IN THE SUPERIOR COURT OF THE STATE OF DELAWARE

IN AND FOR NEW CASTLE COUNTY

Peggy Friedel, Individually and as the Administratrix of the **Estate of Mandy K. Friedel** and as Next Friend of **Makayla Friedel** and **David T. Wheat**, minors, and **David Friedel,** Individually	)	CIVIL ACTION NUMBER
	)	
	)	06C-11-233-JOH
	)	
	)	
Plaintiffs	)	
v.	)	
	)	
Abimbola O. Osunkoya, M.D., Individually and as Agent for **Delaware Primary Care, LLC**	)	
	)	
	)	
Defendants	)	

Submitted: December 14, 2009
Decided: May 7, 2010

MEMORANDUM OPINION

Upon Motion of the Plaintiffs to Preclude the Testimony of Defendants' Pathology Expert - ***DENIED***

Upon Motion of the Plaintiffs to Limit the Testimony of Dr. Bruce Goldberger - ***GRANTED***

Upon Motion of the Plaintiffs to Preclude Evidence of Prior Suicide Attempts - ***DENIED***

Upon Motion of the Defendants to Preclude the Testimony Dr. Osunkoya Violated a Federal Law - ***DENIED, Without Prejudice***

Upon Motion of the Defendants to Preclude Plaintiffs Standard of Care Testimony by Dr. John Kirby - ***DENIED***

Upon Motion of the Defendants to Preclude Dr. Jack Rosenberg's Standard of Care Testimony - ***GRANTED***

Appearances:

Martin J. Siegel, Esquire, of the Law Offices of Martin J. Siegel, Wilmington, Delaware, Attorney for the Plaintiffs

Colleen D. Shields, Esquire, of Elzufon Austin Reardon Tarlov & Mondell, P.A., Wilmington, Delaware, Attorney for the Defendants

HERLIHY, Judge

Background

This is a wrongful death medical negligence action against Dr. Amibola O. Osunkoya. The decedent, Mandy Friedel, was twenty-four years old when she died. The complaint alleges she saw Dr. Osunkoya on November 24, 2004, with various complaints including opiate withdraw and stress. On that occasion he prescribed methadone for her. She came back to see him on November 30th complaining of chest pain, shortness of breath, nose congestion, fever, and sore throat. Dr. Osunkoya continued Mandy Friedel on methadone and prescribed an additional drug Ketek for those new symptoms.

On December 2, 2004, she was found on the floor of her home in an unresponsive condition. She was taken to Kent General Hospital where she died two days later. The Assistant State Medical Examiner lists the cause of Mandy Friedel's death as "anoxic ancephalopathy due to cardiovascular pulmonary arrest, status post resuscitation, most likely secondary to ingestion to prescription medications including Methadone, Toprol, Rispardril, Wellbutrin and Depakote. Contributory causes include bronchopneumonia of the upper right lung as well as morbid obesity."

As the discussion will soon show, the autopsy and this report are controversial.

Plaintiffs, Friedel's parents, children, grandmother, and her estate filed a medical negligence action against Dr. Osunkoya and his practice Delaware Primary Care, LLC.[1]

---

[1] The limited liability company for whom the doctor works or is a member, Delaware Primary Care, L.L.C., is also a defendant. For purposes of this opinion the Court will refer only (continued…)

They allege that Dr. Osunkoya was negligent specifically by:

- Prescribing a 30 days supply of methadone without monitoring.
- Treating Friedel for opiate withdrawal in a non-opiate maintenance program as required by 21 C.F.R. §291.505 and without a license as required by Federal or State law.
- Exceeding the usual starting dose of methadone.
- Failure to properly monitor Friedel while on a methadone regiment to determine if a smaller dosage was more appropriate.
- Prescribing methadone when it was unnecessary to her symptoms.
- Prescribed methadone and other drugs which had a dangerous combination.[2]

Both parties have filed a number of motions *in limine*. The case is scheduled to go to trial on September 27, 2010.

Plaintiffs' Motion to Preclude Testimony of Defendants' Pathology Expert

Dr. Osunkoya has retained David Strayer, M.D. as an expert to opine about the adequacy of Dr. Judith Torbin's autopsy. Dr. Strayer is a board certified pathologist. He teaches pathology at Jefferson Medical College and is an attending pathologist at Thomas Jefferson University.

In his discovery deposition, Dr. Strayer was very critical of the autopsy and identified a member of areas where he believed it was deficient.[3] At various times in his deposition he testified:

---

[1](…continued)
to Dr. Osunkoya.

[2] Compl. at ¶ 16.

[3] Strayer Depo. Tr. at 85-87, 97.

Q. Is it fair to say that you cannot testify within a reasonable degree of medical probability as to any specific cause of Miss Friede's death?

A. It is fair to say that there is nothing I have seen that establishes a cause of death in this case.

* * * * *

A. Part of the process of making a determination of an individual's cause of death is excluding other possible causes of death and that simply cannot be done on the basis of the autopsy protocol that is reported.

* * * * *

A. I would say that if the autopsy had been done the way the autopsy should have been done or reported - - and reported the way an autopsy should have been reported, that it is certainly possible that it would have been able to exclude methadone as a potential contributor to this woman's death.[4]

In a somewhat confusing answer, Dr. Strayer also said:

A. And in that respect the incompleteness of the autopsy is a critical problem in analyzing or trying to understand how this woman died. So I am not -- and I'll repeat that. I am not asserting that methadone absolutely -- with any reasonable probability or whatever the terminology is in Delaware, we call it reasonable probability, I am not asserting that methadone did not have an effect. What I am saying is it cannot be established that it did. Okay.[5]

Plaintiffs seek to limit Dr. Strayer's testimony about alternative causes of Mandy Fridel's death. They also seek to exclude him from saying whether methadone can be excluded as a cause of death. Plaintiffs claim that because the autopsy was not complete, by Dr. Strayer's own admission, that he does not then have the necessary basis to opine on Friedel's cause of death, nor can he exclude methadone as its cause.

