be used in a woman of childbearing potential only if the medication

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is shown to be essential in the management of their condition?
A. I'm not aware of that specific wording.
Q. Okay. Now, whenever a medication is prescribed, I take it that a doctor has to weigh the potential benefits versus the downside of a medication, correct?
A. Yes.
Q. And with the -- specifically to Depakote, that a doctor determining whether or not to give Depakote has to look at what effect it will have on stabilizing the mood of a psychiatric patient versus the potential adverse side effects, true?
A. True.
Q. And among these adverse side effects that would have to be considered would be its teratogenic effect on fetuses, true?
A. True.
Q. And that would have included all potential fetal malformations, Spina bifida, and all other ones that it can cause, true?
A. True.
Q. Now, when you took over supervising Dr. Stepansky in July of 2005, isn't it correct that he

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had already placed Mrs. Muhammad on Depakote?
A. I believe he -- I believe he started her on the medication, yes.
Q. According to the records -- Did you look at the records before coming here today?
A. I did.
Q. And if you need to refer to them, I'm giving you a binder that's marked as Plaintiff's Exhibit No. 2 which contains the medical records from the rehabilitation clinic.
All right. When you had one of your weekly meetings with Dr. Stepansky, did you -- do you recall ever addressing directly the issue of whether or not it was appropriate to be giving Depakote to Angie Muhammad?
A. Yes.
Q. Do you recall when you first had that conversation?
A. I recall it was soon after starting my job.
Q. Okay. And do you recall -- How did the topic come up?
A. I remember hearing about Angie as a woman who was in the hospital pretty frequently throughout the spring of that year of 2005, and that she was started on Depakote, and since then has been a lot better, and has

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been -- remained -- has remained out of the hospital. And -- That's it.
Q. All right. I'm sorry. So do you recall how soon it was after you took over on July 1st that you had this conversation?
A. Probably within one to two weeks, during that first or second supervision.
Q. Okay. And what was your understanding in this conversation as to how long she had been on Depakote?
A. My understanding is she started it in May; and I started there in July, so two months.
Q. All right. According to the records, I believe the first prescription for Depakote or the first order for Depakote was entered on May 24th of 2005. So that -- this conversation would have been within the first two months that she was on Depakote?
A. Oh, I believe so, yes.
Q. Now, is there a certain therapeutic level of blood level that's required in order for the Depakote to be therapeutic?
A. It depends on the lab and -- but generally, yes, there is.
Q. Do you know when Mrs. Muhammad first reached a level where she -- a point where her blood level had a

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therapeutic amount of Depakote after it was started in May of 2005?
A. I would have to check. I don't remember.
Q. All right. Why don't we start out page 87. Do you see -- This is a handwritten note of Dr. Stepansky, and two-thirds of the way down, do you see DPA 53105 19.4?
A. Yes.
Q. And I believe Dr. Stepansky told us that that indicated the blood level that Mrs. Muhammad had on that date, you would have no reason to quarrel with that, correct?
A. No reason to what? I'm sorry.
Q. Quarrel.
I mean, you would agree if -- Well, you would have no reason to dispute that?
A. If I see it here, I believe that's accurate.
Q. All right. And if we could turn to page 201 in Exhibit No. 2.
A. Okay.
Q. All right. This is a laboratory report from Northwestern, correct?
A. Yes.
Q. And it looks like there it's for blood that

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was collected on July 29th of 2005.
Do you see that?
A. Yes.
Q. And if we go down toward the middle of the page, it indicates that the Valproate, V A L R O A T E, concentration was 29.3.
Do you see that?
A. Yes.
Q. And it indicates that for this laboratory the therapeutic range was between 50 and a hundred?
A. Yes.
Q. And so 29.3 would not be a therapeutic level; is that correct?
A. That's correct.
Q. And based on your prior testimony, this blood work would have been done at or near the time that you and Dr. Stepansky had your discussion about Mrs. Muhammad being on Depakote, correct?
A. I believe so, yes.
Q. All right. So you would agree then, that based on the laboratory data, Mrs. Muhammad was not yet at a therapeutic level of Depakote, is that correct, based on the lab test?
A. The only thing I know from this lab test is at

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the time it was drawn the level was low.
Q. Okay. All right. If we go back, all right, page 199. All right. The therapeutic level there, the blood is 60.1. So that -- that would have been therapeutic level above 50; is that correct?
A. Yes. One thing, in order to be a true level, it has to -- the blood has to be drawn 12 hours after the last dose is taken. And these lab reports don't indicate if it's a true trough level or not.
So even though it may say a number, I would have to consult the patient to find out when the last dose was taken to make sure it's an accurate level.
Q. Okay. So if the test was taken too soon after the last dose, you would have an artificially high reading?
A. Exactly.
Q. Okay. All right. Now, when you were talking about Mrs. Muhammad with Dr. Stepansky in this first meeting when you discussed Depakote, do you recall what you discussed? I mean, you told us that she had -- it was your knowledge she had been on Depakote for about two months; is that correct?
A. Right.
Q. And it was your understanding or it was

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reported to you by Dr. Stepansky then in his observation, he thought her condition had improved with the Depakote?
A. Yes.
Q. Now, with -- if you are giving Depakote to a woman who is of child-rearing age or a woman who is menstruating and capable of being pregnant, would it be correct that your instructions to the woman would be to not get pregnant while taking the Depakote?
A. It's recommended not to get pregnant while on Depakote.
Q. All right. Now, have you been involved in patients where you've been the person -- the doctor that prescribed Depakote?
A. (Nodding.)
Q. Is that a yes?
A. I'm sorry. Can you rephrase the question?
Q. Sure.
In your practice, have you been in a position where you -- Well, let me back up.
When you -- By the time you had this meeting with Dr. Stepansky about Depakote, at that point, you had not formally seen Mrs. Muhammad as a patient, had you?

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A. I don't believe formally in an appointment.
Q. Okay.
A. I may have seen her in the hallway or been introduced to her.
Q. All right. And it was Dr. Stepansky and not you who actually prescribed the Depakote?
A. I believe so, yes.
Q. All right. And based on a document that was provided to us by the hospital -- I'll give it to you -- it's Exhibit No. 24 for identification.
If you could turn to the last page, it's called a Stone Institute of Psychiatry Policy and Procedure. Do you see that?
A. Yes.
Q. And it says: Effective date, April of 2004. Are you -- Were you familiar with this policy and procedure?
A. Yes.
Q. Okay. And this policy and procedure, it was in effect in July of 2005?
A. Yes, I believe so, unless it was revised. I don't know.
Q. All right. It was represented to us by the hospital that this was the one in effect at the time.

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And this policy and procedure relates to the prescribing of psychotropic medication; is that correct?
A. Yes.
Q. And Depakote, when it's being used as to treat a mood disorder, would that fall into the category of psychotropic medication?
A. Yes.
Q. All right. And this policy here describes what a physician must tell the patient when prescribing such a medication; is that correct?
A. Yes.
Q. All right. And one of -- it says in line 2 under the policy that the patient must notify or -- Strike that.
The policy says that the physician will notify patients of the frequently significant side effects, risks and benefits of the psychotropic medication; is that correct?
A. Yes.
Q. So in the case of Depakote, to meet this policy, it would be necessary for the physician to advise the patient or, in this case Mrs. Muhammad, of the potential risk that the Depakote could have in causing fetal malformation if she became pregnant?

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A. I lost -- I'm sorry. Can you repeat that?
MR. LUNDBLAD: Can you read it back for me, please.
(Record read as requested.)
BY THE WITNESS:
A. That was one of the risks that -- yes, that we would have had to notify her about.
Q. Okay. And if we continue on in that same sentence, it also says that the physician will notify the patient of -- or alternative -- alternatives to the proposed treatment with such medications.
Do you see that?
A. Yes.
Q. So in this particular case, when Mrs. Muhammad was prescribed the Depakote, in order to meet this policy and procedure, it would have been necessary for the physician to have advised Mrs. Muhammad of the alternatives of Tegretol and lithium, correct?
A. That's correct.
Q. And as part of that information, the doctor would have to tell Mrs. Muhammad about the varying degrees of risk that would go along with Tegretol and lithium as far as causing fetal malformations?
MS. SOCOL: I'm going to object, lack of foundation and that is not -- it misstates the policy.

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BY MR. LUNDBLAD:
Q. Well, let me just ask the question this way, Doctor. Where it says: Physicians will notify patients of the frequent significant side effects, risks, and benefits of psychotropic medications as well as alternatives to the proposed treatment of -- with such medications -- Do you see that?
A. Yes.
Q. And can you explain to me, what is your understanding, based on having practiced at Stone Institute of Psychiatry and supervised residents, as to what that policy meant where it says that: The doctor will notify the patient of risks as well as alternatives to the proposed treatment with such medications?
A. My understanding is we needed to explain to the patient the risks and benefits of not only the medication we're offering but also of the alternatives.
Q. Okay. And in this particular case with Depakote, the alternatives would be Tegretol and lithium, correct?
MS. SOCOL: I'm going to object, lack of foundation. I don't believe that's -- that was his testimony.
But go right ahead.

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BY THE WITNESS:
A. I don't remember the alternatives suggested at the time.
Q. All right. All right. It was your understanding that Depakote was prescribed in May of 2005 to treat or to -- as an attempt to stabilize Mrs. Muhammad's mood, correct?
A. Yes.
Q. Would you agree that Tegretol was a medication that was available in 2005?
A. Yes.
Q. So was Tegretol, in 2005, a potential alternative to Depakote?
A. Potential, yes.
Q. And likewise, was lithium a potential alternative to Depakote?
A. Yes.
Q. Okay. Now, in 2005 when you got involved in caring for Angie Muhammad, you were aware that she was of an age where he could become pregnant?
A. Yes.
Q. And you also knew that she was married?
A. Yes.
Q. And as part of your review of Mrs. Muhammad,

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would you have reviewed the notes of Janet Peden?
A. Yes.
Q. So then based on your review of the records, you would have been aware that Mrs. Muhammad was actively engaging in sexual relations with her husband?
MS. SOCOL: Objection, calls for speculation.
BY THE WITNESS:
A. I don't know specifically if she was actively engaging in sexual relations at the time.
Q. All right. In prescribing Depakote or continuing to give Depakote to a woman who is of childbearing age, I think you told us or agreed earlier that a patient should be informed that -- that were to be recommended not to get pregnant, correct?
A. Right.
Q. And as part of the process of prescribing Depakote to a woman who is of childbearing age, you would agree that the recommendation should be, do not get pregnant, correct?
A. Correct.
Q. And to follow up on that, does that mean that in order to prescribe Depakote, should a patient inquire as to whether or not the patient is sexually active?
MS. SOCOL: Objection, calls for speculation,

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vague.
BY THE WITNESS:
A. I don't know.
Q. You don't know?
A. I don't know.
Q. All right. If --
A. If you could repeat the question, please.
Q. Well, let me ask this question: In July of 2005 when you were reviewing Dr. Stepansky's prescription of Depakote, if you disagreed with the Depakote being given to Mrs. Muhammad, could you have told Dr. Stepansky to stop the Depakote?
A. Yes.
Q. Okay. And so when you discussed Depakote, you had to make your own personal weighing of the benefits versus the disadvantage of Depakote, correct?
A. Yes.
Q. And as part of your weighing that decision, you had to look at the risk that Mrs. Muhammad had of getting pregnant and of having a fetus that was malformed as a result of Depakote, correct?
A. Correct.
Q. And in order to make that assessment, would you not have to know whether or not Mrs. Muhammad was

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engaged in sexual activity?
MS. SOCOL: Objection, vague, calls for speculation. He answered your question. It's been asked and answered.
BY MR. LUNDBLAD:
Q. Well, can you answer the question or --
A. I -- One can assume that a woman of childbearing age possibly is having sex.
Q. All right. But my question is: When you're evaluating whether or not the benefits of Depakote outweigh the risks, you have to assess the likelihood that the patient might get pregnant, correct?
A. Correct.
Q. And in order to make that assessment, you would have to know whether or not the patient is sexually active, correct?
MS. SOCOL: I'm going to object to this line of questioning, lack of foundation, vague.
BY MR. LUNDBLAD:
Q. Well --
A. There's a risk, because she was of childbearing age, that she could become pregnant.
Q. All right. Well, my -- All right. Let me ask it this way, and that is: When you're assessing whether

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or not the benefit of Depakote outweighs the risk, do you have to -- what did you do as a physician to determine what risk there was that the patient such as Mrs. Muhammad would get pregnant while taking Depakote?
A. That she was taking all precautions to prevent pregnancy.
Q. All right. So when prescribing Depakote, you would inquire as to what birth control methods the woman was using?
A. Yes.
Q. And in the case of Mrs. Muhammad, in making the assessment of whether the risk of Depakote outweighed the benefit, you would have to know what birth control method she was using, correct?
A. Correct.
Q. And in July of 2005, what was your understanding as to what method she was using?
A. That she was on the contraceptive patch.
Q. All right. And what was your understanding in July of 2005 as to her history of using the patch or any problems or difficulties there had been with her using the patch?
A. My understanding is she was taking the patch as prescribed.

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Q. Okay. Were you aware that in May of 2005, that Mrs. Muhammad at that point in time, did not have a doctor/patient relationship with a gynecologist?
A. I'm -- I remember reading that in the medical records yesterday, but I don't remember at that time specifically.
Q. All right. So sitting here today, in July of 2005, were you aware of the notes from Dr. Peden when she was talking about how Mrs. Muhammad's prescription for patch had run out, she didn't have a gynecologist, and she needed more birth control patches? Do you recall that -- Did you know that in July of 2005?
MS. SOCOL: I'm going to object. I'm not sure that that's accurate. It's vague.
BY THE WITNESS:
A. I don't remember those details. I don't know if they're accurate either.
Q. All right. Were you aware that Dr. Stepansky and Dr. Peden, in May of 2005, had to make arrangements for a prescription to be given for two additional birth control patches?
A. I don't know specifically. I know they worked closely with the prescriber in helping to get her the patches.

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Q. Well, are you aware that in May of 2005 Mrs. Muhammad stated she did not have a gynecologist and did not have anyone who was prescribing her the patches?
MS. SOCOL: Objection, asked and answered. He answered that question.
BY MR. LUNDBLAD:
Q. Were you aware of that in July of 2005?
MS. SOCOL: And it assumes facts not in evidence.
BY MR. LUNDBLAD:
Q. Can you answer that?
MS. SOCOL: I'm going to object as to the accuracy of the statement.
BY THE WITNESS:
A. All I can say is, I -- my understanding was that she had patches. Whether she had a gynecologist or not, it didn't imply she didn't have patches.
Q. Okay. Were you aware that on May 31st Mrs. Muhammad had reported that she had missed her period?
A. On May 31st?
Q. Yes.
A. Yes, I am aware of that.
Q. And were you aware of the fact that at that

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point in time that a pregnancy test had to be ordered to determine whether or not she was pregnant?
A. Yes.
Q. And if you had known about the potential -- Well, strike that.
Based on the history that Mrs. Muhammad presented with where she didn't have a gynecologist, she was on her last patch and did not have a prescription to get more, and then reported that she thought she might have been pregnant because she thought she missed a period, under those circumstances, was it appropriate to continue giving Mrs. Muhammad Depakote based on the risk of her getting pregnant?
MS. SOCOL: Objection, it assumes facts not in evidence and incomplete hypothetical.
BY THE WITNESS:
A. That's a hypothetical. I -- In the timeline, I -- I don't know the exact dates and the intervening factors.
Q. All right. With a birth control patch, does the patch have to be changed every month?
A. Hers had to be changed more frequently.
Q. Okay. How frequently?
A. I don't know specifically about the kind she

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had.
Q. Okay. And in order for that to occur, it meant that Mrs. Muhammad was the one that had to do it, correct?
A. I believe she had help but I don't know for sure.
Q. Okay. And from the history, you knew that Mrs. Muhammad, in April up until early May, had been institutionalized because of an exacerbation of her symptoms, correct?
A. Repeat the date.
Q. In April, I believe, up until early May, she had been in hospitals being treated?
A. I have to check for sure.
MS. SOCOL: I'm going to object because this is before Dr. Allen was involved with her care.
MR. LUNDBLAD: Right.
BY MR. LUNDBLAD:
Q. Well, let me just ask you this question: Were you aware of her history of having been hospitalized in April to early May 2005?
A. I have to look at the exact -- I don't know the exact dates. I believe so, yes, but I don't know the exact dates.

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Q. All right. I mean, the exact dates are not significant but, you would -- the significant fact is that Mrs. Muhammad had been institutionalized for treatment and you were aware of that, correct?
A. Yes. Yes.
Q. Now, if a patient has been hospitalized, and I believe if we look at the records it will show that she was discharged in early May, would that patient be -- in your opinion, was she mentally capable of making sure that she was using birth control devices appropriately?
A. My understanding is she was.
Q. All right. Did you make any personal inquiry to determine whether or not she was?
A. Yes.
Q. And what did you do?
A. Clinically in talking with Dr. Stepansky, that was one of the questions, is she able to make decisions in terms of her medications? Is she able to stick to a medication regimen? Is she taking precautions in terms of her birth control?
Q. Now, with regard to the topic of birth control in a patient who is being prescribed Depakote, would that discussion have to include the husband or the partner to that person?

