

THE STATE OF SOUTH CAROLINA
IN THE SUPREME COURT

RECEIVED

JAN 30 2024

S.C. SUPREME COURT

Appeal from Spartanburg County

The Honorable J. Mark Hayes, II
Circuit Court Judge

Case No. 2019-CP-42-01605

Stephanie Irene Greene, # 359489

Petitioner,

v.

State of South Carolina

Respondent.

**APPENDIX
VOLUME VI**

NELSON MULLINS RILEY & SCARBOROUGH, LLP John F. Kuppens Blake T. Williams Caroline A. Warner 1320 Main Street / 17th Floor Post Office Box 11070 (29211-1070) Columbia, SC 29201 (803) 799-2000 ROSS & ENDERLIN, P.A. Susannah C. Ross 330 East Coffee St. Greenville, SC 29601 <i>Attorneys for Petitioner</i>	OFFICE OF THE ATTORNEY GENERAL Alan Wilson Donald J. Zelenka Danielle Dixon 1000 Assembly Street / Room 519 P.O. Box 11549 (29211) Columbia, SC 29201 <i>Attorneys for the Respondent</i>
--	---

INDEX

	PAGE
Index	i-iii

Volume I

Indictments.....	0001
The State of South Carolina v. Greene, Trial Transcript, Vol. I [pgs. 75-248]	0075

Volume II

The State of South Carolina v. Greene, Trial Transcript, Vol. I [pgs. 249-380].	0249
The State of South Carolina v. Greene, Trial Transcript, Vol. II [pgs. 381-496]	0381

Volume III

The State of South Carolina v. Greene, Trial Transcript, Vol. II [pgs. 497-690]	0497
Sentencing Sheets, April 4, 2014.....	0691

Volume IV

Final Brief of Respondent, July 7, 2015	0694
Final Brief of Appellant, July 15, 2015	0750
Final Reply Brief of Appellant, July 20, 2015.....	0778
Order Certifying Appeal, May 5, 2016.....	0794
South Carolina Supreme Court Opinion No. 27802	0795
Petition for Rehearing, June 5, 2018.....	0825
Return to Petition for Rehearing, June 15, 2018.....	0837
Reply to Return to Petition for Rehearing, June 20, 2018	0849
Order Denying Petition for Rehearing, June 26, 2018.....	0853
Petition for Writ of Certiorari, November 19, 2018	0855
U.S. Supreme Court Order denying Petition for Writ of Certiorari, January 7, 2019	0874

Volume V

Application for Post-Conviction Relief, May 2, 2019	0930
Addendum to Application for Post-Conviction Relief, July 18, 2019.....	1125
Return to Application for Post-Conviction Relief, August 5, 2019.....	1133

Volume VI

First Amended Application for Post-Conviction Relief, July 22, 2021	1170
Second Amended Application for Post-Conviction Relief, April 22, 2022	1180
Third Amended Application for Post-Conviction Relief, August 5, 2022	1191
Pre-Trial Brief and Return to Third Amended Application for Post-Conviction Relief, August 29, 2022	1201
Greene v. The State of South Carolina, Post-Conviction Relief Hearing Transcript [pgs. 1235-1417].....	1235

Volume VII

Greene v. The State of South Carolina, Post-Conviction Relief Hearing Transcript [pgs. 1418-1643].....	1643
Parvaz Madadi, et al., <u>Safety of codeine during breastfeeding. Fatal morphine poisoning in the breastfed neonate of a mother prescribed codeine</u> , Can Fam Physician, 53:33-5 (2007)	1644
Zipursky & Juurlink, <u>The Implausibility of Neonatal Opioid Toxicity from Breastfeeding</u> , 108(5) Clinical Pharmacology & Therapeutics (May 2020)	1647

Volume VII

Pimlott & Tsuyuki, <u>Risks of maternal codeine intake in breastfed infants: a joint statement of retraction from Canadian Family Physician and the Canadian Pharmacists Journal</u> , Can Fam Physician (2020)	1667
Applicant's Post-Trial Brief, November 28, 2022	1669
Respondent's Post-Trial Brief, November 28, 2022	1713
Order of Dismissal, May 8, 2023	1762
Motion to Reconsider and Amend, May 18, 2023	1778
Return to Applicant's Rule 59(e), SCRC Motion, June 5, 2023	1801
Order Denying Applicant's Rule 59(e), SCRC Motion, November 17, 2023	1823

STATE OF SOUTH CAROLINA	)	IN THE COURT OF COMMON PLEAS
	)	SEVENTH JUDICIAL CIRCUIT
COUNTY OF SPARTANBURG	)	
Stephanie Irene Greene, # 359489,	)	Case Action No. 2019-CP-42-01605
Applicant,	)	
v.	)	<u>FIRST AMENDED APPLICATION FOR</u>
	)	<u>POST-CONVICTION RELIEF</u>
State of South Carolina,	)	
Respondent.	)	

FILED
 2021 JUL 26 AM 9:10
 CLERK OF COURT
 SPARTANBURG COUNTY
 S.C.

Applicant Stephanie Irene Greene, # 359489 ("Applicant") filed the above action seeking post-conviction relief on May 2, 2019. In the initial *pro se* application, Applicant alleged, *inter alia*, actual innocence, lack of extreme indifference/mens rea, and several grounds of ineffective assistance of trial and appellate counsel. The State filed a Return and Partial Motion to Dismiss on August 5, 2019.

On July 8, 2020, the Court entered a Consent Order granting Applicant's motion for leave to conduct discovery. On December 16, 2020, the Court entered a Consent Order assigning the Honorable J. Mark Hayes, II to hear all issues related to the above captioned post-conviction relief application. On December 16, 2020, the Court also granted Respondent's Motion for Reciprocal Discovery.

Petitioner submits this First Amended Application and Memorandum in Support to clarify and elaborate on several of the grounds asserted in Applicant's initial *pro se* application and to add additional claims warranting post-conviction relief.

1. Place of detention Leath CI, 2809 Airport Rd., Greenwood, SC 29659
2. Name and location of Court which imposed sentence 7th Circuit Court, Spartanburg, SC
3. Name(s) of co-defendant(s) (if any) Not applicable

4. The indictment number or numbers (if known) upon which and the offenses for which sentence was imposed:
- (a) 2011-GS-42-5758
 - (b) 2011-GS-42-5758A
 - (c) 2011-GS-42-5758B
5. The date upon which sentence was imposed and the terms of the sentence:
- (a) April 4, 2014 – 20 years, concurrent
 - (b) April 4, 2014 – 5 years, concurrent (vacated by S.C. Supreme Court)
 - (c) April 4, 2014 – 5 years, concurrent
6. Check whether a finding of guilty was made:
- (a) after a plea of guilty No
 - (b) after a plea of not guilty Yes
 - (c) after a plea of nolo contendere No
7. Did you appeal from the judgment of conviction or the imposition of sentence? Yes
8. If you answered "yes" to (7), list:
- (a) the name of each Court to which you appealed:
 - i. Supreme Court of South Carolina (Applicant filed direct appeal to Court of Appeals and case was sua sponte transferred to the Supreme Court)
 - ii. Supreme Court of the United States
 - (b) the result in each such Court to which you appealed:
 - i. Involuntary manslaughter conviction vacated; homicide by child abuse and unlawful conduct toward a child convictions and sentences affirmed (Supreme Court of South Carolina)
 - ii. Petition for a writ of certiorari denied (Supreme Court of the United States)
 - (c) the date of each such result:
 - i. May 23, 2018 (petition for rehearing denied June 26, 2018) (Supreme Court of South Carolina)

FILED
2021 JUL 26 AM 9:10
CLERK OF COURT
SPARTANBURG COUNTY
AMY W. COX

- ii. January 7, 2019 (Supreme Court of the United States)
- (d) if known, citations of any written opinion or orders entered pursuant to such results:
 - i. State v. Greene, 423 S.C. 263, 814 S.E.2d 496 (2018)
 - ii. Greene v. South Carolina, 139 S.Ct. 844 (2019)

9. If you answered "no" to (7), state your reasons for not so appealing:

(a) N/A

10 & 11. GROUND FOR RELIEF WITH SUPPORTING FACTS

Please see Appendix A, *infra*.

12 & 13. PROCEDURAL HISTORY

Applicant filed a mandatory direct appeal to the South Carolina Supreme Court. After the Supreme Court proceedings ended, Applicant also timely filed a petition for a writ of certiorari to the U.S. Supreme Court.

Applicant has not previously filed an application for post-conviction relief.

Applicant filed a petition for a writ of habeas corpus on December 2, 2019 with the U.S. District Court for the District of South Carolina, C/A No. 4:19-cv-03365-MGL. On February 27, 2020, the District Court issued an order adopting the Magistrate Judge's Report and Recommendation that the matter be dismissed *without prejudice* while Applicant exhausts her state court remedies. The District Court entered the judgment that same day.

- 14. None of the grounds set forth in (10) have been previously presented to this or any other court, state or federal.
- 15. Not applicable.
- 16. These grounds rely on additional facts outside the record that was before the previous courts.
- 17. Applicant was previously represented by counsel.
- 18. Trial and Appellate Counsel:

C. Rauch Wise 305 Main St., Greenwood, SC 29646 (trial and direct appeal)
- 19. Applicant seeks relief from her conviction and sentence.
- 20. Applicant is not under sentence from any other court.

APPENDIX A

(Grounds for Relief and Supporting Facts)

I. Ineffective Assistance of Trial Counsel

Applicant was denied the right to effective assistance of counsel guaranteed by the Sixth and Fourteenth Amendments to the United States Constitution and by Article I, §§ 3 and 14 of the South Carolina Constitution. Trial counsel's performance was both unreasonable and prejudicial as outlined below. *See Strickland v. Washington*, 466 U.S. 668 (1984). Trial counsel's acts or omissions included:

- (1) Trial Counsel (hereinafter "Counsel") failed to properly advise Applicant regarding a guilty plea to involuntary manslaughter. Counsel failed to advise Applicant of the maximum sentence she faced, assured Applicant she would win at trial, and advised applicant to reject a plea deal. *See Lafler v. Cooper*, 566 U.S. 156 (2012). The trial court would likely have accepted the plea, and Applicant received a greater sentence following trial than she would have received had she accepted the plea.
- (2) Counsel failed to investigate the State's failure to test Applicant or her breast milk. Counsel also failed to argue and explain to the jury that there was no testing of the Applicant and no testing of her breastmilk. The State collected fresh milk samples that were in the refrigerator at the time of the death, but never tested the contents. Without testing the Applicant, the State failed to prove that Applicant (1) was taking more medication than prescribed, or (2) that morphine was even present in her breastmilk. Counsel never requested that the State do so. Likewise, Counsel failed to seek genetic testing of Applicant and her daughter to determine if either suffered from a genetic defect that could cause an inability to sufficiently process

and clear morphine. *See Bagwell v. State*, 410 S.C. 259, 266-67, 763 S.E.2d 630, 634 (Ct. App. 2014).

- (3) Counsel failed to offer an alternative theory of causation to rebut the State's theory that the level of morphine tested in Applicant's daughter came from breastmilk, and Counsel failed to investigate and develop evidence to develop and present an alternative theory of causation. The State's expert witnesses presented a *res ipsa loquitor* theory that, since Applicant was taking morphine, was breastfeeding, and that lethal morphine levels were detected in her daughter, transmission through the breast milk must have caused her death. Counsel, however, failed to present any expert opinion supporting that it was, in fact, to a reasonable degree of medical certainty impossible for a lethal level to pass through breast milk.
- (4) Counsel failed to adequately rebut the State's argument that Applicant met the extreme indifference requirement of S.C. Code Ann. § 16-3-85. Counsel failed to secure the assistance of an expert in obstetrics and gynecology, particularly with experience in addiction medicine and pain management, who could explain that Applicant's behavior did not rise to the level of "extreme indifference" required by S.C. Code Ann. § 16-3-85.
- (5) Counsel failed to request a *State v. Council* hearing as to the reliability of the testimony and opinions that the State's expert witnesses intended to offer. *See State v. Council*, 335 S.C. 1, 20, 515 S.E.2d 508, 518 (1999) (discussing the reliability factors that the trial court must apply to determine if expert testimony is sufficiently reliable under Rule 702, SCORE). Applicant suffered prejudice because the State's experts ultimately offered testimony that was not supported by the scientific

evidence and also offered testimony beyond the scope of their expertise and, but for these errors, the result of the proceeding would have been different.

- (6) Counsel failed to file motions in limine including, but not limited to, failing to move to exclude any testimony that the morphine transmitted in a lethal level through Applicant's breast milk, due to a lack of scientific evidence on this point;
- (7) Counsel failed to object to the State's experts testifying beyond the scope of their expertise and offering opinions not based on scientific evidence. (Tr. 383-384, 444)
- (8) Counsel failed to object and seek a ruling excluding reference to drugs aside from morphine and clonazepam and precluding the state from arguing synergistic effect.
- (9) Counsel failed to argue that S.C. Code Ann. § 16-3-85 is unconstitutionally vague.
- (10) Counsel failed to request a jury instruction regarding homicide by child abuse or take exception to the charge as given for speaking to the facts of the case and misstating the law. (Tr. 581 & 590)
- (11) Counsel failed to object to leading questions and redirect beyond the scope of cross-examination. (Tr. 113, 234, 249, 262, 265, 298, 347, 358-59, 361, 439, 443-44).

II. Ineffective Assistance of Appellate Counsel

Applicant was denied the right to effective assistance of Appellate Counsel—guaranteed by the Sixth and Fourteenth Amendments to the United States Constitution and by Article I, §§ 3 and 14 of the South Carolina Constitution—during the appellate proceedings. Appellate Counsel's performance was unreasonable and prejudicial, as outlined below. *Strickland v. Washington*, 466 U.S. 668 (1984). Appellate Counsel's acts or omissions included:

- (1) Appellate Counsel failed to argue that the homicide by child abuse and involuntary manslaughter verdicts were inconsistent and that only the manslaughter verdict should stand based on the evidence presented.

III. Due Process

Applicant's conviction and sentence were obtained in violation of the due process clause of the Fourteenth Amendment of the United States Constitution, and the corresponding provisions of the South Carolina Constitution. This included:

- (1) The State's expert witnesses testified that they believed transmission of morphine through breast milk was the cause of the victim's death. This testimony was not based on reliable scientific evidence and was, therefore, false. The State's use of this evidence against a defendant violates the Fourteenth Amendment. *Napue v. Illinois*, 360 U.S. 264, 269 (1959). This is true even when the State has not deliberately introduced the false evidence, but fails to correct it after it is introduced. See *Giglio v. United States*, 405 U.S. 150, 153 (1972); *Napue*, 360 U.S. at 269; *Riddle v. Ozmint*, 369 S.C. 39, 47-48, 631 S.E.2d 70, 75 (2006).

IV. New Evidence

There exists evidence of material facts, not previously presented and heard, that requires vacation of the conviction or sentence in the interest of justice. See S.C. Code Ann. 17-27-20(A)(4). This included:

- (1) When asked if there were any reported cases of a lethal dose through breast milk, the State's toxicology expert, Dr. David Eagerton, cited a study out of Canada. Madadi P, Koren G, Cairns J, Chitayat D, Gaedigk A, Leeder JS, et al. Safety of codeine during breastfeeding. Fatal morphine poisoning in the breastfed neonate of

a mother prescribed codeine, Can Fam Physician 2007;53:33-5 (the "Canadian study"). This study was directly rebutted by a paper published in May of 2020: Zipursky, The Implausibility of Neonatal Opioid Toxicity from Breastfeeding, 108(5) Clinical Pharmacology & Therapeutics (May 2020). In light of this new study (the "Zipursky study"), the original Canadian study was retracted. See Ross T. Tsuyuki & Nicholas Pimlott, Risks of maternal codeine intake in breast-fed infants: A Joint Statement of Retraction from the Canadian Pharmacists Journal and Canadian Family Physician, Canadian Pharmacists Journal v. 154(1) (Nov. 18, 2020).

NELSON MULLINS RILEY & SCARBOROUGH LLP

By: Blake T. Williams

Daniel J. Westbrook

SC Bar No. 12939

E-Mail: dan.westbrook@nelsonmullins.com

John F. Kuppens

SC Bar No. 12948

E-Mail: john.kuppens@nelsonmullins.com

Blake T. Williams

SC Bar No. 100794

E-Mail: blake.williams@nelsonmullins.com

Caroline A. Warner

SC Bar No. 104280

E-Mail: caroline.warner@nelsonmullins.com

1320 Main Street, 17th Floor

Post Office Box 11070 (29211-1070)

Columbia, SC 29201

(803) 799-2000

ROSS & ENDERLIN, P.A.

Susannah C. Ross

S.C. Bar No. 11205

E-Mail: susannah@rossenderlin.com

330 East Coffee St.

FILED
2021 JUL 26 AM 9:11
CLERK OF COURT
SPALDING COUNTY
AMY W. COX

Greenville, SC 29601
(864) 242-0029

Attorneys for Stephanie Irene Greene

Columbia, South Carolina

July 22, 2021

FILED
2021 JUL 26 AM 9:11
CLERK OF COURT
SPARTANBURG COUNTY
AMY W. COX

STATE OF SOUTH CAROLINA)
)
County of Spartanburg)

VERIFICATION

I, Blake T. Williams, being duly sworn upon my oath, depose and say that I have subscribed to the foregoing application; that I know the contents thereof; that it includes every ground known to me for vacating, setting aside or correcting the conviction and sentence attacked in this application; and that the matters and allegations therein set forth are true.

Blake T. Williams

SWORN to and subscribed before me this 22nd
day of July, 2021

Gileen H. Hindman
Notary Public

My Commission Expires: 04/29/2024



2021 JUL 26 AM 9:11
CLERK OF COURT
SPARTANBURG COUNTY
AMY W. COX

FILED

FILED

2022 APR 26 AM 9:26

CLERK OF COURT
SPARTANBURG COUNTY
ANYWAY.COM

STATE OF SOUTH CAROLINA
COUNTY OF SPARTANBURG

Stephanie Irene Greene, # 359489,
Applicant,

v.

State of South Carolina,
Respondent.

IN THE COURT OF COMMON PLEAS
SEVENTH JUDICIAL CIRCUIT

Case Action No. 2019-CP-42-01605

**SECOND AMENDED APPLICATION
FOR POST-CONVICTION RELIEF**

Applicant Stephanie Irene Greene, # 359489 ("Applicant") filed the above action seeking post-conviction relief on May 2, 2019. In the initial *pro se* application, Applicant alleged, *inter alia*, actual innocence, lack of extreme indifference/mens rea, and several grounds of ineffective assistance of trial and appellate counsel. The State filed a Return and Partial Motion to Dismiss on August 5, 2019.

On July 8, 2020, the Court entered a Consent Order granting Applicant's motion for leave to conduct discovery. On December 16, 2020, the Court entered a Consent Order assigning the Honorable J. Mark Hayes, II to hear all issues related to the above captioned post-conviction relief application. On December 16, 2020, the Court also granted Respondent's Motion for Reciprocal Discovery.

Petitioner submitted a First Amended Application and Memorandum in Support to clarify and elaborate on several of the grounds asserted in Applicant's initial *pro se* application and to add additional claims warranting post-conviction relief on July 26, 2022. Petitioner now submits this Second Amended Application and Memorandum in Support to further clarify the grounds asserted and identify areas where expert testimony is expected.

1. Place of detention Leath CI, 2809 Airport Rd., Greenwood, SC 29659
2. Name and location of Court which imposed sentence 7th Circuit Court, Spartanburg, SC

3. Name(s) of co-defendant(s) (if any) Not applicable
4. The indictment number or numbers (if known) upon which and the offenses for which sentence was imposed:
 - (a) 2011-GS-42-5758
 - (b) 2011-GS-42-5758A
 - (c) 2011-GS-42-5758B
5. The date upon which sentence was imposed and the terms of the sentence:
 - (a) April 4, 2014 – 20 years, concurrent
 - (b) April 4, 2014 – 5 years, concurrent (vacated by S.C. Supreme Court)
 - (c) April 4, 2014 – 5 years, concurrent
6. Check whether a finding of guilty was made:
 - (a) after a plea of guilty No
 - (b) after a plea of not guilty Yes
 - (c) after a plea of nolo contendere No
7. Did you appeal from the judgment of conviction or the imposition of sentence? Yes
8. If you answered "yes" to (7), list:
 - (a) the name of each Court to which you appealed:
 - i. Supreme Court of South Carolina (Applicant filed direct appeal to Court of Appeals and case was sua sponte transferred to the Supreme Court)
 - ii. Supreme Court of the United States
 - (b) the result in each such Court to which you appealed:
 - i. Involuntary manslaughter conviction vacated; homicide by child abuse and unlawful conduct toward a child convictions and sentences affirmed (Supreme Court of South Carolina)

Petition for a writ of certiorari denied (Supreme Court of the United States)
 the date of each such result:

2022 APR 26 AM 9:27

FILED

- i. May 23, 2018 (petition for rehearing denied June 26, 2018) (Supreme Court of South Carolina)
 - ii. January 7, 2019 (Supreme Court of the United States)
 - (d) if known, citations of any written opinion or orders entered pursuant to such results:
 - i. State v. Greene, 423 S.C. 263, 814 S.E.2d 496 (2018)
 - ii. Greene v. South Carolina, 139 S.Ct. 844 (2019)
9. If you answered "no" to (7), state your reasons for not so appealing:
- (a) N/A

10 & 11. GROUND FOR RELIEF WITH SUPPORTING FACTS

Please see Appendix A, *infra*.

12 & 13. PROCEDURAL HISTORY

Applicant filed a mandatory direct appeal to the South Carolina Supreme Court. After the Supreme Court proceedings ended, Applicant also timely filed a petition for a writ of certiorari to the U.S. Supreme Court.

Applicant has not previously filed an application for post-conviction relief.