---

[4] *Id*. at 81-89.

[5] *Id*. at 108.

In response, Dr. Osunkuyo represents that Dr. Strayer was contacted to review the material and to offer an opinion regarding whether the medical examiner's determination of cause of death was reasonable. He stated that he was not able to ascertain a definitive cause of death because the autopsy was incomplete. However, based upon the evidence, Dr. Osunkoya argues, he is able to opine on other causes of death in an effort to show that there are other factors more likely than a methadone overdose.

In reading the deposition transcripts on the above-quoted pages along with others,[6] it appears that Dr. Strayer is not able to testify to a reasonable degree of medical probability that there were any other causes of death other than methadone. However, it does appear that he should be permitted to attack the plaintiffs' conclusion that methadone was the causal agent in Friedel's death, because, in his opinion, the autopsy was inadequately performed.

The crux of his opinion is that the autopsy was insufficient to establish a cause of death. His testimony should be limited to that fact. It leads to the conclusion that if he determines that the autopsy report are insufficient to establish a cause of death, he cannot definitively state a cause of death. Any testimony about her cause of death would be speculative and lack the required medical probability. However, he can testify how a finding that methadone caused her death is impossible from the autopsy as it was performed. His conclusion chips away at the plaintiffs' argument (for which they have the

[6] *Id*. at 48, 50-62, 108.

burden of proving) that Dr. Osunkoya's alleged breaches of the standard of care caused Friedel's death vis a vis his methadone prescription. After reading his deposition, it does not appear that Dr. Strayer is going to offer opinions with reasonable medical probability about what did cause Friedel's death. Nor based on his answers would the Court allow such testimony at trial.

The plaintiffs' motion is **DENIED**.[7]

Plaintiffs' Motion to Limit Dr. Bruce Goldberger's Testimony

Dr. Osunkoya intends to call Bruce Goldberger, Ph.D., a forensic toxicologist for these apparent purposes:

> Dr. Goldberger is expected to testify that the dose of Methadone prescribed by Dr. Osunkoya is typical for the treatment of pain.
>
> Dr. Goldberger is expected to testify that the methadone concentrations reported by the Office of the Chief Medical in femoral blood (110ng/mL) and by NMS Labs in Cardiac blood (60ng/mL) are unremarkable, and thus, methadone ingestion is not the proximate cause of death. Dr. Goldberger will also testify that, although the medical examiner's autopsy report contributes the ingestion of Toprol, Risperdal, Wellbutrin, and Depakote to Ms. Friedel's death, the Office of the Chief Medical and NMS Labs do not report results for these drugs.[8]

Plaintiffs' argument boils down as follows:

---

[7] The Court with Dr. Strayer, as with some other experts in this case, is dealing with deficient depositions. Sometimes it is a motion of unfocused questions and sometimes it is a lack of follow-up examination. Regrettably, it is conceivable that the deficiencies in some of the challenged testimony now being indicted might be rectified at trial.

[8] Supplemental Identification of Defense Experts at 5.

> As a toxicologist, Mr. Goldberger is qualified to testify about the "actions of a drug on a biological system like a human" as well as a drug's toxic effects. During his deposition, Mr. Goldberger noted, when asked about contributing factors to a cause of death, that he was not a pathologist, and could not speak to those matters as an expert. He also frequently mentioned that he could not testify to any standard of care issues, such as typical dosages a physician may prescribe, as he was not a physician. Finally, the decedent's response to Narcan is irrelevant to the toxicology of methadone.[9]

The plaintiffs seek to limit his testimony concerning:

1. Mandy Friedel's cause of death.

2. Her lack of response to Narcan.

3. "Typical dosages" of methadone.

The Court serves as a "gatekeeper" whenever expert testimony is challenged.[10] That function involves the following inquiry:

> (1) the witness is qualified as an expert by knowledge, skill, experience, training or education; (2) the evidence is relevant; (3) the expert's opinion is based upon information reasonably relied upon by experts in the particular field; (4) the expert testimony will assist the trier of fact to understand the evidence or to determine a fact in issue; and (5) the expert testimony will not create unfair prejudice or confuse or mislead the jury.[11]

Dr. Goldberger's credentials include being head of the toxicology lab at the University of Florida College of Medicine. He obtained his Ph.D. from the University of Maryland in 1993. He has held a number of faculty positions in the field of toxicology

---

[9] Pls.' Mot. *in Limine* to Limit Goldberger's Testimony at ¶ 4.

[10] *Bowen v. E.I. duPont de Nemours, & Co.*, 906 A.2d 787, 795 (Del. 2006)

[11] *Id.*

within the University of Florida. He has expertise in toxicology and pharmacology. He works with police agencies in Florida in death cases and has testified in over 150 criminal and civil cases, including case involving methadone. He works throughout Florida with medical examiners on toxicology issues. He has authored articles on methadone. Though not a pathologist, he has experience developing causes of death in drug related cases.

Clearly Dr. Goldberger has impressive credentials. The issue is whether those credentials and his experience enable him to opine about Friedel's *cause of death*. There appear to be potentially significant toxicological issues in this case about which Dr. Goldberger is obviously competent to testify. But the issue before the Court is not Dr. Goldberger's competence as a toxicological expert. That is not in doubt. The issue is more discrete: does his expertise enable him to opine about the issues Dr. Osunkoya has proffered?

This discrete issue is a subset of the overall expert qualification issue. An expert may be highly qualified and competent to offer many opinions. But that expert must be competent to offer opinions in a given specific factual setting.[12]

First, Dr. Goldberger may be familiar with methadone dosages used to treat pain. But, he is not a physician and does not prescribe methadone. His experience/expertise may be such that he has seen cases where methadone was so prescribed, but to go to the level Dr. Osunkoya would like in his testimony crosses impermissibly into the realm where

[12] *Eskin v. Carden*, 842 A.2d 1222 (Del. 2004).

medical training and expertise is needed. Such, the role of a pathologist.[13]

The same point must be made for any testimony that Friedel's ingestion of methadone was not the proximate cause of her death.