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A. Not necessarily.
Q. All right. So -- And why not?
A. She was the patient of ours, she was able to make her own decisions. The husband could have been involved and he may have been a help; however, he may not have been a help and he could have gotten in the way of her treatment.
Q. All right. I'm talking specifically here about birth control. I think you would agree that if you're prescribing Depakote that you do not want your patient -- female patient to become pregnant, correct?
A. Correct.
Q. So with regard to making sure that the patient does not become pregnant, is it necessary to include the husband in the plan to make sure that the pregnancy doesn't occur?
MS. SOCOL: Objection, asked and answered.
BY MR. LUNDBLAD:
Q. In your opinion, no?
A. In my opinion, no.
Q. Okay. And let me put it in this way; and that is, are you familiar what's called the standard of care?
A. Yes.
Q. And is it your understanding that that's what

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a reasonably well-qualified and careful physician would do under the same or similar circumstances?
MS. SOCOL: You're asking about the definition?
MR. LUNDBLAD: Yes.
BY MR. LUNDBLAD:
Q. Correct?
A. Yes.
Q. Just so we're on the same page, when I use the term, that's your understanding?
A. Correct.
Q. Were you aware of the notes of Dr. Peden, when you got involved in Mrs. Muhammad's care, where it indicated that her husband wanted to have a third child?
A. Was I aware of that?
Q. Yes.
A. I don't believe so.
Q. Okay. Now, if you were not wanting Mrs. Muhammad to get pregnant, wouldn't it be necessary to talk to the husband who wanted another child to educate him on the fact that Mrs. Muhammad could not get pregnant while she was on Depakote?
MS. SOCOL: I'm going to object, lack of foundation, asked and answered.
BY THE WITNESS:

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A. I don't believe it's necessary.
Q. Okay. During the time that you were involved in treating Mrs. Muhammad, from July of 2005 until the time she became pregnant in October of 2005, did you personally have any conversation with Angie Muhammad's husband Charles to talk to him about the fact that his wife should not get pregnant?
A. I don't believe I directly had a conversation with him about that, no.
Q. Okay. Do you know if Dr. Stepansky ever did?
A. I don't know.
Q. In your opinion, to meet the standard of care, should Dr. Stepansky have had a conversation with Mr. Muhammad to explain to him that his wife could not get pregnant while taking Depakote?
A. I don't believe that's the standard of care.
Q. Okay. All right. I think you told us that you would have personally done your own risk/benefit analysis of giving Depakote to Mrs. Muhammad?
A. I -- If I -- If she were my -- I'm sorry. Rephrase the question.
Q. Well, as supervisor of Dr. Stepansky and supervising his care and treatment of Mrs. Muhammad, did you perform your own risk/benefit analysis of giving

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Depakote to Mrs. Muhammad?
A. I didn't personally talk to her about the risks/benefits.
Q. I'm not talking about talking to her about it. I'm asking you whether you yourself weighed the pros versus the cons of Depakote to make a decision that she should be continued on Depakote once you learned that Dr. Stepansky had prescribed it?
A. Yes.
Q. All right. And can you tell me, what were the -- can you describe for me your analysis?
A. That Angie understood the risks, benefits, and alternatives of Depakote and that Depakote was chosen. It was rec- -- It was chosen. Angie agreed to take it because of an understanding that it could help her mood -- treat her mood disorder, and that there was a thorough discussion about the risk of fetal abnormalities if she were to become pregnant on this medication, and that she understood that and agreed to take it despite that risk, and that she was taking all precautions possible to prevent that.
Q. To prevent "that" being ...
A. Meaning pregnancy.
Q. All right. Now, you personally did not have

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this conversation with Angie Muhammad, correct?
A. I personally did not.
Q. Okay. So you're relying on what was reported to you by Dr. Stepansky?
A. There was a personal conversation I had in a meeting with the family after she learned that her baby had Spina Bifida.
Q. All right. I'm not there yet. I'm talking about in the period between July of 2005 and when she became pregnant in October of 2005.
And my question -- my question was: In that period of time, you did not personally talk to Mrs. Muhammad to discuss with her the risks and benefits of Depakote, correct?
A. I personally did not.
Q. Okay. And so anything you just talked about when you -- Well, strike that.
If I understood your prior testimony, you're indicating that in that time period you did your own risk/benefit analysis, true?
A. I did. And Dr. Stepansky talked to her about the risks and benefits.
Q. All right. I understand.
But right now I'm just talking about your

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affirmation of Dr. Stepansky's plan to give her Depakote. I mean, you said, if you decided it was wrong you could have stopped it, correct?
A. Exactly.
Q. And so you had to do your own risk analysis to determine whether or not it was appropriate to give Depakote to Mrs. Muhammad under the circumstances, correct?
A. That's correct.
Q. And I was just trying to flesh out how you reached -- And I take it you concluded that the risks did not outweigh the benefits; is that correct?
A. That's correct.
Q. I just want to explore what it is you thought about at the time. So the first thing was, is that all your information came second-handed through Dr. Stepansky, correct?
MS. SOCOL: That's not entirely true.
BY THE WITNESS:
A. No, that's not entirely true.
Q. What other -- What other source of information did you have?
A. Well, the - Dr. Stepansky was one. The rest of the team, in terms of the clinical information, was

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another.
And repeat your question again.
Q. All right. So I'm just looking at the source of your data when you made your risk analysis. So it would have been the team members who interacted with Mrs. Muhammad including Dr. Stepansky; is that correct?
A. Correct. Yes.
Q. So that would have been Janet Peden and also I believe there's a Nurse Wilson who was involved --
A. Mm-hmm.
Q. -- is that correct?
A. That's correct. Yes.
Q. All right. So in forming your risk -- doing your risk analysis, obviously you recognized that Mrs. Muhammad could become pregnant, correct?
A. Correct. Yes.
Q. But you did not speak personally with Charles about birth control and avoiding pregnancy, true?
MS. SOCOL: Asked and answered, objection.
BY THE WITNESS:
A. I answered that, yes.
Q. Okay. And did you analyze what potential risk there was that Mrs. Muhammad would become pregnant while taking Depakote?

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A. Yes.
Q. And what did you look at? What did you use to -- in your analysis?
A. Well, I looked at how more -- how more stable she became after being on Depakote, staying out of the hospital, doing very well. She was not threatening to kill her kids or yourself, which was new. And she was staying on her medications, which was a positive, functioning very well. And she also was adherent with her medications including her patch.
She was able to think more clearly about family planning in terms of what, you know, she wanted. For example, I remember reading or I remember at some point she said she did not want to have another child. She was very able to articulate that the medications, that there was a risk. She did not want to get pregnant while on them.
Q. And, again, this is what you gleaned from the records, Dr. Stepansky and the others, the team?
A. Yes.
Q. Now --
A. Also -- May I add? Also, I did see her anecdotically in the clinic and she looked -- she looked good. I mean, she looked stable.

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Q. Okay. Now, you did make a statement that when or after the time that Depakote was started it was indicated that she was more compliant with her medications?
A. I believe so, yes.
Q. And if we look at the records, isn't it true that there -- she had had a history of noncompliance?
A. She does have a history of noncompliance, yes.
Q. Okay. And so in order for this balance to work, it was necessary for Mrs. Muhammad to be compliant in her use of birth control, correct?
A. Correct.
Q. Now, the record indicates that at some point in May Dr. Stepansky arranged for a two-month renewal of Mrs. Muhammad's prescription for the birth control patch. Did you in any way follow up to determine whether or not she received prescriptions for patches that went beyond those two months?
A. I did not, no.
Q. Do you know if Mrs. Muhammad had prescriptions for a birth control patch after that two-month prescription ran out?
A. My understanding is she had prescribers to continue to prescribe the patch.

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Q. Okay. Who prescribed it; do you know? My question was: Do you know for certain that she had birth control patches after that prescription ran out that was given to her in May?
A. All I remember is she was seeing a provider at the PAC Clinic, the OB/GYN clinic and that Janet Peden was regularly checking on her to make sure she was on her patch, but I don't know specifically what days.
Q. Okay. Now, you mentioned that the patch, to your understanding, had to be changed more frequently than once a month; is that correct?
A. Yes.
Q. To your knowledge, was there any time period when the patch is first put on where its efficacy is inadequate and other means of birth control would have to be used at the same time?
MS. SOCOL: I'm going to object to lack of foundation. He's not a OB/GYN.
BY MR. LUNDBLAD:
Q. I'm just asking if you knew whether or not that was the case.
A. I don't know.
Q. Okay. Now, when you were doing your risk analysis, did you consider the possibilities of using

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Tegretol or lithium in place of the Depakote?
A. Yes.
Q. And how did you -- what did you consider when you were evaluating whether or not to use those two medications as opposed to Depakote?
A. They both have potential teratogenic risks; and she had been doing well on the Depakote. So one, I didn't see an argument for changing it; and two, I thought it could have been potentially negligent to switch her off of something that was working well.
Q. Okay. You know, later on after Mrs. Muhammad became pregnant, you then had to consider whether or not to put Mrs. Muhammad on a mood stabilizer, correct?
A. Well, she got pregnant in -- When we found out she was pregnant in --
Q. October of 2005?
A. Yes.
Q. All right. And Mrs. Muhammad ended up having or was hospitalized, I believe, in late November, early December of 2005?
A. I believe so.
Q. All right. And it was after that that you then considered whether or not you needed to renew a mood stabilizer for her, correct?

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A. Correct.
Let me add, she was on Risperdal at that time which can act as a mood stabilizer, so she was being covered, but I worried that it wasn't sufficient. I wanted to add a second one. Because of that hospitalization in November, I worried that she was clinically getting worse.
Q. All right. And when you made that decision, you consulted with another physician, a Dr. Dresner, correct?
A. Correct. Yes.
THE WITNESS: May I interrupt? I have to use -- May I take a break?
MS. SOCOL: Sure, absolutely.
MR. LUNDBLAD: Sure.
(A short break was had.)
BY MR. LUNDBLAD:
Q. In your years of practice, have you prescribed Depakote as a mood stabilizer to a female patient of childbearing years?
A. Yes.
Q. And in your practice, when you made the decision to prescribe Depakote, you did the risk/benefit analysis that we've been talking about, correct?

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A. Yes.
Q. If, in your opinion, you believed your patient was not capable of using birth control properly and had a risk of becoming pregnant, would you then not prescribe Depakote?
A. Hypothetically.
MS. SOCOL: Hypothetically -- If you can answer, then -- Don't speculate because ...
BY THE WITNESS:
A. If I felt the risks of -- Well, if I felt the patient was at risk of getting pregnant or intended to get pregnant, I wouldn't prescribe the Depakote.
Q. All right. And you gave two reasons there. Let me break it down.
You said, if there was a risk that they would become pregnant, you would not give it to them either?
A. I'm sorry. I -- Let me rephrase that.
If there was -- If the patient was saying, Look, I am going to get pregnant, or if the patient was not able to understand the need for birth control or taking precautions or was not taking precautions, then I would not feel comfortable prescribing the Depakote.
Q. All right. So if you thought there was a high risk your patient would become pregnant, you would not

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prescribe Depakote, correct?
MS. SOCOL: And I'm going to object to high risk as being vague.
BY THE WITNESS:
A. Of a woman of childbearing age, there's a risk of the person becoming pregnant, sure, I will prescribe Depakote if there's -- even though there's a risk. But if the patient is telling me she's going to get pregnant or is demonstrating behaviors that -- so she's not able to understand the risk or is not sticking with the birth control plan, then I wouldn't feel comfortable prescribing it.
Q. Okay. And that decision, is that something, in your opinion, that would be required by the standard of care --
MS. SOCOL: I'm going to --
BY MR. LUNDBLAD:
Q. -- not to prescribe under those circumstances?
MS. SOCOL: I'm going to object to standard of care.
If you can understand that or have an opinion about that ...
BY THE WITNESS:
A. No, I can't.

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Q. All right. Now, one thing that is required by the standard of care is that the physician has to adequately describe to the patient the risks and benefits so that the patient can make an informed decision, true?
A. Yes.
Q. And going back to Exhibit No. 24, the policy and procedure, do you have that in front of you?
A. Right here, yes.
Q. Do you see under Procedure where it says: Each time the physician writes an order for a psychiatric medication on NMH's physician's order form, he or she attests that the frequent significant side effects, risks, and benefits of psychotropic medications as well as alternatives to treatment with such medications were reviewed with the patient.
Is that correct? Is that what it says?
MS. SOCOL: Wait. I'm not following.
MR. LUNDBLAD: Under procedure.
MS. SOCOL: Okay.
BY THE WITNESS:
A. What you read is correct.
Q. And under that procedure as it's stated, does that mean that every time the order for the medication

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is renewed that the risk analysis has to be done or that there's -- again, it's an affirmation that the risks are outweighed by the benefits?
A. It's not --
MS. SOCOL: I'm going to object to the speculative nature of your question and the vagueness.
Go ahead.
BY MR. LUNDBLAD:
Q. Well, I take it when you were practicing at Stone Institute, you had to follow this policy and procedure?
A. Right. Yes.
Q. And where it says Procedure, what is your understanding as to what you were required to do to meet the procedure?
A. My understanding is when we started a medication, we had to make sure the patient is aware of the risks, benefits, alternatives of that medication.
Every time -- Every time a pat- -- medication is renewed, my understanding is it's not necessary to go through all of the risks, benefits, and alternatives. It's necessary to make sure the patient still understands that and that the benefits outweigh the risks.

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Q. So the point I was trying to make is that, would you agree that the evaluation of the benefits versus risks is something that's ongoing and has to continue as long as the drug is being prescribed?
A. Yes.
Q. All right. In the second sentence, it says there: The physician will also document whether the patient has the capacity to make a reasoned decision about such treatment.
What documentation was required to meet that procedure?
A. I don't -- I don't know what Northwestern Memorial Hospital's documentation was at that time. I know every time a physician -- an order is renewed and the patient consents to it, we need to -- we, as clinicians, make sure that the patient is able to make an informed decision meaning that he or she is aware of the risks and benefits. I don't know the space where this needs to be documented.
Q. All right. If you could turn -- use the binder, Exhibit No. 2, and turn to page 183.
All right. This document is entitled Psychotropic Medication Information; is that correct?
A. Yes.

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Q. And to your knowledge, does this form correspond to the policy and procedure that we've been discussing, Exhibit No. 22?
A. I don't know if it's the same form for that policy, though.
Q. All right. Are you -- From your years of practicing at the Stone clinic, are you familiar with this form?
A. I'm familiar with this form. I believe it was done on intake at the clinic when patients came, but I don't know that it was continued.
Q. Well, the first paragraph doesn't that say, "I have discussed and provided the patient or patient's parent or guardian with written information about the nature and frequency of side effects of the following medications"?
Is that what it says?
A. I have discussed and provided the patient or the patient's parent or guardian with written information about the nature and frequency of side effects of the following medications. Yes.
Q. And my question is: Based on your years of practice at the clinic, was this form used to document, first of all, that the benefits and risks were explained

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to the patient and whether or not the patient was capable of giving consent to taking the medication?
MS. SOCOL: Objection, asked and answered.
BY THE WITNESS:
A. If I could -- I believe this form, honestly, was being phased out. It had to be documented somewhere that the conversation happened, and I believe that was done in the notes; but this form, in and of itself, was not necessary for documentation.
This form showed up once, and I believe it was just on intake, but further documentation was in the notes.
Q. All right. This particular form at the bottom, it looks like it has Dr. Cohen's signature. Do you recognize that?
A. Yes.
Q. And it has a date of Jan- -- it looks 1/26 of 2004?
A. Right.
Q. And it has checked off Prozac and Risperdal; is that correct?
A. That's correct, yes.
Q. And if we look, there's also a section called Mood Stabilizers?

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A. That's correct.
Q. And it includes lithium, Tegretol, and Depakote, which is referred to by it's generic name, correct?
A. That's correct.
Q. And when this form was in use, did you ever use this form?
A. I believe so, yes.
Q. And was the intent to -- when the checkmarks are made in the boxes, is that to indicate the medications that were discussed with the patient?
A. Yes.
Q. In this particular case, it would have been the Prozac and the Risperdal, correct?
A. That's correct, yes.
Q. And while this form was being in use and a prescription was being made for Depakote, then there should have been a checkmark in the valproic acid box, correct?
A. No.
Q. No. I'm saying, it wasn't prescribed at this particular time, but I'm saying that, had Dr. Cohen chosen to prescribe Depakote on -- in January of 2004, he would have put a checkmark in the valproic acid box,

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correct?
A. He could have been or he could have written longhand into the note.
Q. So what you're saying, in May of 2005, was this form -- was this form used and did it have to be completed if a psychotropic medication was prescribed?
A. I don't believe so.
Q. Okay. And if we look through the -- you looked through the records before the deposition today?
A. Yes.
Q. And you did not find any form such as this relating to the Depakote that was prescribed in May of 2005, correct?
A. Correct.
Q. All right. Did you ever talk to representatives from drug companies who were at the hospital or clinic, I guess, they're called, what, detailed men, talking about various prescription medications?
MS. SOCOL: I'm going to object, relevancy.
BY THE WITNESS:
A. I don't remember. I don't know.
Q. Specifically, do you recall speaking to any detail person from Abbott Labs regarding Depakote?