Applicant filed a petition for a writ of habeas corpus on December 2, 2019 with the U.S. District Court for the District of South Carolina, C/A No. 4:19-cv-03365-MGL. On February 27, 2020, the District Court issued an order adopting the Magistrate Judge's Report and Recommendation that the matter be dismissed *without prejudice* while Applicant exhausts her state court remedies. The District Court entered the judgment that same day.

- 14. None of the grounds set forth in (10) have been previously presented to this or any other court, state or federal.
- 15. Not applicable.
- 16. These grounds rely on additional facts outside the record that was before the previous courts.
- 17. Applicant was previously represented by counsel.
- 18. Trial and Appellate Counsel:
C. Rauch Wise 305 Main St., Greenwood, SC 29646 (trial and direct appeal)
- 19. Applicant seeks relief from her conviction and sentence.

FILED
2022 APR 26 AM 9:27
CLERK OF COURT
SPARTANBURG COUNTY
AMY W. COX

20. Applicant is not under sentence from any other court.

APPENDIX A

(Grounds for Relief and Supporting Facts)

I. Ineffective Assistance of Trial Counsel

Applicant was denied the right to effective assistance of counsel guaranteed by the Sixth and Fourteenth Amendments to the United States Constitution and by Article I, §§ 3 and 14 of the South Carolina Constitution. Trial counsel's performance was both unreasonable and prejudicial as outlined below. *See Strickland v. Washington*, 466 U.S. 668 (1984). Trial counsel's acts or omissions included:

- (1) Trial Counsel (hereinafter "Counsel") failed to properly advise Applicant regarding a guilty plea to involuntary manslaughter. Counsel failed to advise Applicant of the maximum sentence she faced, assured Applicant she would win at trial, and advised applicant to reject a plea deal. *See Lafler v. Cooper*, 566 U.S. 156 (2012). The trial court would likely have accepted the plea, and Applicant received a greater sentence following trial than she would have received had she accepted the plea.

- (2) Counsel failed to investigate the State's failure to test Applicant or her breast milk. Counsel also failed to argue and explain to the jury that there was no testing of the Applicant and no testing of her breastmilk. The State collected fresh milk samples that were in the refrigerator at the time of the death, but never tested the contents.

Without testing the Applicant, the State failed to prove that Applicant (1) was taking more medication than prescribed, or (2) that morphine was even present in her breastmilk. Counsel never requested that the State do so. Likewise, Counsel failed to seek genetic testing of Applicant and her daughter to determine if either

FILED
CLERK OF COURT
SPARTANBURG COUNTY
SOUTH CAROLINA
JAN 26 2017
12:56 PM

suffered from a genetic defect that could cause an inability to sufficiently process and clear morphine. *See Bagwell v. State*, 410 S.C. 259, 266-67, 763 S.E.2d 630, 634 (Ct. App. 2014).

(3) Counsel failed to offer an alternative theory of causation to rebut the State's theory that the level of morphine tested in Applicant's daughter came from breastmilk, and Counsel failed to investigate and develop evidence to develop and present an alternative theory of causation. The State's expert witnesses presented a *res ipsa loquitor* theory that, since Applicant was taking morphine, was breastfeeding, and that lethal morphine levels were detected in her daughter, transmission through the breast milk must necessarily have caused her death. Counsel failed to present any expert opinion supporting that, to a reasonable degree of medical certainty, there was no scientific basis for the premise that a lethal dose of morphine can pass through breast milk. The amount of morphine that can pass to the infant through breast milk does not pose a risk of harm to an infant under normal circumstances. If the infant has some health issue, *e.g.*, renal failure, the amount of morphine can build up in the infant's body to a harmful level. Counsel failed to secure the assistance of an expert in pediatric nephrology who could opine that, to a reasonable degree of medical certainty, renal failure was the most likely explanation for the lethal level of morphine found in the child.

(4) Counsel failed to adequately rebut the State's argument that Applicant met the extreme indifference requirement of S.C. Code Ann. § 16-3-85. Counsel failed to secure the assistance of an expert in obstetrics and gynecology, particularly with experience in addiction medicine and pain management, who could explain that

FILED
2022 FEB 26 AM 9:27
CLERK OF COUNTY
ALBUQUERQUE COUNTY
NEW MEXICO

FILED

Applicant's behavior did not rise to the level of "extreme indifference" required by S.C. Code Ann. § 16-3-85. Counsel also failed to secure the assistance of an expert in reproductive psychology who could opine regarding the management of Applicant's mental health and the appropriateness of the medications she was taking during pregnancy, including the morphine-containing MS Contin.

- (5) Counsel failed to request a *State v. Council* hearing as to the reliability of the testimony and opinions that the State's expert witnesses intended to offer. *See State v. Council*, 335 S.C. 1, 20, 515 S.E.2d 508, 518 (1999) (discussing the reliability factors that the trial court must apply to determine if expert testimony is sufficiently reliable under Rule 702, SCRE). Applicant suffered prejudice because the State's experts ultimately offered testimony that was not supported by the scientific evidence and also offered testimony beyond the scope of their expertise and, but for these errors, the result of the proceeding would have been different.
- (6) Counsel failed to file motions in limine including, but not limited to, failing to move to exclude any testimony that the morphine transmitted in a lethal level through Applicant's breast milk, due to a lack of scientific evidence on this point.
- (7) Counsel failed to object to the State's experts testifying beyond the scope of their expertise . Dr. Wendy Bell was qualified as a forensic toxicologist. During her testimony, the State asked if Applicant should have told her doctors about the medications she was taking and that she was breastfeeding, and Dr. Bell acknowledged "I would think so but I – that's a little out of my area of expertise."

SPARTANBURG COUNTY
CLERK OF COURT
APR 26 2022 9:27 AM
(17:262) Counsel failed to object to this testimony.

2022 APR 26 AM 9:27

FILED

- (8) Counsel failed to object to the State's experts offering opinions not based on scientific evidence. Quintus Leon Young, III; Dr. Wendy Bell; Dr. Kaushik Kotecha; Dr. David Eagerton; and Dr. John David Wren all testified regarding the supposed "synergistic effect" of the particular drugs that Applicant was taking and/or that "one plus one equals three" or "one plus one equals five" when analyzing drug interactions (*see tr.* 148; 259-61; 265; 322; 350-53; 431-44,) despite this theory not being supported to a reasonable degree of medical certainty.
- (9) Counsel failed to object and seek a ruling excluding reference to drugs aside from morphine and clonazepam and precluding the state from arguing synergistic effect.
- (10) Counsel failed to argue that S.C. Code Ann. § 16-3-85 is unconstitutionally vague.
- (11) Counsel failed to request a jury instruction regarding homicide by child abuse or take exception to the charge as given for speaking to the facts of the case and misstating the law. (Tr. 581 & 590)
- (12) Counsel failed to object to leading questions and redirect beyond the scope of cross-examination. (Tr. 113, 234, 249, 262, 265, 298, 347, 358-59, 361, 439, 443-44).

II. Ineffective Assistance of Appellate Counsel

Applicant was denied the right to effective assistance of Appellate Counsel—guaranteed by the Sixth and Fourteenth Amendments to the United States Constitution and by Article I, §§ 3 and 14 of the South Carolina Constitution—during the appellate proceedings. Appellate Counsel's performance was unreasonable and prejudicial, as outlined below. *Strickland v. Washington*, 466 U.S. 668 (1984). Appellate Counsel's acts or omissions included:

2022 APR 26 AM 9:27
FILED
CLERK OF COURT
SPARTANBURG COUNTY
AMY W. COX

- (1) Appellate Counsel failed to argue that the homicide by child abuse and involuntary manslaughter verdicts were inconsistent and that only the manslaughter verdict should stand based on the evidence presented.

III. Due Process

Applicant's conviction and sentence were obtained in violation of the due process clause of the Fourteenth Amendment of the United States Constitution, and the corresponding provisions of the South Carolina Constitution. This included:

- (1) The State's expert witnesses testified that they believed transmission of morphine through breast milk was the cause of the victim's death. This testimony was not based on reliable scientific evidence and was, therefore, false. The State's use of this evidence against a defendant violates the Fourteenth Amendment. *Napue v. Illinois*, 360 U.S. 264, 269 (1959). This is true even when the State has not deliberately introduced the false evidence, but fails to correct it after it is introduced. *See Giglio v. United States*, 405 U.S. 150, 153 (1972); *Napue*, 360 U.S. at 269; *Riddle v. Ozmint*, 369 S.C. 39, 47-48, 631 S.E.2d 70, 75 (2006).

IV. New Evidence

There exists evidence of material facts, not previously presented and heard, that requires vacation of the conviction or sentence in the interest of justice. *See* S.C. Code Ann. 17-27-20(A)(4). This included:

- (1) When asked if there were any reported cases of a lethal dose through breast milk, the State's toxicology expert, Dr. David Eagerton, cited a study out of Canada.

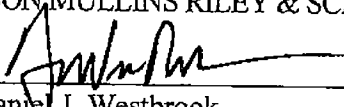
XOO 'M ANW Madadi P, Koren G, Cairns J, Chitayat D, Gaedigk A, Leeder JS, et al. Safety of codeine during breastfeeding. Fatal morphine poisoning in the breastfed neonate of

2022 APR 26 AM 9:27

FILED

a mother prescribed codeine, Can Fam Physician 2007;53:33-5 (the "Canadian study"). This study was directly rebutted by a paper published in May of 2020: Zipursky, The Implausibility of Neonatal Opioid Toxicity from Breastfeeding, 108(5) Clinical Pharmacology & Therapeutics (May 2020). In light of this new study (the "Zipursky study"), the original Canadian study was retracted. See Ross T. Tsuyuki & Nicholas Pimlott, Risks of maternal codeine intake in breast-fed infants: A Joint Statement of Retraction from the Canadian Pharmacists Journal and Canadian Family Physician, Canadian Pharmacists Journal v. 154(1) (Nov. 18, 2020).

NELSON MULLINS RILEY & SCARBOROUGH LLP

By: 

Daniel J. Westbrook

SC Bar No. 12939

E-Mail: dan.westbrook@nelsonmullins.com

John F. Kuppens

SC Bar No. 12948

E-Mail: john.kuppens@nelsonmullins.com

Blake T. Williams

SC Bar No. 100794

E-Mail: blake.williams@nelsonmullins.com

Caroline A. Warner

SC Bar No. 104280

E-Mail: caroline.warner@nelsonmullins.com

1320 Main Street, 17th Floor

Post Office Box 11070 (29211-1070)

Columbia, SC 29201

(803) 799-2000

ROSS & ENDERLIN, P.A.

Susannah C. Ross

S.C. Bar No. 11205

E-Mail: susannah@rossenderlin.com

330 East Coffee St.

2022 APR 26 AM 9:27
FILED
CLERK OF COURT
SPARTANBURG COUNTY
ANY WAY

Greenville, SC 29601
(864) 242-0029

Attorneys for Stephanie Irene Greene

Columbia, South Carolina

April 22, 2022

FILED
2022 APR 26 AM 9:27
CLERK OF COURT
SPARTANBURG COUNTY
AMY W. COX

STATE OF SOUTH CAROLINA)
)
County of Richland _____)

VERIFICATION

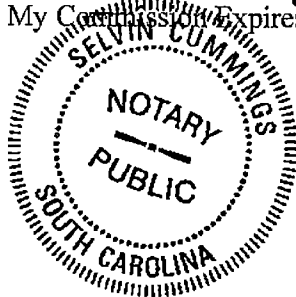
I, Daniel J. Westbrook, being duly sworn upon my oath, depose and say that I have subscribed to the foregoing application; that I know the contents thereof; that it includes every ground known to me for vacating, setting aside or correcting the conviction and sentence attacked in this application; and that the matters and allegations therein set forth are true.

Daniel J. Westbrook

SWORN to and subscribed before me this 22
day of April, 2022

Sevin Cummings
Notary Public

My Commission Expires: 6-24-2031



CLERK OF COURT
SPARTANBURG COUNTY
KIM W. COX

2022 APR 26 AM 9:27

FILED

STATE OF SOUTH CAROLINA	)	IN THE COURT OF COMMON PLEAS
	)	SEVENTH JUDICIAL CIRCUIT
COUNTY OF SPARTANBURG	)	
	)	
Stephanie Irene Greene, # 359489,	)	Case Action No. 2019-CP-42-01605
	)	
Applicant,	)	
	)	
v.	)	<u>THIRD AMENDED APPLICATION</u>
	)	<u>FOR POST-CONVICTION RELIEF</u>
State of South Carolina,	)	
	)	
Respondent.	)	

Applicant Stephanie Irene Greene, # 359489 ("Applicant") filed the above action seeking post-conviction relief on May 2, 2019. In the initial *pro se* application, Applicant alleged, *inter alia*, actual innocence, lack of extreme indifference/mens rea, and several grounds of ineffective assistance of trial and appellate counsel. The State filed a Return and Partial Motion to Dismiss on August 5, 2019.

On July 8, 2020, the Court entered a Consent Order granting Applicant's motion for leave to conduct discovery. On December 16, 2020, the Court entered a Consent Order assigning the Honorable J. Mark Hayes, II to hear all issues related to the above captioned post-conviction relief application. On December 16, 2020, the Court also granted Respondent's Motion for Reciprocal Discovery.

Petitioner submitted a First Amended Application and Memorandum in Support to clarify and elaborate on several of the grounds asserted in Applicant's initial *pro se* application and to add additional claims warranting post-conviction relief on July 26, 2022. Petitioner submitted a Second Amended Application and Memorandum in Support on April 26, 2022 to further clarify the grounds asserted and identify areas where expert testimony is expected. Petitioner now submits

FILED
2023 AUG 15 12:35
CLERK OF COURT
SPARTANBURG COUNTY
SOUTH CAROLINA

this Third Amended Application and Memorandum in Support to further clarify and narrow the grounds asserted and expected expert testimony.

1. Place of detention Leath CI, 2809 Airport Rd., Greenwood, SC 29659
2. Name and location of Court which imposed sentence 7th Circuit Court, Spartanburg, SC
3. Name(s) of co-defendant(s) (if any) Not applicable
4. The indictment number or numbers (if known) upon which and the offenses for which sentence was imposed:
 - (a) 2011-GS-42-5758
 - (b) 2011-GS-42-5758A
 - (c) 2011-GS-42-5758B
5. The date upon which sentence was imposed and the terms of the sentence:
 - (a) April 4, 2014 – 20 years, concurrent
 - (b) April 4, 2014 – 5 years, concurrent (vacated by S.C. Supreme Court)
 - (c) April 4, 2014 – 5 years, concurrent
6. Check whether a finding of guilty was made:
 - (a) after a plea of guilty No
 - (b) after a plea of not guilty Yes
 - (c) after a plea of nolo contendere No
7. Did you appeal from the judgment of conviction or the imposition of sentence? Yes
8. If you answered "yes" to (7), list:
 - (a) the name of each Court to which you appealed:
 - i. Supreme Court of South Carolina (Applicant filed direct appeal to Court of Appeals and case was *sua sponte* transferred to the Supreme Court)
 - ii. Supreme Court of the United States
 - (b) the result in each such Court to which you appealed:

FILED
2022 AUG -5 PM 12:35
CLERK OF COURT
SPARTANBURG COUNTY
SOUTH CAROLINA

i. Involuntary manslaughter conviction vacated; homicide by child abuse and unlawful conduct toward a child convictions and sentences affirmed (Supreme Court of South Carolina)

ii. Petition for a writ of certiorari denied (Supreme Court of the United States)

(c) the date of each such result:

i. May 23, 2018 (petition for rehearing denied June 26, 2018) (Supreme Court of South Carolina)

ii. January 7, 2019 (Supreme Court of the United States)

(d) if known, citations of any written opinion or orders entered pursuant to such results:

i. State v. Greene, 423 S.C. 263, 814 S.E.2d 496 (2018)

ii. Greene v. South Carolina, 139 S.Ct. 844 (2019)

9. If you answered "no" to (7), state your reasons for not so appealing:

(a) N/A

10 & 11. GROUND FOR RELIEF WITH SUPPORTING FACTS

Please see Appendix A, *infra*.

12 & 13. PROCEDURAL HISTORY

Applicant filed a mandatory direct appeal to the South Carolina Supreme Court. After the Supreme Court proceedings ended, Applicant also timely filed a petition for a writ of certiorari to the U.S. Supreme Court.

Applicant has not previously filed an application for post-conviction relief.

Applicant filed a petition for a writ of habeas corpus on December 2, 2019 with the U.S. District Court for the District of South Carolina, C/A No. 4:19-cv-03365-MGL. On February 27, 2020, the District Court issued an order adopting the Magistrate Judge's Report and Recommendation that the matter be dismissed *without prejudice* while Applicant exhausts her state court remedies. The District Court entered the judgment that same day.

14. None of the grounds set forth in (10) have been previously presented to this or any other court, state or federal.

15. Not applicable.

16. These grounds rely on additional facts outside the record that was before the previous courts.

FILED
2022 AUG -5 PM 12:35
CLERK OF COURT
SPARTANBURG COUNTY
AMY M. COX

17. Applicant was previously represented by counsel.
18. Trial and Appellate Counsel:
C. Rauch Wise 305 Main St., Greenwood, SC 29646 (trial and direct appeal)
19. Applicant seeks relief from her conviction and sentence.
20. Applicant is not under sentence from any other court.

APPENDIX A

(Grounds for Relief and Supporting Facts)

I. Ineffective Assistance of Trial Counsel

Applicant was denied the right to effective assistance of counsel guaranteed by the Sixth and Fourteenth Amendments to the United States Constitution and by Article I, §§ 3 and 14 of the South Carolina Constitution. Trial counsel's performance was both unreasonable and prejudicial as outlined below. *See Strickland v. Washington*, 466 U.S. 668 (1984). Trial counsel's acts or omissions included:

- (1) Counsel failed to investigate the State's failure to test Applicant or her breast milk.

Counsel also failed to argue and explain to the jury that there was no testing of the Applicant and no testing of her breastmilk. The State collected fresh milk samples that were in the refrigerator at the time of the death, but never tested the contents. Without testing the Applicant, the State failed to prove that Applicant (1) was taking more medication than prescribed, or (2) that morphine was even present in her breastmilk. Counsel never requested that the State do so. Likewise, Counsel failed to seek genetic testing of Applicant and her daughter to determine if either suffered from a genetic defect that could cause an inability to sufficiently process and clear morphine. *See Bagwell v. State*, 410 S.C. 259, 266-67, 763 S.E.2d 630, 634 (Ct. App. 2014).

(2) Counsel failed to offer an alternative theory of causation to rebut the State's theory that the level of morphine tested in Applicant's daughter came from breastmilk, and Counsel failed to investigate and develop evidence to develop and present an alternative theory of causation. The State's expert witnesses presented a *res ipsa loquitor* theory that, since Applicant was taking morphine, was breastfeeding, and that lethal morphine levels were detected in her daughter, transmission through the breast milk must necessarily have caused her death. Counsel failed to present any expert opinion supporting that, to a reasonable degree of medical certainty, there was no scientific basis for the premise that a lethal dose of morphine can pass through breast milk. The amount of morphine that can pass to the infant through breast milk does not pose a risk of harm to an infant under normal circumstances. If the infant has some health issue, *e.g.*, renal failure, the amount of morphine can build up in the infant's body to a harmful level. Counsel failed to secure the assistance of an expert in pediatric nephrology who could opine that, to a reasonable degree of medical certainty, renal failure was the most likely explanation for the lethal level of morphine found in the child.

(3) Counsel failed to adequately rebut the State's argument that Applicant met the extreme indifference requirement of S.C. Code Ann. § 16-3-85 by developing the alternative cause detailed above and presenting it to the jury.

(4) Counsel failed to request a *State v. Council* hearing as to the reliability of the testimony and opinions that the State's expert witnesses intended to offer. See *State v. Council*, 335 S.C. 1, 20, 515 S.E.2d 508, 518 (1999) (discussing the reliability factors that the trial court must apply to determine if expert testimony is sufficiently

reliable under Rule 702, SCRE). Applicant suffered prejudice because the State's experts ultimately offered testimony that was not supported by the scientific evidence and also offered testimony beyond the scope of their expertise and, but for these errors, the result of the proceeding would have been different.

(5) Counsel failed to file motions in limine including, but not limited to, failing to move to exclude any testimony that the morphine transmitted in a lethal level through Applicant's breast milk due to a lack of scientific evidence on this point.

(6) Counsel failed to object to the State's experts testifying beyond the scope of their expertise. Dr. Wendy Bell was qualified as a forensic toxicologist. During her testimony, the State asked if Applicant should have told her doctors about the medications she was taking and that she was breastfeeding, and Dr. Bell acknowledged "I would think so but I – that's a little out of my area of expertise." (Tr. 262.) Counsel failed to object to this testimony.

(7) Counsel failed to object to the State's experts offering opinions not based on scientific evidence. Quintus Leon Young, III; Dr. Wendy Bell; Dr. Kaushik Kotecha; Dr. David Eagerton; and Dr. John David Wren all testified regarding the supposed "synergistic effect" of the particular drugs that Applicant was taking and/or that "one plus one equals three" or "one plus one equals five" when analyzing drug interactions (*see tr.* 148; 259-61; 265; 322; 350-53; 431-44.) despite this theory not being supported to a reasonable degree of medical certainty.

(8) Counsel failed to object and seek a ruling excluding reference to drugs aside from morphine and clonazepam and precluding the state from arguing "synergistic effect" of any other medications.

FILED
2022 AUG 17
CLERK OF COURT
SARASOTA COUNTY
AM. W. CO. CLERK
12:35

- (9) Counsel failed to argue that S.C. Code Ann. § 16-3-85 is unconstitutionally vague.
- (10) Counsel failed to request a jury instruction regarding homicide by child abuse or take exception to the charge as given for speaking to the facts of the case and misstating the law. (Tr. 581 & 590)
- (11) Counsel failed to object to leading questions and redirect beyond the scope of cross-examination. (Tr. 113, 234, 249, 262, 265, 298, 347, 358-59, 361, 439, 443-44).