The Court is unclear about the role of the proffered testimony from Dr. Goldberger regarding Friedel's response to Narcan. The record before the Court is insufficient to allow the Court to determine what this testimony is all about and Dr. Goldberger's ability to opine about it.

The Court is satisfied, however, that Dr. Goldberger cannot testify about the typical dosage of methadone for pain management nor can he testify about methadone ingestion was not a proximate cause of Friedel's death. Plaintiffs' motion *in limine* is **GRANTED**.

Plaintiffs' Motion to Preclude Evidence of Prior Suicide Attempts

Plaintiffs seek to bar evidence of Mandy Friedel's prior suicide attempts. Their grounds are one that under D.R.E. 401 and 402, such evidence is not relevant. But, if relevant, D.R.E. 403, they argue, should preclude such evidence. They contend that there is only a "suggestion" in the medical records of a history of such attempts. Further, they assert, Mandy Friedel's mother and grandmother will "question" such history.

---

[13] In this case, an autopsy was performed by a Deputy Medical Examiner. By law, the Chief Medical Examiner and any Deputy Medical Examiner must be physicians. 29 *Del. C.* § 4703. By law, 29 *Del. C.* § 4707(a). Only the Chief Medical Examiner or one of the Deputies can establish the cause of death in situations specified by statute. 29 *Del. C.* § 4706(a).

First, the Court must note that the plaintiffs did not include any of the medical records in which this suggestion is made. Second, there is no testimony offered to the Court from the mother and grandmother. Third, of course, the Court could not resolve at this state any such factual conflict.

The defendants contest the motion. They point to the deposition testimony of plaintiffs' standard of care expert as raising questions about prescribing methadone to a person who had overdosed in the past. They cite, however, to only one page of his eighty-two page deposition. They, too, provide no medical records to the Court in which "suggestions" are made that there were prior suicide attempts. They refer to records, such as an October 14, 2003, admission to Kent General Hospital when Mandy Friedel had slashed her wrists. Those records, of course, are far more than suggestion. Their most cogent argument is that if Mandy Friedel's death was an overdose of methadone even in conjunction with Ketek, then there was no breach because the amount of methadone prescribed was alone insufficient to cause her death. Without a breach, no medical negligence.

Once again, the Court is compelled to research the record supplied with all the motions, not just this one - as incomplete as it is - to provide better understanding of the issues presented with this motion. One part of the record not referenced by either side on this motion is an office record of Dr. Osunkoya. It was Exhibit A to the plaintiffs' opposition to the defendants' motion to preclude plaintiffs from introducing testimony

about a possible federal law regulation.[14]

The record says, "Recent narcotic overdose, Now with withdrawal (sic)."

The Court's reading of the plaintiffs' standard of care expert's deposition testimony reveals the following:

> Q. I want to ask you for purposes of this question, it's a hypothetical, I'm asking you to assume that Dr. Osunkoya was truthful in his testimony of chronic pain, okay? Would you still offer testimony that that was a breach in the standard of care in and of itself to select methadone for the treatment of pain?
>
> A. In this case, I think it was because, for several reasons: The first being that her symptoms and her physical examination did not warrant the use of Methadone in her case; second reason being that she had a history of suicide attempts and he wouldn't be able to monitor her Methadone use on a daily basis as one would expect if she were in a Methadone treatment program.
>
> * * * * *
>
> Q. Are you telling me that it would be a breach in the standard of care for any physician to prescribe Methadone on an outpatient basis to someone who had a history of suicide attempts?
>
> A. Not under all circumstances, no.
>
> Q. Why under the circumstances in this case?
>
> A. Because she recently, Miss Friedel recently had overdosed on Percocet that she was taking from her relatives. She had a history of suicide attempts, I believe.
>
> * * * * *
>
> Q. Do you intend to offer an opinion at trial that he performed an inadequate physical examination of the patient?

[14] *Infra* at 13.

A. No. I think that my opinions are going to center on the fact that the does not offer anything on his physical examination or by history that would have justified use of long-acting Methadone in a patient who had recently attempted to or recently had overdosed on Percocet.

Q. Do you believe that the recent overdose on Percocet was a suicide attempt?

A. I'm not sure that's clear from the record. I'm not sure it matters to my opinion. Clearly, she overdosed. Whether it was intentional - - if it were intentional and she was trying to kill herself, then prescription use of Methadone prescribed in pill form wasn't a very smart thing for the doctor to do. If it was unintentional, then she's, obviously, not capable of managing her pain medication; and to prescribe a larger number of Methadone tablets at one time, again, was not a very smart thing to do. In either instance, that would have deviated from generally accepted standards of medical care.

* * * * *

A. Part of my criticism of the doctor, there was no particular urgency to putting her on an opiate analgesic in the face of her recent overdose.

* * * * *

Q. If I'm understanding you correctly, you're telling me that that's what the standard of care would require in order for an internist or family doctor to prescribe an opiate analgesic to a patient with a history of suicide attempt or recent drug overdose, that they would have to provide two or three tablets at a time and get an evaluation with a psychiatrist and/or pain management specialist?

A. Yes.

Q. On what do you base that opinion?

A. Common sense. Again, standards of care are based on common sense oftentimes.

It's folly to give somebody narcotics who just had a narcotic overdose and to give them enough so if they took another narcotic overdose, the patient might kill him or herself or, and, again, that overdose, whether intentional or a suicide attempt or unintentional, as in a patient who

> doesn't understand or won't comply with instructions, in either case, an overdose is an overdose. And if you supply them with enough mediation that's potentially lethal, the doctor is performing under acceptable standards of care in this context.[15]

One thing which is unclear to the Court is what *did* Dr. Osunkoya know about the alleged prior suicide attempts? Based on what Dr. Kirby said, there must be some evidence of that, but the Court has not been blessed with getting those records or testimony.