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A. I don't believe so.
Q. Now, Depakote -- Well, strike that.
Are you familiar with the designation by the Food and Drug Administration of what's called a Class D medication?
A. Yes.
Q. And what is your understanding of what a Class D medication is?
A. My understanding is that there evidence -- there is evidence of human abnormalities as a result of the medication being taken while the woman is pregnant.
Q. Okay. And what is your understanding as to what's required under this Class D designation before a medication can be prescribed?
A. A thorough discussion of the risks and benefits and alternatives is made, and that the benefits have to outweigh the risks.
Q. All right. Did the Stone clinic, in 2005, did they have any specific policies and procedures for prescribing a Class D drug? Was there any special policy or procedure that had to be followed before a woman could be prescribed a Class D medication?
A. Not that I know of.
Q. Okay. Do you know if there was any form such

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as page 183 of Exhibit 2 that had to be completed if a Class D medication was being prescribed?
A. I don't know of any form like that.
Q. So to your knowledge, there was not, is that what you're saying?
A. Yes.
Within psychiatry or just generally in the hospital?
Q. No, within psychiatry?
A. Yeah. I don't --
Q. You're not aware of any?
A. No.
Q. Okay. And likewise, you're not aware of any special procedure that had to be followed for prescribing a Class D medication in the psychiatry hospital, correct?
A. Not a specific procedure.
Q. Okay. Now, based on what you've told us at the very beginning, if I understood you correctly, that the job that you took at the Stone clinic and specifically in the rehabilitation clinic, that was your first employment after completing your residency, correct?
A. I worked as a -- I worked in the ER at

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Evanston Hospital moonlighting, and I started that before completing residency. I believe I continued even after but I don't remember.
Q. All right.
A. So this was my first -- It's one of my first jobs, one of two.
Q. All right. This was your first full-time non-moonlighting job?
A. Yes.
Q. All right. Were you familiar with a physician by the name of Dr. Pedro -- is it Dago?
A. Dago.
Q. Dago?
A. Yes.
Q. And who is he?
A. He's attending psychiatrist at Northwestern or was.
Q. Do you know if he's still there?
A. I believe he is but I don't know.
Q. Do you know if he had any involvement in providing care and treatment to Angie Muhammad?
A. I believe he did, yes.
Q. Okay. Have you ever spoken to Dr. Drago -- Dago --

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MS. SOCOL: Dago.
BY MR. LUNDBLAD:
Q. -- Dr. Dago about Angie Muhammad?
A. No.
Q. There was some references in a note that you made that you were attempting to obtain a consultation that he had prepared relating to Mrs. Muhammad. Did you ever obtain it and read it?
A. I don't believe I did, no. But I know we were trying to obtain it, yes.
Q. And why were you trying to get it?
A. I was trying to understand his understanding of her clinically in terms of an overall treatment plan for Angie.
Q. All right. And that inquiry was made after Mrs. Muhammad was pregnant, correct?
A. I don't remember.
Q. Go to page 162. Page 162, this is an outpatient progress note from The Stone Institute of Psychiatry correct?
A. That's correct, yes.
Q. And this is a note that you prepared, right?
A. Right.
Q. And if we look at the bottom of the paragraph

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under S/O, it talks about how you obtain consent forms so you could talk and get a copy of Dr. Dago's consultation report, correct?
A. Correct. Yes.
Q. And the date on this note is May 3rd of 2006, true?
A. Right.
Q. And that was toward the end of Mrs. Muhammad's pregnancy with Charles, IV, correct?
A. I believe so, yes.
Q. And so my question is: Why did you, at this point in time, toward the end of her pregnancy, want Dr. Dago's report?
A. I wanted to -- Primarily for continuity of care, I wanted to inquire into another attending psychiatrist's impression of her and treatment options. I wanted to see if he thought of any other medications that could help her.
Q. Were you aware that Dr. Dago had seen Mrs. Muhammad back in July of 2005 when you went and Dr. Stepansky were discussing Depakote and her medications?
A. Yes.
Q. Did you, at that point in time, make any

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attempt to contact and talk to Dr. Dago about Mrs. Muhammad and his impressions and opinions?
A. At which time?
Q. July of 2005.
A. I don't believe so, no.
Q. Did you speak to Dr. Dago at all in any way -- or communicate in any way with him in July through October of 2005?
A. I don't believe so.
About Angie Muhammad?
Q. Correct.
A. No, I don't think so.
Q. Now, before we took the break, I believe I had brought up the topic of -- at some point you had contacted another physician by the name of Dr. Dresner, true?
A. Yes.
Q. And what kind of physician is Dr. Dresner? What's her specialty?
A. She's a psychiatrist.
Q. Is she also at Northwestern?
A. I don't believe -- She might be on faculty but I don't know if she's still there on staff.
Q. Was she back in 2005?

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A. I don't believe she -- I don't know. She had her own practice. I believe she was doing consult liaison work at Northwestern at that time, yes.
Q. All right. Why did you reach out to Dr. Dresner?
A. She has a familiarity with women's mental health.
Q. Okay. And what was it about her familiarity with women's mental health that prompted you to reach out to her? Why did you reach out to her because of that expertise?
A. She's a colleague. I reached out to other -- I talked to other colleagues over time about the care of patients, about this patient.
I wanted to see if there was specifically a medication we could start Angie on after stopping the Depakote that might work as effectively and be safe in pregnancy.
Q. If we go to page 251 of Exhibit 2, it's in the binder. If we go to the bottom of the page, it appears that the bottom is an e-mail that you sent to Dr. Dresner that's dated Monday December 19, 2005, correct?
A. Yes.

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Q. And if we turn to the next page, which is page 252, you were talking about that you wanted to add a mood stabilizer to her medication regimen, true?
A. That's true.
Q. And you indicated that you were considering three different stabilizers -- Depakote, lithium, and Lamictal, right?
A. Yes.
Q. What is Lamictal?
A. It's also called lamotrigine, and it's an anticonvulsive and a mood stabilizer.
Q. Do you know -- Why were you -- Strike that.
When you were consulting with Dr. Dresner, were you seeking her opinion as to which of those three drugs would be best suited to use while Mrs. Muhammad was pregnant?
A. I was seeking her opinion of what -- which of those three med- -- I was seeking her opinion of what type of mood stabilizer to add given that she was pregnant that could increase her mood stabilization. And I just listed those three as examples.
Q. All right. Now, the reason that you were concerned about adding the mood stabilizer is because you were concerned about the potential of fetal harm,

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correct?
A. I wanted to add a mood stabilizer because I worried that she wasn't stable enough on her current regimen and I wanted to make sure that whatever we added was safe given that she was pregnant.
Q. All right. And that's the reason you sought out the advice of Dr. Dresner, most -- both -- on both of those issues, which would work best and which would be safest?
A. Yes.
Q. Okay. And if we could turn to page 251, in her response of -- to you a couple of days later, on the 21st of December 2005, Dr. Dresner indicated there that: Depakote is absolutely contraindicated, physical and neurobehavioral, teratogen.
Is that what she wrote back to you?
A. She's what she wrote, yes.
Q. All right. And she said: Lamictal is -- it looks like -- not really indicated for acute more maintenance.
Is that what it says?
A. Yes.
Q. You know, going back to July of 2005, did you consider Lamictal as a potential mood stabilizer, as a

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substitute for Depakote?
A. I believe -- Of course, when thinking of different alternatives, I think that was probably one of them, yes.
Q. Do you recall, what is the relative safety of Depakote compared to Lamictal?
A. My understanding is Lamictal has a lower risk in pregnancy than Depakote.
Q. Okay. And knowing that, you still chose Depakote over Lamictal, correct?
A. Correct. I chose to continue Depakote as opposed to starting the Lamictal, yes.
Q. Okay. Did you have any discussion with Dr. Dresner regarding her opinions that she expressed here in the e-mail?
A. Not in July.
Q. All right. What about after -- after the exchange of these two e-mails, did you talk to her in person?
A. I don't believe so. I think it was just e-mail.
Q. Okay. And it was her recommendation that you should use the lithium during the pregnancy; is that correct?

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A. It was her recommending that I use lithium at that point during the pregnancy, yes.
Q. Okay. And that was a recommendation that you, in fact, followed; is that correct?
A. Right.
Q. Now, I take it that Dr. Dresner was a colleague that you knew and had a relationship with in July to October of 2005?
A. Yes.
Q. If you had chosen, would you have been able to discuss what mood stabilizer would have been best, in her opinion, for Mrs. Muhammad based on her circumstances in July through October of 2005?
A. I could have discussed it with her or any other attending psychiatrist. Yes, I could have talked to her.
Q. Okay. But, in fact, you, in that period of time -- September to October -- did not talk to Dr. Dresner about a mood stabilizer, which one would be best for Mrs. Muhammad, correct?
A. I believe I did not talk with her, yes.
Q. Is there any psychiatrist that you did, in fact, talk to in that time period, July to October of 2005, regarding whether Depakote was the best and

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safest mood stabilizer for Mrs. Muhammad under her circumstances?
A. I believe there were multiple. I just don't remember specifically.
Q. Is there any note in these records indicating where you documented having such a conversation?
A. I don't believe so, no.
Q. If I could refer you to page -- I believe it's 132, do you have that?
A. I do.
Q. And for the record, it's page 132 out of Plaintiff's Exhibit No. 2. This is a note that's in your handwriting?
A. Yes.
Q. And it's dated October 25th, 2006; is that correct?
A. Yes.
Q. And it's signed by you at the end, correct?
A. I'm sorry. It's dated February 25th, 2006.
Q. The did I say October?
A. I thought you did, yeah.
Q. You're right. It's dated February 25th, 2006. However, in the top line, you start out with the words medical management -- MED management?

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A. Yes.
Q. And you have it underlined, correct?
A. Yes.
Q. And then you have there: Late note for 10/20/05, correct?
A. Yes.
Q. And that would refer to the date of October 20th, 2005?
A. Yes.
Q. Now, isn't it true that on October 11th, according to the records, Mrs. Muhammad saw Dr. Stepansky and reported that she had missed her period?
A. On October 11th?
Q. Yes. Page 101, it's Item No. 3 where it has 1, 2, 3, 4, under the Section P?
A. Oh, I see it, yes.
Q. And it says there that: Patient reporting or reports missed period.
Do you see that?
A. Yes.
Q. All right. And, in fact, I believe the records show that on the 18th of October there was pregnancy test done -- a urine pregnancy test that

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confirmed that Mrs. Muhammad was pregnant, true?
A. That's what I believe, yes.
Q. And isn't it also correct that there's a note on page 104 of Dr. Stepansky that indicates that on October 20th Dr. Stepansky told Mrs. Muhammad to stop taking the Depakote and the Cogentin that she was on, correct?
A. Correct.
Q. And that was -- She was told to stop Depakote and Cogentin after Dr. Stepansky knew from the test that she was pregnant, correct?
A. Correct.
Q. And in your opinion, was it appropriate for Dr. Stepansky to stop Angie from taking any additional Depakote and Cogentin?
A. Yes.
Q. And beyond being appropriate, was that required by the standard of care to stop the Depakote once it was known that Mrs. Muhammad was pregnant under her --
MS. SOCOL: I'm going to --
BY MR. LUNDBLAD:
Q. -- under her circumstances?
MS. SOCOL: I'm going to object to standard of

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care.
BY THE WITNESS:
A. My belief is it was the standard of care.
Q. Okay. Now, if we go to your note on page 132 -- and you may want to keep 104 also -- you put in what you called the late note?
A. Yes.
Q. And when you add and designate something as a late note, what does that mean?
A. It means I wanted to add some clarity to the medical record.
Q. Okay. And what is it you wanted to clarify?
A. I think I wanted to clarify my -- I included the e-mail conversation with Dr. Dresner in the chart and I wanted to explain why I put that in there.
Q. Why you put the e-mail into the chart?
A. Exactly.
Q. All right. Going back to October 20th, do you recall if Dr. Stepansky talked to you about the fact that Mrs. Muhammad was pregnant?
A. I believe so, yes.
Q. And were you a part of the decision to stop the Depakote and the Cogentin?
A. Yes.

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Q. And why -- You told us before that stopping the Depakote and Cogentin on that date was something required by the standard of care. Why was it required?
A. Well, she was pregnant. Depakote obviously is teratogenic in pregnancy. At that point, we didn't see that the benefits of Depakote outweighed the risk of it potential it causing birth defects -
Q. Okay.
A. -- knowing -- knowing that she's pregnant.
Q. All right. Now, if we go back to page 101 -- and this is the note of Dr. Stepansky, from 10/11 -- October 11 of 2005, and that's note that we looked at before where it says, "reports missed period." Did Dr. Stepansky talk to you on the 11th regarding the report of the missed period?
A. I'm not sure if we talked on that day or not. I don't remember.
Q. Knowing that Mrs. Muhammad had missed her period and there was a risk that she was pregnant, should Dr. Stepansky have stopped the Depakote on October 11th, based on that report?
A. I don't believe so, no.
Q. How was that -- Why not?
A. A missed period could mean many things not

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just potential pregnancy.
Q. All right. If a female patient misses their period while taking Depakote, does the standard of care required that there has to be a pregnancy test?
MS. SOCOL: I'm going to object, again, to standard of care and he's not an obstetrician, lack of foundation.
Q. Well, I'm talking from the terms -- from a perspective of a psychiatrist. If you have a patient to whom you prescribe Depakote and that patient, a female, reports she has missed her period, is it necessary for the psychiatrist to obtain a urine test to confirm whether or not the person is pregnant?
A. I believe that if a patient misses a period, it's necessary to confirm whether that's pregnancy or not.
Q. Okay. And then that's something required by the standard of care for a psychiatrist?
MS. SOCOL: Again, I'm going to object, lack of foundation.
BY MR. LUNDBLAD:
Q. Well, if you're a psychiatrist and your patient reports missing a period, you don't want them to continue taking Depakote if they're pregnant, correct?

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A. Rephrase that question, please.
Q. All right. In this particular case, the Depakote was stopped with Mrs. Muhammad once it was known she was pregnant?
A. Right.
Q. Okay. And my question is that: If you have a patient who reports missing their period, you need to determine whether or not their pregnancy you can determine if you must stop the Depakote?
A. Yes.
Q. Okay. And now, you're familiar with Mrs. Muhammad's rather extensive history of mental disorder and treatment for those illnesses, correct?
A. Yes.
Q. And that's something that had been going on for at least 2002?
A. I be- -- I don't know the exact date, but for many years.
Q. Okay. If we look at the records, that there are references, I believe, there's discharge summaries from December of 2002 involving Mrs. Muhammad, correct?
A. I don't know how far back they go, but they go back many years.
Q. All right. And ...

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THE WITNESS: Is it okay if I -- I'm sorry - take another bathroom break?
MS. SOCOL: That's fine.
MR. LUNDBLAD: That's fine.
(A short break was had.)
BY THE WITNESS:
A. I was thinking, there are situations where, at times, physicians would keep a patient on Depakote even after the physician learns the patient is pregnant. I'm thinking of, like, in epilepsy or really severe bipolar disorder where that's the only medication that works for them.
As long as they have a discussion with the patient about the risks and the benefits and they agree to do this together. So I don't think it's absolutely standard of care that once one becomes pregnant the Depakote is stopped. It's just, I'm thinking specifically about Angie and my decision; but I'm thinking if standard of car, I don't know that that's the case.
Q. All right. With regard to Angie, it was your analysis that -- I think you mentioned -- you stated before that the risk of injury to her fetus outweighed any benefit of the Depakote at that point in time?

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A. Yes.
Q. And that was, for that reason you stopped the Depakote?
A. Yes.
Q. And -- All right. Going back, you have a patient who -- bipolar disorder, is on mood stabilizers, comes in and says, I missed my period. What is required of the psychiatrist at that point in time to meet the standard of care?
A. To obtain a confirmatory lab result --
Q. Okay.
A. -- an objective test.
Q. And under the standard of care, what's required of the psychiatrist as far as obtaining that lab test to confirm or disconfirm pregnancy?
A. You make -- You offer to send the patient to a lab to get the test. Some patients will opt to do a home pregnancy test. Those are the two I'm thinking of.
Q. All right. Is it -- Does it meet the standard of care to rely upon the patient you're treating for mental illness to obtain a home -- obtain and use a home pregnancy test?
MS. SOCOL: Objection, vague, foundation.
BY THE WITNESS:

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A. Yeah. I'm not ...
Q. All right. Well, you just indicated that one of the alternatives is to tell the patient to go and get a home pregnancy test to determine whether or not they're pregnant, correct?
A. You could offer a home pregnancy test or the patient may opt to do -- I'm sorry. You can offer a lab test, but the patient may opt to do a home pregnancy test, as long as some test is done to confirm pregnancy.
Q. The question I'm getting at and based on -- in your opinion, if a physician allows a patient to get a home pregnancy test to determine whether or not that patient is pregnant while taking Depakote, does that meet the standard of care?
MS. SOCOL: Dr. Allen already answered that question.
BY THE WITNESS:
A. Yeah, I believe so.
Q. Okay. In your practice, Doctor, if you knew -- Well, strike that.
In your practice, if you had a patient you were treating with Depakote who came in and said, I missed my period, would you allow that patient to leave the hospital or facility without first getting a pregnancy test?

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A. I would --
MS. SOCOL: I'm going to object, incomplete hypothetical. His practice now, his practice when? And it's still an incomplete hypothetical.
THE WITNESS: Yeah, you're right. It's a hypothetical.
BY MR. LUNDBLAD:
Q. I know it's a hypothetical.
My question is: What -- How would you handle the situation?
A. With Angie? Are we talking about Angie?
Q. Well, we can start with Angie. If you had been in Dr. Stepansky's shoes on October 11th, 2005 and she had said, Doctor, I missed my period, would you have made sure she got a pregnancy test before she left the Stone Institute?
A. I would recommend she get a pregnancy test. And whether she does it in our lab or whether she does it on her own, that's really up to her.
Q. All right.
A. I can't force her to have a test.
Q. Okay. To do a pregnancy test, all you need is a sterile cup to gather the urine in, correct?