II. Ineffective Assistance of Appellate Counsel

Applicant was denied the right to effective assistance of Appellate Counsel—guaranteed by the Sixth and Fourteenth Amendments to the United States Constitution and by Article I, §§ 3 and 14 of the South Carolina Constitution—during the appellate proceedings. Appellate Counsel's performance was unreasonable and prejudicial, as outlined below. *Strickland v. Washington*, 466 U.S. 668 (1984). Appellate Counsel's acts or omissions included:

- (1) Appellate Counsel failed to argue that the homicide by child abuse and involuntary manslaughter verdicts were inconsistent and that only the manslaughter verdict should stand based on the evidence presented.

III. Due Process

Applicant's conviction and sentence were obtained in violation of the due process clause of the Fourteenth Amendment of the United States Constitution, and the corresponding provisions of the South Carolina Constitution. This included:

- (1) The State's expert witnesses testified that they believed transmission of morphine through breast milk was the cause of the victim's death. This testimony was not based on reliable scientific evidence and was, therefore, false. The State's use of this evidence against a defendant violates the Fourteenth Amendment. *Napue v. Illinois*, 360 U.S. 264 (1959).

Illinois, 360 U.S. 264, 269 (1959). This is true even when the State has not deliberately introduced the false evidence but fails to correct it after it is introduced. See *Giglio v. United States*, 405 U.S. 150, 153 (1972); *Napue*, 360 U.S. at 269; *Riddle v. Ozmint*, 369 S.C. 39, 47-48, 631 S.E.2d 70, 75 (2006).

IV. New Evidence

There exists evidence of material facts, not previously presented and heard, that requires vacation of the conviction or sentence in the interest of justice. See S.C. Code Ann. 17-27-20(A)(4). This included:

- (1) When asked if there were any reported cases of a lethal dose through breast milk, the State's toxicology expert, Dr. David Eagerton, cited a study out of Canada. Madadi P, Koren G, Cairns J, Chitayat D, Gaedigk A, Leeder JS, et al. Safety of codeine during breastfeeding. Fatal morphine poisoning in the breastfed neonate of a mother prescribed codeine, Can Fam Physician 2007;53:33-5 (the "Canadian study"). This study was directly rebutted by a paper published in May of 2020: Zipursky, The Implausibility of Neonatal Opioid Toxicity from Breastfeeding, 108(5) Clinical Pharmacology & Therapeutics (May 2020). In light of this new study (the "Zipursky study"), the original Canadian study was retracted. See Ross T. Tsuyuki & Nicholas Pimlott, Risks of maternal codeine intake in breast-fed infants: A Joint Statement of Retraction from the Canadian Pharmacists Journal and Canadian Family Physician, Canadian Pharmacists Journal v. 154(1) (Nov 18, 2020).

FILED
22 AUG -5 PM 12:35
CLERK OF COURT
ANDERSON COUNTY
ALABAMA

NELSON MULLINS RILEY & SCARBOROUGH LLP

By: Blake T. Williams

Daniel J. Westbrook

SC Bar No. 12939

E-Mail: dan.westbrook@nelsonmullins.com

John F. Kuppens

SC Bar No. 12948

E-Mail: john.kuppens@nelsonmullins.com

Blake T. Williams

SC Bar No. 100794

E-Mail: blake.williams@nelsonmullins.com

Caroline A. Warner

SC Bar No. 104280

E-Mail: caroline.warner@nelsonmullins.com

1320 Main Street, 17th Floor

Post Office Box 11070 (29211-1070)

Columbia, SC 29201

(803) 799-2000

ROSS & ENDERLIN, P.A.

Susannah C. Ross

S.C. Bar No. 11205

E-Mail: susannah@rossenderlin.com

330 East Coffee St.

Greenville, SC 29601

(864) 242-0029

Attorneys for Stephanie Irene Greene

Columbia, South Carolina

August 2, 2022

FILED
2022 AUG -5 PM 12:35
CLERK OF COURT
SPARTANBURG COUNTY
AMY W. COX

STATE OF SOUTH CAROLINA)

COUNTY OF Richland)

VERIFICATION

I, Blake T. Williams, being duly sworn upon my oath, depose and say that I have subscribed to the foregoing application; that I know the contents thereof; that it includes every ground known to me for vacating, setting aside or correcting the conviction and sentence attacked in this application; and that the matters and allegations therein set forth are true.

Blake T. Williams

SWORN to and subscribed before me this 2
day of August . 2022

Lucian O. Smilno
Notary Public

My Commission Expires: 05.19.2025

FILED
2022 AUG -5 PM 12:35
CLERK OF COURT
SPARTANBURG COUNTY
AMY W. COX

STATE OF SOUTH CAROLINA	)	IN THE COURT OF COMMON PLEAS
	)	FOR THE SEVENTH JUDICIAL CIRCUIT
COUNTY OF SPARTANBURG	)	
Stephanie Irene Greene,	)	Case No.: 2019-CP-42-01605
S.C.D.C. No. 359489,	)	
	)	
Applicant,	)	
	)	RESPONDENT STATE'S
v.	)	PRETRIAL BRIEF AND RETURN
	)	
State of South Carolina,	)	
	)	
Respondent.	)	
	)	

This matter is a post-conviction relief (PCR) matter before this Court, currently set for a hearing commencing September 19, 2022. On August 2, 2022, Applicant filed her third amended PCR application. To the extent a return to the third amended application is required, Respondent denies each allegation and demands strict proof thereof.

I. PROCEDURAL HISTORY

A jury found Applicant guilty as charged for homicide by child abuse, involuntary manslaughter, and unlawful conduct towards a child following trial on August 30 to September 2, 2014. C. Rauch Wise, Esq. represented Applicant. Barry J. Barnette and Timi Poulos, Esqs., of the Seventh Circuit Solicitor's Office, prosecuted the case. Judge Cole sentenced Applicant to concurrent sentences of twenty years' imprisonment for homicide by child abuse, five years' imprisonment for involuntary manslaughter, and five years' imprisonment for unlawful conduct towards a child.

Applicant's infant child, Alexis, died at forty-six days old. Toxicology results showed lethal levels of morphine and the presence of other drugs in Alexis' blood, liver, and brain. Applicant received prescriptions for numerous drugs including MS Contin, a form of slow

release morphine, without the prescribing doctor aware that Applicant was pregnant with Alexis and later, breastfeeding Alexis. The prosecution's theory of the case was morphine and other drugs passed through Applicant's breastmilk and caused Alexis to die from respiratory depression. The Supreme Court succinctly summarized evidence at trial below:

The State's causation theory was [Applicant] consumed excessive amounts of central nervous system depressants, principally morphine, while breastfeeding Alexis and these drugs passed through [Applicant's] breast milk, resulting in Alexis's death. The evidence at trial revealed that [Applicant] took more morphine than her doctors prescribed. In addition, [Applicant] exclusively breastfed Alexis until approximately one week before her death. [Applicant] told investigators that she began supplementing with formula due to her new blood pressure medication; however, [Applicant] also told investigators that she breastfed Alexis extensively during the two nights immediately preceding Alexis's death. Thus, sufficient evidence was shown that [Applicant] took many drugs, including morphine, and breastfed Alexis.

Greene, 423 S.C. at 267, 814 S.E.2d at 498.

Mr. Wise continued to represent Applicant on appeal, raising the following issues:

1. Did the trial court err in failing to direct a verdict when the State failed to prove through competent medical evidence or otherwise that the morphine in the deceased child came from the mother through breast-feeding?
2. Did the trial court err in failing to direct a verdict or grant a new trial when the State failed to prove Stephanie Greene acted with extreme indifference as required by South Carolina Code § 16-3-85?
3. Did the trial court err in failing to instruct the jury they could convict on only one of the charges as a conviction of more than one charge would violate the double jeopardy provisions of Article I, § 12 of the Constitution of the State of South Carolina and Fifth Amendment to the Constitution of the United States of America as the same fact was used to prove the cause of death in each case?
4. Did the trial court err in failing to require the state to open fully on the law and the facts of the case and replying only to new arguments of defense counsel when the defendant was deprived of a fair trial in violation of the due process clause of Article I, § 3 of the Constitution of the State of South Carolina and the Fourteenth Amendment to the constitution of the United States of America by her counsel not being able to respond to new arguments made by the state in its closing argument?

By order filed May 5, 2016, the Supreme Court of South Carolina certified the appeal pursuant to Rule 204(b), SCACR, immediately lifting the matter from the South Carolina Court of Appeals. By opinion issued on May 23, 2018, the South Carolina Supreme Court affirmed Applicant's convictions for homicide by child abuse and unlawful conduct towards a child, but vacated the conviction for involuntary manslaughter. State v. Greene, 423 S.C. 263, 814 S.E.2d 496 (2018). The Remittitur was issued on June 26, 2018. Applicant petitioned the Supreme Court of the United States for a writ of certiorari on November 19, 2018, which was denied by summary disposition published January 7, 2019.

II. STATEMENT OF THE FACTS

On November 13, 2010, Applicant Greene's infant child ("Victim") was deceased when officers and medical personnel responded at approximately 6:00 a.m. The death was the result of intoxication by morphine in combination with other medications. Evidence indicates the morphine and other substances were ingested by Alexis through Greene's breast milk. Due to Greene's efforts to conceal information from her treating physicians, the doctor prescribing the extended release morphine, known as "MS Contin," was unaware that Greene was breastfeeding.

The first witness for the State was Terri Carter, an investigator for the Spartanburg County Coroner's Office. Carter and fellow investigator Ellen Holmes responded to a call to Greene's residence concerning the death of an infant on November 13, 2010. (Tr. 43). Holmes interviewed Greene while Carter inspected the house. Carter noticed Greene was stumbling, slurred her words, spilled her coffee, her eyes were not focused, and she seemed cognitively unsound. Her husband was also present during the interview and needed to direct Greene to sit up. However, as the interview progressed over time, Greene became more alert and focused.

Then at a later point in the interview, Greene left the room to use the restroom. Shortly after she returned, Greene's speech became slurred again, and she was clumsy once more. (Tr. 43-46).

Walking into the master bedroom, Carter observed numerous pill bottles covering the dresser. Carter published some of the warnings on the labels of these pill bottles that warned about taking the pills while pregnant or breastfeeding. (Tr. 50-53). Carter cataloged the medications found on the dresser and checked to see the number of pills remaining in each bottle, the dates the prescriptions were made available, and the dosage instructions found on the bottles. These tabulations were memorialized in a pill chart that was admitted into evidence. (Tr. 50-56; State's Trial Exhibit No. 60).

Notably, the label for the morphine pills indicated it originally contained 90 pills and the instructions allowed for one pill every eight hours. The prescription was filled on October 20, 2010. Accordingly, eighteen pills should have been left in the bottle, but only twelve remained. The morphine pill bottle was six pills short. (Tr. 59; Tr. 65; State's Trial Exhibits Nos. 7, 8, 60).

Even more hydrocodone pills were missing. The prescription was filled November 4, 2010, with ninety pills and was to be taken three times a day. Nine days later, only twenty-seven pills should have been missing, but instead there were forty-eight missing. (State's Trial Exhibit No. 60; Tr. 59-60). The pill count was short for Baclofen and Gabapentin as well. (Tr. 63-64).

Ellen Holmes was the investigator from the Coroner's Office who interviewed Greene and her husband at their home the day Victim was found dead. She responded at 6:16 a.m., November 13, 2010. Victim was already in the back of the EMS vehicle, dressed in an oversized red turtle neck shirt and wearing a wet diaper. Victim was only six-and-a-half weeks old. Victim was "extremely" pale and cold to the touch. Mild lividity had set in on her back. (Tr. 86-87). Holmes noticed Greene "had a very flat affect, slurred speech, almost incomprehensible at

times. Her eyes were very heavy and glassy. . . . [W]hen she walked it was a very unsteady gait.” (Tr. 87, ll. 19-22). Holmes testified Greene seemed intoxicated, but when Holmes asked Greene if she had taken any medications that morning, Greene claimed she had not. (Tr. 87-88).

Greene told Holmes that on Wednesday (Victim died on Friday night/Saturday morning), Victim was congested, and the doctor’s office recommended a vaporizer and baby rub. Victim was not running a temperature. According to Greene, she woke up at 4:30 a.m. (her husband said 5:00 a.m.) Saturday to find Victim unresponsive. (Tr. 89-90). Greene told Holmes she breastfed Victim the night before at around 11:00 p.m., claiming she fell asleep, and later claiming she breastfed Victim for thirty minutes on each side. (Tr. 90-91).

The interview was recorded. (Tr. 88; State’s Trial Exhibit No. 34). During the interview, Greene’s speech was markedly slurred evidencing her intoxicated state. She explained she called Victim’s physician, Dr. Bridges, on Thursday night about Victim’s upper respiratory system. Dr. Bridges said she did not need to bring Victim in for a visit. (State’s Trial Exhibit No. 34 (00:15 – 1:00)). According to Greene, after following Dr. Bridges’ recommendations to use a vaporizer and baby rub, Victim seemed to do better. Greene and her husband described Victim as bright-eyed and Thursday night, she nursed all night long. Greene told Holmes that Alexis was attached to Greene’s breast the whole night, feeding when needed. State’s Trial Exhibit No. 34 (2:00 – 3:30; 9:20 – 9:45). Friday, she remained bright-eyed and they did not notice anything out of the ordinary. Greene breastfed Victim that evening. (State’s Trial Exhibit No. 34 (4:45 – 6:15)). Greene told Holmes she started supplementing breastfeeding with formula for the last week because Greene’s blood pressure spiked and she started taking blood pressure medication. Greene was concerned about the blood pressure medication affecting Victim and she claimed she

spoke with the lactation expert about the blood pressure medication and her other medications. (State's Trial Exhibit No. 34 (13:45 – 14:30)).

This prompted Holmes to ask about the other medications, and Greene slowly and deliberately listed several medications, but MS Contin was not one of them. (State's Trial Exhibit No. 34 (15:00 – 17:30)). Greene told Holmes she was taking Amlodipine, Baclofen, Vicoprofen, Pristiq, Keppra, and Klonopin. The other medications found, **which Greene did not tell Holmes about**, were Requip, Durotan, Savella, Soma, alert tabs, and Morphine. (Tr. 91). On the extended form provided by Holmes for Greene to fill out, Greene was asked to list medications she took during her pregnancy. Greene listed MS Contin. However, **Greene did not tell Holmes that she took MS Contin while breastfeeding**. Greene was asked several times about her prescriptions. (Tr. 91-92).

RN Elaine Olsen worked at Piedmont Women's Healthcare. On March 25, 2010, Greene called and informed Nurse Olsen that Greene took a home pregnancy test on March 20, 2010, and tested positive. An appointment was scheduled for April 12, 2010, but Greene never came to the appointment. (Tr. 116-117). An ultrasound was also scheduled for March 26, 2010, but Greene did not show up for that appointment either. (Tr. 123).

Vera Andrus is an LPN for Carolina OBGYN. She took down the initial information from Greene on May 10, 2010, after Greene took a pregnancy test during a visit to Dr. Nichols on May 7, 2010. Nurse Andrus testified she asked Greene about the medications Greene was taking. (Tr. 97-98; Tr. 100). Nurse Andrus explained the reason why it was important to ask patients about their medications as follows:

It's important to know that because we want to know anything that the baby has been exposed to during pregnancy. And if those medications shouldn't be taken during pregnancy, then we need to

advise the patient, you know, to have her stop or to stop or to wean off them.

(Tr. 98, ll. 15-19). Nurse Andrus testified that each time a patient comes in, the patient is asked if there are any changes to their medications. (Tr. 98, ll. 20-23). Nurse Andrus asked Greene for a list of medications she was currently taking or had taken since her last period. Greene told her Soma, Vicoprofen, Clonazepam, Keppra, Lortab, Neurontin, Claritin, Benadryl, Savella, and a prenatal vitamin. (Tr. 99, ll. 6-11). Greene did not tell Nurse Andrus she was taking morphine or MS Contin. Greene also did not tell Nurse Andrus she was taking morphine or MS Contin when she came in for a follow up visit. (Tr. 99, ll. 15-25).

Emile Marks Horne is a labor and delivery nurse who testified for the State. She testified that on September 27, 2010, Greene was treated and then admitted into the hospital. Nurse Horne testified Greene reported taking some medications, but she did not mention that she took MS Contin, Vicoprofen, or Neurontin. Greene delivered Victim the next day. (Tr. 109-112).

SLED forensic toxicologist Quintus Leon Young, II, performed an initial screen from Alexis' blood and it tested positive for benzodiazepines, cocaine metabolite, opiates and salicylates. (Tr. 141). This prompted Young to perform a more comprehensive screen which indicated Alexis' blood contained .52 mg/liter of morphine. Young testified this was within lethal levels. Young's testing also indicated the blood sample contained .19 mg/liter of acetaminophen, .03 mg/Liter Methorphan, .03 mg/liter Benadryl, .04 mg/L Methorphanan, and .01 mg/L Clonazepam. (Tr. 141-144). Young received and tested samples of Victim's brain and liver tissue to verify the morphine levels. These tests further confirmed the lethal ranges of morphine in Victim's body. The sample from the brain tested at .54 mg/liter, and the liver sample indicated a morphine level of .56 mg/liter. (Tr. 144; Tr. 147-148). Young testified the

combination of morphine and other medications could have a synergistic effect on each other. (Tr. 148).

Dr. Suzanne Kovacs, Greene's primary physician, testified she treated Greene from November 2007 into 2010. Dr. Kovacs testified she never knew Greene was pregnant or had a child and was breastfeeding. Dr. Kovacs adjusted Greene's medications during an April 30, 2010 visit, changing the prescription from a Duragesic patch to a prescription for MS Contin. This was based on Greene reporting the patch was falling off or not working. Dr. Kovacs referred Greene to a gynecologist to have a contraceptive device known as a Mirena removed. Greene never told Dr. Kovacs she was pregnant when changing medications. At the time of the April 30 visit, Greene had minimal weight gain from the previous visit: she weighed 133.9 pounds compared to 131 pounds the previous visit. (Tr. 163-168).

Dr. Kovacs gave Greene further prescriptions for MS Contin on May 27, 2010, June 28, 2010, July 27, 2010, August 26, 2010, and October 15, 2010. On October 29, 2010, Greene was given a new prescription for Klonopin. (Tr. 168-169; Tr. 171, ll. 4-8; Tr. 174, ll. 10-13).

Dr. Kovacs testified she was unaware of any prescriptions that her other doctors, Dr. Kooistra or Dr. Bridges, gave Greene. Dr. Kovacs testified Greene was not supposed to be receiving the prescriptions from Dr. Kooistra at that point in time. Greene never told Dr. Kovacs about the other doctors' prescriptions. (Tr. 170-171). Dr. Kovacs did not know about Dr. Kooistra's prescription for Klonopin from July 3, 2010. Dr. Kovacs also did not know about the August 5, 2010 prescriptions from Dr. Kooistra for Vicophen and Klonopin. (Tr. 171). Likewise, Dr. Kovacs did not know that Dr. Bridges had prescribed Darvocet on June 30, 2010, July 23, 2010, and August 23, 2010. (Tr. 173-174).

Dr. Kovacs testified she would not have prescribed morphine or any pain medication during pregnancy had she known Greene was pregnant. Dr. Kovacs would have let the gynecologist or obstetrician issue any prescriptions. (Tr. 171, ll. 20-24; Tr. 176).

Dr. Kovacs did not know Greene was breastfeeding. Dr. Kovacs was unaware that Dr. Kooistra gave Greene a prescription for Baclofen, Vicoprofen, Neuroton, and Klonopin on November 4, 2010. Dr. Kovacs testified she would not have gave Greene a prescription for Klonopin on October 29, 2010, if she had known that Dr. Kooistra gave Greene another prescription for Klonopin five days later. (Tr. 172-173).

Dr. Kovacs did not know Greene was pregnant, had a child, and lost the child until Dr. Kovacs was visited by law enforcement in 2011. (Tr. 174-176). Greene did not even tell Dr. Kovacs during visits subsequent to Alexis' death. (Tr. 175, ll. 4-6).

On cross-examination, Dr. Kovacs confirmed in 1998 Greene suffered a car accident and suffered from pelvic pain. She also suffered a skull fracture in the accident and suffered from seizures. She agreed it was appropriate to use long-term pain medication if short-acting pain medication fails to hold the pain. (Tr. 177-178).

Dr. Carol Kooistra, a neurologist, testified she first saw Greene in 2006 when Greene was pregnant. Greene was referred to her for a seizure disorder. Dr. Kooistra did not prescribe any narcotics during Greene's prior 2006 pregnancy. She testified she tries to avoid prescribing medications during pregnancy. The only medicine she prescribed was for the seizure disorder (Levetiracetam, aka Keppra). (Tr. 209-210). Greene signed a narcotic pain medication contract with Dr. Kooistra's office on January 5, 2006. (Tr. 209, ll. 20-25; Tr. 211, ll. 4-7; State's Trial Exhibit No. 59). One of the contract terms is as follows:

I will not request or accept controlled substance medication from any other physician or individual while I am receiving such

medication from my physician at Carolina Neurology. Besides being illegal to do so, it may endanger my health. The only exception is if it is prescribed while I am admitted in the hospital.

(Tr. 212, lines 4-9; State's Trial Exhibit No. 59). The second page of the contract contains the relevant laws on the matter – S.C. Code sections 44-53-390 and 395. (Tr. 212, ll. 20-25; State's Trial Exhibit No. 59, page 2). The contract further reads as follows:

I understand that if I violate any of the above conditions my controlled substance prescriptions and/or treatment at Carolina Neurology may be ended immediately. If the violation involved obtaining controlled substances from another individual as described above or the concomitant use of nonprescription or illicit or illegal drugs I may also be reported to my physician, medical facilities and other appropriate authorities.

(Tr. p. 213, ll. 8-15, State's Trial Exhibit No. 59). In the contract, Greene indicated she had a college degree and a Bachelor of Science in nursing. (Tr. 213, ll. 16-21).