Richard Berg, M.D., defendants' standard of care expert, testified in deposition that it was in Mandy Friedel's best interest to prescribe Methadone for her back pain since the pain contributed to why she was abusing narcotic medications.[16] He was not asked, however, by plaintiffs' counsel about any issues relating to prescribing methadone to someone with an attempted suicide history.

Plaintiffs seem to want it both ways. Their own standard of care expert criticizes Dr. Osunkoya for prescribing methadone to Mandy Friedel, in part, because of her history of attempted suicides. He criticized Dr. Osunkoya for letting Mandy Friedel having so many pills and in the dosage he did, and not giving them to her in a controlled setting. They cannot have this testimony without getting into her attempted suicide history.

---

[15] Kirby Depo. Tr. at. 22-23, 25, 31-35.

[16] Berg Depo. Tr. at 41.

Defendants have offered another unrelated reason to allow this history. They point to a series of medical or mental health treatment records in 2003 and 2004 reflecting, they contend, suicide attempts, suicidal ideation, and alleged internal family turmoil. That turmoil, defendants represent, may have had a role in Mandy Friedel's suicide ideations and/or attempts.

If so, they assert, this would be contrary to the much rosier picture plaintiffs Peggy Friedel (mother) and David Friedel (father) would try to portray at trial. It would have been more helpful to the Court to have seen records referring to intra-family issues in order to make a more informed decision. But based on the record presented, it would appear defendants have the better argument on this reason for admitting the records plaintiff seek to exclude.

Plaintiffs' motion to preclude admission of Mandy Friedel's attempted suicide attempts or ideations is **DENIED**.

Defendants' Motion to Preclude Testimony that Dr. Osunkoya Violated a Federal Law Concerning Dispensing Methadone

In undated office notes attached to plaintiffs' opposition to this motion, Dr. Osunkoya notes:

"Recent narcotic overdose, now on withdrawal."

"Start Methadone 10 mg 2 tbs BID x3d followed by 1 tab BID #60."[17]

[17] Pls.' Resp. to Mot. to Preclude at Ex. A.

Plaintiffs seek to argue that this note, and perhaps other records, meant that Dr. Osunkoya prescribed or dispensed methadone to Mandy Friedel as part of a opiate maintenance or detoxification program. They contend to be qualified to do so, the practitioner doing so must be registered with the Drug Enforcement Administration (DEA) as a treatment program. Plaintiffs rely upon 21 C.F.R. § 1306.07.

It is their assertion that Dr. Osunkoya was not registered - and there appears to be no dispute about that - and that his actions and that status in this instance constitutes negligence *per se*.

Defendants move to exclude any testimony of Dr. Osunkoya violated any federal law by prescribing methadone to Mandy Friedel without being registered. They argue § 1306.07 does not establish a standard of care for administering methadone for maintenance or detoxification. They contend allowing testimony of an alleged violation of federal law would not assist the jury in deciding if Dr. Osunkoya breached a standard of care. In any event, such testimony would be unduly prejudicial.

The analysis of the issues presented starts with the federal regulation each side cites:

§ 1306.07 Administering or dispensing of narcotic drugs.

(a) A practitioner may administer or dispense directly (but not prescribe) a narcotic drug listed in any schedule to a narcotic dependent person for the purpose of maintenance or detoxification treatment if the practitioner meets both of the following conditions:

(1) The practitioner is separately registered with DEA as a narcotic treatment program.

(2) The practitioner is in compliance with DEA regulations regarding treatment qualifications, security, records, and unsupervised use of the drugs pursuant to the Act.

(b) Nothing in this section shall prohibit a physician who is not specifically registered to conduct a narcotic treatment program from administering (but not prescribing) narcotic drugs to a person for the purpose of relieving acute withdrawal symptoms when necessary while arrangements are being made for referral for treatment. Not more than one day's medication may be administered to the person or for the person's use at one time. Such emergency treatment may be carried out for not more than three days and may not be renewed or extended.

(c) This section is not intended to impose any limitations on a physician or authorized hospital staff to administer or dispense narcotic drugs in a hospital to maintain or detoxify a person as an incidental adjunct to medical or surgical treatment of conditions other than addiction, or to administer or dispense narcotic drugs to persons with intractable pain in which no relief or cure is possible or none has been found after reasonable efforts.[18]

Under federal law,[19] methadone is, and was in 2004, a Schedule II drug. Therefore, to prescribe or dispense it, one has to be registered with the DEA. To show his duty to register, and negligence flowing from failing to be so, plaintiffs rely upon testimony from defendants' standard of care expert, Dr. Berg, who has testified by deposition:

Q. Under the law existing in November of 2004, were you allowed to prescribe methadone for withdrawal symptoms?

A. Not for withdrawal symptoms. It was prescribed for pain. Pain indications. I'm not a methadone clinic.

---

[18] 21 C.F.R. § 1306.07.

[19] 21 U.S.C. § 812.

Q. So under the law that existed in November of 2004 you could not prescribe methadone for withdrawal symptoms?

A. That's true. I wouldn't prescribe methadone strictly - -

Q. I just asked whether you were allowed to under the law.

A. No.

Q. And your understanding of the law that would prohibit you from prescribing methadone for withdrawal symptoms, is that - - that is a federal law, correct?

A. That's true.

Q. And that applies to doctors in every state of the union?

A. Presumably, yes.

Q. Do you have any reason to believe that that federal law prohibiting you from prescribing methadone for withdrawal symptoms does not apply to physicians in Delaware?