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A. I don't know.
MS. SOCOL: Objection, lack of foundation -
MR. LUNDBLAD: All right.
MS. SOCOL: He's not an obstetrician.
BY MR. LUNDBLAD:
Q. Is -- There's a laboratory in the building or nearby where the Stone Institute is?
A. I believe so.
Q. Do you know if urine is ever -- is urine specimens are ever acquired in the Institute of patients?
A. In the psychiatrist institute?
Q. Right.
A. I don't believe so.
Q. So they have to go to another part of the hospital?
A. I believe so, yes.
Q. Now, you're aware that on May 31st of 2005, there was a similar circumstance where Mrs. Muhammad reported she missed her period, correct?
A. That's correct.
Q. And isn't it true that a urine test was done on the same day, May 31st?
A. I don't know when the test was done.

Q. Page 192.
A. Okay. Yes.
Q. All right. Page 192, this is a laboratory report and it's relating to a urine pregnancy test, correct?
A. Correct.
Q. And it indicates the sample was acquired at 17:12 on May 31st, 2005, true?
A. That's true.
Q. And that test was returned as negative, correct?
A. Correct.
Q. Now, do you have any knowledge as to how long it takes to get a result from the lab on a pregnancy test?
A. I don't know.
Q. Would you agree that if your patient's on Depakote, a female who reports missing a period, that under the standard of care you would be required to order a pregnancy test, correct?
A. If a woman misses her period, are we required to order a pregnancy test? I would recommend to the patient that she get confirmatory testing, whether that's, I write an order for a lab test or she obtains

it on her own.
Q. Okay.
MS. SOCOL: And that's been asked and answered.
BY MR. LUNDBLAD:
Q. And if a patient refused or declined to follow the recommendation to go to the hospital's lab to get a pregnancy test, would the standard of care require the physician to explain why the test was necessary?
A. If a patient's refusing, I don't know about standard of care.
MS. SOCOL: Objection to the vagueness of that.
BY THE WITNESS:
A. I can sat what I would do.
Q. What would you do?
A. I would -- Obviously, I would recommend that the patient do it. If she says no, I would try to understand why and explain the importance of it.
Q. Okay. And what would you say to the patient to explain the importance of getting the pregnancy test?
A. That you're on a medicine that can cause birth defects and that we need to know, truly, if you're on this medication so that we can decide whether it's in your best interest for you to stay on it or not.
Q. Okay. And if you had such a conversation with

your patient, is that something you would document in the records?
A. By which conversation?
Q. That a patient -- You recommend a laboratory test, the patient declines, and you've explained to her why she needs it, would you document that conversation and what you said to the patient in the medical record?
A. I believe I would, yes.
Q. Okay. Mrs. Muhammad did not get a pregnancy test at Northwestern on October 11th, correct?
A. I don't believe she did, correct. At least I don't know, according to the medical record, if she got one through our lab, but it doesn't look as though she did through our lab.
Q. And if we go back to the page 101 of the exhibit, Exhibit No. 2 the medical chart ...
A. Yes.
Q. It's, again, the note of Stepansky. And under Item No. 3 under P for plan, it says: Patient reports missing period.
And I believe he told us it says: Resistant to lab pregnancy test but agreed to take home pregnancy test and inform me of result ASAP.
Do you see that?

A. Yes. I think it said resistant. Is that --
Q. That's what I -- Resistant or Resist.
A. No. Recommend stat?
Possibly.
Q. All right.
MS. SOCOL: Wait. Don't guess at what it would be.
BY THE WITNESS:
A. I'm sorry. I don't know what it says.
Q. Well, I mean, I believe that when Dr. Stepansky read this note into the record he said: Resistant to lab pregnancy test but agreed to take home pregnancy test and inform me of the result ASAP.
Did --
A. I don't know what that word says.
Q. All right. Assuming it says "resistant to," did Dr. Stepansky call to ask for your advice as to what he should do, assuming that Mrs. Muhammad turned down his recommendation to go to the lab for a pregnancy test?
A. I don't remember.
Q. If a patient taking Depakote reports missing a period and is resistant to getting a lab test at the hospital, is that a circumstance where you would expect your resident to call you to discuss this issue -- to

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discuss the situation?
A. Not necessarily.
Q. When you say "not necessarily," it implies that sometimes you would expect them to do that?
A. No. It's reasonable if the patient doesn't want to get the test in the lab, that the patient would obtain another way to get testing.
Q. Knowing Mrs. Muhammad's long history of mental illness, should Dr. Stepansky have called to consult with you regarding Mrs. Muhammad's resistance to getting a lab test at the hospital?
MS. SOCOL: I'm going to object, asked and answered. He just explained.
MR. LUNDBLAD: I'm not sure he did.
BY MR. LUNDBLAD:
Q. Can you answer the question again, please.
A. Can you ask the question again?
Q. I'll have the court reporter read it back.
(Record read as requested.)
BY THE WITNESS:
A. Not necessarily.
Q. And, again, when you say "not necessarily," it implies -- what would need to change in order to make it necessary?

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A. I don't understand the question.
Q. Well, your answer says -- you didn't say never, you said "not necessarily." So it implies that there would be circumstances under which you would expect your resident to call and talk to you about a circumstance where a patient reports missing their period but doesn't want to take a pregnancy test?
A. I don't think there are circumstances. I think he could opt to call or not call. That's what I meant by not necessarily.
Q. All right. Is there a -- As a person in charge or supervising residents in the clinic, would there be circumstances where you would expect and demand your residents to call you to discuss a patient who's on Depakote reports a missing period and refuses to get a lab test?
A. Are there situations where I would want that -- I would demand that?
Q. Yes.
A. I can't think of any. Where a patient is on Depakote, they missed their period, they're refusing to get a test, but they're choosing to get a test elsewhere -- home pregnancy test -- would I demand that the patient call me when that happens?

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Q. No, that the physician call you.
A. I'm sorry. That the physician would call me? I can't think of why I would demand them to call me.
Q. So in other words, I just want to make this so I understand it. So what you're saying is that if a patient reports a missing period who is on Depakote, you would not require your resident to call you if the patient refused a lab test as long as the patient was going to go get a home pregnancy test, is that what you're saying?
A. Let me -- If the patient refused to get a lab test for pregnancy and refused to do any confirmatory testing, the resident would call me. I would want him to call me. And I think that's pretty understandable that he would -- he or she would.
The fact that she did obtain alternative testing, sounds sufficient.
Q. Okay. All right. So what you're saying then is that in your opinion your, from your perspective you're saying that the patient agreeing to do a home pregnancy test is adequate under the circumstances?
A. That's adequate.
Q. Okay. Under the circumstances where there's going to be a home pregnancy test, does the psychiatrist

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have any obligation to follow up to find out the result of the test?
A. We would want to know, yes, the result of the test.
Q. And it says here, as soon as possible. what -- How soon should the resident be trying to get ahold of the patient to find out what the result of the test was?
A. I can't give a number. I'm assuming once we have an idea that the test has been done or that we know the test was done or the results are available, we would have an agreement that the patient call us or we would try to reach out to the patient.
Q. Right.
And my question is: At what point in time would it be necessary for the doctor to reach out to the patient?
MS. SOCOL: I think that's been asked and answered. He said there was no specific time.
BY THE WITNESS:
A. Yeah. I can't be more specific.
Q. Okay. If Mrs. Muhammad had gotten a pregnancy test on October 11th, based on the later test, would it be correct to say that more likely than not that test

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would have also come back positive?
MS. SOCOL: Objection, calls for speculation.
BY THE WITNESS:
A. I don't know.
Q. Don't know.
All right. If Mrs. Muhammad had gotten a laboratory test on October 11th that indicated she was pregnant, would you have made the same decision to stop the Depakote and Cogentin as you did on the 20th?
A. It's hard to know given that clinical situation then, but I believe I -- we would have stopped it had we known she was pregnant.
Q. Okay. Because there was no change in her circumstances between the 11th and the 20th, was there?
A. I don't know. I don't know. I don't believe so.
Q. All right. So you would have reached the same conclusion and stopped the Depakote and Cogentin on the 11th if you knew she was pregnant, correct?
MS. SOCOL: Objection, calls for speculation.
BY THE WITNESS:
A. If she had missed her -- If she were found to be pregnant, we would have stopped the Depakote.
Q. Okay. Cogentin is that also an antiepileptic

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medication?
A. No. It's an antiparkinsonian. It's used to treat side effects of antipsychotics.
Q. Okay. And Dr. Stepansky -- Well, strike that.
Prior to May 31st, Mrs. Muhammad was on Haldol, correct?
A. She was in the past, yes.
Q. And the records from -- Strike that.
The notes indicate that - again, going back to April to early May, Mrs. Muhammad was hospitalized and that while she was in one of the institutions that she was given Haldol intermuscularly. Do you recall seeing that?
A. I don't know specifically when that was given. I know she received it, though.
Q. Okay. And Haldol, is that medication appropriate for treating bipolar disorder?
A. It can be used as a mood stabilizer for bipolar disorder, yes.
Q. And what is your knowledge about the teratogenic effect of Haldol?
A. I think it's one of the safer medicines used for bipolar disorder or psychotic disorder in women who are pregnant.

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Q. The decision to stop Haldol, that took place before you came into the picture, correct?
A. I don't know.
Q. I believe the Haldol was stopped in May?
A. Then yes.
Q. All right. When you got involved in treating Mrs. Muhammad, did you ever review that decision to stop Haldol?
A. I don't believe so.
Q. All right. And after May, Mrs. Muhammad was given Risperdal among her medications?
A. I believe so, yes.
Q. And what was the purpose of the Risperdal?
A. Risperdal, like Haldol, is an antipsychotic to prevent psychotic symptoms but also can work as a mood stabilizer for the bipolar disorder.
Q. Okay. And the Risperdal, that was continued after you took over or became involved in the treatment, correct?
A. Correct.
Q. And then the Depakote, what's its purpose if you're using Risperdal, which is also a mood stabilizer?
A. They have different mechanisms of action. They both work to stabilize the patient's mood.

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Risperdal is not often sufficient. Patients can have breakthrough mood episodes even just on an atypical antipsychotic like Risperdal. So often they need a mood stabilizer like lithium or Depakote to more optimally stabilize them.
Additionally, the Risperdal was preventing psychosis where as Depakote doesn't treat psychosis.
Q. And what is psychosis?
A. Psychosis is generally being out of touch with reality; so delusions, hallucinations, disorganized thinking.
Q. Okay. In 2005, obviously you were aware that Mrs. Muhammad was receiving multiple medications to treat her condition?
A. Yes.
Q. And we just talked about several of them -- the Risperdal, the Depakote, Cogentin; and she was also getting Prozac, correct?
A. Correct.
Q. Are you -- Were you aware in 2005 that studies had shown that Depakote, when given in combination with other medications, the incidence of fetal malformations increases? Were you aware of that?
A. I don't know of that fact or study or opinion.

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I don't know.
Q. You don't know.
Okay. So you don't know whether Depakote, in combination with Risperdal or Cogentin, whether or not that increased the risk of a fetal malformation? You don't know that?
MS. SOCOL: I think he means you didn't know --
BY MR. LUNDBLAD:
Q. Didn't know it in 2005?
MS. SOCOL: -- you didn't know if it's true or not. I'm going to object to the vague nature --
BY THE WITNESS:
A. Now, or in 2005?
Q. Well, were you aware of any studies in July of 2005 through October of 2005 that indicated that Depakote had the propensity of having even a higher incidence of fetal malformations if used in conjunction with other medications?
MS. SOCOL: I'm going to object. That's 12 years ago.
BY THE WITNESS:
A. I don't remember.
Q. Okay. When you were doing your risk/benefit analysis on Mrs. Muhammad, did you consider whether or

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not there would be any synergistic adverse result of combining the Risperdal, Prozac, and Cogentin with the Depakote as far as increasing the risk of fetal malformation?
MS. SOCOL: Objection, calls for speculation, vague, lack of foundation
BY THE WITNESS:
A. I'm aware of drug interactions.
Q. But my question was: Did you consider that combination of drugs and whether -- and what risks they posed in combination for a fetal malformation in the event Mrs. Muhammad became pregnant?
A. I don't remember. That was too long ago.
Q. Were you aware of any medical literature that existed in 2005 that suggested that the incidence of fetal malformation is less if only one mood stabilizer is used rather than multiple?
A. Will you define a "mood stabilizer"?
Q. Well, you talked about it here. Risperdal is a mood stabilizer, correct?
A. What is the article referring to?
Q. I mean, it's referring to the drugs by these names.
MS. SOCOL: I'm going to object to --

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BY THE WITNESS:
A. I don't know the specific- --
MS. SOCOL: -- the lack of foundation and literature in general, it's vague.
BY THE WITNESS:
A. Yeah. I can't make an opinion on that. I don't know.
Q. Well, I'm asking: Were you aware that studies suggested using Depakote by itself decreased the risk of fetal malformation?
A. By itself as opposed to ...
Q. Other mood stabilizers?
A. I don't remember anything to that. I don't remember anything that said that.
Q. Okay.
MS. SOCOL: We're approaching three hours so ...
MR. LUNDBLAD: Well, if I recall, your depositions went well beyond three but we'll be done shortly.
BY MR. LUNDBLAD:
Q. Let's go back. I got sidetracked here a bit. Page 132 ...
It's the note that you made as a late entry relating to October 20th 2005. I was able to read some but not all of what you wrote. So can you just read

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into the record what you wrote in that note, please.
A. Sure.
It's entitled Medication Management Late Note for 10/20/05.
When patient learned she was pregnant, Chris Stepansky called Dr. Dresner for clinical guidance. She is a women's mental health specialist and recommended Risperdal and Prozac but to discontinue Cogentin and Depakote. We followed her advice.
A few days later I call her and asked her directly her advice for meds -- medications, and she reiterated these recommendations. After her hospitalization in 2005, meaning Angie's, I e-mailed Dr. Dresner with questions of what mood stabilizer to start. The content of our ongoing correspondence on this matter is in the correspondence section of this chart.
Q. All right. So based on your note then, I gather then it was Dr. Stepansky, after the pregnancy was confirmed, what -- he was the one that first initiated contact with Dr. Dresner, is that ...
A. I believe so.
Q. And she was the one then who recommended the Depakote and Cogentin be stopped?

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A. I believe so, yes.
Q. Do you recall if you spoke with Dr. Dresner directly on or about October 20th of 2005?
MS. SOCOL: That's been asked and answered.
BY THE WITNESS:
A. Yes.
Q. On the 20th?
Did you speak to her in October or was your conversation later?
A. It's in the note.
Q. Well, where is it indicated in the note? I'm sorry. I'm being obtuse.
A. That's okay.
A few days later I called her, meaning Dr. Dresner, and asked her directly her advice for medications and she reiterated these recommendations.
Q. All right. Do you recall the reason she gave you for her advice on medications, namely stopping Depakote and stopping Cogentin?
A. That they're teratogenic and have risk in pregnancy.
Q. Did you talk to her at all about the relative risks of the drugs that she was maintained on -- the Risperdal, the Prozac and -- what else was she on -- or

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did she recommend Risperdal and Prozac?
A. Yes.
Q. Okay. So those were the two that she recommended be continued?
A. Yes.
Q. Okay. Do you recall what she said, if anything, about the relative risks of those two drugs for harm to the fetus?
A. My understanding is that Prozac is well-studied in women who are pregnant and that the risk is very low, and that Risperdal is not as well-studied; however, there's no evidence to suggest that -- no evidence to suggest that it's an obvious teratogen.
Q. Okay. Why didn't you make a note in October regarding these conversations?
A. Well, Chris Stepansky was -- he reached out to her. I know that Chris and I talked the day we found -- I'm remembering that we talked the day we found out she was pregnant; and it was my recommendation that these medicines being stopped but I wanted him to confirm with Dr. Dresner because she's a women's mental health specialist. Since he's the primary -- the primary physician, and I was trying to teach him how to coordinate care with other providers, to reach out to

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her to confirm this reason -- to confirm this decision.
Q. All right. So I just want to make sure I understand the sequence. What you're saying is that Dr. Stepansky contacted you after he learned that Mrs. Muhammad was pregnant, correct?
A. I'm pretty sure that we talked.
Q. All right. And then during that conversation, you recommended stopping Depakote and the Cogentin?
A. I recommended stopping Depakote. I don't know specifically about Cogentin.
Q. Okay. And then you also, then, suggested or directed Dr. Stepansky to call Dr. Dresner?
A. To confirm, yes.
Q. All right. And then after he spoke with Dr. Dresner, you later called to get confirmation of her recommendation?
A. I don't know I called her, but I -- she and I talked. I don't know how that started.
Q. All right. Now, this note that you entered on February 25th, 2006, isn't it true that by this date you knew that the fetus had Spina bifida?
A. I don't remember when we found out.
Q. All right. How about page 129?
A. Okay.

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Q. Just so the record is clear, page 129 is an outpatient note from February 21st of 2006, correct?
A. Yes.
Q. And in that note, I believe it's, what, Dr. Jeff Murdick (phonetic) --
A. Mudrick.
Q. (Continuing.) -- Mudrick indicates that there was a discussion about a recent ultrasound showing Spina bifida?
A. Yes.
Q. And, in fact, I think if we look at the notes, there's an indication that there was a family meeting that was conducted on February 23rd of 2006. Do you recall that?
A. What page are you looking at?
Q. Let's see if I can find it here. Well, it's a team meeting for certain. If you look at page 56.
A. Yes.
Q. All right. Page 56, this is one of your -- it's a report for the team meeting that was conducted relating to Angie Muhammad, correct?
A. Correct.
Q. And according to the record, it says, this is meeting occurred on February 24th of 2006, right?