Dr. Kooistra saw Greene on February 16, 2010, and did not see her again until November 4, 2010. There were two scheduled appointments in between that were no shows: May 13, 2010, and August 25, 2010. Instead, Greene requested her prescriptions by phone. Dr. Kooistra testified she was willing to issue the prescription on August 5, 2010, anticipating Greene would make her August 25, 2010 appointment. Greene requested a prescription by phone for Soma on October 28, 2010. Dr. Kooistra declined the request since she had not seen Greene since February. Subsequently, Greene came to her November 4, 2010 appointment. At that appointment, Greene did not tell Dr. Kooistra that between visits she became pregnant and gave birth or that she was currently breastfeeding. (Tr. 213-215). When Dr. Kooistra asked why she had not made any of her appointments since February, Greene claimed she was in a severe depression and unable to leave her house. (Tr. 215, ll. 14-16).

Greene never told Dr. Kooistra she was pregnant in March 2010. However, Greene continued to receive prescriptions for Vicoprofen, Soma, Klonopin, and Gabapentin. (Tr. 215-

216). Dr. Kooistra did not know Greene was seeing an OBGYN and did not know that Dr. Kovacs was prescribing MS Contin. (Tr. 216).

On November 4, 2010, Dr. Kooistra prescribed Klonopin, unaware that Dr. Kovacs wrote a prescription for Klonopin on October 29, 2010. (Tr. 219-220). She was unaware Dr. Bridges was also prescribing medicines. (Tr. 220). On redirect, Dr. Kooistra published the medication guide for MS Contin that advises the following:

Pregnant or planning to become pregnant. MS Contin may harm your baby, unborn baby. Tell your healthcare provider if you are breastfeeding. MS Contin passes into breast milk and may harm your baby. Tell your healthcare provider if you are taking prescription or over-the-counter medicines, vitamins or herbal supplements.

(Tr. p. 235, ll. 4-9).

On cross-examination, when Dr. Kooistra was asked: "And the American Academy of Pediatric finds nothing wrong with taking morphine while breastfeeding?" Dr. Kooistra answered, "So I've read." However, Dr. Kooistra clarified she has not researched the issue closely. (Tr. 231-232).

Doctor Kelly Ann Bridges is a doctor with Carolina OBGYN and treated Greene. When she saw Greene for the first time on June 30, 2010, Greene was twenty-six weeks pregnant. Greene advised her she was taking Vicoprofen. She changed Greene's medication to Darvocet because Vicoprofen is dangerous during pregnancy. Greene did not tell Dr. Bridges that she was taking morphine during that visit or the other two visits in August and September 2010. Dr. Bridges testified her office asks what medications the patient is taking at every visit. Greene was given additional prescriptions for Darvocet on July 23 and August 23, 2010. Dr. Bridges gave prescriptions for Motrin and Percocet on September 29, 2010. (Tr. 236-241). Dr. Bridges testified she would not have prescribed Darvocet if she knew Greene was taking morphine and

other drugs, "[b]ecause you could potentially overdose on narcotics if you're combining those medications. It could be dangerous." (Tr. 242, ll. 5-11).

Reviewing the office records, Dr. Bridges testified the last time Greene visited Carolina OBGYN was November 4, 2010, for a six week postpartum exam with Dr. John Nichols. Nothing in the records of that visit indicated Greene informed Dr. Nichols that she was taking morphine. (Tr. 242-243).

Wendy Bell, an expert in forensic toxicology involving drugs and alcohol, testified for the State. She reviewed SLED toxicologist Quintus Young's report. She testified every phase of testing in the laboratory is triple-checked to ensure correct results. (Tr. 253). Bell testified as follows on the accuracy of her laboratory:

Our laboratory is an accredited laboratory, and as such we have to go into rigorous testing. We have outside agencies come in and look at our protocols and make sure that we're performing them properly and that they're scientifically valid.

We also participate in . . . proficiency testing programs where they send us samples every year and we have to accurately report them. And if not, then we're cited. We have to undergo corrective action to find out why. And we haven't had any of those . . . particularly for opiates. We've been highly reliable in our opiate results.

(Tr. 266, ll. 12-22). The results of the testing were as follows:

Acetaminophen: .19 mg/Liter;

Diphenhydramine (antihistamine): .03 mg/Liter;

Chlorpheniramine (antihistamine): .06 mg/Liter;

Methorphan DM: .03 mg/Liter;

Methorphanan: .04 mg/Liter;

Morphine: .52 mg/Liter;

Clonazepam (benzodiazepine): .01 mg/Liter.

(Tr. 257-259) (emphasis added). Bell noted there is limited pediatric information on the type of medications involved. (Tr. 260). Bell testified the effects of drugs like Klonopin with morphine will act together synergistically. She explained the medications "are central nervous system depressants, which means it's going to slow the respiratory system, the breathing, the heart rate. And they can act together synergistically to have affects on each other." (Tr. 260, ll. 8-12). Bell testified "a lot of these drugs aren't prescribed for children because their livers have not fully developed yet. So it's very, very difficult for them to metabolize this type of medication." (Tr. 260, ll. 19-22). Bell noted, "Children under ten months old cannot tolerate high levels of narcotics" and noted a lot of literature supports that proposition. (Tr. 261, ll. 10-15).

Investigator William Robert Gary testified he responded to Greene's house on the day of the incident. Victim was in the ambulance. Investigator Gary passed Greene sitting on the porch, unaware she was Victim's mother. Greene "was sitting there smoking a cigarette, drinking coffee." (Tr. 286, ll. 11-19). Investigator Gary noted Greene was slow in her speech. "Everything she was doing was slow." (Tr. 287, ll. 20-22). Greene appeared to be under the influence of something. Greene denied taking any medications since she found Victim. (Tr. 287-288).

Investigator Gary interviewed Greene on June 24, 2011. Investigator Gary spoke with Greene about her omitting information from her doctors about either her pregnancy or the drugs she was taking – Greene claimed they were covering themselves by not documenting it. Greene claimed her sister dropped some medication and claimed one of children could have picked up the pills and given it to the baby. Later in the interview, Investigator Gary inquired if the reason she did not tell doctors about being pregnant and breastfeeding was because of her morphine addiction and the awareness that the doctors would not give her the medication if they knew.

Her response was the only time she showed emotion during the interview, and she answered "that was part of it." (Tr. 293-294; Tr. 302 (direct quote, Tr. 294, ll. 22-23)).

Greene claimed she was not taking the pills while she was pregnant, but filled the prescriptions because her insurance covered it. She claimed her husband locked up the medication and gave her three days' worth of medication at a time. Of course, Investigator Gary was skeptical about this since he had seen the pill bottles sitting on the dresser. In response, Greene said that by that point, her husband trusted her enough to leave them out, but still kept some locked up. (Tr. 295).

Investigator Gary testified as follows about his conversation with her about breastfeeding Victim:

She said she supplemented a good bit with formula and that she didn't breastfeed a lot, you know, which hearing her talk about before with her talk about that there'd be nights that Alexis would just – she'd lay in the bed and she'd stay latched on all night and feed as she wanted to, to me that's not – it was – if you're doing that, I don't know how you're not breastfeeding a lot.

(Tr. 297, ll. 14-20). Investigator Gary testified the investigators confronted Greene about how she filled out the lists of medications she was on at the doctors' offices and omitted morphine, contradicting her claim that they removed or omitted records themselves. Toward the end of the interview, Greene broke down crying and admitted they would stop prescribing morphine to her if they knew about her pregnancy or other medications. (Tr. 299-300). Greene admitted she and her husband discussed the possibility Victim's death could be from the drugs and she admitted the morphine levels in the coroner's report were high. (Tr. 300-301).

On cross-examination, Investigator Gary agreed that Greene claimed she spoke with a lactation nurse at the hospital, however, there were no notes in the hospital records. Greene also claimed to have researched the issue online on her computer. (Tr. 303).

Kaushik Kotecha, who at the time of Alexis' death was employed by the State Bureau of Drug Control, part of the Department of Health and Environmental Control (DHEC), testified. Without objection, he was qualified as an expert in the field of pharmacy. Following time as a uniformed police officer, Kotecha went to pharmacy school and was a licensed pharmacist for twenty-five years. His duties with DHEC included both law enforcement and regulatory enforcement of drug control laws. (Tr. 307-310).

Kotecha testified as follows about morphine: "The problem with morphine of course you have – I usually when I was practicing pharmacy, I would tell them that this is very strong drug. . . Sometimes you'd be unstable on your feet." (Tr. 315, ll. 10-15). Looking at State's Trial Exhibit No. 7, the bottle for morphine sulfate ER, Kotecha testified it is an extended release morphine. When asked if he would recommend morphine sulfate ER for someone who was breastfeeding, Kotecha responded, "I certainly would have had additional questions and I would want to talk to the doctor if I knew they were breastfeeding." (Tr. 317, ll. 17-19). Likewise, Kotecha indicated he would double check with the prescribing physician if someone was being prescribed medication containing Hydrocodone while breast feeding. (Tr. 317-318).

Kotecha published to the jury the warnings contained on the pill bottle photographed in State's Trial Exhibit Nos. 9 and 10, which advise: "DO NOT TAKE MEDICATION IN 3RD TRIMESTER OF PREGNANCY." (Tr. 318). The warnings for Clonazepam advise in part as follows: "Do not use if pregnant or suspect you are pregnant or breastfeeding." (Tr. 318, ll. 20-23; State's Trial Exhibit No. 12). The warnings on a bottle of Keppra pills likewise warns about discussing use with a doctor if pregnant. (Tr. 319; State's Trial Exhibit No. 14). Another drug found was Ropinirole, used for restless leg syndrome. It likewise warns that breastfeeding is not recommended while using the drug. (Tr. 320, State's Trial Exhibit No. 20).

Kotecha explained the substances may have a synergistic effect on each other, the combination of all these drugs together could cause a baby to stop breathing. (Tr. p. 322). Kotecha noted the hydrocodone pills were originally prescribed for 90 pills on November 4, 2010, and on November 13, 2010, there were only 42 remaining. (Tr. 324). Referring to the pill chart prepared by the Coroner's investigators, he noted that if she took the appropriate doses of morphine since the prescription was filled on October 20, 2010, only seventy-two pills should have been taken. However, only twelve pills remained. (Tr. 323-324). Eighteen pills should have been remaining, so six pills were missing.

Kotecha was present during the June 2011 interview. During the interview, Greene admitted she was addicted to pain killers. She admitted she lied to doctors to avoid losing her prescriptions. Greene was upset and wanted to know what was going to happen to her. (Tr. 325-326). On cross-examination, Kotecha admitted that with the exception of one prescription, all the prescriptions were from one pharmacy, the Inman CVS. Tr. pp. 329-330. On redirect examination, Kotecha noted that Greene used two different names to fill her prescriptions, Stephanie Greene and Stephanie Neet. (Tr. 340). Greene said she used Rite-Aid once because it had a drive-thru. That prescription was the October 20, 2010 prescription for MS Contin. (Tr. 340-341).

Dr. David Eagerton, an assistant professor at the Presbyterian College School of Pharmacy, testified as an expert in forensic toxicology and pharmacology. Dr. Eagerton received a Ph.D. in pharmacology in 1992. Dr. Eagerton was the chief forensic toxicologist with SLED for approximately twelve years until he retired in 2009 and became a professor. Dr. Eagerton testified as a forensic toxicologist and pharmacologist between eighty and a hundred times by the time of trial. (Tr. 343-345).

Dr. Eagerton testified Alexis had toxic levels of morphine. He also noted Clonazepam or Klonopin is a very potent benzodiazepine. Dr. Eagerton testified these medicines may have a synergistic effect on each other. (Tr. 346-350). Dr. Eagerton published FDA warnings about MS Contin from the Medication Guide, approved by the U.S. Food and Drug Administration, which provides the following warnings:

Tell your healthcare provider if you are:

- **pregnant or planning to become pregnant.** MS Contin may harm your unborn baby.
- **breastfeeding.** MS Contin passes into the breast milk and may harm your baby.

(States Trial Exhibit No. 67; Tr. 354-55) (emphasis in original). Dr. Eagerton noted while studies indicated treatment with morphine for short periods of time for acute pain might not be dangerous, the studies, even prior to 2010-2011, did not recommend use of the sustained release morphine products. Tr. pp. 357-358. Specifically, Dr. Eagerton noted:

[I]f you look at the fine print they – they talk about sustained release and . . . continued use of these products. It . . . drops it down to an . . . uncertain level or an unsafe level, and they don't . . . recommend it even prior to these studies.

(Tr. 358, ll. 6-10). Dr. Eagerton noted infants' livers are not fully developed, specifying on cross-examination that they do not reach adult level liver function until towards six months of age. (Tr. 360-361; Tr. 400). Dr. Eagerton testified that "the lethargy, maybe trouble breathing. . . I don't know how to interpret that exactly, but . . . there were some symptoms that were conveyed that were consistent with morphine toxicity." (Tr. 361, ll. 15-18). "[I]f you can't metabolize it, then the drug may build up in your body and you become – you have a toxic dose whenever you wouldn't normally have a [toxic] dose." (Tr. 361-62).

Dr. Eagerton agreed on cross-examination that a 2000 article listed morphine as safe to take while breastfeeding. (Tr. 375, ll. 4-7). Dr. Eagerton testified as follows on cross-examination:

Q: Okay. But you don't have any basis for saying that it came through breast milk.

A: Had to get into the baby somehow.

Q: That's not my question. You have no basis for saying that number came into the baby through breast milk.

A: I don't know that I'd say I have no basis. I'd say the basis is the mother is taking MS Contin, which is morphine. She is breastfeeding. We know that based on the literature we've already talked about that at least small amounts certainly do pass through into the breast milk. . . .

(Tr. 383-84). Dr. Eagerton talked about the blood-brain barrier on cross-examination, agreeing with defense counsel it keeps some drugs from getting to the brain. Dr. Eagerton agreed with defense counsel that heroine and oxycontin pass through the blood-brain barrier quicker than morphine, but noted morphine passes through the blood-brain barrier in a pretty good concentration. (Tr. 393-94).

Dr. Eagerton noted taking morphine **acutely** while breastfeeding may be perceived as acceptable because "you don't get that good penetration into this, into the brain." (Tr. 396, ll. 2-10). But "[o]nce it gets in the brain it – there are receptors there. These – these opioid receptors there that are responsible for the actions of the drug are going to bind to it, and it's going to stay there longer than just regular blood." (Tr. 396, ll. 11-15).

Dr. Eagerton was asked to consider other modes of delivery than breast milk for explaining the morphine level in Victim. Dr. Eagerton noted the lack of needle marks on Victim and discounted the possibility of morphine being injected. Dr. Eagerton also discounted the possibility that the baby swallowed the pill, agreeing there would likely be pill remnants in her

stomach. Although the pill could be crushed up, Dr. Eagerton opined this would have killed the baby in thirty to sixty minutes. Instead, Dr. Eagerton opined: "I think what we see here is – is more of a chronic type exposure, which is more consistent with through the breast milk. Or it could be some combination of both. I don't know." (Tr. 398-399 (direct quote, Tr. 399, ll. 8-11)). Defense counsel claimed in his question posed to Dr. Eagerton that no literature supported his opinion. Dr. Eagerton disagreed, explaining the following:

I believe that if we take the reports that we have where it comes through in small levels that means if it – if you're getting a small dose of it you gotta to take it longer over a period of time.

If we've got evidence that the – these little babies, this six-and-a-half-week-old – **probably can't metabolize and get rid of the morphine as fast, so therefore it's going to build up in its body.** So that would suggest the more chronic type exposure. And I believe that's what the literature that we've already gone over – in my opinion that's what it points to.

Does it come out and out and say that? No. I don't believe I've seen any literature that says that. But for everything there's got to be a first.

(Tr. p. 399-400).

On redirect, Dr. Eagerton published a portion of LactMed pertaining to the use of morphine, as follows:

Epidural morphine given to mothers for postcesarean section analgesia results in trivial amount of morphine in their colostrum and milk. Intravenous or oral doses of maternal morphine in the immediate postpartum period results in higher milk levels than with epidural morphine. . . . Maternal use of oral narcotics during breastfeeding can cause infant drowsiness, central nervous system depression and even death.

(Tr. 404-05).

Dr. John David Wren was admitted as an expert in forensic pathology. He performed the autopsy on Victim. At the time of the autopsy, he observed Victim was normally developed and

of normal weight. Some rigor mortis and liver mortis had set in. Dr. Wren found no evidence of trauma. Dr. Wren testified that Victim did not have any of the tell-tale signs of SIDS. He observed her lung was congested. Dr. Wren observed nothing physically wrong with Victim. (Tr. 415-429).

Dr. Wren testified about the drug levels in Victim's blood. Acetaminophen levels were .19 mg/Liter, which was in the high end of therapeutic levels. (Tr. 428-426). Chlorpheniramine levels were .06 mg/Liter. Dr. Wren testified therapeutic levels are .01 to .04 mg/Liter. So the Chlorpheniramine level was above therapeutic levels and needed to be taken into account. Tr. p. 431. The dextromethorphan metabolite was .04 mg/Liter and therapeutic levels are .007 to .021 mg/Liter, indicating elevated levels of this drug. As to morphine, the level was .52 mg/Liter. Dr. Wren testified therapeutic levels were .001 to .200 mg/Liter according to his references. Toxic levels would be from .30 to 2.5 mg/Liter. Lethal levels are from as low as .20 mg/Liter to 7.2 mg/Liter. (Tr. 432). Dr. Wren testified deaths were reported with levels as low as .20 mg/Liter. (Tr. 432). Dr. Wren confirmed, "It's well known that infants and children do react differently to medications than adults, and it takes some – infants are much more susceptible to any drugs than others. . . . They don't need as much and they're more susceptible to effects of them." (Tr. 434, ll. 14-20).

Dr. Wren concluded Alexis died as a result of respiratory insufficiency secondary to synergistic drug intoxication. Dr. Wren explained, "I could just as easily have said morphine intoxication, lawyers like to split hairs, and so I included them all." (Tr. 433, ll. 18-22). Dr. Wren noted "all of these drugs essentially lead to respiratory depression." (Tr. 433, ll. 15-16).

Dr. Wren also concluded the morphine was administered orally, as there were no signs of injection. However, Dr. Wren declined to opine if the morphine was transmitted through

breastmilk. (Tr. 434-435). As to the determination of blood levels, Dr. Wren noted lethal levels were found in the blood, brain, and liver, and he noted the level and sort of testing employed by SLED was "kind of hard to mess up [by] an experienced operator." (Tr. 436, ll. 6-8).

The defense presented Dr. Steven Bernard Karch as an expert in the effect of drugs on the human body. Dr. Karch earned his M.D. from Tulane University and undertook a fellowship at the Royal London Hospital in neuropathology. From there he worked at the only heart transplant lab in the world during the 1980's and 1990's. Dr. Karch worked for the San Francisco Medical Examiner for roughly a decade. Importantly, Dr. Karch authored the "Pathology of Drug Abuse, Fourth Edition." (Tr. 485-492).

Dr. Karch disagreed a lethal amount of morphine could pass through breast milk, although he agreed a toxic level sufficient to make a child sick could be achieved. Dr. Karch claimed the American Academy of Pediatrics did not even list morphine as being dangerous for women who are breastfeeding. (Tr. 492-494). Dr. Karch testified a one-month-old baby would already have developed an 80% normal metabolism rate.¹ (Tr. 497).

Dr. Karch confirmed "the mode of death for morphine is to stop respiration." (Tr. 510, ll. 20-21). Dr. Karch testified as follows on the cause of death:

Q: All right. Yet you said in this case where 52 mg – nanograms of morphine – you would believe that that could have been a cause of death if that number is accurate.

A: If the number is accurate and if the baby was intolerant. I don't – I have no way of proving what the mother's drug usage was or was not during that period.

¹ See The Transfer of Drugs and Therapeutics Into Human Breast Milk: An Update on Selected Topics, 132, PEDIATRICS, Official Journal of the American Academy of Pediatrics, e796, e801 (September 2013) ("Clearance of morphine is decreased in infants younger than 1 month and approaches 80% of adult values by 6 months of age.").

(Tr. 511, ll. 5-10). Dr. Karch testified he did not know of any medical group that advises against taking morphine while breastfeeding because of dangers to the child. (Tr. 513, ll. 22-25). Dr. Karch testified about the physical traits a baby would develop if the baby was slowly building up morphine in their system. (Tr. 515, ll. 17-23).

Holmes was recalled as a reply witness for the State. She testified the medical records indicated Victim was 7 lbs., 2 oz. when born. In her second week, Victim weighed 7 lbs., 11 oz. At the time of death, Victim only weighed 7 lbs., 6 oz—a loss of five ounces since her two week check-up. Holmes also testified when she saw Victim the day she died, she was “extremely pale, very pale, all over.” (Tr. 525, ll. 11-15). The weight loss is confirmed by Greene’s interview with the Coroner’s Office where she admits that she had noticed Alexis had lost a lot of weight and was going to ask the doctor to weigh Alexis at an upcoming visit. (State’s Trial Exhibit No. 34 (circa 11:30)).

Ineffective Assistance of Trial Counsel, Generally

Where the application alleges ineffective assistance of counsel as a ground for relief, Applicant must prove that “counsel's conduct so undermined the proper functioning of the adversarial process that [it] cannot be relied upon as having produced a just result.” Strickland v. Washington, 466 U.S. 668, 686 (1984).

In order to prove counsel was ineffective, a PCR applicant must show counsel’s performance was deficient and the applicant was prejudiced by the deficient performance. Strickland v. Washington, 466 U.S. 668, 687 (1984). Counsel’s performance will be deemed deficient if it falls “outside the wide range of professionally competent assistance.” Id. The applicant is prejudiced by the deficient performance if “there is a reasonable probability that but

for counsel's unprofessional errors, the result of the proceeding would have been different." Id. at 694.

"A fair assessment of attorney performance requires that every effort be made to eliminate the distorting effects of hindsight, to reconstruct the circumstances of counsel's challenged conduct, and to evaluate the conduct from counsel's perspective at the time." Id. at 689. "Judicial scrutiny of counsel's performance must be highly deferential." Id., at 689. In order to prove a claim of ineffectiveness, "the defendant must overcome the presumption that, under the circumstances, the challenged action 'might be considered sound trial strategy.'" Id.