A. *No. You were the first state. You were five days before Pennsylvania in ratifying the constitution. You are the first state so, of course, you are a very law-abiding state.*

Q. So then you would agree that in November of 2004 Dr. Osunkoya was prohibited by federal law from prescribing methadone for withdrawal symptoms?

A. Of course.

* * * * *

Q. Would it be a breach of the standard of care, would it have been a breach of the standard of care for a physician in the United States who was not operating a methadone clinic to prescribe methadone for a patient's withdrawal symptoms in the absence of any other reason for prescribing the methadone?

A. Yes. If it were simply for withdrawal, yes. It would be a breach of the standard of care.[20]

The Court must note at this point that Dr. Osunkoya testified in deposition that he prescribed or dispensed Methadone to Mandy Friedel for relief of her back pain. The defendants contend that his purpose, based on that answer and the possibly contradictory office record, is a factual issues for the jury to resolve.[21]

Delaware law provides that a violation of a statute enacted for the safety of others is negligence *per se*.[22] Regulations promulgated for the same purpose can form a basis for negligence *per se*.[23] Further, there must be a connection between such a statutory or regulatory violation and the injury alleged.[24] The plaintiff must be a member of the class of persons for whose protection or benefit the statute (regulation) was enacted.[25]

Mandy Friedel, at first glance, may seem to meet several of those criteria; her death from methadone prescribed by someone not registered with DEA, and that registration requirement was possibly promulgated for her (and others) benefit.

---

[20] Berg Dep. Tr. at 102-04. (Emphasis supplied).

[21] Defs.' Mot. to Preclude - Federal Law at ¶ 8.

[22] *Sammons v. Ridgeway*, 293 A.2d 547, 549 (Del. 1972).

[23] *Id.*

[24] *Wright v. Moffitt*, 437 A.2d 554, 557 (Del. 1981).

[25] *Ford v. JA-Sin*, 420 A.2d 184, 186 (Del. Super. 1980).

But this Court finds converting § 1306.07 into a negligent *per se* claim goes too far. The regulation is a *registration* requirement, not some public safety standard. Most likely, the DEA wants to know *who* is prescribing or dispensing methadone. In many ways, therefore, it is more of a licensing regulation. This regulation does not define a standard of conduct other than a need to be registered. As such it is not a basis for a claim of negligence *per se*.[26]

But that holding does not finish the analysis. A violation of a regulation may be evidence of negligence.[27] The testimony presented though Jack Rosenberg, Pharm. D., Ph.D. and John Kirby, M.D. manifest there is a clear and bright line separating the use of methadone as an analgesic and using it to treat opiate withdrawal or to maintain treatment. There are treatment/dispensing steps a physician uses in each of those two situations which differ markedly and substantively. One is highlighted in this case, and that is the alleged number of methadone pills a doctor would "give" (or more precisely not give) to a patient on withdrawal over a patient not on withdrawal for whom the methadone is strictly an analgesic.

As quoted above,[28] the defendants' own expert, Dr. Berg, discuss the breach of the standard of care to prescribe methadone strictly for withdrawal. His testimony can be

---

[26] *Tydings v. Loewenstein*, 505 A.2d 443 (Del. 1986).

[27] *Toll Bros, Inc. v. Consadine*, 706 A.2d 493, 498 (Del. 1998).

[28] *Supra* at 15-17.

interpreted that under the circumstances of the case, Dr. Osunkoya was negligent.[29] The plaintiffs have apparently not retained their own expert on this issue.

Yet the analysis of the issues raised does not end there. If a jury determines that Dr. Osunkoya's purpose in prescribing methadone to Mandy Friedel was for her opiate withdrawal problems, the issue becomes how do the plaintiffs present sufficient evidence to make out their negligence claim?

There is deposition testimony from two physicians about the need to adhere to § 1306.07 if one prescribes methadone for maintenance or withdrawal. The plaintiffs' pharmacologist has chimed in on that too. The Court, however, after reading all the expert discovery depositions, has some doubt that these experts, while qualified in many areas, are sufficiently qualified to opinion about § 1306.07 and the consequences flowing from a failure to register. Or at least, no real effort was made to qualify them to opine about failing to adhere to § 1306.07 (and possible other related federal regulations).

Of course, this leaves the plaintiffs' potential claim *in nubibus*; **DENIED without prejudice**.

Defendants' Motion to Preclude Standard of Care Testimony Because it is not Causally Related

Defendants move to preclude plaintiffs' standard of care experts' testimony because none of the alleged breaches are causally linked to Friedel's death. Defendants argue that

---

[29] *Del. Elec. Co-op, Inc. v. Duphilly*, 703 A.2d 1202, 1209 (Del. 1997).

neither Dr. Kirby, an internist, nor Dr. Rosenberg, a pharmacologist, can state with reasonable medical probability that any of the identified breaches of the standard of care caused Mandy Friedel's death.

The plaintiffs have identified several breaches:

> Plaintiffs' medical expert, John Kirby, M.D., identifies a number of breaches in the standard of care attributable to Dr. Osunkoya. Among his criticisms are following items: (i) Criticism of the dose Dr. Osunkoya selected as being too high; (ii) criticism of Dr. Osunkoya's decision to provide a patient who has a history of attempted suicide with methadone pills to be taken in an unsupervised setting; (iii) criticism of Dr. Osunkoya for providing tablets in quantities large enough to be used in connection with a suicide attempt; (iv) criticism of Dr. Osunkoya for failing to decrease the dose of methadone when he prescribed the antibiotic, Ketek; (v) criticism of the prescription of methadone in combination with other medications known to contribute to respiratory distress, including Wellbutrin, Risperdal and Depakote and (vi) criticism of the use of methadone in combination with Ketek and Toprol because of the potential for cardiac depressant effects. However, when asked to opine regarding the proximate cause connection between each of these breaches and Ms. Friedel's death, the experts were unable to offer an opinion within a reasonable degree of medical probability without engaging in speculation.[30]

These same breaches were repeated in greater length and detail in Dr. Kirby's deposition. While the defendants' offer a few citations to the deposition testimony of Dr. Kirby, the Court has read all eighty-six pages of it. Plaintiffs, too, make some fleeting references to parts of his testimony. But because of the crucial nature of the issued raised, reading the entire deposition became unnecessarily necessary.