A. Right.
Q. And it indicates there that in mid-February patient had ultrasound which revealed the fetus had loss of fluid in the brain and Spina bifida, correct?
A. Correct.
Q. And you signed in as being the attending physician, so you were at this meeting and learned that Mrs. Muhammad's fetus had Spina bifida?
A. Exactly.
Q. All right. And then if we go back to page 132, on the day after this team meeting, that's when you made your late note and you documented at that point your conver- -- Dr. Stepansky's conversations and your conversations regarding the stopping of Depakote after it was learned Mrs. Muhammad was pregnant, true?
A. Right.
Q. Did you ever talk to Dr. Cohen regarding the situation with Angie Muhammad, about her taking Depakote while she was pregnant?
MS. SOCOL: That's been asked and answered.
BY THE WITNESS:
A. I don't know specifically.
Q. Did you -- So you have the team meeting on the 24th of February, you learn that Angie's child has

Spina bifida. So why is it then the following day you make this note to document conversations that took place in October?
A. I don't remember.
Q. Were you asked to make this entry by anybody?
A. No. I believe it was because I -- I know that Dr. Dresner and I were communicating by e-mail and she was a consultant informally, and I wanted to make sure that her input in this case was reflected in the chart. So I just wanted to -- I put that in on February 25th and I wanted a note to reflect that it was in there.
Q. Well, you had your e-mail conversation in December --
A. Yeah.
Q. -- two months earlier?
And at that point, it appeared that the fetus was normal, correct?
A. As far as I know, yes.
Q. So why didn't you make your entries in December after -- contemporaneous with the time that you were having these e-mail conversations?
MS. SOCOL: That's been asked and answered.
BY THE WITNESS:
A. I don't know.

Q. You don't know?
A. I don't know.
Q. All right. However, you did. The day after learning that the child had Spina bifida, make the note?
A. I put it in there on a date that happened to be after we found out, but I don't know why I put it in then.
Q. Well, were you motivated to make this note because you learned the day before that the fetus had Spina bifida?
A. I don't believe so.
Q. It was just a coincidence?
A. I think I was trying to have the medical record reflect the comprehensive care of this patient and I wanted to make sure that all parties involved in her care were in the medical record; and that included OB/GYN because this is a multiple decision. This is a decision with them and that includes any informal consultation I had. And I was just -- I wanted to make sure that the medical record reflected the true interdisciplinary treatment of this patient.
Q. Which included the decision to give Depakote?
MS. SOCOL: I'm going to object. I'm not quite sure -- The question is vague.

MR. LUNDBLAD: All right. I'll withdraw it.
BY MR. LUNDBLAD:
Q. One last -- hopefully one last -- Lawyers are never accurate when they give that statement, but ...
All right. Page 116 ...
A. 16.
Q. Right. 116, Exhibit 2, the medical chart. All right. This is a document that's dated January 3rd of 2006, correct?
A. Correct.
Q. And at the bottom, it's signed by Angie Muhammad, true?
A. That's true.
Q. And if we read through this, this starts out by saying: I am recommending we begin therapy with a medication called lithium.
Do you see that?
A. Yes.
Q. And in the second paragraph, it talks about how there are potential adverse reactions to lithium, correct?
A. That's correct.
Q. And in the paragraph right above where it says "please sign below," it says: Lithium is known to

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increase the risk of congenital malformation in a fetus when taken by pregnant patients.
Is that what it says?
A. Yes.
Q. And then it goes on to describe a specific malformation, a risk of cardiac malformations, true?
A. True.
Q. And then says: These risks are thought to be greater when it's administered in the first trimester. You must aware of these potential risks to the fetus.
Is that what it says?
A. Yes.
Q. Now, why -- whose idea was it -- Well, strike that.
Was there a policy or procedure at Northwestern that existed in January of 2006 that required a written description such as this signed off by the patient for the administration of lithium, which is known to have teratogenic effects?
A. No.
Q. All right. Who decided that it was necessary to have Mrs. Muhammad sign this document before the lithium was given to her?
A. I don't remember.

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Q. Was this something that you required of Dr. Stepansky?
A. I believe it was something that Dr. Stepansky and I decided together to do.
Q. All right. And did you consult with anybody from the hospital before doing this?
A. I don't remember.
Q. Did you talk to Dr. Dresner about having Mrs. Muhammad sign off on this?
A. I don't remember.
Q. If we go ahead three pages, page 119, this document, I believe, Dr. Stepansky testified in his deposition was basically a summary he prepared because he left the group or was no longer working with Mrs. Muhammad after January of 2006, correct?
A. I believe so, yes.
Q. All right. If we lock at the bottom of the page where it says Plan, number 3, it says: Patient's OB/GYN is Dr. Komal, K O M A L, Bajaj, B A J A J. I've spoken with her regarding lithium administration. She advised us that a document be placed in power chart detailing our recommendations for lithium, discontinuation during post- -- or during peripartum period to prevent neonatal lithium toxicity; DW, Tom

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Allen.
Do you see that?
A. Yes.
Q. All right. Do you recall the discussion that's documented here that -- with Dr. Stepansky?
A. Yes.
Q. And what do you recall about the conversation?
A. That we -- Angie was planning to have birth at -- to give birth at Northwestern and we needed recommendations for how to taper off or continue the lithium at -- during labor. And the OB/GYN wanted us to put those recommendation in power chart, which is the medical record for the hospital, to detail how they should dose the lithium at the time she gives birth.
Q. Okay. So that would relate to events that were in the future and expected sometime in April or May of 2006, correct?
A. Exactly.
Q. All right. Did anyone -- Going back to page 116, the document Mrs. Muhammad signed, was there anyone who directed you to have this document prepared and signed by Mrs. Muhammad?
A. I don't believe so.
Q. All right. In going through the chart,

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there's no similar document that relates to Depakote, is there?
A. Not similar to this, no.
Q. All right. Specifically, there's no document that was signed by Mrs. Muhammad where the risks of Depakote were stated including the risk of fetus malformations, correct?
A. We gave the patient paperwork on Depakote when she started.
Q. All right. My question was: Isn't it true there's no paper such as this that's signed by Mrs. Muhammad indicating that someone had explained to her the risks of fetal injury from Depakote, correct?
A. There's a note in the medical record of discussing the risks.
Q. But my question is: There's no signed doc- -- no document signed by Mrs. Muhammad similar to this that lays out the risks of Depakote and her agreement to take it notwithstanding the risk, correct?
A. I see. You're, correct.
Q. All right.
A. May I add why?
Q. Your attorney can ask a question later if she wishes.

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Now, in addition to this discussion that's documented relating to a Dr. Bajaj, you also spoke to another physician regarding how to handle Depakote -- strike that -- how to handle lithium during the pregnancy, correct?
A. Correct.
Q. And that was Dr. Laura Miller?
A. Yes.
Q. And Dr. Miller, she was, where, at University of Illinois?
A. I believe so, yes.
Q. And why did you reach out to Dr. Miller?
A. She's a national expert on women's mental health.
Q. And, again, what was it about her expertise in women's mental health that you reached out to her for?
A. To get advice on how to dose lithium at the time of delivery.
Q. Okay. And on page 137, this documents the conversation that you had with Dr. Miller?
A. Yes.
Q. During the time that you spoke with Dr. Miller, did you talk at all about the fact that Depakote had been given to Mrs. Muhammad?

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A. I don't remember.
Q. Did you follow the recommendations of Dr. Miller at the end of the pregnancy?
A. I believe so, yes.
I passed those recommendations on to the OB/GYN and the psychiatric consult service who were treating the patient in the hospital.
Q. Okay. All right. At that point, you needed coordination because you needed to treat Mrs. Muhammad as well as avoid injuring, further, the fetus?
A. I wasn't treating her in the hospital. She was being seen by other physicians.
Q. But you were still supervising her care, correct?
A. I was -- No, I was her outpatient psychiatrist.
Q. Right. I'm saying is that, at this point in time, what you had to do is balance between treating Mrs. Muhammad's illness and not harming any further the fetus?
A. Those recommendations were to treat both, make sure the baby and the patient were both safe at the time of delivery.
Q. Okay. For how long had you been aware that

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Dr. Miller was one of the experts in treating women in mental health?
MS. SOCOL: Don't guess if you don't know.
BY THE WITNESS:
A. I don't remember.
Q. Well, you were aware of her in July of 2005?
A. On what date? July of 2000- --
I don't remember. I -- I was aware of her prior to contacting her.
Q. Do you know how you became aware of Dr. Miller and her expertise?
A. I believe in some of the lectures there were references to her work. She published papers.
Q. All right. So lectures during your medical education?
A. Exactly.
Q. Okay. So goes back then, you were -- based on that, you were aware of Dr. Miller prior to July of 2005?
A. I think so.
Q. All right. And you did not reach out to Dr. Miller to consult with her in July through October regarding the use of Depakote with Mrs. Muhammad, true?
A. I did not reach out to her, correct.

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Q. All right. Going back to a couple things you said earlier, I believe you testified that you were aware, in July of 2005, of at least two others but actually, probably three other mood stabilizers that were available that could be used in place of Depakote, correct?
MS. SOCOL: Objection, mischaracterizes his testimony. I don't think he ever said in place of.
BY MR. LUNDBLAD:
Q. Well, in July of 2005, you were aware that lithium was a mood stabilizer, correct?
A. Correct.
Q. And you also knew that Tegretol was a mood stabilizer, true?
A. Yes.
Q. And you also were aware that Lamictal was a mood stabilizer?
A. Yes.
Q. So those three were options available in July as they were in December and January, correct?
A. That's correct.
Q. And I believe you testified that -- in July that you were aware that Depakote posed a higher risk of causing fetal malformation than did lithium or Tegretol,

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true?
MS. SOCOL: Objection, asked and answered.
BY THE WITNESS:
A. Yeah, I already answered that.
Q. And your answer is, you agree that that's correct, you knew that in July?
MS. SOCOL: Objection, asked and answered.
BY THE WITNESS:
A. I'll defer to my previous answer.
Q. Well, I need it for -- Isn't it correct that you knew in July of 2005 that lithium and Tegretol posed a lesser risk of fetal malformation than Depakote?
MS. SOCOL: I object. That mischaracterizes his testimony.
MR. LUNDBLAD: He can say yes or no.
BY MR. LUNDBLAD:
Q. Did you know that or not?
A. It depends on what fetal malformation you're talking about.
Q. Spina bifida?
A. Depakote is higher risk than lithium. I believe it's a higher risk than Tegretol as well.
Q. And what about with Lamictal?
A. I believe Depakote is a higher risk than

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Lamictal.
Q. Okay. Now, you previously testified that in your opinion that -- Well, strike that.
Did you consider trying lithium, Lamictal, or Tegretol prior to using Depakote to see if it would provide mood stabilization for Mrs. Muhammad before starting the Depakote?
A. I wasn't working there then.
Q. Okay. You're right.
Did you consider switching Mrs. Muhammad to any one of those three after you got involved, to lessen the risk of fetal malformation in the event she got pregnant?
MS. SOCOL: Objection, several questions in one.
BY THE WITNESS:
A. Yeah, I guess ...
MS. SOCOL: It's compound questions.
MR. LUNDBLAD: All right.
BY MR. LUNDBLAD:
Q. All right. When -- You took over Mrs. Muhammad or supervising Dr. Stepansky and Mrs. Muhammad's care in July of 2005, correct?
A. Correct.
Q. At that time, you knew that she was on

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Depakote?
A. Yes.
Q. And you knew the teratogenicity of Depakote?
A. Yes.
Q. And you also knew that lithium, Lamictal, and Tegretol had lesser teratogenicity, correct?
MS. SOCOL: Objection, asked and answered.
BY THE WITNESS:
A. Yes.
Q. So my question is: Did you consider changing Mrs. Muhammad from Depakote to lithium, Lamictal, or Tegretol to reduce the risk of fetal malformation in the event she were to become pregnant while you were supervising her care?
A. I believe so. I considered alternatives while she was on it.
Q. All right. And why did you reject switching Mrs. Muhammad to lithium, Lamictal, or Tegretol to reduce the potential teratogenicity of the medication she was taking?
A. Well, my -- she had been doing very well on Depakote so I didn't want to change that. Lamictal is good to prevent mood destabilization but it often takes five weeks to work, and I thought that would be

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dangerous that to switch her to something that takes so long to work.
Tegretol, in my opinion, is not as effective as Depakote for rapid cycling bipolar disorder, and it also can -- it can reduce the efficacy of other medications she's on.
And lithium, in the literature, is really better for pure manic episodes, and it also has a teratogenic risk. I didn't want to switch her from something that's working well to another medication that can also have teratogenic risks and may not work as well.
Q. All right. Under the PDR warnings relating to Depakote that had been published in 2005, it states that women of childbearing age or -- Strike that. Let me start over.
The 2005 PDR relating to Depakote states that women of childbearing potential should be given Depakote only if it's shown to be clearly essential in the management of the condition.
A. (Nodding.)
Q. So was -- In light of the fact that you had alternatives that were of lesser teratogenicity, how was Depakote essential to Mrs. Muhammad's treatment?

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MS. SOCOL: I'm going to object, lack of foundation. That is a drug manufacturer's representation and you know it's used to save them in product liability cases. It's not necessarily anything other put out by a drug manufacturer.

So I object to asking Dr. Allen to comment on why the drug manufacturer calls something essential or not. I don't think it's fair. I don't think it has any relevancy.

So you have don't have to answer that.

MR. LUNDBLAD: So you're directing him not to answer?

MS. SOCOL: Yes.

You do not have to answer that.

BY MR. LUNDBLAD:

Q. And are you following the advice of counsel and not answering?

A. Yes.

MR. LUNDBLAD: All right. Then I would ask that the question be certified.

BY MR. LUNDBLAD:

Q. In your evaluation of Mrs. Muhammad, in whether or not Depakote was appropriate for her when you took over in July, did you make a determination as to

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whether or not the use of Depakote was essential to the care and treatment of Mrs. Muhammad?

MS. SOCOL: Again, I'm going to object the use of the word essential for the reasons previously stated. It's not relevant. There's no reason why he had to prove anything was essential or not.

I think he's testified and given you answers as to his rationale and reasons.

MR. LUNDBLAD: So are you directing him not to answer?

MS. SOCOL: Yes.

BY MR. LUNDBLAD:

Q. Are you following counsel's advice?

A. Yes.

MR. LUNDBLAD: Certify the question, please.

BY MR. LUNDBLAD:

Q. I take it in order to be a psychiatrist you had to have, what is it, some sort of number that allows to write out prescriptions for controlled drugs?

A. DEA.

Q. DEA, true?

A. True.

Q. And are you familiar that the FDA puts out directives that are -- that doctors are required to

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follow when prescribing and using certain medications?

A. What do you mean by "directives"? I don't understand.

Q. Well, as I understand it, currently, it's something that happened after this event, but there's limitations now on the amount of opioids that could be prescribed to a person. Are you aware of --

A. I don't know of those.

Q. You're not aware.

Well, in your practice, were you aware of whether you, as a physician, were obligated to follow directives put out by the FDA related to drugs?

MS. SOCOL: I'm going to object to the vagueness. I'm going to lack of foundation, to form, and relevancy.

BY THE WITNESS:

A. I can't answer that.

Q. Are you familiar with the term black box warning?

A. Yes.

Q. And what's your understanding of a black box warning?

A. My understanding is it's a contraindication for giving the medication.

Q. Okay. And as a physician, are you expected to

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follow black box warnings put out by the FDA?

A. It's one of the risks that we inform patients about in deciding whether the risks outweigh the benefits.

Q. All right. You used the contraindicated previously?

A. (Nodding.)

Q. And contraindicated means don't use, correct?

A. There are relative contraindications and there are absolute contraindications.

Q. If something is absolutely contraindicated as stated in the FDA regulations, as a physician, are you obligated to follow and not prescribe a medication that's absolutely contraindicated?

MS. SOCOL: I'm going to object to the vagueness. I don't know who's obligating him or not. The drug manufacturer --

MR. LUNDBLAD: No.

MS. SOCOL: -- is he obligated to --

MR. LUNDBLAD: Well --

MS. SOCOL: -- follow drug manufacturers -- It's vague. I don't understand the question. I'm sorry.

BY MR. LUNDBLAD:

Q. All right. We talked early on about the term

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standard of care. Under the standard of care, if the FDA in a black box warning says a drug is absolutely contraindicated, to meet the standard of care, are you required to follow those directives and not give the drug?

A. There's so many layers to your questions. I mean --

MS. SOCOL: If you can't answer it, just tell him you can't answer it.

BY THE WITNESS:

A. I don't know how to answer that.

Q. All right. If a black box warning says a drug is absolutely contraindicated, can you prescribe it to a patient?

MS. SOCOL: That's been asked and answered. He said yes.

MR. LUNDBLAD: No. He's doing quite well without you coaching.

MS. SOCOL: Well, I'm not coaching him, but it's getting late and we're well beyond three hours, and everybody is getting tired. So ...

MR. LUNDBLAD: Well, it's --

MS. SOCOL: We started late because -- to you accommodate your schedule, and it's now 6:30 and I think

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everybody is tired. Actually, it's past 6:30.

MR. LUNDBLAD: Can you read back the question, please.

(Record read as requested.)

BY THE WITNESS:

A. I guess it depends on the drug and the situation. That's a hypothetical.

Q. Okay. As a physician, are you required to take into consideration black box warnings when you're prescribing a medication?

MS. SOCOL: And, again, vague; I object.

BY THE WITNESS:

A. We're required to be aware of the risks of medications.

Q. Okay. Specifically, are you required to be aware of black box warnings relating to drugs?

MS. SOCOL: I object to black box. It doesn't relate to this case. It's not relevant, and he answered the question.

BY MR. LUNDBLAD:

Q. I'll give you what's been marked as Exhibit 25 --

MS. SOCOL: Exhibit 23.