Counsel's articulation of valid trial strategy defeats a claim of ineffective assistance of counsel. Roseboro v. State, 317 S.C. 292, 454 S.E.2d 312 (1995); Underwood v. State, 309 S.C. 560, 425 S.E.2d 20 (1992); Stokes v. State, 308 S.C. 546; 419 S.E.2d 778 (1992). "Courts must be wary of second guessing counsel's trial tactics; and where counsel articulates a valid reason for employing such strategy, such conduct is not ineffective assistance of counsel." Whitehead v. State, 308 S.C. 119, 417 S.E.2d 529 (1992). Strickland requires extreme deference to counsel's strategic judgments that are adequately investigated; as Strickland explains: "[S]trategic choices made after thorough investigation of law and facts relevant to plausible options are virtually unchallengeable. . . ." Strickland, 466 U.S. at 690-91.

"Under Strickland, counsel's representation must be only objectively reasonable, not flawless or to the highest degree of skill." Strickland, 466 U.S. at 688-89, 104 S.Ct. 2052. "[E]ven if an omission is inadvertent, relief is not automatic. The Sixth Amendment guarantees reasonable competence, not perfect advocacy judged with the benefit of hindsight." Yarborough v. Gentry, 540 U.S. 1, 6 (2003); see also Murphy v. Davis, 901 F.3d 578, 592 (5th Cir. 2018) ("[C]ounsel's performance need not be optimal to be reasonable.").

Second, counsel's deficient performance must have prejudiced Applicant such that "there is a reasonable probability that, but for counsel's unprofessional errors, the result of the proceeding would have been different." Cherry, 300 S.C. at 117-18, 386 S.E.2d at 625. "The prejudice analysis requires the court deciding the ineffectiveness claim to consider the totality of the evidence before the judge or jury." United States v. Basham, 789 F.3d 358, 371-72 (4th Cir. 2015) (quoting Elmore v. Ozmint, 661 F.3d 783, 858 (4th Cir. 2011)).

Failure to investigate the prosecution's failure to test breast milk/failure to argue to the jury the lack of testing of breast milk:

Applicant alleges that fresh breastmilk samples were in Applicant's refrigerator at the time of death. However, Ellen Holmes, the investigator from the Coroner's Office testified: "There were two bottles in the refrigerator. We opted not to take those because they had – the defendant and her husband told us that those bottles were freshly made **and they were formula, they were not breast milk.**" Tr. p. 466, lines 4-7.

Regardless, Respondent anticipates Applicant will not be able to meet her burden of proving either prong of Strickland. Counsel, through expert testimony and in closing argument asserted the State failed to perform other tests that Counsel contended would have shown whether Applicant was taking high levels of narcotics, such as testing her hair. Counsel also argued Alexis' stomach contents could be tested which based on the presence of metabolites, would show the source of morphine. Tr. pp. 495-96; pp. 511-13; p. 544; p. 553; p. 555.

Further, the toxicology testing was not performed until sometime after Alexis' death and therefore, by the time law enforcement became aware a crime occurred, testing Applicant's breastmilk would not be probative in determining the consumption of morphine and other narcotics through Applicant's breast milk. Of course, it is speculative at best that if breastmilk

was tested contemporaneously with Alexis' death, the results would be beneficial to Applicant's case.

Failure to conduct genetic testing:

Applicant alleges counsel should have sought genetic testing of both Applicant and her deceased daughter to determine if a genetic defect could have caused Alexis to be unable to sufficiently process and clear morphine. Assuming, without agreeing, that any genetic defects would constitute a legitimate defense to the charges, Respondent anticipates Applicant is unable to meet the burden of proving prejudice because this Court would need to speculate as to the results of such testing. Moorehead v. State, 329 S.C. 329, 334, 496 S.E.2d 415, 417 (1999) (holding trial counsel's failure to conduct an independent investigation does not constitute ineffective assistance of counsel when the allegation is supported only by mere speculation as to the result).

Alternative theory of causation:

Applicant alleges counsel was ineffective for failing to offer an alternative theory of causation and failed to argue it was impossible for a lethal dose of morphine to pass through morphine. The latter position is refuted in several portions of the transcript, but most directly perhaps by the following portion of counsel's closing argument:

This child did not die from taking breast milk from Stephanie Greene. It simply did not happen. There's no scientific basis for saying it; there's no evidentiary basis for saying it. It's not there.

* * *

The literature says it's impossible. The literature says it doesn't happen with children. Our expert clearly said it. David Wren, their expert, says I do not know how the child got the morphine, . .

Tr. p. 555, line 19 – p. 556, line 12.

Counsel presented an expert in toxicology, Dr. Karch. Dr. Karch testified as to his impressive credentials. For instance, he reviewed every drug-related death in San Francisco for a ten year period while an assistant medical examiner with the San Francisco Medical Examiner's Office. Dr. Karch advised he is published in toxicology and published the Pathology of Drug Abuse, 4th edition. Tr. pp. 487-89. Dr. Karch testified as an expert by his estimation between fifty to a hundred times. Tr. p. 490.

Dr. Karch testified he does not know of any cases of death by morphine passing through breast milk. Tr. p. 492-93. He noted articles that indicate morphine consumption by a breast feeding mother is not dangerous to the breast-fed child. Tr. pp. 494-95.

Dr. Karch opined that the contents of the stomach should have been analyzed to see if any pills were taken orally in the child or any intravenous entry occurred (which would create ion trapping). Tr. pp. 495-96. Dr. Karch countered testimony concerning the ability of a child to metabolize opioids, opining that by one month, the child's liver has 80% of adult function, and humans only need about 20% function to live. Tr. pp. 497-98. He testified that you should "never ever ever ever ever ever ever ever" take blood from the heart or anywhere near the heart "because you know you're going to get a phony number that is way high." Tr. p. 501, lines 1-4. Dr. Karch bemoaned the use of the application of therapeutic ranges of blood levels to post-mortem assessment, arguing that it is an "intuitive leap" that is unproven. Tr. pp. 501-02.

Dr. Karch testified "and one of the biggest controlling factors for our blood level and one that's probably operative here is the fact that if this baby didn't have the proper enzyme, which is named U.D.G.P.6, he – she could not have broken down any morphine, any – the little bit of morphine that is in normal breast milk of mothers taking morphine." Tr. p. 503, lines 8-16. Dr.

Karch testified that a test could be run for that. Tr. p. 503. He testified that the lack of the enzyme would not be known to the mother. Tr. p. 503, lines 6-22.

Dr. Karch was skeptical of the blood level of morphine, but explained if accepting that number, then, "If I accept that, then either the baby got an overdose of morphine or the baby has a genetic defect and is unable to metabolize morphine exactly in the same way that the Canadian case could [sic] metabolize . . . codeine." Tr. p. 504, lines 7-18. Dr. Karch agreed with trial counsel's calculations that Applicant would need to take 125 times more morphine to reach the level in the present case than a woman in a study who took five milligrams of morphine, resulting in her infant receiving four nanograms of morphine. Tr. pp. 507-08.

Dr. Karch noted that the SLED lab could have tested Applicant's urine for the presence of morphine metabolites (M-3-G). Dr. Karch also noted Applicant's hair could be tested to determine the use of morphine. Tr. pp. 511-13. Additionally, he noted in the Canadian study, the mother preserved milk, which was available for testing. Tr. pp. 516-17.

Dr. Karch referenced recent research showing an undetected genetic defect was the main cause of sudden deaths among people ages zero to forty. Tr. p. 509. Dr. Karch reiterated that not very much morphine is found in breastmilk. He confirmed that no medical group advises against taking morphine while breastfeeding and he was unaware of any case where an infant received a lethal dose of morphine through breastmilk. Tr. pp. 513-14.

In many cases, a range of hypothetical experts exist that a trial attorney could theoretically consult. However, a trial attorney is not expected to consult every conceivable type of expert possibly applicable to the case – such a task may turn distractive – instead counsel is entitled to formulate a focused strategy cognizant of the reasonable use of resources and time. Harrington v. Richter, 131 S.Ct. 770, 789 (2011).

Respondent anticipates further testimony that will further elucidate counsel's reasonable strategic decisions in presenting expert testimony to challenge the prosecution's evidence and theory. In contrast, Respondent anticipates that Applicant's expert witness testimony, rather than present an exculpatory defense to the charges, will instead establish causation and proof that enough morphine can accumulate in a breastfeeding neonate to result in chronic respiratory depression and death. To the extent Applicant might be able to present credible evidence that Alexis suffered renal failure, which in turn allowed lethal levels of morphine to accumulate, this establishes causation of death and in turn, guilt. State v. McCall, 304 S.C. 456, 405 S.E.2d 414 (Ct. App. 1991). Counsel's strategy was reasonable and frankly better suited to attack the State's case than the proposed alternate strategy suggested in this allegation, meaning neither prong of Strickland will be proved.

Failed to rebut extreme indifference

Applicant relies on the same allegations to assert that counsel failed to adequately rebut the State's argument that it met the extreme indifference element of homicide by child abuse. The record is replete with questioning and arguments challenging the State's proof. Counsel contended Applicant received the prescriptions lawfully, emphasized her medical need for the prescribed opioids, and presented expert testimony from Dr. Karch suggesting the potential for a genetic defect that Applicant could not be reasonably aware of. In particular, Dr. Karch testified "and one of the biggest controlling factors for our blood level and one that's probably operative here is the fact that if this baby didn't have the proper enzyme, which is named U.D.G.P.6, he – she could not have broken down any morphine, any – the little bit of morphine that is in normal breast milk of mothers taking morphine." Tr. p. 503, lines 8-16. Dr. Karch testified that a test

could be run for that. Tr. p. 503. He testified that the lack of the enzyme would not be known to the mother. Tr. p. 503, lines 6-22.

Respondent anticipates counsel will provide testimony showing his reasonable strategy in attacking the State's proof for the extreme indifference element. Further, the prosecution presented considerable evidence to prove Applicant's extreme indifference and therefore, Respondent believes Applicant will be unable to prove the prejudice element of Strickland.

Remaining allegations of ineffective assistance of trial counsel.

Applicant presents a sundry of further allegations of ineffective assistance of trial counsel. Respondent denies these allegations and demands strict proof thereof. Respondent anticipates Applicant will fail to meet her burden of proof as testimony is developed concerning these allegations.

Ineffective Assistance of Appellate Counsel

A defendant is constitutionally entitled to effective assistance of appellate counsel. Evitts v. Lucey, 469 U.S. 387 (1985). "However, appellate counsel is not required to raise every non-frivolous issue that is presented by the record." Thrift v. State, 302 S.C. 535, 539, 397 S.E.2d 523 (1990). Appellate counsel has a professional duty to choose among potential issues according to their merit. Jones v. Barnes, 463 U.S. 745 (1983). Where the strategic decision to exclude certain issues on appeal is based on reasonable professional judgment, the failure to appeal all trial errors is not ineffective assistance of counsel. Tisdale v. State, 357 S.C. 474, 476, 594 S.E.2d 166, 167 (2004) (quoting Jones v. Barnes, 463 U.S. 745, 754 (1983) ("For judges to second-guess reasonable professional judgments and impose on . . . counsel a duty to raise every 'colorable' claim suggested by a client would disserve the very goal of vigorous and effective advocacy")).

Applicant must show that appellate counsel's performance was deficient and that he or she was prejudiced by the deficiency. Thrift, at 537; Gilchrist v. State, 364 S.C. 173, 612 S.E.2d 702 (2005); Anderson v. State, 354 S.C. 431, 581 S.E.2d 834 (2003). When a claim of ineffective assistance of counsel is based upon failure to raise viable issues, the presumption of effective assistance of counsel will be overcome only when the alleged ignored issues are clearly stronger than those actually raised on appeal. Smith v. Robbins, 528 U.S. 259, 288 (2000) (citing Gray v. Greer, 800 F.2d 644, 646 (7th Cir. 1986)).

In the present case, Mr. Wise, who continued representation on appeal presented four issues. The first two, issues concerning directed verdict, if successful would have resulted in a functional acquittal of all the charges. Justice Few dissented from the majority on the issue of causation, evidencing reasonable strategy from appellate counsel in raising these issues. Appellate counsel argued a double jeopardy violation and in turn, the Supreme Court vacated the involuntary manslaughter sentence on a similar ground. The fourth issue concerned the procedure for closing arguments and presented a viable issue at the time of briefing and argument, but was mooted by the Supreme Court's substituted opinion in State v. Beaty, 423 S.C. 26, 813 S.E.2d 502 (2018).

Applicant argues that appellate counsel should have argued "that the homicide by child abuse and involuntary manslaughter verdicts were inconsistent and that only the manslaughter verdict should stand based on the evidence presented." The rule against inconsistent verdicts has been abolished. State v. Alexander, 303 S.C. 377, 401 S.E.2d 146 (1991). Further, as discussed in the Supreme Court's analysis in State v. Greene, 423 S.C. 263, 814 S.E.2d 496 (2018), it is proper to allow the State to proceed on both charges even if principles of double jeopardy or due process precludes multiple punishments. State v. Cavers, 236 S.C. 305, 311-12, 114 S.E.2d 401,

404 (1960) (cited with approval in Greene). Given that the jury found Applicant guilty of homicide by child abuse, it was proper to vacate involuntary manslaughter as opposed to the homicide by child abuse charge.

Due Process

In this allegation, Applicant misapprehends the law. Applicant alleges the prosecution presented false scientific evidence, relying on Giglio v. United States, 405 U.S. 150, 153 (1972) and related authority. Those cases stand for the proposition that a prosecutor may not elicit testimony the prosecutor knows to be false. This simply is not the case. The pleadings indicate Applicant disputes the testimony and conclusions presented by the prosecution's experts. The remedy for this dispute is to challenge the prosecution's case, which counsel did, in part by presenting testimony from a preeminent toxicology expert – Dr. Karch. Further, this allegation seems to suggest an issue for direct appeal and PCR is not a substitute for direct appeal issues.

New evidence/after-discovered evidence

One of the studies discussed during trial by both prosecution witnesses and Dr. Karch (the Canadian study) was retracted in 2020. The paper discussed the death of a thirteen day-old child from high-morphine levels after the breastfeeding mother took lawfully prescribed codeine (codeine metabolizes to morphine). Madadi P. et al. Safety of codeine during breastfeeding. Fatal morphine poisoning in the breastfed neonate of a mother prescribed codeine, Can Fam Physician 2007; 53:33-5. The retraction cited in Applicant's pleadings notes that the study published in 2007 had been cited in hundreds of articles prior to the 2020 retraction. Ross T. Tsuyuki & Nicholas Pimlott, Risks of maternal codeine intake in breast-fed infants: A Joint Statement of Retraction from the Canadian Pharmacists Journal and Canadian Family Physician, Canadian Pharmacists Journal v. 154(1) (Nov. 18, 2020).

The retraction followed the publication in May 2020 of a paper criticizing the study. The Implausibility of Neonatal Opioid Toxicity from Breastfeeding, 108(5) Clinical Pharmacology & Therapeutics (May 2020). The conclusion from that article is as follows:

Neonatal opioid toxicity resulting from maternal codeine use during breastfeeding could only arise from a highly improbable combination of factors: **a high maternal codeine dose**, unusually high concentrations of opioids in breast milk, a large volume of neonatal milk intake, and – critically – profoundly impaired neonatal opioid clearance. The unlikely occurrence of such a scenario is consistent with the paucity of reports of neonatal opioid toxicity, despite the use of these drugs by millions of nursing mothers over the past two decades.

This should not be viewed as an endorsement of opioid use while breastfeeding. Codeine in particular is an unpredictable analgesic choice given its variable conversion to morphine, while other opioids such as oxycodone carry greater abuse liability. Acetaminophen and non-steroidal anti-inflammatory drugs are generally sufficient for the management of postpartum pain. When opioids are required, **short courses** should not be viewed as hazardous to breastfeeding neonates.

(Emphasis added).

An applicant requesting a new trial based on after-discovered evidence after a conviction must show that the evidence:

- (1) Is such as would probably change the result if a new trial was had;
- (2) Has been discovered since the trial;
- (3) Could not by the exercise of due diligence have been discovered before the trial;
- (4) Is material to the issue of guilt or innocence; and,
- (5) Is not merely cumulative or impeaching.

Hayden v. State, 278 S.C. 610, 611, 299 S.E.2d 854, 855 (1983) (citing State v. Caskey, 273 S.C. 325, 256 S.E.2d 737 (1979)).

The retraction is not evidence sufficient to grant a new trial based on after-discovered evidence. First, the retraction is unlikely to change the result if a new trial was held. For instance, the conclusion confirms that high dose, long-term use of opioids by breast-feeding mothers may be dangerous. Further, it is not material to Applicant's guilt or innocence because even assuming, without agreeing, the retraction is evidence that the child in the Canadian study did not in fact die from codeine metabolized to morphine and contained in breast-fed milk, it does not preclude the likelihood that morphine and its metabolites contained in breastmilk led to Alexis' death in the present case. Further, the retraction, at best, is merely evidence that is impeaching and as a matter of law does not qualify as after-discovered evidence.

ASSERTION OF RIGHTS TO NOTICE OF AMENDMENTS

Applicant must specify any claims she intends to raise at the PCR evidentiary hearing. Any claims not specifically laid out in this PCR application or in amendments *will be opposed by the State at an evidentiary hearing* pursuant to §§ 17-27-10 to -160 of the South Carolina Code of Laws and Rule 71.1 of the South Carolina Rules of Civil Procedure. See also Rules 15(a)-(b), SCRCP; Mangal v. State, 421 S.C. 85, 805 S.E.2d 568 (2017). All claims should be made well in advance of the evidentiary hearing. Because Applicant has been appointed an attorney, the attorney, and not Applicant, is the only individual authorized to file amendments to this application. See Rule 11, SCRCP. Pro se filings will not be considered at the PCR hearing. Respondent reserves the right to request that any amendments withheld until the last minute be stricken because of undue prejudice to Respondent. See Rule 15(a), SCRCP.

GENERAL DENIAL

Respondent denies each allegation not expressly admitted, qualified, or explained.

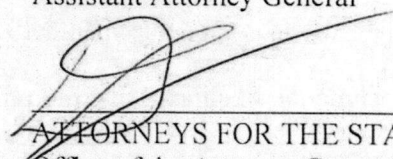
Respectfully submitted,

ALAN WILSON
Attorney General

DAVID SPENCER
Senior Assistant Attorney General

CHELSEY MARTO
Assistant Attorney General

By:



ATTORNEYS FOR THE STATE
Office of the Attorney General
P.O. Box 11549
Columbia, S.C. 29211

August 29, 2022

State of South Carolina	)	
	)	
County of Spartanburg	)	
Stephanie Irene Greene,	)	2019-CP-42-01605
	)	
Applicant,	)	
	)	
v.	)	Transcript
	)	
The State of SC,	)	of
	)	
Defendant.	)	Day 1 of
	)	Post-conviction
	)	Relief Hearing
	)	
	)	
	)	
	)	
	)	
	)	

Date: September 19, 2022

Time: 9:33 a.m.

Location: Spartanburg County Courthouse

180 Magnolia St.

Spartanburg, SC 29306

Reported by
Amber Payne, CVR

APPEARANCES

Presiding: The Honorable J. Mark Hayes II

For the Applicant: Blake T. Williams, Esq.
Nelson Mullins
1320 Main St., 17th Floor
Columbia, SC 29201

Daniel J. Westbrook, Esq.
Nelson Mullins
1320 Main St., 17th Floor
Columbia, SC 29201

For the State/Defendant: David A. Spencer, Esq.
SC Attorney General's Office
P.O. Box 11549
Columbia, SC 29211

Chelsey Marto, Esq.
SC Attorney General's Office
1000 Assembly St., Room 519
Columbia, SC 29201

Also Present: Law Clerk: Harry Turner, Esq.

INDEX

(AW) - Denotes Applicant's Witness

(SW) - Denotes State's Witness

Page No.

Exhibits.....4

(AW) DR. ANTHONY SCIALLI:

Voir Dire Examination by Mr. Williams.....6

Voir Dire Examination by Mr. Spencer.....18

Direct Examination by Mr. Williams.....22

Cross-Examination by Mr. Spencer.....79

Redirect Examination by Mr. Williams.....174

(AW) DR. KATHERINE TWOMBLEY:

Voir Dire Examination by Mr. Westbrook.....181

Direct Examination by Mr. Westbrook.....192

Cross-Examination by Mr. Spencer.....209

Redirect Examination by Mr. Westbrook.....229

Certificate of the Court Reporter.....236

EXHIBITS

NO.	DESCRIPTION	PAGE NO.
-----	-------------	----------

(Applicant's Exhibits)

1	Dr. Scialli's CV.....	40
2	Pharmacokinetics Article.....	50
3	Morphine/Breast Milk Article.....	50
4	Journal Article.....	53
5	Case Report.....	61
6	Commentary by Madadi.....	62
7	Zipursky Paper.....	65
8	Codeine Article.....	68
9	Dr. Twombly's CV.....	183
10	Well-Child Check Report.....	209
11	Coroner's Report.....	209
12	SLED Report.....	40

(State's Exhibits)

1	LACTMED Article.....	81
2	Case Report/Contribution of Morphine Article.....	82
3	MOTHERISK Article.....	167

(Court's Exhibits)

1	Website Article.....	159
---	----------------------	-----

1 PROCEEDINGS

2 (On the Record at 9:33 a.m.)

3 THE COURT: Now, I've got that we are now on
4 the matter of the "Stephanie Irene Greene vs.
5 the State of South Carolina," 2019-CP-42-
6 01605. The court reporter informs me that she
7 has all the information, so thank you-all for
8 giving that to her.

9 We had a pretrial conference, and the
10 attorneys were -- I didn't feel like I needed
11 an opening statement with any great detail,
12 but if you wanted to give me one, I'll
13 definitely will receive it, but I'm not -- but
14 don't feel like that you need to give me one
15 because I think that our game plan is to try
16 to get the expert witnesses out of the way
17 today, so that we can move forward with other
18 -- any lay witnesses tomorrow. Does the
19 applicant wish to present any type of opening
20 statement?