---

[30] Defs.' Mot. to Exclude Standard of Care Testimony at ¶ 2.

Q. Can you say, within a reasonable degree of medical probability, which of those three it was?

A. I think the most likely scenario, with a reasonable degree of medical probability, based on the absence of the 23 pills that should have been in her bottle and the additional Ketek, is that it was taking extra Methadone and having Ketek added.

Q. Okay. So, now, working with that as being, in your opinion, the most probable, can you say, I guess, within that there are two options, either the overdose of the Methadone that she took contributed to her death by itself or Methadone in conjunction with Ketek contributed to her death?

A. Or both.

Q. Or both.

Well, I think it's either she would have died as a result of the Methadone alone or she would have died as a result of a combination of Methadone and Ketek. So there are two options?

A. The latter possibility, I think, is more likely.

* * * * *

A. It might because the interaction between Ketek and Methadone is not simply respiratory depression, for example. There are effects on what's called the QT Interval which is part of - - when you look at an EKG, the electric blips that we see have certain markers. One of them is the QT Interval, which is the interval between - - it marks when the heart is actively beating, left ventricle and right ventricle are actively beating, and when the heart muscle begins to relax.

There is a correlation between sudden cardiac death from cardiac arrhythmia and a prolonged QTC interval. Methadone increases that. Ketek increases that.

The combination of the two could have produced a potentially lethal cardiac arrhythmia, really, at anytime if not necessarily dose or level correlated. So , we don't know what the inciting event was that caused Mrs. Friedel to collapse. All we know is, she was found unresponsive

and at the time she was found unresponsive and unconscious, she had no pulse and no respirations.

It's impossible to go back and reconstruct whether the primary event was a cardiac event, cardiac arrhythmia, or respiratory event, respiratory depression from a combination of Methadone and the Ketek.

* * * * *

A. I can tell you that, again, within a reasonable degree of medical probability, that the level of methadone found in her blood at autopsy would have been lower had she not been on Ketek.

* * * * *

Q. At trial, what are you going to say is, in your opinion, the most probable cause of this patient's death?

A. Methadone overdose precipitated by over dosage of Methadone, inappropriate use of Methadone and augmented by the addition of Ketek.

Q. So, you will not be offering an opinion at trial that intersection between Risperdal and Methadone was the most probable cause of the patient's death?

A. A potential contributing cause.

Q. Can you say, within a reasonable degree of medical probability, that it was a contributing cause?

A. I can say, within a reasonable degree of medical probability, that there is the potential that it potentiated the central nervous system respiratory depressant effects of Methadone and contributed to her death.

* * * * *

Q. So putting those three things together, you're saying that you then conclude, within a reasonable degree of medical probability, that it must have been the combination of these medications, even though there's no laboratory evidence.

A. That's correct.

* * * * *

Q. I want to review to make sure we have covered all of the potential causes of death that you think are possible. One of them is that Mandy Friedel

hoarded her medications and overdosed on Methadone?

A. Correct?

Q. One of the possibilities is that Mandy Friedel hoarded her medications and overdosed on Methadone and combined with the effect of Ketek that resulted in her death?

A. Yes.

Q. One of the possibilities is that Ketek interacted with Toprol and resulted in a cardiac arrhythmia that resulted in her death?

A. Correct.

Q. One of the possibilities is that Methadone caused and interfered with the QT [interval] in a manner which lead to a cardiac arrest?

A. Yes. That would be either alone or with Ketek, but more likely with Ketak.

* * * * *

Q. Was that all of the potential cause of death?

A. We have Risperdal in there and it's interaction with the Methadone. That should be in there.

Q. Okay. So, another possibility is that Methadone and Risperdal interacted to result in respiratory distress causing the patient's demise?

A. Yes. I think that covers it.

Q. And they are all possibilities and you can't rule any one of them out?

A. I can't. But, I think, most likely would be the combination of Methadone and Ketek.

Q. And, well, let me ask this. You can't rule any of them out; and based on the autopsy report and the toxic screen, you can't say one of them was the definitive cause of death?

> A. I would be willing to come down with almost complete certainty that Miss Friedel's death occurred because of a combination of Methadone and Ketek.[31]

Delaware law requires that plaintiffs present expert medical testimony that a breach or breaches of the standard of care caused death.[32]

Dr. Kirby utters the "magic phrase" reasonable medical certainty and links it to several different potential causes of death which relates to several breaches of the standard of care. It is not always necessary for an expert in a medical negligence case to use magic phrases.[33] And here, Dr. Kirby's causation discovery deposition testimony is far more definitive about causation than that which the Supreme Court said passed muster in *Froio v. DuPont Hospital for Children*.[34]

If there is any problem with his testimony in this discovery deposition, rather than making this generalized motion, the defendants had the opportunity to do it then. The defendant's motion to preclude Dr. Kirby's trial testimony regarding breaches in standard of care causing Mandy Friedel's death is **DENIED**.

---

[31] Kirby Depo. Tr. at 41-42, 45-46, 56, 62-63, 68, 83-84. *See also id*. at 37-39, 53-54, 76.

[32] 10 *Del. C.* § 6853(c); *Hackerman v. Christiana Care Health Servs., Inc.*, 882 A.2d 742, 744 (Del. 2004).

[33] *Green v. Weiner*, 766 A.2d 492 (Del. 2000).

[34] 816 A.2d 784 (Del. 2003).