BY MR. LUNDBLAD:

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Q. -- 23. Excuse me.

On the second page, the first page with printing on it, do you see where it says Depakote?

A. Yes.

Q. All right. And it has in there box warning. Do you see that?

A. Yes.

Q. And it's -- the box is -- it has a black line going around the box, correct, or forming the box?

A. Yes.

Q. And is that what we are referring to as the black box warning?

A. I believe so, yes.

Q. And if we look there, it talks about teratogenicity regarding Depakote?

A. Yes.

Q. And it says: Valproate can produce teratogenic effects such as neural tube defects, e.g. Spina bifida. Accordingly, the use of valproate products in women of childbearing potential, requires that the benefits of its use be weighed against the risk of injury to the fetus.

Is that what it says?

A. Yes.

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Q. And is -- as a doctor, are you required to follow the recommendations that are contained in black box warnings?

MS. SOCOL: Objection.

BY THE WITNESS:

A. These are -- These are risks that are given in the medication information and I need to be aware of risks.

Q. All right. My question, though, is: Besides being aware, are you required to follow the recommendations of the drug manufacturer in the black box warning?

A. Required by whom?

Q. The standard of care of being a doctor?

A. Rephrase your question.

Q. All right. Sure.

It goes back to where we were. As a physician, to meet the standard of care, are you required to follow the black box recommendations of a drug manufacturer regarding risks of harm that the medication may have?

MS. SOCOL: I'm going to the object to the vagueness. I don't know what you mean by "follow," and I don't know if you mean every single drug that the --

that comes out in the --
MR. LUNDBLAD: Well, we can make it specific.
BY MR. LUNDBLAD:
Q. As a physician, were you required to follow the black box recommendation relating to Depakote?
A. I'm required to be aware of the black box recommendation and use that in my decision making.
Q. All right.
MR. LUNDBLAD: Can we have a couple minutes.
(A short break was had.)
BY MR. LUNDBLAD:
Q. We've talked about Dr. Dresner and Dr. Miller, and I believe you indicated that it was your understanding that they were experts in women's mental health issues; is that correct?
A. That's correct, yes.
Q. Do you know -- And I think you indicated that you became aware of Dr. Miller through lectures you had heard in your training, articles that you may have seen or read that were written by her; is that correct?
A. That's correct.
Q. Do you know what depth of Dr. Miller's experience was as far as women's mental health issues?
A. No.

Q. However, you did recognize or you had an opinion, anyway, that Dr. Miller had greater knowledge, experience, and expertise in prescribing lithium during the course of her pregnancy?
MS. SOCOL: I'm going to object. I don't think he's ever testified to that and he doesn't know the depth of Dr. Miller's training or experience. So lack of foundation.
Read the question back, please.
(Record read as requested.)
BY THE WITNESS:
A. Greater than ...
Q. Than you?
A. She was a consultant. I wanted to discuss this decision with a consultant.
Q. And you sought her out because you believed she had greater knowledge, experience, and expertise in using lithium during pregnancy?
MS. SOCOL: Objection, asked and answered, and that is not his testimony.
BY MR. LUNDBLAD:
Q. Then why did you seek her out?
A. She was a fellow psychiatrist who had experience with women's mental health, and I wanted

input -- her input on this case.
Q. You also indicated that -- Going to Dr. Dresner, how did you become aware of her expertise in women's mental health issues?
MS. SOCOL: I'm going to the object to the use of the term expertise. I do not believe Dr. Allen ever said she's an expert or has expertise other than a colleague in psychiatry. That's been the testimony.
BY MR. LUNDBLAD:
Q. Well, did you believe Dr. Dresner had greeter expertise than you in prescribing mood stabilizers to a pregnant woman?
A. I don't believe she had greater expertise. She had knowledge of women's mental health and I wanted to consult her.
Q. And how did you know that she had this knowledge in women's mental health?
A. She used to teach at -- when I was a resident on women's mental health, and she functions as a women's mental health psychiatrist.
Q. Okay. Is there a specialty recognized in psychiatry for treating women's mental health issues?
A. I don't know if it's official. You mean a subspecialty?

Q. Right.
A. I don't know if it's official or not.
MR. LUNDBLAD: All right. We'll conclude.
MS. SOCOL: All right. We're going a take a break. We may have a few questions.
(A short break was had.)
MS. SOCOL: Dr. Allen, I have some questions to clarify a few things.
EXAMINATION
BY MS. SOCOL:
Q. You wanted to explain you were -- why there was a note with respect to lithium that you had Angie Muhammad sign and there was no such note regarding Depakote.
Was the reason because Angie Muhammad was already pregnant when the lithium was prescribed?
A. Yes.
Q. Okay. And she was not pregnant when the Depakote was prescribed?
A. Exactly.
Q. So you wanted to make sure that Angie understood that lithium was teratogenic as well?
A. Because she was pregnant.
Q. Okay. Now, Janet Peden -- Dr. Janet Peden,

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was she part of your team? She was part of the interdisciplinary team?
A. May I add one more thing to the lithium question?
Q. Yes.
A. And also there were different the monitoring requirements for lithium that were required because she was pregnant, and that was on there as well.
Q. Okay. Now, Dr. Janet Peden was part of your interdisciplinary team?
A. Yes.
Q. Okay. So you would be familiar with her notes?
A. Yes.
Q. And you would discuss Angie Muhammad with her?
A. Yes.
Q. Was it your understanding, based on her notes, based on your conversations with Dr. Peden, that Dr. Peden told Angie Muhammad and her husband about the teratogenic effects of Depakote?
A. Yes.
Q. And that Dr. Peden informed Angie Muhammad and her husband Charles that Angie should not get pregnant?
A. Yes.

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Q. And that's actually in a written note, correct?
A. Yes.
Q. And that's also something you discussed with her, so you were aware of the fact that she told Angie and her husband that Angie should not get pregnant because she was on Depakote and that was potentially risky for a fetus?
MR. LUNDBLAD: Objection, lack of foundation in the question.
BY MS. SOCOL:
Q. Is that correct?
A. Yes.
Q. And one of the risks was neural tube defects, correct?
A. Correct.
Q. And Janet Peden discussed that risk with Angie Muhammad and with her husband Charles, correct?
A. Yes.
MR. LUNDBLAD: Objection to the foundation.
BY MS. SOCOL:
Q. And that was before Angie became pregnant, correct?
A. That's correct.

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Q. Now, are there occasions in which pregnant women remain on Depakote?
A. As I said previously, there are times when women who are pregnant would remain on Depakote if the benefits outweigh the risks.
Q. Okay. And are there consequences and risks to abruptly stopping Depakote?
A. Definitely.
Q. What are those risks?
A. In a person with bipolar disorder, the risk of rebound mania or depression; someone with epilepsy, it's a risk of seizure.
Q. Okay. And that's a risk that you were aware of when you first met Angie Muhammad?
A. Yes.
Q. And that's a risk you took into consideration in deciding with Dr. Stepansky to continue her on Depakote?
A. Yes.
Q. And was it your opinion that Depakote was actually improving Angie's mental abilities?
A. Yes.
Q. And she actually stayed out of the hospital and was calm and able to care for herself and her

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children, whereas she was not able to do so before the Depakote; is that true?
A. That is true.
Q. Okay. And Angie had been on multiple medications for her bipolar disorder and her other psychiatric problems, correct?
A. Correct.
Q. And nothing seemed to be as effective as Depakote; is that true?
A. That's true. That's true for stabilizing her mood; however, she needed antipsychotics to treat her psychosis.
Q. Okay. Now, is it true that you first learned that Angie's fetus had a neural tube defect on February 21st of 2006 as shown in the records? And I'll let you look of the them.
A. Yes, that's correct.
Q. And --
MR. LUNDBLAD: Is there a page that you're referring to?
MS. SOCOL: It's 350 of our records. Let's see if you have it in here.
BY THE WITNESS:
A. It's here. It's 129.

MS. SOCOL: 129 of your records.
BY MS. SOCOL:
Q. Is it also true that you were present at the family meeting with Angie Muhammad and her husband on February 23rd of 2006?
A. Yes, that's true.
Q. Do you have a recollection of that meeting with Angie?
A. Yes. It was after she learned her baby had Spina bifida and we wanted to assemble the treatment team with her and her family to talk about her emotional reactions to that, planning for caretaking of the baby, whether she understood the responsibility that it entails in having a disabled child, and to provide support.
And also, I remember asking her of her understanding of the illness that her baby had and she understood what it was. And I also asked her to understand -- asked her if she understood that Depakote was a med- -- that she was on Depakote and that is a risk of causing birth defects like this; and she said she was aware of that risk.
Q. And did Angie also tell you she was aware of the fact that she was not supposed to get pregnant while

on Depakote?
A. Yes.
Q. And she verbalized that to you at that meeting?
A. Yes.
And the timing ...
Q. And then after -- I'm sorry. What was the timing?
And then after the February 23rd, when you had the family meeting, did you then go back and write that note on February 25th to just explain everything that had occurred in your conversation with Dr. Dresner in an effort to be complete?
A. Yes. We were trying to compile the whole -- the entire treatment team and everybody involved and I wanted to document in the record everybody who had a part to play in her care.
Q. Okay. So you actually learned of the complication of Spina bifida on the 21st, and then after meeting with Angie and her family and having the family meeting with others, you wrote that note four days later, on February 25th, 2006 --
A. Yes.
Q. -- as a culmination for everything that

occurred?
A. Yes.
Q. In the interest of continuity of care and completeness?
A. Exactly.
Q. Okay. Dr. Allen, did you conform to the standard of care and act as a reasonably, careful, and well-qualified psychiatrist in your care and treatment of Angie Muhammad?
A. Yes.
Q. And did Dr. Stepansky, in your opinion, conform to the standard of care as a resident who you were working with and supervising in his care and treatment of Angie Muhammad?
A. Yes.
MR. LUNDBLAD: Objection, foundation.
BY THE WITNESS:
A. My answer is yes.
MS. SOCOL: Okay. That's all I have.
MR. LUNDBLAD: All right. A couple of follow up questions to those.
FURTHER EXAMINATION
BY MR. LUNDBLAD:
Q. Go to page 131, please.

This is a note relating to the family meeting you were talking about, correct?
A. Yes.
Q. And it's a note dated February 23rd, 2006, and it was written by the new resident, Dr. Jeff Mudrick?
A. Yes.
Q. And if we look at his note, his note contains nothing about what you testified to where Mrs. Muhammad allegedly said that she knew the risks of taking Depakote and that she knew she was not supposed to get pregnant while Depakote. There's nothing in Dr. Mudrick's note relating to those topics, is there?
A. This was a conversation I had with Angie on the side. So I don't know that he was aware of that.
Q. Okay. So the answer to my question is that there's nothing in the notes relating to the -- to those two things, correct?
A. Right, there's nothing in the notes.
Q. All right. And you said that you had a private conversation. Is there any note that you made in this record you can point to that documents this private conversation?
A. I don't believe so.
Q. Okay. Now, you would agree that by the time

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you had this family meeting, I think you told us, you knew that the fetus had been diagnosed through ultrasound with Spina bifida, true?
A. One second. I may have found a note that was answering your last question.
Q. What page?
A. 135.
MS. SOCOL: Page 135.
BY MR. LUNDBLAD:
Q. What part of that note are you referring to?
A. This note was a case coordination meeting for Angie that occurred among the treatment team on March 16th of '06. And I wrote the note.
I thought I summarized parts of the previous family meeting that you referred to on the 21st of -- sorry -- of the 23rd of February but I'm not seeing it. So I'm sorry. I thought I saw it but I don't.
Q. All right. So the record is clear, you're talking about a note that's on two pages, page 135 and 136, correct?
A. Exactly.
Q. And the note is dated March 16th of 2006?
A. Yes.
Q. And so the record is clear, if we read the

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note on those two pages, it says nothing about a conversation where Mrs. Muhammad acknowledged that she knew the risks of fetal abnormalities due to Depakote, true?
A. I cannot see it here, that's correct.
Q. And likewise, there's nothing in this note on page 135 and 136 where Mrs. Muhammad acknowledged that she knew she should not get pregnant with Depakote, correct?
A. Not in this note.
Q. All right. Now, you talked about timeline and how the family meeting occurred, and then you wrote your note on page 132, the late note relating back to October.
Question: In that time period, after it was learned that the fetus had Spina bifida, was there an investigation started by the hospital where you were asked to give statements?
A. I don't believe so.
Q. Have you ever been asked to give a statement relating to this incident?
A. I don't believe so.
Q. Going to the letter that was signed by Mrs. Muhammad dated January 3rd of 2006 regarding the

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lithium, in answer to counsel's question, you had said something to the effect that a reason that the letter or that that document had to be signed by Mrs. Muhammad was because there was something to the effect of different monitoring requirements for lithium.
What did you mean by that?
A. Let me look. We would be monitoring blood levels of lithium with frequent blood tests. So it means that as she gets closer to pregnancy, we have to monitor her levels more often.
MS. SOCOL: Delivery.
BY THE WITNESS:
A. I'm sorry. As she gets closer to delivery, we have to monitor the levels more quickly and more frequently.
Q. So why does that -- why is that a difference and why did the monitoring require this document to be signed by Mrs. Muhammad?
A. It's just one additional feature. The main one was that she was pregnant and we were starting her on a potentially teratogenic medication knowing that she's pregnant. So we wanted to make sure that she was aware and that she signed --
Q. All right.

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A. -- the risks.
Q. You were asked a question about whether pregnant women remain on Depakote. And my question is: If you have a woman who is pregnant and you -- it is determine to continue Depakote, is the dosage of Depakote reduced?
A. If -- Rephrase the question.
Q. Sure.
Early on in the deposition I referred to some articles from the medical literature that existed before 2005 that indicate findings that there's an increase in incidences of fetal malformation related to the amount of Depakote being ingested by the patient.
So my question is: If a pregnant woman is allowed to remain on Depakote, is the dosage reduced so that it's below this level where they're -- to reduce the teratogenicity effect of the drug?
A. I don't believe so.
Q. So in your opinion then, it's full speed ahead and just keep the patient on the same dosage even if they're pregnant, if their circumstances warrant it?
A. It's clinically -- It varies patient to patient.
Q. And under what circumstances would Depakote

being used a mood stabilizer where the benefits would outweigh the risks of fetal malformation in a pregnant patient?

A. Say, it's the -- really, the only medication shown to help a person remain stable, out of the hospital, not suicidal or homicidal; and that without the medication, she's at high risk of harm to herself or others.

Q. Okay.

MR. LUNDBLAD: All right. That's all I have.

MS. SOCOL: Okay. Signature is reserved.

(Witness excused.)

STATE OF ILLINOIS)
) SS.
COUNTY OF COOK)

IN THE CIRCUIT COURT OF COOK COUNTY, ILLINOIS
COUNTY DEPARTMENT, LAW DIVISION

CHARLES MUHAMMAD and ANGIE MUHAMMAD, As Parents of CHARLES MUHAMMAD, a minor, and CHARLES MUHAMMAD, Individually,

Plaintiffs,

vs. No. 12 L 12174

NORTHWESTERN MEMORIAL HOSPITAL and MEDICAL CENTER, DANIEL YOHANNA, M.D., and THOMAS W. ALLEN, M.D.,

Defendants.

I, THOMAS W. ALLEN, M.D., state that I have read the foregoing transcript of the testimony given by me at my deposition on January 9, 2017, and that said transcript constitutes a true and correct record of the testimony given by me at the said deposition except as I have so indicated on the errata sheets provided herein.

THOMAS W. ALLEN, M.D.

SUBSCRIBED AND SWORN to before me this _____ day of _____, 2017.

NOTARY PUBLIC

STATE OF ILLINOIS)
) SS.
COUNTY OF COOK)

I, Kim Kocimski, Certified Shorthand Reporter, do hereby certify that on January 9, 2017, the deposition of the witness, THOMAS W. ALLEN, M.D., called by the Plaintiffs, was taken before me, reported stenographically, and was thereafter reduced to typewriting under my direction.

The said deposition was taken at the offices of Hughes, Socol, Piers, Resnick & Dym, 70 West Madison Street, Suite 4000, Chicago, Illinois; and there were present counsel as previously set forth.

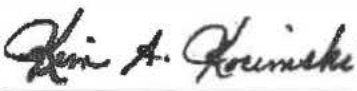
The said witness, THOMAS W. ALLEN, M.D., was first duly sworn to tell the truth, the whole truth, and nothing but the truth, and was then examined upon oral interrogatories.

I further certify that the foregoing is a true, accurate, and complete record of the questions asked of and answers made by the said witness, THOMAS W. ALLEN, M.D., at the time and place hereinabove referred to.

The signature of the witness, THOMAS W. ALLEN, M.D., was reserved by agreement of counsel.

The undersigned is not interested in the within case, nor of kin or counsel to any of the parties.

Witness my official signature on this 27th day of January, A.D., 2017.



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No. _____

In the Illinois Supreme Court

CHARLES MUHAMMAD and ANGIE MUHAMMAD, as parents of C.M, a minor, and C.M., individually,	)	On Appeal from the Appellate Court of Illinois, First Judicial District No. 1-21-0478
Plaintiffs-Respondents	)	
v.	)	On Appeal from the Circuit Court of Cook County, Illinois – Law Division
ABBOTT LABORATORIES INC. and ABBVIE INC.,	)	Case No. 2019-L-6254 Hon. Brendan A. O'Brien
Defendants-Petitioners	)	

PETITION FOR LEAVE TO APPEAL

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Oral Argument Requested If The Petition Is Allowed

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PRAYER FOR RELIEF

The First District's decision in this case radically alters the causation standard for product liability failure-to-warn claims in Illinois, and Defendants request leave to appeal it. Specifically, in such cases where a plaintiff alleges that a pharmaceutical company failed adequately to disclose a medicine's risks to the prescribing doctor—causation turns on whether a different warning would have caused the prescribing physician to change course. For forty years in Illinois, following this Court's precedent, that inquiry has been subjective (what would *this doctor*, treating *this patient*, have done with a different warning?). Many other States frame causation in the same way. The decision below makes a mess of that standard by allowing objective evidence (what would a hypothetical reasonable doctor do with a different warning?) to overcome uncontroverted testimony from the actual treating physicians.