21 MR. WILLIAMS: We're prepared to go forward
22 with witnesses.

23 THE COURT: Does the State wish to have an
24 opening statement?

25 MR. SPENCER: No, Your Honor.

1 THE COURT: Okay. All right. Then, Applicant
2 ready to proceed?

3 MR. WILLIAMS: Yes, Your Honor. Applicant
4 calls Dr. Tony Scialli.

5 THE COURT: (To the witness) Sir, just come
6 on up here.

7 There's a Bible right there on the
8 witness stand. Just walk up there. Place
9 your left on the Bible and raise your right
10 hand and I'll swear you in.

11 (WHEREUPON, the witness was sworn.)

12 THE COURT: Again, watch your step as you're
13 stepping up. Just have a seat in the chair,
14 and pull the chair up to the microphone.

15 MR. WILLIAMS: Judge, do you mind if I move
16 that podium over?

17 THE COURT: Sure. And, Doctor, if ever during
18 this process you need water or anything, just
19 let the bailiff next to you know, and he'll
20 try to accommodate you.

21 THE WITNESS: Thank you, Your Honor.

22 **VOIR DIRE EXAMINATION OF DR. SCIALLI**

23 BY MR. WILLIAMS:

24 Q Good morning, Dr. Scialli.

25 A Good morning.

- 1 Q Could you please introduce yourself to the Court?
- 2 A My name is Anthony Scialli.
- 3 Q And what is your current occupation?
- 4 A I'm a physician and a consultant in reproductive
5 and developmental toxicology.
- 6 Q And who is your current employer?
- 7 A I am self-employed for most of my consulting work
8 in my own company called "Scialli Consulting, LLC."
9 I'm also employed by the Reproductive Toxicology
10 Center, which is a nonprofit foundation. I'm
11 employed by Georgetown University to teach, and I
12 also work for George Washington University, but
13 they don't pay me, so I don't think that counts as
14 employment.
- 15 Q Where do you live?
- 16 A I live in Washington, D.C.
- 17 Q Okay. I'm gonna hand up a document to you.
- 18 MR. WILLIAMS: And this is the CV, David. May
19 I approach, Your Honor?
- 20 THE COURT: Yes, sir.
- 21 Q If you can take a look at that and tell the Court
22 what that is.
- 23 A This is my curriculum vitae or CV.
- 24 Q And does that look like an accurate copy of your
25 CV?

- 1 A Yes, sir.
- 2 Q All right. Will you please detail your educational
3 history for the Court beginning with college?
- 4 A I went to college at Rensselaer Polytechnic
5 Institute in Upstate New York. And then after two
6 years went to Albany Medical College as part of a
7 combined program and awarded the medical degree,
8 the MD degree, and the bachelor's degree after six
9 years. After that, I did my residency in -- in
10 Obstetrics and Gynecology at George Washington
11 University, and then I did a fellowship a couple of
12 years later at the Columbia Hospital for Women
13 Medical Center, which is also in Washington, D.C.
- 14 Q So you covered residency and fellowship. What are
15 your specialty areas?
- 16 A My specialty is obstetrics and gynecology and
17 reproductive and developmental toxicology.
- 18 Q And can you explain for the Court what reproductive
19 and developmental toxicology is?
- 20 A Reproductive and developmental toxicology is the
21 study of the effects of drugs, chemicals,
22 radiation, viruses, other exposures on all aspects
23 of reproduction. So that would include fertility,
24 embryo development, labor and delivery,
25 breastfeeding, and effects on the child up to the

1 age of sexual maturity.

2 Q How did you choose that specialty?

3 A When I was a resident, my mentor was a -- an MD,
4 PhD, who had done a lot of work in that specialty,
5 and he invited me to join him in his academic
6 activities.

7 Q And are you board-certified?

8 A Yes, sir.

9 Q And what specialty are you board-certified in?

10 A Obstetrics and gynecology.

11 Q What was the date of your certification?

12 A 1981.

13 Q And do you have to renew that certification?

14 A No, sir.

15 Q Can you tell the Court about some of your
16 professional experience in reproductive and
17 developmental toxicology?

18 A I have taught reproductive and developmental
19 toxicology. I've been a consultant for the FDA,
20 that's the Food and Drug Administration, for EPA,
21 and the World Health Organization. I've written a
22 number of articles and review articles both
23 chapters and books in the field. And I've been
24 active in professional activities, including the
25 Teratology Society, where I was a president; and

1 the Society of Toxicology in the specialty section
2 on reproductive and developmental toxicology; and
3 also in risk assessment. The Middle Atlantic
4 Reproductive and Teratology Association, the
5 European Teratology Association, and the
6 Organization of Teratology Information Specialists.

7 Q And what does "teratology" mean?

8 A Teratology is the study of birth defects, whether
9 due to an exposure or whether genetic or
10 spontaneous.

11 Q Have you previously been retained in litigation as
12 an expert in the field of reproductive and
13 developmental toxicology?

14 A Yes, sir.

15 Q And if you had to guess, about how many occasions
16 or estimate?

17 A I would estimate probably about 150.

18 Q And have you ever been qualified to testify at
19 trial as an expert in the field of reproductive and
20 developmental toxicology?

21 A Yes, sir.

22 Q And about how many times?

23 A I think I've been to trial perhaps ten times.
24 About eight of those cases were in reproductive and
25 developmental toxicology, and I was qualified in

1 all of them.

2 Q Will you please describe your professional history
3 from when you finished residency through the
4 present day?

5 A I initially was in practice. I -- I've been in a
6 couple of private practices; one for a health
7 managed organization, one in Downtown Washington,
8 D.C. where I practiced child obstetrics and
9 gynecology. I then, after my fellowship, became
10 the associate program director for the residency
11 program in obstetrics and gynecology following
12 which I joined the university. That would be
13 Georgetown University full-time as the program
14 director of obstetrics and gynecology.

15 I was at Georgetown as a full-time faculty
16 member for, I think, about 20 years, and -- and
17 then I worked for a consulting company on a -- a
18 government contract. I was the principal
19 investigator on that contract with the Centers for
20 the Evaluation of Risk to Human Reproduction, which
21 was part of the National Toxicology Program. I
22 then went -- after I finished that -- the
23 consulting company, I went back to clinical
24 practice initially at George Washington University
25 where I worked in labor and delivery and then in

1 the outpatient clinic. In 2019, I left that
2 position and worked full-time my consulting company
3 practicing consultation in reproductive and
4 developmental toxicology.

5 Q That was gonna be my next question. So what types
6 of work do you do in your current consulting role?

7 A Currently, I consult for clients who are a diverse
8 group, including: law firms, some academic
9 consulting, government, drug companies and chemical
10 companies who want to know my interpretation of
11 studies that they've performed on their products,
12 and I've also done some -- some work for nonprofit
13 organizations.

14 Q And you touched on this, but do you currently hold
15 any academic appointments?

16 A Currently, I'm an emeritus professor at George
17 Washington University in obstetrics and gynecology
18 and an adjunct professor in obstetrics and
19 gynecology at -- at Georgetown University. I also
20 have a faculty appointment in the graduate school,
21 which is separate from the -- the medical school at
22 -- at Georgetown University.

23 Q Can you detail for the court some of the other
24 academic appointments you've had during your
25 career?

- 1 A Yes. When I was full-time at Georgetown
2 University, I was ultimately a tenured full
3 professor of obstetrics and gynecology.
- 4 Q Okay.
- 5 A At Georgetown University, I was a clinical
6 professor in obstetrics and gynecology.
- 7 Q Do you have any published research or articles?
- 8 A Yes, sir.
- 9 Q About how many?
- 10 A I have about 60-plus peer reviewed articles in the
11 literature. In addition, I've written maybe some
12 hundreds of review articles, book chapters, and --
13 and other academic writings.
- 14 Q And will you please describe for the Court some of
15 the topics you've published about?
- 16 A Most of what I've published on is reproductive and
17 developmental toxicology. I have also published on
18 some of the gynecologic topics that I specialized
19 in, including chronic pain and endometriosis. I
20 think that -- that covers most of what I've
21 published.
- 22 Q Okay. And have you given invited lectures?
- 23 A Yes, sir.
- 24 Q And about how many of those if you had to estimate?
- 25 A The -- the last I counted it was about 350 invited

1 lectures.

2 Q And can you tell the Court what an invited lecture
3 is?

4 A So an invited lecture is beyond your -- the lecture
5 you might do for a course you're teaching. It's
6 where a professional society, for example, or an
7 academic department out of town, asks you if you
8 can come and give a lecture and is part of their
9 Grand Round series, for example.

10 Q Will you describe for the Court some of the
11 teaching that you've had during your career?

12 A So teaching has included teaching residents and
13 medical students at both George Washington
14 University and Georgetown University. When I was
15 at George Washington and when I was at Georgetown
16 University and I was director of the residency
17 program, I was responsible for the curriculum and
18 for getting the curriculum approved by the
19 regulatory body and -- and making sure that the
20 curriculum was carried out.

21 Q Can you describe some of the other administrative
22 duties you've had in connection with your academic
23 work?

24 A So as director of the -- of the residency program
25 at Georgetown, I had to be in compliance with the

1 requirements of the residency review committee who
2 would come periodically to do an inspection of the
3 program to make sure we were in compliance. As
4 director of the Reproductive Toxicology Center, I
5 take responsibility for the compliance with the
6 regulatory agencies over the -- the business
7 requirements for a nonprofit foundation, as well as
8 managing the six employees of the organization.

9 Q And do you currently have any clinical duties?

10 A I do not currently see patients.

11 Q When did you last see patients?

12 A I last saw patients in -- in June of 2019.

13 Q And up until that time, what was the time frame for
14 how long you saw patients? Years span?

15 A Well, I saw patients certainly as part of my
16 residency between 1975 and 1979. Thereafter, I saw
17 patient's full-time in the various clinical
18 practices that I was a part of. And then, more
19 recently at George Washington University, I saw
20 patients one or two days a week either on labor and
21 delivery, that would be women in labor or
22 postpartum. And in the clinic, and that would be
23 largely obstetrical patients coming from prenatal
24 care or postpartum care.

25 Q At the peak, how many patients did you see each

- 1 week?
- 2 A How many patients I seen in what period?
- 3 Q At your peak, how many patients were you seeing a
- 4 week?
- 5 A I -- I would estimate 1- or 200 a week.
- 6 Q If you had to make a rough estimate how many
- 7 patients have you seen during your career?
- 8 A I would roughly say thousands.
- 9 Q What were some of the typical issues that a patient
- 10 might see you about?
- 11 A I had a -- a general obstetric and gynecologic
- 12 practice for much of my career, and that would
- 13 include routine visits either for prenatal care or
- 14 for what was called "well-woman visits." I also
- 15 saw special problems, particularly pelvic pain and
- 16 consultations in reproductive and developmental
- 17 toxicology. So if a patient called the scheduling
- 18 clerk, saying I have a concern about a medication
- 19 to which I've been exposed, I would automatically
- 20 be scheduled to see that patient.
- 21 Q And can you explain what you mean by exposure?
- 22 A An exposure is anything coming from outside the --
- 23 the body, so that would be a medication, a work-
- 24 place chemical, a -- an environmental chemical, an
- 25 infectious agent, a physical agent, such as; heat

- 1 or vibration or radiation.
- 2 Q And you touched on this before, but have you served
- 3 as an expert consultant or witness before?
- 4 A Yes, sir.
- 5 Q And about how many times have you been deposed in
- 6 your work as an expert?
- 7 A I've been deposed about a hundred times.
- 8 Q And you said how many times have you testified at
- 9 trial?
- 10 A I'm think it's been about ten times.
- 11 Q And has the Court ever refused to qualify you?
- 12 A No, sir.
- 13 Q Can you briefly detail for the Court what all you
- 14 did in working on this case?
- 15 A I reviewed the trial transcript. I reviewed
- 16 medical records. I reviewed the literature on
- 17 morphine and lactation.
- 18 Q And did you do any calculations, as well?
- 19 A Yes, sir. I -- I performed a calculation to see
- 20 whether it was credible that the concentration of
- 21 morphine that was reported in L.G.
- 22 (infant/verbatim) had come from breastfeeding
- 23 alone.
- 24 Q Thank you.
- 25 MR. WILLIAMS: Your Honor, based on his

1 knowledge, skill, experience, training, and
2 education, the applicant would offer Dr.
3 Scialli as an expert in reproductive and
4 developmental toxicology and obstetrics and
5 gynecology, and we'd also move that his CV as
6 Applicant's Exhibit 1.

7 THE COURT: All right. At -- give me one more
8 time the areas that you're offering as an
9 expert.

10 MR. WILLIAMS: Reproductive and developmental
11 toxicology and obstetrics and gynecology.

12 THE COURT: Any objection from the State?

13 MR. SPENCER: Your Honor, I'd just like a
14 short voir dire.

15 THE COURT: Sure. Yes, sir?

16 **VOIR DIRE EXAMINATION OF DR. SCIALLI**

17 BY MR. SPENCER:

18 Q Dr. Scialli, when would it have been -- when would
19 the first time you've been qualified as a witness
20 be?

21 A As I recall, it was in the late 1980s. I don't
22 recall the year.

23 Q And as I understand it, you're gonna do some
24 calculations today. What -- how much do you use
25 pharmacokinetics in your --

1 A How much do I use --

2 Q -- practice right now?

3 A Could you repeat what you said, please?

4 Q How much do you use pharmacokinetics in your
5 practice right now?

6 A Pharmacokinetics is certainly a basic part of
7 reproductive and developmental toxicology, so it
8 sometimes is relevant and it has to be considered.

9 Q Are those calculations you perform yourself?

10 A Yes, sir. If you're talking about the ones you and
11 I've discussed at my deposition.

12 MR. SPENCER: Beg the Court's indulgence.

13 THE COURT: Yes, sir.

14 THE COURT REPORTER: Your Honor, can he put
15 his name on the record, please?

16 MR. SPENCER: Certainly. Thank you.

17 THE COURT REPORTER: Can you put your name on
18 the record?

19 MR. SPENCER: David Spencer.

20 THE COURT REPORTER: Okay.

21 MR. SPENCER: And I'm with the Attorney
22 General's office.

23 THE COURT REPORTER: Thank you.

24 **VOIR DIRE EXAMINATION CONTINUES**

25 BY MR. SPENCER:

1 Q I think the last thing I was gonna ask is: In your
2 practice, have you ever prescribed MS Contin?

3 A MS Contin I don't remember, but MS Contin is -- is
4 a brand of morphine, and I've certainly prescribed
5 morphine.

6 Q How about slow-release morphine?

7 A I'm not sure what you mean by "slow-release."

8 Q MS Contin is, as I understand, is a slow-release
9 morphine.

10 A Yes, sir. That's one of its characteristics.

11 Q Okay. Have you ever prescribed any other slow-
12 release morphine?

13 A I don't recall having -- having done so, but I've
14 certainly prescribed a lot of morphine.

15 MR. SPENCER: Your Honor, as to the CV, I have
16 no objection to that being entered into
17 evidence. As to the qualifications in
18 developmental toxicology -- and what were the
19 other two things? I've -- I can never say
20 these words right. Obstetrics, or whatever,
21 and ginocology (verbatim). I also don't have
22 any objection.

23 Your Honor, the calculations -- and we
24 can do that when we get to that. I am gonna
25 have an objection to those. You know,

1 particularly one of the methodology
2 calculations -- I don't know if now's the best
3 time to take that up. I can certainly want to
4 get to that present my objection to that, Your
5 Honor.

6 THE COURT: Okay. Well, I think right now
7 he's just being offered as an expert in those
8 two areas outlined by the applicant, and I
9 will find that he is qualified in those two
10 areas, and the applicant can proceed.

11 On the issues of the calculations, you
12 can take that up through cross-examination as
13 to the credibility of the witness or his work
14 and inform the Court as to what you mean.

15 MR. SPENCER: All right, Your Honor. And,
16 Your Honor, you know -- you know, briefly, I
17 have an objection that's gonna be under
18 "Graves versus" -- I'm always about to pick
19 the wrong case -- "Graves vs. Cas Meds
20 Systems," which in that case the expert wasn't
21 -- the trial court did not allow the expert to
22 testify, so that's going to be the nature of
23 my objection -- my first objection.

24 THE COURT: Is your objection that you're
25 stating goes to his qualifications as an

1 expert or the Court's finding that he's an
2 expert?

3 MR. SPENCER: It's gonna be the calculations
4 under the Jones test --

5 THE COURT: Okay.

6 MR. SPENCER: -- as not a reliable
7 methodology.

8 THE COURT: All right. I look forward then to
9 hearing that at the appropriate time.

10 MR. SPENCER: Okay. Thank you, Your Honor.

11 THE COURT: Uh-huh.

12 **DIRECT EXAMINATION OF DR. SCIALLI**

13 BY MR. WILLIAMS:

14 Q All right. Dr. Scialli, I wanna again begin by
15 asking you: Have you formed any opinions in this
16 case?

17 A Yes, sir.

18 Q All right. And does this slide accurately reflect
19 on your opinions?

20 MR. SPENCER: Your Honor? I'm sorry. I mean,
21 we're already putting up the objections. We
22 don't have -- excuse me -- the opinions. We
23 don't have a foundation yet.

24 THE COURT: All right.

25 MR. SPENCER: Certainly, some of this, I'm

1 thinking, looking at this, I -- I just got
2 this and I'm just starting to look at it. I
3 think we need foundation before we put up a
4 "This is my opinion" --
5 THE COURT: Okay.
6 MR. SPENCER: -- "conclusion."
7 THE COURT: I've seen it done both ways and
8 then if the -- the foundation is not laid,
9 then the opinions then get removed from the
10 record. You know, I'm -- I'm going to allow
11 it. I mean, we don't have a jury at this
12 point, so I think I can -- if -- if the State
13 would at the appropriate time, then say that
14 the opinion was not supported, I will be more
15 than happy to hear from them -- from the
16 State.
17 MR. SPENCER: Thank you, Your Honor.
18 THE COURT: Yes, sir?
19 MR. WILLIAMS: And, of course, my objective is
20 going to try to get there, so thank you, Your
21 Honor.
22 THE COURT: I will let you know, y'all have
23 done a nice job putting them on the screens,
24 but I can't see the screen from where I'm
25 sitting, so --

1 MR. WILLIAMS: (To the State) I've got a
2 copy --
3 THE COURT: Yeah.
4 MR. WILLIAMS: -- I mean, do you mind me
5 handing that up?
6 MR. SPENCER: I mean, I would prefer we just
7 get the foundation out there first.
8 THE COURT: All right. (To Mr. Williams)
9 You've got a copy of what?
10 MR. WILLIAMS: The slide show if -- if you --
11 THE COURT: That'll be --
12 MR. SPENCER: I mean, if I could have a moment
13 to look at it --
14 THE COURT: Sure.
15 MR. SPENCER: -- or --
16 THE COURT: Take a moment. And you may give
17 me one. That might be helpful. We used to
18 have a TV screen up here, as well, but they've
19 taken it away. That would be hooked up,
20 so . . . Like I said, we're in the process of
21 building a new building.
22 MR. WILLIAMS: May I approach?
23 THE COURT: Tell you what. We'll step down
24 for a couple of moments and come right back.
25 (To the witness) You're in the process

1 of giving testimony, so you can step down, but
2 don't have any discussion with anyone about
3 the substance of your testimony. We'll come
4 back in a couple of minutes.

5 (Off the record from 9:57 a.m. until
6 10:12 a.m.)

7 THE BAILIFF: All rise and come to order.

8 THE COURT: Keep your seats. Keep your seats.

9 THE BAILIFF: Be seated, please. Be seated,
10 please.

11 THE COURT: (To the witness) Just go ahead
12 and have a seat, Doctor.

13 The break allowed us an opportunity to
14 officially transfer custody of the applicant,
15 as well.

16 (To the attorneys) Yes, sir. Y'all
17 ready to proceed?

18 MR. WILLIAMS: I'm ready, Your Honor.

19 MR. SPENCER: Your Honor, if I may be heard --

20 THE COURT: Yes, sir.

21 MR. SPENCER: -- briefly. Your Honor, this
22 PCR is a interesting setting since, obviously,
23 we're looking at her criminal matters during a
24 civil evidentiary hearing. You know, first of
25 all, if this was a criminal trial, this was

1 **00:45:15 rock under Rule 5, they wouldn't
2 have been able to just -- you know, day of
3 trial, just throw this up, and, you know, give
4 this to us, so a report would be something
5 that would clearly be produced under Rule 5,
6 but, you know, that's criminal trial,
7 obviously, Your Honor.

8 The content of this includes the
9 calculations that I just don't think get off
10 the ground under the Haynes (phonetic) -- I'm
11 sorry -- Graves case that I've referenced
12 before. And so that's my problem with that.
13 I, you know, I don't think they have the
14 foundation now to get into this.

15 Certainly, one of the things we're gonna
16 be talking about a lot during this trial is
17 morphine has two metabolites. The important
18 one is going to be one that shorthand is
19 referred to "M6G." That is -- that metabolite
20 is part of the problem that I have with these
21 numbers, you know, and we can get into the
22 weeds of it, as some testimonies develop, but
23 I don't think it's time you have to start
24 doing calculations and have this report. I
25 don't think they have the foundation for it,

1 yet, Your Honor.

2 MR. WILLIAMS: Briefly, Your Honor?

3 THE COURT: Uh-huh.

4 MR. WILLIAMS: At this time, I'm only gonna
5 put up the opinions as a initial, and then
6 we'll walk through all of that. I'm not going
7 to put up anything about the calculations
8 until Dr. Scialli starts talking about them.
9 These calculations are the same calculations
10 that the State went through in Dr. Scialli's
11 deposition. It's nothing new and so that's
12 all this slide show memorializes is the
13 opinions he's gonna give, and I will lay the
14 foundations of that and then the calculations
15 that they're already aware of and he's been
16 through. They can draw all that up in cross
17 if they disagree.