Defendants' Motion to Preclude Standard of Care Testimony by Dr. Jack Rosenberg

Defendants have moved to bar certain standard of care testimony of plaintiffs' expert Dr. Rosenberg. He is an expert in pharmacology and pharmacy. Since 1982 he has been a professor of Pharmacy Practice and Pharmacology at the Arnold and Maris College of Pharmacy and Health. While there is more in his professional background to demonstrate his experience and expertise, the defendants do not challenge his expertise.

What they ask this Court to do is to prevent Dr. Rosenberg from offering standard of care opinions about that Dr. Osunkoya did or did not do or should have done of not done. One of the issues, among others, to be resolved at trial is the reason Dr. Osunkoya prescribed methadone for Mandy Friedel. In contemporaneous office or medical notes, Dr. Osunkoya stated he was prescribing methadone for a withdrawal symptoms. But in a later deposition, he testified he prescribed it for analgesic - pain relieving - purposes. As a general matter, Dr. Rosenberg testified in deposition that the dosages of methadone prescribed vary depending on the purpose for which it is prescribed. Such as an analgesic or for opiate maintenance or withdrawal.

The defendants' motion is broad, imprecise and not too helpful in identifying the portion of Dr. Rosenberg's deposition testimony where he offers standard of care opinions against Dr. Osunkoya.[35] One such area could be this:

---

[35] At his discovery deposition, Dr. Rosenberg offered a number of standard of care criticisms directed at Dr. Osunkoya. Defs.' Mot. *in Limine* at 2.

A. It's a major respiratory - - forget it. It's icing on the cake, the other drugs. Methadone in and of itself is a major respiratory depressant. The major respiratory depression occurs three to five days after you start the drug, so the time relation and the temporary relationship is such. The conversion was absolutely incorrect in what the physician used.

He states that I'm using it for maintenance - - withdrawal. I have it in his records, legal records, medical records. He says, I'm using it for withdrawal, which he shouldn't have done. He gives a person, an unreliable person, 60 tablets. This person is a known drug user, alcoholic, does everything. He gives a load of methadone. She gets respiratory depression, which is warned about with this drug. She's taking some other drugs that add to the respiratory depressant. She has pneumonia, which depresses respiration. She's supposed to be monitored very carefully. A patient like this you put on methadone should be in an inpatient setting.

In the documents for this, he says he's treating her backache with methadone. No protocol that I have of all the guidelines for the treatment of backache. He's treating with methadone. He takes a strong second-line drug. He's not using it for withdrawal. He's treating a backache with this. I have records from the clinic. She didn't complain from two days earlier that she has any back pain. All of a sudden, she's getting a big dose of methadone that's used for heroin addicts, for back pain, with notes that he was using it for withdrawal. The dose is way too big. She's on other CNS depressants. She dies. Hello.[36]

In another area he states it is a "tenable" use of methadone to use it for analgesic purposes.[37] A little later, he testified it was a breach of the standard of care to prescribe

[36]Rosenberg Dep. Tr. at 93-94.

[37] *Id*. at 113.

it for the reasons Dr. Osunkoya did.[38] There are other implicit portions of his deposition where Dr. Rosenberg offers testimony about breaches of the standard of care.[39]

He does offer this opinion about the amount of methadone prescribed to Friedel:

> Q. But can you say, within a reasonable degree of pharmacological probability, that it would have killed her?
>
> A. It was a contributory factor. I, a hundred percent, agree with the medical examiner that she had pneumonia and this was a contributory factor to her death. I believe - - I believe that without the methadone, that she would have not died. I honestly believe it, that without this methadone ingestion she would not have died. That I can tell you.[40]

It does not appear, however, defendants are seeking to exclude testimony along the lines of the toxicological effects of methadone.

The issue raised is one of first impression in Delaware: may a pharmacist/pharmacologist who is not a physician offer standard of care opinions regarding a physician? In this case, in actuality, the issue is a little more discrete in that the opinions relate, in part, to dosages and amounts prescribed.

The answer to this issue has several analytical routes. A starting point for one route is 18 *Del. C.* § 6854:

> No person shall be competent to give expert medical testimony as to applicable standards of skill and care unless such person is familiar with the

---

[38] *Id.* at 114.

[39] *Id.* at 115-17, 120, 127-28.

[40] *Id.* at 132.

> degree of skill ordinarily employed in the field of medicine on which he or she will testify.

There is no explicit language barring a pharmacologist from offering a standard of care opinion against a physician. A reading of Dr. Rosenberg's lengthy deposition shows he has a great deal of working familiarity with the use of methadone as an analgesic drug interaction with other drugs, and the various kinds of circumstances influencing the chain of events leading up to Friedel's death.

But he neither practices medicine nor is entitled to prescribe methadone.

Despite the apparent broad phrasing of § 6854, it has received over a long period of time an accepted judicial interpretation:

> At the close of the case, the jury was instructed with the standard medical malpractice jury instruction, which read as follows:
>
> Under a Delaware statute, a healthcare provider that does not meet the applicable standard of care commits medical malpractice: The standard of skill and care required of every healthcare provider in rendering professional services or healthcare to a patient shall be that degree of skill and care ordinarily employed, under similar circumstances, by member of the profession in good standing in the same community or locality, and the use of reasonable care and diligence.
>
> * * * * *
>
> Each physician and healthcare provider is held to the standard of care and knowledge commonly possessed by members of his or her profession and specialty in good standing. It is not the standard of care of the most highly skilled, not is it necessarily that of average members of this profession, since those who have somewhat less than average skills may still possess the degree of skill and care to treat patients competently. When a physician chooses between appropriate alternative medical treatments, harm resulting from a physician's good faith choice of one proper alternative over the other

is not medical malpractice.[41]

Both Dr. Osunkoya and Dr. Rosenberg are medical professionals. But they are not in the same profession and do not receive the same training. In short, this judicial language, given as the law in medical negligence cases, disqualifies Dr. Rosenberg from rendering standard of care opinions about Dr. Osunkoya.[42]

Candidly, the area is not black and white but gray. Presumably, doctors are familiar with dosage issues and usage issues in a way arguably overlapping the knowledge a pharmacologist would have. Yet that still does not empower Dr. Rosenberg to offer these opinions about Dr. Osunkoya. All of this is not meant to say there is not a *per se* rule to be created here for all cases, but it is a firm line.