The First District's decision is wrong, and it deviates from the law as this Court has announced it in a significant way, undercutting the learned intermediary rule, a doctrine that has governed cases like this for decades. The learned intermediary rule turns on the personal and specific relationship between *the* patient and *the* doctor. The treating physician is the learned intermediary responsible for evaluating the risks and benefits of a medicine for a particular patient, taking into account that patient's unique medical history and problems. Pharmaceutical manufacturers must warn treating physicians of a medicine's risks, and those physicians must translate the risks

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and benefits to their particular patients. The core problem with the decision below is that it allows a putatively objective opinion about what a hypothetical doctor would do to contradict the uncontroverted factual testimony of the actual doctors themselves about their subjective medical judgments. This decision calls the very foundation of the learned intermediary doctrine into question and will leave trial courts adrift as they attempt to navigate these cases going forward.

The rationale the First District gave for contradicting the law as this Court has announced it blurs the distinction between product liability claims—in which manufacturers defend their warning labels—and medical malpractice claims—in which doctors defend their treatment decisions. And the First District defended its exclusive use of medical malpractice authority in this product liability case by saying, without explanation, that "it makes no difference" that the two torts are distinct. But they are: Patients injured by drugs they should not have been prescribed retain the power to hold their doctor to account for that treatment decision by suing for medical malpractice, as Plaintiffs here did. But where, as here, the prescribing physician would have prescribed the drug even with a different warning, simple but-for causation precludes a failure-to-warn claim against the drug manufacturer. Whether the many distinctions between these two different causes of action "makes no difference" merits this Court's review.

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The decision below also conflicts with the learned intermediary rule as it is understood in other States. Elsewhere, claims like this one are precluded when the prescribing physician would not have acted differently with respect to the particular plaintiff-patient if a medicine he prescribed had included a different warning label. This decision renders Illinois an outlier in how it applies the learned intermediary rule in cases like this. That, too, is a reason for this Court to hear the appeal.

Pursuant to Rule 315, Defendants-Appellees respectfully request that this Court grant this petition and consider these important questions.

JURISDICTION

The First District issued its decision on June 23, 2022. Defendants timely filed a petition for rearing, which was denied on July 20, 2022. This petition is therefore timely under Rule 315(b)(1).

POINTS RELIED ON

The First District's decision impacts Illinois law in a monumental way. It rejects the law this Court announced nearly forty years ago and conflicts with the law in other States. If not reversed, the decision will create widespread confusion among Illinois courts and will take Illinois out of the mainstream. This Court should grant review to consider this flawed holding.

Before this decision, Illinois required a plaintiff alleging a drug manufacturer gave inadequate warnings to prove that *her doctor*—the learned intermediary—would have acted differently if provided with a stronger drug

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warning. That causation inquiry has been (until now) subjective and specific: It asks what *this doctor* (with knowledge of the patient's medical history and medical issue) would do with regard to the treatment of *this patient*. The Order below rejects that precedent, instead holding that causation can be established regardless whether the plaintiff-patient's doctor would have acted differently, so long as a plaintiff can proffer what she believes a hypothetical reasonable physician—with no relationship to the actual patient—would have done. This Court has never allowed counter-factual expert opinions about a "reasonable person" to overcome uncontroverted facts.

This decision blurs the important distinction between proving causation in medical malpractice cases and proving it in product liability failure-to-warn cases. In a medical malpractice case, a plaintiff must prove that a reasonable physician would not have caused her harm, something she usually does through expert opinion. But in a failure-to-warn case, a plaintiff must prove as a matter of fact that a different drug label would have caused her physician to act differently.

The First District did not just ignore this critical difference: It said it did not matter. That is a sea change, abandoning what has long-been a subjective factual inquiry in favor of what an expert might say. The decision, and the lack of legal support for it, will sow confusion among the lower courts and increase their workload, as judges will no longer understand how to reconcile past precedent, with its subjective fact-based inquiry, with the

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objective standard employed here. It also sets Illinois apart from other States, which would preclude claims like this one from proceeding based on a straightforward application of the learned intermediary doctrine. This Court should grant review to consider whether the First District's holding accords with its precedent and other cases from lower courts in Illinois and throughout the country.

STATEMENT OF FACTS

A. Mrs. Muhammad's Medical History And Treatment.

Plaintiff Angie Muhammad suffers from schizoaffective and bipolar disorders with a history of acute psychotic episodes and multiple hospitalizations. A.2-3. Her symptoms include auditory hallucinations and suicidal and homicidal thoughts and ideations (thoughts of killing herself, her husband, and her two children). A.2. Her psychotic episodes are mixed—she suffers simultaneously from manic and depressive symptoms and cycle rapidly—her episodes of mania and depression are frequent. A.3. Mrs. Muhammad's condition is severe, complicated, and difficult to treat. A.2-3.

In December 2003, when Mrs. Muhammad began treatment at Northwestern's psychiatry department, her symptoms were not controlled by her antipsychotic medication and she was at risk of harming herself and others. A.2-3. Dr. Christian Stepansky, a second-year resident, treated Mrs. Muhammad. A.2. He was overseen, during the relevant time, by Dr. Thomas Allen, Mrs. Muhammad's attending physician. A.4. Dr. Stepansky evaluated

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medications Mrs. Muhammad could use and prescribed Depakote, which was more effective at controlling symptoms. A.3.

Dr. Stepansky knew that Depakote could cause birth defects, including spina bifida, if taken in pregnancy. A.3. He discussed the risks with Mrs. Muhammad who, at the time, was using a birth control patch (which Dr. Stepansky could monitor) to avoid pregnancy. A.4. Mrs. Muhammad did not want to become pregnant. A.4.

Nevertheless, Mrs. Muhammad became pregnant with her son, C.M, in September 2005.[1] A.5. C.M. was born with spina bifida allegedly caused by his *in utero* exposure to Depakote. A.5.

B. Plaintiffs' Prior Lawsuit For Negligence And Current Lawsuit For Failure-to-warn.

The Muhammads first sued Dr. Allen and Northwestern for medical negligence in 2012, alleging that "Depakote was well known . . . as a drug that could cause serious, debilitating birth defects . . . and was therefore well known within the same health care communities to be contraindicated for women who are or might become pregnant[.]" A.5. The Muhammads alleged that doctors had the information necessary for the safe use of Depakote, and it was their failure to utilize that information that caused their harm. A.5, 1. A jury awarded them $18.5 million (reduced to $12 million pursuant to a high-low agreement). A.7.

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[1] C.M. and his father, Charles, are also Plaintiffs.

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In June 2019, Plaintiffs pursued this action against Defendants Abbott Laboratories, Inc. and AbbVie ("Abbott"), manufacturers of Depakote, alleging that they failed sufficiently to warn physicians of the risk of birth defects from Depakote. A.2, 7.

In 2005, when these doctors prescribed Depakote, a Black Box Warning, the most extreme warning allowed by the FDA, stated that the drug could cause birth defects, including a 1-2% risk of spina bifida if taken during the first trimester of pregnancy and an unquantified risk of other less severe birth defects. A.3, 8. According to Plaintiffs, discovery revealed that, in 2004, Abbott possessed information suggesting that the overall risk of birth defects was in the range of 8% or, perhaps, as high as 10.7-17%. A.8.

While Depakote's label correctly included a warning that the risk at issue in this action—spina bifida—was 1-2%, Plaintiffs claim the warning should have provided a range to quantify the potential risks of the other birth defects reflected in this research.

Both Dr. Allen and Dr. Stepansky were deposed regarding their knowledge of Depakote's risks and decision to prescribe it. A.8-9. Dr. Allen testified that, given the severity of Mrs. Muhammad's illness, the risk she posed, and the fact that she was on birth control, even if the reported risk of birth defects other than spina bifida had been higher, he still would have prescribed Depakote. A.9. His testimony was unwavering: "[R]egardless [] what the percentage of risk was," because Mrs. Muhammad was on birth

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control, even if it were "100%," he still would have prescribed it. A.9, 53. Dr. Stepansky likewise testified that because Mrs. Muhammad was "using reliable birth control," the 1-2% spina bifida risk was "all he needed to know" to prescribe Depakote. A.9.

Plaintiffs submitted a 5-page affidavit from a psychiatrist who never treated Mrs. Muhammad, Dr. Suhayl Nasr, stating that a reasonably prudent psychiatrist adhering to the appropriate standard of care would not have prescribed Depakote if the drug came with a label warning of a 10%-17% risk of birth defects. A.8, 52. He concluded that the "testimony of Dr. Stepansky and Dr. Allen is contrary to the standard of care and does not represent what a reasonably careful psychiatrist would have done in under [sic] the circumstances in 2005." A.53.

Abbott moved for summary judgment because: (1) Plaintiffs' prior statements in their previous lawsuit claimed that the physicians had all the information necessary to prescribe the medicine safely, contradicting their theory of liability in this case such that they should be judicially estopped; and (2) Plaintiffs could not establish causation because the uncontroverted testimony of the treating physicians established that they would not have changed their treatment decision even if the Depakote label had different warnings. A.9-10. The trial court granted summary judgment on judicial estoppel, and Plaintiffs appealed. A.10.

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The First District reversed. On causation, the court held that a treating physician's testimony that he would not have changed his prescribing decisions even with additional information could be challenged by expert testimony that "such conduct would not conform to the standard of care." A.22. In support, the First District exclusively cited medical malpractice cases. That those decisions did not arise in the context of product liability claims for failure-to-warn, the Court said, "makes no difference." A.22.

The decision below thus holds for the first time in Illinois that a drug manufacturer can be liable on a failure-to-warn claim under a medical malpractice standard, even when the uncontroverted facts demonstrate that a different warning would not have caused the prescribing physicians who actually treated the patient to make different decisions.

ARGUMENT

I. THE DECISION BELOW CONFLICTS WITH THIS COURT'S PRECEDENT ON THE LEARNED INTERMEDIARY RULE AND CONFLATES THE TORTS OF MEDICAL NEGLIGENCE AND FAILURE-TO-WARN.

This Court has long held that a pharmaceutical manufacturer's duty to warn about the risks posed by prescription medicines runs only to the physician who prescribes the medicine and given the complexity of medical care and the particularity of individual treatment decisions—the physician has a duty to utilize that information to make prescribing decisions for a patient. Stated simply: Manufacturers must warn doctors, and doctors must warn patients. This approach, aptly called the "learned intermediary" doctrine,

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treats doctors as "learned intermediaries" who translate the risks and benefits of particular treatment options for their lay patients. Numerous other States apply the learned intermediary doctrine in the same way Illinois did before the decision below.

The First District's decision rejects decades of precedent by grafting medical malpractice law (in which experts establish what a reasonable doctor would do) onto the learned intermediary rule (in which courts ask a factual question, namely, what the treating doctor would do). Whether the Order misapplied that precedent warrants review.

A. The Order Contravenes This Court's Precedent On The Learned Intermediary Doctrine.

This Court announced the learned intermediary doctrine would govern failure to-warn claims in Illinois nearly forty years ago in *Kirk v. Michael Reese Hosp. & Med. Ctr.*, 117 Ill. 2d 507 (1987). *Kirk* describes the learned intermediary doctrine as follows: "[M]anufacturers of prescription drugs have a duty to warn *prescribing physicians* of the drugs' known dangerous propensities, and *the* physicians, in turn, using *their* medical judgment, have a duty to convey the warnings to their patients." *Id.* at 517 (emphases added).

The doctrine turns on the prescribing physician's unique first-hand experience with a particular patient. The prescribing physician—not the drug manufacturer is in the best position to weigh a drug's risks and benefits on a patient-by-patient basis. And *the* learned intermediary is not *any* learned intermediary—it is the particular doctor caring for the specific patient. Indeed,

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it is the individualized relationship and history between *the* physician and *the* patient that is the foundation of the learned intermediary doctrine. The treating physician "take[s] into account the propensities of the drug as well as the susceptibilities of [the] patient" and "weigh[s] the benefits of any medication against its potential dangers." *Id.* at 518. The physician's decision "is an informed one, and *individualized medical judgment* bottomed on a knowledge of both patient and palliative" governs it. *Id.* (emphasis added).

Deferring to this personalized expertise, *Kirk* and its progeny make clear that pharmaceutical companies "are required to warn only the prescribing physician, who acts as a learned intermediary." *Id.* (quoting *Stone v. Smith, Kline & French Labs.*, 731 F.2d 1575, 1580 (11th Cir. 1984)); *Happel v. Wal-Mart Stores, Inc.*, 199 Ill. 2d 179, 193 (2002) (It "is the proper province of the prescribing physician, not the drug manufacturer," to warn patients.); *Proctor v. Davis*, 291 Ill. App. 3d 265, 277 (1st Dist. 1997).

Illinois courts have described the rule consistently in intervening years, reaffirming that the actual treating physician (not any physician, and certainly not the drug manufacturer) considers the risks of a drug and makes treatment decisions for a particular patient. *See, e.g.*, *Happel*, 199 Ill. 2d at 193 ("[T]he rationale underlying the learned intermediary doctrine is that because the prescribing physician has knowledge of the drugs he is prescribing and, more importantly, knowledge of his patient's medical history, it is the physician who is in the best position to prescribe drugs and monitor their use."); *Kennedy v.*

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Medtronic, Inc., 366 Ill. App. 3d 298, 305 (1st Dist. 2006) ("[A] doctor is considered in the best position to prescribe drugs and monitor their use because he is knowledgeable of the propensities of the drugs he is prescribing and the susceptibilities of his patient.") (citation omitted).

A plaintiff who alleges harm from a drug and brings a failure-to-warn claim must satisfy the learned intermediary doctrine. For purposes of proving that an allegedly inadequate warning caused her harm, this means "the plaintiff must be able to prove that if there had been a proper warning, the learned intermediary . . . would have declined to prescribe or recommend the product." *Vaughn v. Ethicon, Inc.*, 2020 WL 5816740, *4 (S.D. Ill. 2020). The law "requires a plaintiff to prove that a warning would have caused the learned intermediary to alter his recommendation for the allegedly defective product." *Id.* In the words of *Kirk*, the plaintiff must prove that the doctor's "individualized medical judgment" would have been different with a different warning. *Kirk*, 117 Ill. 2d at 518. The inquiry focuses on what, as a matter of fact, the actual treating physician knew and did and whether, as a matter of fact, the doctor involved would have made a different treatment decision if provided a different warning.

The First District's decision turns this on its head by ignoring the learned intermediary's role in the causation analysis. The facts here were unequivocal and specific to this patient: The treating physicians would *not* have changed course *even if* Depakote came with the additional information

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Plaintiffs claim was required. Because Mrs. Muhammad was on birth control, just as they had prescribed Depakote despite a Black Box Warning about the risk of birth defects including a 1-2% risk of spina bifida, they would have done the same even if the risk of other birth defects was 17%.

Dr. Stepansky testified that, because Mrs. Muhammad was using birth control, whether Depakote's birth defect risks were different was not important in his prescribing decision. A.45. Dr. Allen similarly testified that "regardless [] what the percentage of the risk was," he "would have still prescribed [Depakote]." A.32. Because Mrs. Muhammad was on birth control and her psychotic illness was severe, the additional information regarding the risk of birth defects would not have changed his mind. A.9, 53.

The Order acknowledged this—"both [doctors] testified that they would not have acted differently,"—but missed the import of that testimony. A.22. Under *Kirk*, the Court's inquiry should have ended when the treating physicians unequivocally testified they would not have acted differently with a different warning. The prescribing physicians, who are best positioned to "weigh[] the benefits of any medication against its potential dangers" and make an "individualized medical judgment" for their specific patient testified that they would have prescribed Depakote even with a different drug warning label. *Kirk*, 117 Ill. 2d at 518.

In allowing this case to proceed, and in relying on putative (and non-treating) expert testimony about what a hypothetical physician would have

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done, the First District misapplied the subjective standard this Court has imposed. A.22-23. That holding converts the learned intermediary inquiry into a reasonable doctor test, thereby negating the unique physician-patient relationship that is the foundation of the learned intermediary doctrine. It alters the operative legal question, which until this case asked *what this doctor would have done*, by instead asking *what a reasonable doctor should do*. It allows an opinion to overcome uncontested facts and erases the line between medical malpractice and failure-to-warn. This Court's holdings are clear that a failure-to-warn claim cannot proceed unless *this doctor* would have acted differently. By asking what *a reasonable doctor* would have done, the Order transforms the subjective inquiry the learned intermediary doctrine spells out into an objective exercise in hypothetical reasonableness. That rebuke of *Kirk* amounts to grave error meriting this Court's review and reversal.

B. The Decision Below Conflates The Separate Torts Of Medical Negligence And Failure-To-Warn, Which Have Distinct Causation Tests.

Because failure-to-warn precedent does not support the First District's decision, the decision looked elsewhere for support and reached into medical malpractice doctrine to sustain its holding. Confronted with that problem, the Court candidly insisted that the fact this is a product liability failure-to-warn case, not a malpractice suit, "makes no difference." A.22. But it does matter, and the fact that no other product liability precedent could support the holding is telling.