18 THE COURT: Okay. (To the State) Anything in
19 reply?

20 MR. SPENCER: Just kind of the same -- what I
21 mentioned before, once we get to the
22 calculations and have some foundation, that's
23 when I intend to make my Graves objection, and
24 I can explain that better probably at that
25 point in time than I could right now.

1 THE COURT: Okay. All right. I'm gonna allow
2 the applicant to proceed. You know, it's
3 beneficial to the fact finder to have such
4 demonstrative types of -- of items, and if
5 there is not the proper foundations made, I'm
6 sure the State will point that out, and I'll
7 make that decision at the appropriate time.

8 (To Mr. Williams) Okay. Go ahead.

9 MR. WILLIAMS: Thank you, Your Honor.

10 **DIRECT EXAMINATION OF DR. SCIALLI CONTINUES**

11 BY MR. WILLIAMS:

12 Q All right. Dr. Scialli, I'm wanna begin by asking
13 you: Have you formed any opinions in this case?

14 A Yes, sir. I have.

15 Q Okay. And does this slide accurately reflect your
16 opinions or one of your opinions?

17 A Yes, sir. I made these slides, and first -- my
18 first opinion is that the amount of morphine that
19 was measured in --

20 MR. SPENCER: Your Honor, I object. We need
21 the foundation before we hear the opinion.

22 THE COURT: All right. I believe that you
23 have stated that already. I think I've made
24 myself clear that I'm going to allow the
25 applicant to proceed as they are proceeding.

1 The State then, on cross-examination, may go
2 into the credibility of the statements and
3 point out to the fact finder where the State
4 believes that credibility or lack thereof
5 lies.

6 MR. SPENCER: Understood, Your Honor. And
7 I -- I apologize. I'm just -- you know, I'm
8 trying to just keep the -- preserve the record
9 for our sake.

10 THE COURT: Preserving the record --

11 MR. SPENCER: I didn't know what that -- that
12 opinion was going to be. I'm sorry. I didn't
13 mean to cut you off, Your Honor.

14 THE COURT: Preserving the record is a
15 wonderful thing, but we also have to conduct
16 the actual trial -- the actual proceeding in
17 order for this case to get on appeal, okay?
18 So you may object however you wish to object,
19 but we have to get this case done.

20 MR. SPENCER: Certainly, Your Honor.

21 Certainly. I'm just making --

22 THE COURT: So how would you suggest that we
23 get this witness' testimony in?

24 MR. SPENCER: Thank you, Your Honor. That is
25 absolutely a fair question. I think we just

1 need some foundation. How does morphine work?

2 That sort of thing.

3 THE COURT: All right. I have found this
4 witness qualified in the areas. You have
5 conducted your voir dire.

6 MR. SPENCER: Certainly, Your Honor.

7 THE COURT: How else would you suggest the
8 applicant present their case other than
9 already we have a qualified witness who's
10 testifying as to his opinions in this case
11 that you have had the opportunity to take a
12 deposition of.

13 MR. SPENCER: Certainly, Your Honor.

14 THE COURT: You already have an idea as to
15 what his testimony is going to be. I'm sure
16 you're loaded with information to which you
17 may cross-examine this witness. That goes to
18 his --

19 MR. SPENCER: Certainly, Your Honor.

20 THE COURT: -- credibility.

21 MR. SPENCER: Certainly. I understand, Your
22 Honor. I understand. I was just trying to --
23 you know, and I don't know what the first
24 opinion was going to be, Your Honor. I just
25 wanted to head that out to -- we can -- I

1 certainly understand your point, Your Honor.
2 And, you know, I -- again, I wasn't trying to
3 upset Your Honor, I'm just trying to --
4 THE COURT: I am not upset. I'm just trying
5 to make my point clear.

6 MR. SPENCER: Certainly.

7 THE COURT: I have made rulings in this case.
8 I expect the lawyers to respect those rulings,
9 because we need to move this case along.

10 MR. SPENCER: Right, right. And if I can just
11 make an apology and I'll be done. I
12 apologize. I didn't realize I was kind of
13 exceeding the scope of the -- of the
14 objection, Your Honor. And it is my fault,
15 Your Honor. And, certainly, we can just
16 proceed. I -- I mean, obviously, but, Your
17 Honor, I -- I appreciate your comments.

18 THE COURT: Thank you, sir. (To Mr. Williams)
19 You may proceed.

20 MR. WILLIAMS: Thank you, Your Honor.

21 DIRECT EXAMINATION OF DR. SCIALLI CONTINUES

22 BY MR. WILLIAMS:

23 Q We will go into more detail for each of these, of
24 course, but could you please detail your opinions
25 for the Court?

1 A The amount of morphine concentration measured in
2 L.G. could not have been present due to
3 breastfeeding alone without another circumstance.
4 And that circumstance was almost certainly renal
5 failure preventing the excretion of morphine and
6 its metabolites.

7 The State's witness relied on a case that came
8 from Toronto. I believe in the trial transcript it
9 was referenced as the "Canada case," but that --
10 that paper that was referenced, or they're actually
11 a series of papers, were about codeine, not about
12 morphine and were inappropriate. Moreover, it -
13 the papers were unreliable even with respect to
14 codeine as a 2020 paper detailed. And the State's
15 witnesses also referred to synergy, a toxicologic
16 principle, that was not appropriate because there
17 is no literature supporting synergy in this case.

18 Q Thank you, Doctor. Now, let's take a step back and
19 start with the basics. Can you describe for the
20 Court how an oral medication is processed and
21 metabolized by the human body?

22 A After the medication is swallowed, it's in the
23 stomach, and it goes into the small intestine.
24 Depending on the medication, it may be absorbed in
25 the small intestine as morphine is. From the small

1 intestine, the medication goes directly to the
2 liver where it is metabolized. That's -- we call
3 that the first pass effect because the first pass
4 of the medication is to the liver. In the case of
5 morphine, the medication is almost completely
6 metabolized, and then morphine and its metabolites
7 are circulated to the other organs in the body,
8 including the kidney, where the morphine and
9 chiefly its metabolites are excreted.

10 Q And does the process vary -- vary based on the type
11 of medication consumed?

12 A Yes, sir. The -- the absorption will vary
13 depending on the medication. Morphine, including
14 MS Contin, is about 30 to 40 percent absorbed in
15 the intestine. Other medications may be absorbed
16 to a greater or a lesser extent.

17 Q And are there differences between oral consumption
18 and other mechanisms such as intravenous or
19 intramuscular?

20 A Yes, sir. When a medication is given intravenously
21 or intramuscularly, it is absorbed directly into
22 the systemic circulation. There is no first pass
23 effect through the liver, and the medication gets
24 to the liver because the liver is one of the organs
25 being to which the medication is distributed. But

1 that distribution to the liver will occur to a
2 lesser extent and later than a medication given
3 orally.

4 Q And you touched on oral morphine, so would there be
5 differences between oral versus intravenous or
6 intramuscular administration of morphine?

7 A The major difference is the extent of absorption,
8 so intravenous morphine is 100 percent absorbed;
9 oral morphine is 30 to 40 percent absorbed, and the
10 first pass effect through the liver, which occurs
11 for oral morphine, but not intravenous or
12 intramuscular morphine.

13 Q Okay. Will you please detail for the Court the
14 general process of how medication would then make
15 its way to a nursing mother's breast milk?

16 A When the medication is systemically absorbed and
17 distributed to the other organs in the body, one of
18 those organs is the breast, and with respect to
19 morphine when it reaches the breast, it diffuses
20 into the milk.

21 Q And what happens after the milk is consumed by the
22 child?

23 A The child consuming the medication will absorb it,
24 and, again, it depends on the medication where it
25 is absorbed. Morphine is absorbed in the small

- 1 intestine, and then it will go to the child's
2 liver, which will metabolize whatever morphine
3 might be present, depending on the maturity of the
4 child. In other words, the extent of metabolism
5 depends on how old the child is, how mature the
6 child is.
- 7 Q Okay. Let's talk next about your own practice.
8 How frequently did you encounter breastfeeding
9 mothers in your clinical practice?
- 10 A In my patients, about one out of three women
11 breastfed.
- 12 Q If you had to make a rough estimate, how many total
13 patients would you have seen that were
14 breastfeeding?
- 15 A I would say I've seen hundreds.
- 16 Q Did you ever treat patients who were taking
17 opioids?
- 18 A Yes, sir.
- 19 Q How about patients who were taking morphine?
- 20 A Yes, sir.
- 21 Q Have you ever prescribed opioids to someone who is
22 pregnant?
- 23 A Yes, sir.
- 24 Q How about morphine?
- 25 A Yes, sir.

- 1 Q Have you ever prescribed opioids to someone who is
2 breastfeeding?
- 3 A Yes, sir.
- 4 Q How about morphine?
- 5 A Yes, sir.
- 6 Q Is MS Contin the brand name for morphine?
- 7 A Yes, sir.
- 8 Q Is it within the standard of care to prescribe
9 opioids to nursing mothers?
- 10 A Yes, sir.
- 11 Q How about morphine?
- 12 A Yes, sir.
- 13 Q Are neonates ever directly prescribed opioids?
- 14 A Yes, sir.
- 15 Q Would that be within the standard of care under the
16 appropriate circumstances?
- 17 A Yes, sir.
- 18 Q Morphine, as well?
- 19 A Yes, sir.
- 20 Q What are some of the reasons a neonate might be
21 directly prescribed morphine?
- 22 A Morphine is used in neonates who have had surgery,
23 so that -- some neonates about 3 percent of
24 children are born with a birth defect, which may
25 require surgery for the survival of the child. In

- 1 -- in those cases, you have to give the baby
2 something for pain relief. Not to give something
3 for pain relief would be inhumane, and morphine is
4 commonly used.
- 5 Q What are some reasons a physician might prescribe
6 morphine generally?
- 7 A Morphine generally is used for pain. It's a -- a
8 pain-relieving medication.
- 9 Q And do you recall why it was prescribed to Ms.
10 Greene?
- 11 A Yes, sir. Ms. Greene was given morphine for
12 chronic pain associated with fibromyalgia.
- 13 Q In your clinical practice, did you ever see
14 patients with fibromyalgia?
- 15 A Yes, sir.
- 16 Q And did you ever prescribe opioids to those
17 patients?
- 18 A Yes, sir.
- 19 Q Now, I know you didn't see Ms. Greene yourself, but
20 if you were her treating physician at that time,
21 and you agreed with the fibromyalgia diagnosis,
22 would it have been within the standard of care to
23 prescribe morphine to her?
- 24 A Yes, sir.
- 25 Q Okay. Next, if we can get the toxicology report.

1 MR. WILLIAMS: And, Your Honor, I believe you
2 have this. It probably would have been on the
3 trial record.
4 MR. SPENCER: I don't know if that would have
5 been as a trial record. I don't think it's in
6 the Judge's packet, Your Honor.
7 MR. WILLIAMS: Okay. Well, I've got a copy.
8 MR. SPENCER: It could be in there somewhere,
9 but I don't know --
10 MR. WILLIAMS: Okay.
11 MR. SPENCER: -- that it is.
12 MR. WILLIAMS: I've got a copy here.
13 MR. SPENCER: Thank you.
14 MR. WILLIAMS: (To the Court) May I approach?
15 MR. SPENCER: No objection, Your Honor.
16 THE COURT: Without objection, it will be
17 Applicant's 1?
18 MR. WILLIAMS: Two.
19 THE COURT: Applicant's --
20 THE COURT REPORTER: I haven't marked anything
21 yet. You haven't given me --
22 MR. WILLIAMS: Okay.
23 THE COURT: Okay.
24 THE COURT REPORTER: -- anything to mark.
25 MR. WILLIAMS: I was gonna say --

1 THE COURT: Did you give her the --
2 MR. WILLIAMS: -- we had them marked and now
3 it'll be out of order if we -- but that's
4 fine.
5 THE COURT: You introduced the CV?
6 MR. WILLIAMS: That's right.
7 THE COURT: You want to give it to the court
8 reporter?
9 MR. WILLIAMS: Yes. (To the witness) Do you
10 still have it?
11 (To the court reporter) Why don't we mark
12 that -- will I get you out of order if I --
13 beg the Court's indulgence. Just a second.
14 MR. SPENCER: All right.
15 MR. WILLIAMS: We'll mark that 12.
16 THE COURT REPORTER: Twelve?
17 MR. WILLIAMS: Yes. Twelve. Just put it at
18 the end.
19 THE COURT REPORTER: And this is one?
20 MR. WILLIAMS: That's one, yes, ma'am.
21 THE COURT REPORTER: Okay. Okay. Just give
22 me just a minute, please.
23 THE COURT: So what's -- what's two through
24 eleven?
25 MR. WILLIAMS: Other items we intend to

1 introduce --

2 THE COURT: Okay.

3 MR. WILLIAMS: -- if Your Honor admits them.

4 So we put it at the end, but we may have a few
5 missing depending on your rulings. We'll see.

6 THE COURT: Okay.

7 MR. WILLIAMS: Better that than out of order
8 on premarked things.

9 THE COURT: All right. I think I've got it.
10 Yes, sir?

11 (WHEREUPON, the Curriculum Vitae,
12 Applicant's Exhibit No. 1 was marked for
13 identification.)

14 (WHEREUPON, the SLED report, Applicant's
15 Exhibit No. 12 was marked for
16 identification.)

17 **DIRECT EXAMINATION OF DR. SCIALLI CONTINUES**

18 BY MR. WILLIAMS:

19 Q Okay. All right. Dr. Scialli, have you reviewed
20 this document before?

21 A Yes, sir.

22 Q And can you tell me what that is?

23 A This is a toxicology report, which was a -- a part
24 of the postmortem evaluation of -- of L.G.

25 Q Okay. And did you form any opinions about the

1 level of the morphine that's measured on that
2 report?

3 A Yes, sir.

4 Q And what were those?

5 A In my opinion, this amount of morphine is too high
6 to have been achieved through breastfeeding alone
7 without inhibition of the excretion of morphine and
8 its metabolites.

9 Q And did you research the medical literature
10 informing that opinion?

11 A Yes, sir.

12 Q And rely on your professional experience and
13 training?

14 A Yes, sir.

15 Q Did you do any calculations about the amount of
16 milk that L.G. would have had to consume to reach
17 that level?

18 A Yes, sir.

19 Q Can you explain for the Court what your conclusions
20 were based on those calculations?

21 A By my calculations, the --

22 MR. SPENCER: Your honor? Can we approach?

23 That might be the best way.

24 THE COURT: (Nodded head yes.)

25 (WHEREUPON, an off-the-record bench

1 conference was held.)

2 (Off the record from 10:29 a.m.

3 until 10:33 a.m.)

4 THE COURT: We'll go back on the record.

5 Thank y'all, gentlemen, for the information at
6 the bench conference.

7 And the State wishes to express their
8 objection at this time?

9 MR. SPENCER: Yes, Your Honor. And,
10 basically, the conclusions we -- I think as I
11 mentioned before, I think under "Graves vs.
12 Cas," which is a differential diagnosis case,
13 basically, where they sustained the trial
14 judge keeping out expert testimony using
15 differential diagnosis, because the experts in
16 that case failed to take in account another
17 source of, I believe, it was a software
18 malfunction. Our objection is gonna wind up
19 without we think that they're not taking in
20 account another source of morphine other than
21 morphine coming through breast milk. And, you
22 know, we can get into that -- the weeds of
23 that as the testimony is laid out.

24 There is gonna be other objections I have
25 under 702, also, but that's -- I thought the

1 cleanest, easiest one to make, Your Honor. So
2 I understand, based upon the conference, we'll
3 just -- we'll listen to this testimony and
4 take that up on cross-examination.

5 THE COURT: All right. (To Mr. Williams) Any
6 reply to his objection?

7 MR. WILLIAMS: I'll just put on the record
8 that Your Honor is qualified. We're going to
9 lay the foundation for the calculations.
10 They're just an illustration of his opinions
11 and the State's argument of dealing with them
12 in his deposition and, you know, would like to
13 offer the testimony, Your Honor.

14 THE COURT: All right. What we'll do is --
15 this is a civil matter, and -- but we do not
16 have a jury. Normally, what we would -- a
17 Court would do at this time, if we had a jury,
18 would exclude the fact finders from the --
19 from the courtroom, and then receive the
20 testimony, because I cannot rule -- a judge
21 cannot rule on an objection without knowing
22 what the information is going to be.

23 I've talked with attorneys at bench, and
24 I'm -- what I would suggest in a expeditious
25 and efficient way would be let's go ahead and

1 receive the testimony. The State has offered
2 their objection to the record; go ahead and
3 receive the testimony. I may, in fact, rule
4 in the State's favor, but I got to know the
5 testimony one way or the other, you know,
6 whether it is a substantive and informational
7 or whether it's just proffered.

8 Go ahead and receive the testimony at the
9 appropriate time. The State can save their
10 cross-examination for their parts of their
11 case or they can cross-examine as to this
12 particular issue. Now, I'm not going to say
13 that they've waived anything by holding their
14 fire until full cross-examination, but we're
15 gonna go ahead and receive the testimony from
16 the witness at this time.

17 MR. WILLIAMS: Thank you, Your Honor.

18 **DIRECT EXAMINATION OF DR. SCIALLI CONTINUES**

19 BY MR. WILLIAMS:

20 Q Okay. Can you explain for the Court what your
21 conclusions were based on your calculations?

22 A Based on the amount of morphine that can get into
23 milk under ordinary circumstances, the amount of
24 milk that this baby would have had to consume every
25 day in order to reach the concentration that was

1 identified in her blood would be in excess of 50
2 gallons and that's simply not possible.

3 Q And I'll come back to that. Let's go to Slide 3.

4 A Now, I also redid the calculations using a higher
5 concentration of morphine in milk. So that
6 morphine usually is achieved in a concentration of
7 up to 65 micrograms per liter in milk. There is
8 one report of a woman who was receiving morphine
9 intramuscularly and intravenously, which will
10 result in higher concentrations than orally, who
11 had 500 micrograms per liter in her milk. I
12 repeated the calculations using that higher amount
13 just as a worst-case scenario and found that the
14 infant would have had to drink an excess of six and
15 a half gallons per day, which I also believe is not
16 possible.

17 Q So the 65 nanograms per milliliter you worked from
18 on the initial calculation, you describe that as a
19 generous estimate?

20 A I'm sorry. It was 65 micrograms.

21 Q Micrograms, excuse me.

22 A And what was your question again, please?

23 Q Would you describe that as a generous estimate?

24 A Yes. Sixty-five micrograms per liter was described
25 in the first two or three days of life, and

1 thereafter it goes down to about 20 or 40
2 micrograms per liter. I used the 65 again just to
3 use the highest concentration that I could find.

4 Q And if it was a lower number, would a higher milk
5 consumption be expected to be required?

6 A Yes, sir.

7 Q Okay. And on the second calculation, 500 -- again,
8 that's a worst-case scenario that you could find?

9 A Yes, sir. That's after intramuscular or
10 intravenous morphine. Actually, the woman who gave
11 rise to that milk sample, got both intramuscular
12 and intravenous morphine, so true roots of morphine
13 that don't go through that first pass effect in the
14 liver.

15 Q Okay. Now, let's walk how you -- walk through how
16 you've arrived at those numbers for the Court.

17 A I started with the weight of the baby, which was 7
18 pounds; I converted it to -- to grams or kilograms.
19 Next, I looked at the volume of distribution of
20 morphine in children, and the volume of
21 distribution means the amount of liquid in which
22 morphine would be distributed in order to provide a
23 given concentration; and that is 7.3 liters per
24 kilogram in children. For this child, that would
25 be 24.4 liters, so if morphine were given to a

1 child weighing 3.345 kilograms, the morphine would
2 reach a concentration by being dissolved in 24.4
3 liters of fluid.

4 I then took the concentration that was
5 measured in L.G., which was 0.52 milligrams per
6 liter, and I did some algebra in order to come up
7 with how many milligrams would have had to been --
8 be introduced to the child in order to arrive at
9 that concentration and it comes out to 12.7
10 milligrams. So if you put 12.7 milligrams into
11 24.4 liters, you come out with a concentration of
12 0.52 milligrams per liter. Again, I used a human
13 milk concentration up to 65 micrograms per liter,
14 which is high because it represents the
15 concentration in the first two days of life or so,
16 and then I took that 500 micrograms per liter as a
17 worst-case scenario. I did the calculation both
18 ways.

19 What I came up is that to get that 12.7
20 milligrams, that's 12,700 micrograms just to keep
21 it all in the same units, the child would have had
22 to consume 195 liters of milk, which is about 232
23 times the usual milk intake in a day or using the
24 higher end, the 500, it would be 30 times the usual
25 milk intake. And I got that usual milk intake --

1 that's a standard figure. At six weeks, infants
2 consume about 840 milliliters of milk daily, so
3 that's how I came up with the conclusion that L.G.
4 would have had to drink 51.5 gallons of milk daily
5 in order to reach that morphine concentration using
6 the -- the lower number for the morphine
7 concentration in milk.

8 Q And did you rely on medical literature to support
9 your calculations?

10 A Yes, sir.

11 Q Okay. I'm gonna hand you two papers, I think.

12 MR. WILLIAMS: May I approach, Your Honor?

13 THE COURT: Yes, sir.

14 MR. WILLIAMS: (To the court reporter) All
15 right. This will be Applicant's 2, I believe.

16 THE COURT REPORTER: Hold on just a moment.

17 MR. WILLIAMS: You're fine.

18 THE COURT REPORTER: Thank you.

19 MR. WILLIAMS: Uh-huh.

20 THE COURT REPORTER: Just the way it's listed,
21 just two -- or do you want it on top?

22 MR. WILLIAMS: That's fine. Thank you.

23 THE COURT: All right. You handed the witness
24 some documents. Have y'all had a discussion?
25 Is there gonna be any objection to these

1 documents?