Courts in other jurisdictions have ruled on this issue. As the Supreme Court of Washington stated:

> In the instant case, lay testimony may be admitted to show Devan's obvious impairments. However, the physician's standard of care regarding proper dosages of medication is not within the scope of matters on which non-physicians are competent to testify. Although a pharmacist may be more familiar with the names of medication, the literature, and perhaps the usual practice of physicians prescribing certain medications than other non-physicians, a pharmacist is not competent to testify on the physician's

---

[41] *Corbitt v. Tatagari*, 804 A.2d 1057, 1061 (Del. 2002).

[42] See *Myers v. Medical Ctr. of Del., Inc.*, 86 F. Supp. 2d 389 (D. Del.2000) in which the court held a pathologist was not competent to testify about the standard of care of emergency room doctors.

standard of care for treatment using medication.[43]

That case involved a law suit against a physician who had prescribed asthma medication. The claim was the doctor had allowed the medication to reach toxic levels. The patient ultimately suffered permanent brain damage. On summary judgment, the trial court threw out a pharmacologist's affidavit regarding the doctor's breaches of the standard of care. The trial court's holding that the pharmacologist was not competent to opine about a physician's standard of care was affirmed.

The Washington Supreme Court also cited a number of cases from other states reaching the same conclusion.[44] In *Lundgren v. Eirstermann*,[45] the Minnesota Supreme Court found that a psychologist was not competent to offer standard of care opinions against a family physician in regard to prescribing an anti-psychotic drug. Acknowledging the psychologist's expertise, the Court nevertheless found him not competent to offer standard of care opinions against a physician.[46]

These cases, and those cited in them provide overwhelming authority in support of this Court's holding that Dr. Rosenberg is not competent to opine about Dr. Osunkoya's standards of care.

---

[43] *Young v. Key Pharms., Inc.*, 770 P.2d 182, 190 (Wash. 1989).

[44] *Id.* at 189.

[45] 370 N.W.2d 877 (Minn. 1985).

[46] *Id.* at 881.

The other analytical route to the same conclusion is based on statutory construction. This route is not as straightforward. It, too, starts with the same statute, § 6854. As noted, the statute itself is not as explicit as one would expect. In interpreting a statute, this Court's role is to determine and give effect to the legislature's intent.[47] This Court views § 6854 as arguably ambiguous or uncertain. In such a case, the statute must be construed to avoid a construction which would lead to an unreasonable or absurd result.[48]

In this Court's view such would be the result if this Court said § 6854 allows a pharmacologist to opine about the standard of care of a physician. In addition, an absurd result would follow because § 6854 would be out of sync with § 6853. Section 6853 was substantively amended in 2005 to add a requirement that no healthcare negligence suit could be pled unless the complaint is accompanied by an affidavit of merit.

But here is where the curve in the route occurs. Section 6853 was amended nine years after the current § 6854 was enacted. However, § 6854 was not amended at the same time in 2005. Further § 6854(a)(1) refers to an affidavit from an expert as defined in § 6854. Fortunately, however, another section of § 6853 saves the day by providing:

> *Qualifications of expert and contents of affidavit*. – The affidavit(s) of merit shall set forth the expert's opinion that there are reasonable grounds to believe that the applicable standard of care was breached by the named defendant(s) and that the breach was a proximate cause of injury(ies) claim in the complaint. An expert signing an affidavit of merit shall be licensed

---

[47] *Ingram v. Thorpe*, 747 A.2d 545, 547 (Del. 2000).

[48] *State v. Demby*, 672 A.2d 59, 61 (Del. 1996).

> to practice medicine as of the date of the affidavit; and in the 3 years immediately preceding the alleged negligent act has been engaged in the treatment of patients and/or in the teaching/academic side of medicine in the same or similar field of medicine as the defendant(s), and the expert shall be Board certified in the same or similar field of medicine of the defendant(s) is Board certified.[49]

Statutes have to be read *in pari materia*.[50] In that light, reading § 6853 and § 6854 together, Dr. Rosenberg does not meet the necessary qualifications to opine about the standards of care of Dr. Osunkoya under § 6854. If the Court were to hold otherwise, an affidavit of merit would have to be executed by an expert more qualified than an expert who meets the "qualification" of an expert as "defined" in § 6854 and thus permitted to be classified as an expert. Such would be an absurd result.

For all of these reasons, therefore, Dr. Rosenberg will not be able to testify about any standard of care applicable to Dr. Osunkoya. The defendants' motion to preclude the standard of care testimony of Dr. Rosenberg is **GRANTED**.

Conclusion

For the reasons stated herein:

1. The plaintiffs' motion to preclude the testimony of defendants' pathology expert is **DENIED**.

---

[49] 18 *Del. C.* § 6853(c).

[50] *Watson v. Burgan*, 610 a.2d 1364, 1368 (Del. 1992).

2. The plaintiffs' motion to limit the testimony of Dr. Bruce Goldberger is **GRANTED**.

3. Plaintiffs' motion to preclude evidence of prior suicide attempts is **DENIED**.

4. The defendants' motion to preclude the testimony Dr. Osunkoya violated a federal law is **DENIED without prejudice**.

5. Defendants' motion to preclude plaintiffs' standard of care testimony by Dr. Kirby is **DENIED**.

6. Defendants motion to preclude Dr. Rosenberg's standard of care testimony is **GRANTED**.

IT IS SO ORDERED.

_____

J.