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The claim at issue makes a difference because it dictates what legal standard applies. Medical malpractice claims ask whether the plaintiff's physician acted consistently with professional standards of care. *See, e.g.*, *Purtill v. Hess*, 111 Ill. 2d 229, 242 (1986) (The physician-defendant's conduct is judged against "degree of knowledge, skill, and care which a reasonably well-qualified physician in the same or similar community would bring to a similar case under similar circumstances."); IPI 105.01. That inquiry is exactly the objective one that Plaintiffs here sold to the First District in this failure-to-warn case: A reasonable physician standard.

Adjudicating a reasonable physician standard in medical negligence claims thus requires expert testimony. *See Snelson v. Kamm*, 204 Ill. 2d 1, 42 (2003). That is because "a lay juror is not skilled in the profession and thus is not equipped to determine what constitutes reasonable care in professional conduct without the help of expert testimony." *Id.*

As explained above, product liability failure-to-warn claims are different. *See Kirk*, 117 Ill. 2d at 518-19. In these cases, what *a reasonable physician* would have done is irrelevant, because the law asks what *the prescribing physician* would have done. If the prescribing physician would not have altered his decision, any alleged inadequacy simply cannot be the cause of the injury. Expert testimony cannot answer, or even help answer, this question. Experts are not mind-readers.

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The need for expert testimony in medical malpractice cases makes sense in light of the defendant-physician's self-interest in those cases. *See, e.g., Seef v. Ingalls Mem. Hosp.*, 311 Ill. App. 3d 7, 27 (1st Dist. 1999) (Frossard, P.J., dissenting) ("A trial court is not required to accept a defendant's hypothetical testimony as uncontroverted fact" due to the potential for the defendant to offer "self-serving testimony, due to bias"); *Wodziak v. Kash*, 278 Ill. App. 3d 901, 912 (1st Dist. 1996) (finding "scant evidentiary value" in medical malpractice defendant's testimony). No such concern exists when the defendant is the pharmaceutical manufacturer.

II. THE ORDER BELOW CONFLICTS WITH THE LAW IN OTHER STATES.

The learned intermediary doctrine is the law of the land. "[N]ationally, it is well-settled that in prescription drug failure-to-warn cases, courts apply this doctrine." *In re Plavix Mktg., Sales Pracs. & Prods. Liab. Litig.* 2017 WL 3531684, *6 (D.N.J. 2017); *Kirk*, 117 Ill. 2d at 517 (the rule is the law "in numerous jurisdictions" and citing cases).

When courts apply the learned intermediary doctrine, they agree with *Kirk* that (1) causation is a physician-specific inquiry involving an analysis of the actual practices of the plaintiff's physician; and (2) summary judgment is appropriate when the plaintiff's prescribing physician testifies that they would not have changed treatment if a different warning had been provided. The Order below holds otherwise and, if allowed to stand, would put Illinois in conflict with numerous other States.

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A. Causation Is A Physician-Specific, Subjective Inquiry.

Blackletter law establishes that "[t]he question in the learned intermediary context is not what an objective physician would decide but, rather, what the plaintiff's doctor would determine based on knowledge of the particular drug and the plaintiff's risk factors." 33 AM. L. PROD. LIAB. 3d § 37 (2022). "That the treating physician, even when provided with the most current research and warnings, would still have prescribed the product severs any potential chain of causation through which the plaintiff could seek relief against the manufacturer." *Id.*

It is well-settled nationwide that a manufacturer's inadequate warning causes harm *only* if a different warning would have altered the physician's decision and, thus, prevented the injury. Courts have held that to be the law in Alabama,[2] Arkansas,[3] Arizona,[4] California,[5] Colorado,[6] Connecticut[7] Delaware,[8] Florida,[9] Georgia,[10] Indiana,[11] Iowa,[12] Kansas,[13] Kentucky,[14]

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[2] *Bodie v. Purdue Pharma Co.*, 236 Fed. Appx. 511, 521-22 (11th Cir. 2007).
[3] *Sharp v. Ethicon, Inc.*, 2020 WL 1434566, *3 (W.D. Ark. 2020).
[4] *D'Agnese v. Novartis Pharms. Corp.*, 952 F. Supp. 2d 880, 892-93 (D. Ariz. 2013).
[5] *Motus v. Pfizer Inc.*, 358 F.3d 659, 661 (9th Cir. 2004).
[6] *Lynch v. Olympus Am., Inc.*, 2018 WL 5619327, *12 (D. Col. 2018).
[7] *Roberto v. Boehringer Ingelheim Pharms., Inc.*, 2019 WL 1938604, *1 (Conn. Super. Ct. 2019).
[8] *Evans v. Johnson & Johnson Co.*, 2020 WL 616575, *4 (D. Del. 2020).
[9] *Eghnayem v. Bos. Sci. Corp.*, 873 F.3d 1304, 1321 (11th Cir. 2017).
[10] *Ellis v. C.R. Bard, Inc.*, 311 F.3d 1272, 1283 n.8 (11th Cir. 2002).
[11] *Kaiser v. Johnson & Johnson*, 947 F.3d 996, 1015-16 (7th Cir. 2020).
[12] *Kelly v. Ethicon, Inc.*, 2020 WL 4572348, *4 (N.D. Iowa 2020).
[13] *Miller v. Pfizer Inc.*, 196 F. Supp. 2d 1095, 1127-30 (D. Kan. 2002).
[14] *Mitchell v. Ethicon Inc.*, 2020 WL 4550898, *6 (E.D. Ky. 2020).

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Louisiana,[15] Maryland,[16] Michigan,[17] Minnesota,[18] Mississippi,[19] Missouri,[20] New Jersey,[21] New York,[22] North Carolina,[23] Ohio,[24] Oklahoma,[25] Oregon,[26] Pennsylvania,[27] South Carolina,[28] Utah,[29] Washington,[30] West Virginia,[31] Wisconsin,[32] and Wyoming.[33]

Causation is a fact-specific inquiry about the subjective decision of the treating physician. *See, e.g.*, *Ackermann v. Wyeth Pharms.*, 526 F.3d 203, 208 (5th Cir. 2008) (Plaintiff must show "that the alleged inadequacy [of a warning] caused *her doctor* to prescribe the drug *for her*.") (emphasis added) (citation omitted); *Swintelski v. Am. Med. Sys., Inc.*, 521 F. Supp. 3d 1215, 1221 (S.D.

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[15] *Johnson v. Teva Pharms. USA, Inc.*, 758 F.3d 605, 612 n.1 (5th Cir. 2014).
[16] *Grinage v. Mylan Pharms., Inc.*, 840 F. Supp. 2d 862, 868-69 (D. Md. 2011).
[17] *Mowery v. Crittenton Hosp.*, 400 N.W.2d 633, 637-38 (Mich. Ct. App. 1986).
[18] *In re Mentor Corp. ObTape Transobturator Sling Prods. Liab. Litig.*, 2016 WL 7368132, *3 (M.D. Ga. 2016).
[19] *Janssen Pharm., Inc. v. Armond*, 866 So. 2d 1092, 1101 (Miss. 2004).
[20] *Abt v. Ethicon, Inc.*, 2020 WL 4887022, **2-3 (E.D. Mo. 2020).
[21] *Baker v. App Pharms. LLP*, 2012 WL 3598841, *8 (D.N.J. 2012).
[22] *Donovan v. Centerpulse Spine Tech Inc.*, 416 Fed. Appx. 104, 107 (2d Cir. 2011).
[23] *Block v. Woo Young Med. Co.*, 937 F. Supp. 2d 1028, 1035 (D. Minn. 2013).
[24] *Heide v. Ethicon, Inc.*, 2020 WL 1322835, *5 (N.D. Ohio 2020).
[25] *Eck v. Parke, Davis & Co.*, 256 F.3d 1013, 1017-18 (10th Cir. 2001).
[26] *Parkinson v. Novartis Pharms. Corp.*, 5 F. Supp. 3d 1265, 1272-74 (D. Or. 2014).
[27] *Bock v. Novartis Pharms. Corp.*, 661 Fed. Appx. 227, 232 (3d Cir. 2016).
[28] *Bean v. Upsher-Smith Pharms., Inc.*, 2017 WL 4348330, *8 (D.S.C. 2017).
[29] *MacMurray v. Boehringer Ingelheim Pharms., Inc.*, 2017 WL 11496825, *9 (D. Utah 2017).
[30] *Luttrell v. Novartis Pharms Corp.*, 894 F. Supp. 2d 1324, 1344-45 (E.D. Wash. 2012).
[31] *Campbell v. Bos. Sci. Corp.*, 2016 WL 5796906, *8 (S.D.W.Va. 2016).
[32] *In re Zimmer, NexGen Knee Implant Prods. Liab. Litig.*, 884 F.3d 746, 752 (7th Cir. 2018).
[33] *Thom v. Bristol-Myers Squibb Co.*, 353 F.3d 848, 856 (10th Cir. 2003).

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Fla. 2021) ("[W]hat matters is whether the implanting physician would have altered his decision to implant the product had he been equipped with more detailed warnings."); *Vaughn*, 2020 WL 5816740, *4 ("Like Illinois law, Missouri law requires a plaintiff to prove that a warning would have caused the learned intermediary to alter his recommendation for the allegedly defective product.").

Because causation is case-specific, "objective" evidence divorced from the conduct and testimony of the plaintiff's physicians is irrelevant. *See Stafford v. Wyeth*, 411 F. Supp. 2d 1318, 1322 (W.D. Okla. 2006) ("The question in the learned intermediary context is not what an objective physician would decide, but rather what plaintiff's doctor would determine[.]"); *Cooper v. Bristol-Myers Squibb Co.*, 2013 WL 85291, **6-7 (D.N.J. 2013) (Courts "look carefully at the testimony of the prescribing physician," and testimony of a non-prescribing physician is irrelevant); *Isaac v. C. R. Bard, Inc.*, 2021 WL 1177882, *5 (W.D. Tex. 2021), *report and recommendation adopted*, 2021 WL 2773018 (W.D. Tex. 2021) ("[T]he learned-intermediary analysis focuses on the actions of the treating physician, not the opinion of an expert witness."). Ignoring facts in favor of counter-factual expert testimony is illogical, and courts reject this approach. "Under Plaintiff's construction, the court is required to take the rather curious action of ignoring what the treating physician says he would have done given a certain factual setting for no other reason than the fact that he is not an 'objective' physician[.]" *Woulfe v. Eli Lilly & Co.*, 965 F. Supp.

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1478, 1484 (E.D. Okla. 1997).

The decision below brushes this authority aside without even considering it. Failing to grant review and reverse would cleave this State from the law as applied in other jurisdictions. That is not a conflict this Court should countenance blindly (and it is not one a faithful application of *Kirk* allows).

B. Summary Judgment Is Appropriate Where The Treating Physician Would Not Have Altered His Decision With A Different Warning.

Where undisputed testimony from treating doctors demonstrates that a different warning would not have altered their course, a plaintiff cannot establish causation as a matter of law. *Motus v. Pfizer Inc.,* 196 F. Supp. 2d 984, 997 98 (C.D. Cal. 2001) (collecting cases), *aff'd* 358 F.3d 659 (9th Cir. 2004); *In re Zyprexa Prods. Liab. Litig.*, 727 F. Supp. 2d 101, 114 (E.D.N.Y. 2010) (collecting cases); *Cooper*, 2013 WL 85291, *6 ("[W]here a physician testifies that nothing . . . could cause him to change his decision to prescribe, causation is not shown."); *Vaughn*, 2020 WL 5816740, *4.[34] Appellate courts throughout the country affirm summary judgment in this context. *See, e.g.*,

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[34] A plaintiff cannot survive summary judgment by asserting that the jury might disbelieve an opposing witness's testimony. *See* Charles Wright & Arthur Miller, 10A Fed. Prac. & Proc. Civ. § 2726 (4th ed. Apr. 2022) ("[S]pecific facts must be produced in order to put credibility in issue so as to preclude summary judgment. Unsupported allegations . . . will not suffice."); *Schoonejongen v. Curtiss-Wright Corp.*, 143 F.3d 120, 130 (3d Cir. 1998) (It is "axiomatic" that a nonmoving party "cannot defeat summary judgment simply by asserting that a jury might disbelieve an opponent's affidavit[.]'").

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Dietz v. Smithkline Beecham Corp., 598 F.3d 812, 816 (11th Cir. 2010); *Eck*, 256 F.3d at 1020; *Odom v. G.D. Searle & Co.*, 979 F.2d 1001, 1003 (4th Cir. 1992).

But the First District's decision does the opposite, and places that Court on the wrong side of the law. Review and reversal are warranted because summary judgment is appropriate when the uncontroverted facts establish that a treating physician would not have changed course with a different warning.

III. REVIEW IS NEEDED NOW BECAUSE THE IMPACT OF THE DECISION IS SIGNIFICANT AND IMMEDIATE.

The Court should grant this petition and reverse because the decision below will cause significant harm immediately. The First District's new rule opens the floodgates to allow every plaintiff in a failure-to-warn product liability case to survive summary judgment despite uncontroverted facts defeating causation—so long as a purported expert says that a hypothetical reasonable person would have acted differently.

The impact of that decision will be to increase the workload for overburdened trial courts who can no longer rely on undisputed factual testimony to resolve cases at summary judgment. The purpose of summary judgment is "to determine if triable questions of fact exist," and thereby stop claims that would fail before the time and expense of trial. *See Pielet v. Pielet*, 2012 IL 112064, ¶ 53; *Celotex Corp. v. Catrett*, 477 U.S. 317, 323–24 (1986) ("One of the principal purposes of the summary judgment rule is to isolate and

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dispose of factually unsupported claims or defenses[.]"). This decision allows an opinion to assume away undisputed facts and forecloses defendants from obtaining summary judgment when it is appropriate. As the adage attributed to John Adams explains, "facts are stubborn things; and whatever may be our wishes, our inclinations, or the dictates of our passion, they cannot alter the state of facts and evidence." *In re Liotti,* 667 F.3d 419, 429 (4th Cir. 2011) (citing David McCullough, *John Adams* 52 (Simon & Schuster 2001)). So long as the facts control, cases like this should not proceed.

The problem will be amplified for cases that make it to trial, as trial judges struggle to reconcile this decision with the standard jury instructions on causation, which rely on *Kirk* to focus on what the learned intermediary involved would do. *See* IPI 400.07B (duty to warn the physician involved). Because the use of expert testimony contravenes Illinois law in past cases, how will trial courts decide motions to strike expert testimony as irrelevant, and how will they charge juries? Are pharmaceutical manufacturers held to a subjective standard, as they have been in the past, or an objective one, as this decision would allow? Absent clarity from this Court on that question, confusion will reign.

This decision also creates a dangerous playbook that would allow future plaintiffs two bites at the apple in a case like this. Here, Plaintiffs obtained a significant ($18.5 million) verdict for their medical negligence claim based necessarily on the contention that the prescribing physicians had all of the

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information necessary to prescribe the medicine safely. A.7. They did so while holding in abeyance their failure-to-warn claim against the Defendants here (who were not party to that suit). Plaintiffs now claim the doctors did not have the information necessary to prescribe the medicine safely.

Worse still, the impact of the First District's decision could extend beyond the context of prescription failure-to-warn claims, leading to "reasonable person" testimony contravening undisputed facts in other types of product liability cases. For non-pharmaceutical product liability cases, a plaintiff who fails to read a warning cannot sue the maker of a product for failure to warn. *See Maychszak v. Brown*, 2019 IL App (2d) 190042-U, ¶ 76 ("[T]he plaintiff has to show the warnings were actually read."). The First District spelled this out in *Kane v. R.D. Werner Co., Inc.*, 275 Ill. App. 3d 1035 (1st Dist. 1995). There, the plaintiff was injured when he fell off an extension ladder and sued the manufacturer for inadequate warnings. But the First District affirmed summary judgment because the "plaintiff admittedly never read the warnings that were given," and thus the alleged inadequate warning "could not have proximately caused his injuries." *Id.* at 1036-37. The decision here would have allowed the plaintiff in *Kane* to survive summary judgment simply by paying an expert to opine that a "reasonable man" would have read the warning and thus avoided injury. That is not, and has never been, the law in Illinois.

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Following the logic of the decision below, there would be nothing to stop this decision from applying more broadly any time an otherwise subjective standard is litigated. For example, in contract law, courts faced with an ambiguous contract term may rely on parol evidence to understand the contracting parties' intent. *See Quake Constr., Inc. v. Am. Airlines, Inc.*, 141 Ill. 2d 281, 288 (1990). But when using extrinsic evidence to determine intent, "it is axiomatic that the evidence be probative of *the parties'* intent." *In re Marriage of Kuyk*, 2015 Il App (2d) 140733, ¶ 20 (emphasis added). When faced with uncontroverted testimony from the contracting parties as to their intention, no expert report on what a reasonable actor would agree to can defeat summary judgment. The nature of the claim—and the legal standard a court uses to adjudicate it—does matter, and subjective, fact-based inquiries cannot be negated by expert testimony.

The role of the law is to right legal wrongs by holding wrongdoers to account—*not* to allow for serial litigation on the same underlying harm against any and every party, regardless how removed they are from causing harm. Failing to review and reverse this case will create an incentive to repeat this pattern, deepening confusion in the law and multiplying the work of the courts. If not corrected, this decision could bleed into other areas of the law that rely on fact-based, subjective standards to answer legal questions. Contrary to the decision below, the particular cause of action *does make a difference* in how courts apply the law.

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CONCLUSION

The Court should grant the Petition and reverse.

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