2 MR. SPENCER: No, Your Honor.

3 THE COURT: (To Mr. Williams) Now, you want
4 to tell me what these documents are, so I'll
5 know?

6 MR. WILLIAMS: Sure. And -- I mean, I've got
7 copies I can provide. (To Mr. Spencer) Do
8 you have an objection to me doing that?

9 MR. SPENCER: Oh, no, no. The articles are --
10 all those articles are fine.

11 MR. WILLIAMS: And I guess there could
12 be . . . (To the Court) I'm speaking for
13 you. Sorry. Okay.

14 THE COURT: I'm just trying to figure out what
15 you're handing the witness.

16 MR. WILLIAMS: This is -- they've also been
17 Bates stamped with discovery.

18 THE COURT: These are the same things the
19 witness has?

20 MR. WILLIAMS: That's correct, Your Honor.

21 THE COURT: All right. The exertion of
22 morphine in the human breast milk, what number
23 is on that one?

24 MR. WILLIAMS: It should match now what -- two
25 and three.

1 THE COURT: Okay. So two is the pharmacotic
2 (verbatim) of morphine? That's Applicant's 2
3 and the other one's Applicant's 3, okay. And
4 those are without objections. All right.

5 (WHEREUPON, pharmacokinetics of morphine,
6 it is marked as Applicant's Exhibit 2.)

7 (WHEREUPON, morphine/breast milk, it is
8 marked as Applicant's Exhibit 3.)

9 **DIRECT EXAMINATION OF DR. SCIALLI CONTINUES**

10 BY MR. WILLIAMS:

11 Q All right. We'll take Exhibit 2 first. Dr.
12 Scialli, can you take a look at that document and
13 tell the Court what it is?

14 A Yes, sir.

15 Q And what is that?

16 A This is a paper on the pharmacokinetics of morphine
17 and its metabolites in infants and young children
18 after congenital heart surgery. And this is the
19 source of the line with distribution figure that I
20 used in my calculations. That's for young
21 children. Line of distribution changes with age.

22 Q And on Exhibit 3, if you'd also take a look at
23 that, and tell the Court what that is?

24 A This is the report by Feilberg and coworkers called
25 "Excretion of Morphine" --

1 THE COURT REPORTER: (To the witness) I'm
2 sorry. Can you say that again? It's the
3 report by whom?

4 THE WITNESS: Feilberg, F-e-i-l-b-e-r-g.

5 THE COURT REPORTER: Thank you.

6 A And this is the report from which I got that 500
7 micrograms -- excuse me -- nanograms per
8 milliliter.

9 THE COURT REPORTER: (To the witness) I can't
10 hear you. Can you speak up?

11 A Okay. This is the report from which I got the 500
12 nanogram per mL milk concentration, and this is the
13 source.

14 Q And where did the 65 nanograms per milliliter of
15 milk come from?

16 A That came from an abstract published -- or not
17 necessarily published, but that appeared in, I
18 think, the 1990s.

19 Q All right. Are these typical for the types of
20 materials that someone in your field would rely on
21 in formulating their opinions?

22 A Yes, sir.

23 Q Okay.

24 MR. WILLIAMS: And those have been admitted,
25 you said, Your Honor?

1 THE COURT: Yes, sir.

2 MR. WILLIAMS: Okay.

3 Q All right. For the record, can you summarize your
4 opinion about the morphine while measuring L.G.
5 based on your review of the materials, your
6 research, and your calculations?

7 A The -- the concentration measured in -- in L.G. was
8 too high to have been present from milk alone
9 without some other factor, most likely the
10 prevention of excretion or -- or rather lack of
11 excretion of morphine and its metabolites like a
12 kidney.

13 Q Do you think that that's the most likely
14 explanation?

15 A Yes, sir.

16 Q In formulating your opinion regarding renal
17 failure, did you research the medical literature?

18 A Yes, sir.

19 Q Okay.

20 MR. WILLIAMS: You got all the documents?

21 This is another article. (Sotto voce.)

22 MR. SPENCER: (Sotto voce.) No objection.

23 MR. WILLIAMS: Your Honor, may I approach?

24 THE COURT: Yes, sir.

25 MR. WILLIAMS: (To the court reporter) All

1 right. This will be Number 4. (To the Court)
2 Here's a copy for you.

3 (WHEREUPON, Journal of Pain and
4 Palliative Care, it is marked as
5 Applicant's Exhibit 4.)

6 **DIRECT EXAMINATION OF DR. SCIALLI CONTINUES**

7 BY MR. WILLIAMS:

8 Q Okay. If you can tell the Court what that document
9 is.

10 A This is an article on the "Clinical
11 Pharmacokinetics of Morphine" by Lugo and Kern.

12 THE WITNESS: (To the court reporter) Lugo is
13 L-u-g-o.

14 THE COURT REPORTER: L-u-g-o.

15 THE WITNESS: And K-e-r-n is the second name.

16 THE COURT REPORTER: And K-e-r-n. Thank you.

17 Q All right. And is this one example of -- one of
18 the papers that supports your opinion about the
19 renal failure?

20 A Yes, sir. This is a -- a review article that
21 indicates that the excretion of morphine and its
22 metabolites relies primarily on the kidney.

23 Q Is this paper typical for the type of materials
24 that someone in your field would rely on
25 formulating their opinions?

1 A Yes, sir.

2 Q And was this publication available at the time of
3 Ms. Greene's trial?

4 A Yes, sir.

5 Q Okay. Circling back, just to make sure I follow
6 you, was the renal --

7 THE COURT: Just to be sure the record's
8 clear: We've admitted that clinical of the --
9 from the "Journal of Pain and Palliative
10 Care." That is Exhibit Applicant's 4 without
11 objection; is that correct?

12 MR. SPENCER: Yes, Your Honor. And just --
13 this also makes it easier I think for the
14 record. It's Bates stamped -- and I
15 appreciate them Bates stamping these -- 594 --
16 Greene 594 to Greene 608.

17 THE COURT: Okay. Thank you.

18 MR. WILLIAMS: Thank you, Your Honor.

19 **DIRECT EXAMINATION OF DR. SCIALLI CONTINUES**

20 BY MR. WILLIAMS:

21 Q Now, to make sure I'm following you. The renal
22 failure issue you've discussed, was that caused by
23 Ms. Greene's morphine consumption and the
24 morphine's transmission through her breast milk?

25 A No, sir.

1 MR. SPENCER: (To Mr. Williams) I'm sorry. I
2 just -- I didn't -- can I hear that question
3 again?

4 MR. WILLIAMS: Sure.

5 Q Was the renal failure in L.G. caused by Ms.
6 Greene's morphine consumption and the morphine's
7 transmission through her breast milk?

8 MR. SPENCER: And, Your Honor, I'd -- I would
9 think we'd have to hear the basis of that
10 conclusion.

11 THE COURT: I'd like a little bit more
12 explanation, as well.

13 MR. SPENCER: Thank you.

14 THE COURT: (To Mr. Williams) Yes, sir?

15 MR. WILLIAMS: Well, I mean, it's -- Your
16 Honor, it's based on the calculation that Dr.
17 Scialli performed, the medical literature that
18 he's reviewed in the course of formulating his
19 opinions, his review of the underlying trial
20 record, and the -- the child's medical records
21 and full-trial record.

22 THE COURT: I guess I -- (To Mr. Spencer)
23 Yes, sir?

24 MR. SPENCER: I sort of -- now, I mean the
25 idea that, "Did the morphine cause the renal

1 failure?" is different than the question of,
2 "How much morphine might have passed through
3 the -- through the breast milk?" so that's --
4 that's kind of the basis of my objection. I
5 mean . . .

6 MR. WILLIAMS: And, Your Honor, I mean, Dr.
7 Twombly, our other expert, is going to
8 testify extensively on that issue, so . . .

9 THE COURT: Okay. If you could get the
10 witness to clarify what his opinion is on --
11 on the renal failure issue.

12 MR. WILLIAMS: Sure.

13 DIRECT EXAMINATION OF DR. SCIALLI CONTINUES

14 BY MR. WILLIAMS:

15 Q Doctor, could you restate your opinion about renal
16 failure caused by breast milk and morphine through
17 the breast milk?

18 A The renal failure was unlikely to have been caused
19 by morphine. None where that morphine causes renal
20 failure.

21 Q So you're talking about a distinct issue that
22 happened to the child?

23 A I'm talking about the -- the child was in renal
24 failure, but not from having been exposed to
25 morphine.

1 Q Thank you.

2 THE COURT: All right. I'll -- I'll overrule
3 the State's objection. Go ahead.

4 Q All right. Would your opinion on this have been
5 the same at the time of Ms. Greene's trial in 2014?

6 A Yes, sir.

7 Q And the opinions you've expressed here are all to a
8 reasonable degree of medical certainty?

9 A Yes, sir.

10 Q Thank you, Doctor. All right.

11 So next, I want to turn to a related issue.
12 At trial, the State's experts relied on a case
13 study involving transmission of morphine as a
14 metabolite of codeine through breast milk, and this
15 is the Toronto case or the Canadian case.

16 MR. WILLIAMS: And, Your Honor, I'm referring
17 to Dr. Eagerton's testimony at Pages 365 to 71
18 of the transcript.

19 THE COURT: Tell me those pages again, please.

20 MR. WILLIAMS: 365 to 71.

21 THE COURT: Okay.

22 MR. WILLIAMS: And Dr. Wren's testimony at
23 Page 455.

24 THE COURT: Okay.

25 MR. WILLIAMS: And, Your Honor, I'm just going

1 to hand the witness two additional documents.
2 These would be Applicant's 5 and 6, if I may
3 approach?

4 THE COURT: Yes, sir.

5 **DIRECT EXAMINATION OF DR. SCIALLI CONTINUES**

6 BY MR. WILLIAMS:

7 Q Could you take a look at those two documents, and
8 let the Court know what they are? We will start
9 with Number 5.

10 A Number 5 is a case report where the lead author is
11 Koren, K-o-r-e-n.

12 Q And the Document Number 6, what is that?

13 A Number 6 is a commentary by Madadi, M-a-d-a-d-i,
14 and others from 2006.

15 Q Are these the publications associated with the
16 Canadian case or Toronto case?

17 A Yes, sir.

18 Q Did you form any opinions about the State's
19 expert's reliance on the Canadian case?

20 A Yes, sir.

21 Q And what were those?

22 A These were not appropriate to cite --

23 MR. SPENCER: Your Honor, if I may. I
24 think -- you know, these are 2020 studies, so
25 I don't see how you can say -- have an opinion

1 that it was inappropriate for people back in
2 2014 to rely on a article that's retracted in
3 2020. I think that's -- on 403, I just feel
4 like that is just really kind of misleading.

5 THE COURT: (To Mr. Williams) Yes, sir?

6 MR. WILLIAMS: Your Honor, it drives home that
7 reliance on that study at the time was not
8 appropriate. It's a 2020 study that directly
9 rebutts and retracts the -- one of the
10 publications associated with this Canadian
11 case, so I do think it's relevant.

12 MR. SPENCER: Your Honor, they can present
13 something that they're -- you know, that for
14 some reason, absent that 2020 retraction of
15 those two articles, there was some reason to,
16 you know, not rely on it, that wouldn't be a
17 professionally reasonable thing to do that's
18 one thing, but I think under 403, it's just
19 misleading to say, "Look, it's retracted in
20 2020, so it's not appropriate for Dr. Wren or
21 Dr. Eagerton to refer to those studies, when
22 actually, Mr. Wise asked them about him on
23 cross-examination in 2014.

24 MR. WILLIAMS: Your Honor, I'm gonna go in
25 more detail about what the Canadian case is

1 and why Dr. Scialli believes it was unreliable
2 even at that time and I'm happy to provide
3 that additional background.

4 THE COURT: All right. I'm gonna overrule the
5 State's objection. I'm gonna let him proceed.
6 You can develop your line of questioning on
7 cross-examination for sure.

8 MR. SPENCER: Thank you, Your Honor.

9 THE COURT: Yes, sir.

10 **DIRECT EXAMINATION OF DR. SCIALLI CONTINUES**

11 BY MR. WILLIAMS:

12 Q Dr. Scialli, could you provide the Court with a
13 little bit more background about what the Canadian
14 case was and what it concluded?

15 A This is a report of a woman who was nursing who
16 took codeine, and the baby subsequently died. The
17 conclusion of -- of the report and particularly in
18 the Madadi commentary is that the codeine was
19 excessively converted to morphine because of a
20 genetic characteristic of the mother.

21 Q And can you explain why a case study on codeine was
22 not applicable to a case involving morphine?

23 A Codeine requires metabolism to morphine in order to
24 exert any pain-relieving effect. People metabolize
25 codeine to morphine at different rates. In the

1 case we're talking about here, there was no
2 metabolism of codeine to morphine. Morphine is the
3 agent that was given -- that was taken. The
4 calculations used by these authors were unreliable
5 even with respect to codeine showing excessive
6 amounts of and that -- showing amounts in excess of
7 those that would have occurred.

8 Q And aside from the Canadian case, are you aware of
9 any other published literature or case reports
10 confirming that morphine caused the death of a
11 child from exposure through breast milk?

12 A No, sir.

13 Q Okay.

14 MR. WILLIAMS: At this time, I'll go ahead and
15 offer the Koren, MD, articles for admission.

16 MR. SPENCER: Oh, okay. I didn't realize we
17 didn't put those in. That's the -- your five
18 and six?

19 MR. WILLIAMS: That's right.

20 MR. SPENCER: Yeah. No. I have no objections
21 to those.

22 THE COURT: Okay. We'll admit them as State's
23 5 and 6. Five being the case report, and six
24 being the commentary.

25 (WHEREUPON, case study, it is marked as

1 Applicant's Exhibit 5.)

2 (WHEREUPON, commentary, it is marked as

3 Applicant's Exhibit 6.)

4 MR. WILLIAMS: I beg the Court's indulgence.

5 DIRECT EXAMINATION OF DR. SCIALLI CONTINUES

6 BY MR. WILLIAMS:

7 Q Okay. Dr. Scialli, have there been any recent
8 developments regarding the Canadian case?

9 A Yes, sir.

10 Q Okay.

11 MR. WILLIAMS: Your Honor, may I approach?

12 THE COURT: Yes, sir.

13 MR. WILLIAMS: (To the court reporter) This
14 one's seven. Thank you.

15 MR. SPENCER: Your Honor, and the delay is on
16 my part. I'm trying to put something that I
17 feel would be appropriate under the best
18 evidence rule to put in at the same time. Oh,
19 here it is.

20 MR. WILLIAMS: Okay. Might be State's 1?

21 MR. SPENCER: Yeah. I guess so. Technically,
22 it would be -- I mean, I don't care.

23 MR. WILLIAMS: Okay.

24 MR. SPENCER: I think it would be a -- it
25 actually would be a applicant's exhibit, I

1 think. I don't know how that -- I may be
2 wrong about that.

3 Your Honor, if I may, just to --
4 hopefully, I'm doing this right. There's an
5 article that I feel, along with the article
6 that -- attached -- that previous Koren
7 article, that I feel the best evidence rule
8 applies to. It's called "Risk of Codeine to
9 Breastfed Infants - Facts and Fallacies."
10 It's written by Koren and one of his
11 associates. I don't know if they're going to
12 object to me implicating the best evidence
13 rule or not, but -- and I don't know how -- I
14 realized I don't know how to properly mark
15 something that comes in under the best
16 evidence rule, but I would ask that that come
17 in at the same time.

18 It's basically -- that's the article
19 criticize -- they're putting in an article
20 criticizing the previous study. This is
21 basically Gideon's (phonetic) response to the
22 article, and I think under the best evidence
23 rule in the interest of justice, it's
24 appropriate.

25 MR. WILLIAMS: And, Your Honor, we just say

1 that it would be better served on cross and to
2 cross him on it.

3 THE COURT: Okay. So I've been handed the
4 "Implausibility of Neonatal Opioid Toxicity
5 from Breastfeeding" article as Applicant's 7.
6 (To Mr. Spencer) Your objection is the best
7 evidence rule in that you --

8 MR. SPENCER: Correct.

9 THE COURT: -- have an -- an article that you
10 wish to present that you believe is better
11 suited --

12 MR. SPENCER: Right.

13 THE COURT: -- on this topic?

14 MR. SPENCER: Right. As to, you know, the
15 best evidence, Your Honor, you haven't asked
16 me to argue it. It is -- it is, you know,
17 basically a timing in the interest of justice
18 kind of rule, and so I feel it's appropriate
19 at this time, you know -- you know, to admit
20 it for what's that worth.

21 THE COURT: All right. What we'll do is I
22 will go ahead and let Applicant's Exhibit be
23 admitted. You can save that article, use it
24 on the witness of a cross-examination, and
25 then if you wish to offer at that time, I

1 think that's the appropriate, better way to do
2 it.

3 MR. SPENCER: Certainly, Your Honor.

4 THE COURT: Sure. (To Mr. Williams) Yes,
5 sir?

6 MR. WILLIAMS: So any objection to the
7 Zipursky paper?

8 MR. SPENCER: Just that I think the best
9 evidence rule would be --

10 MR. WILLIAMS: Okay.

11 MR. SPENCER: -- appropriate, but --

12 THE COURT: Okay.

13 MR. SPENCER: I guess I'm overruled on that.
14 I'll admit it doesn't really matter in the
15 end.

16 THE COURT: Okay.

17 MR. WILLIAMS: All right.

18 MR. SPENCER: Thank you, Your Honor.

19 THE COURT: Yes, sir?

20 (WHEREUPON, Zipursky paper, it is marked
21 as Applicant's Exhibit 7.)

22 **DIRECT EXAMINATION OF DR. SCIALLI CONTINUES**

23 BY MR. WILLIAMS:

24 Q All right. Dr. Scialli, will you take a look at
25 that document and describe for the Court what that

1 is?

2 A This is a paper by Zipursky and Juurlink that
3 indicates the deficiencies of the Madadi report.

4 Q And -- okay. Does this slide reflect some of the
5 paper's conclusions, and did you ever see its
6 creation?

7 A Yes, sir.

8 Q Okay. Will you please detail some of those
9 conclusions for the Court?

10 A First, the belief that newborns can develop opioid
11 toxicity from breastfeeding is supported by very
12 little data, and converging lines of evidence
13 indicate that neonatal opioid toxicity from
14 breastfeeding is exceedingly improbable, which is
15 their wording.

16 Secondly, the conclusion that the child
17 reported by Koren died from opioid toxicity due to
18 enhanced maternal conversion of codeine to
19 morphine, which led to the passage of large amounts
20 of morphine was unreliable, also their word. Their
21 review of the literature identifies a paucity of
22 convincing reports of neonatal opioid toxicity
23 during the breastfeeding, and there are no other
24 confirmed cases of neonatal death despite the use
25 of these drugs by millions of nursing women over

1 the past two decades.

2 And, finally, neonatal opioid toxicity
3 resulting from maternal codeine use during
4 breastfeeding could arise only from a highly
5 improbable combination of factors: A high maternal
6 codeine milk intake and critically profoundly
7 impaired neonatal opioid clearance. And the
8 emphasis on that slide is added -- those are -- are
9 their words, but I added the emphasis.

10 Q And what does "neonatal opioid clearance"
11 reference?

12 A That's kidney function. Clearance by the kidney.

13 Q And is that the same as renal?

14 A Yes, sir.

15 Q What ramifications follow the Zipursky paper?

16 A The paper was reviewed by the editors of the
17 journals that published the Madadi commentary and
18 those editors also reviewed it -- a reply from Dr.
19 Koren and they, as a result of their deliberation,
20 referred the paper and the Koren reply to two
21 independent reviewers who were familiar with the
22 subject area, both of whom recommended that the
23 paper be retracted. The editors of the journals
24 agreed, and the paper was retracted.

25 MR. WILLIAMS: Your Honor, may I approach?

1 THE COURT: Yes, sir.

2 MR. WILLIAMS: (To the court reporter) This
3 will be our 8; last one.

4 (To the witness) Dr. Scialli . . .

5 (To the State) Same objection?

6 THE COURT REPORTER: I can't hear you.

7 MR. SPENCER: Is this -- are you putting in
8 both retractions or just one?

9 MR. WILLIAMS: Just that one.

10 MR. SPENCER: Do you remember? Is it the
11 exact same verbiage?

12 MR. WILLIAMS: Should be.

13 MR. SPENCER: Should be? (Sotto voce.)

14 MR. WILLIAMS: Yes. (Sotto voce.)

15 MR. SPENCER: Now, this one, I have no
16 objection to, Your Honor.

17 THE COURT: All right. So it will be admitted
18 as Applicant's 8. This is "The Risk of
19 Maternal Codeine Intake in Breastfed Infants."
20 All right.

21 (WHEREUPON, "The Risk of Maternal Codeine
22 Intake in Breastfed Infants," it is
23 marked as Applicant's Exhibit 8.)

24 **DIRECT EXAMINATION OF DR. SCIALLI CONTINUES**

25 BY MR. WILLIAMS:

1 Q And is that the retraction you referenced a minute
2 ago?

3 A Yes, sir. This is a joint statement by the two
4 journals that published the Madadi paper.

5 Q How significant is it for a publication to issue a
6 retraction like this?

7 A It's -- it's very unusual. It's very rare and
8 generally reserved for papers that have presented
9 fraudulent data or where their conclusions are so
10 erroneous that they represent a risk to the reading
11 public.

12 Q Is it fair to say that the only study cited by the
13 State's expert to support the breast milk theory
14 has been disproven?

15 A Yes, sir.

16 Q Thank you, Doctor. Now, I'd like to turn to
17 another issue. So, at trial, Ms. Greene's expert,
18 Dr. Karch suggested a genetic defect to explain
19 what happened to L.G.

20 MR. WILLIAMS: And, Your Honor, I'm
21 referencing the testimony of Dr. Karch at
22 Pages 504 . . .

23 THE COURT: Okay.

24 MR. WILLIAMS: And then 508, 09, and 513.

25 THE COURT: All right. Thank you.

1 Q Based on your experience, review of medical records
2 from L.G., and review of the medical literature, is
3 there any basis for the speculation about a
4 possible genetic defect being the cause?

5 A No, sir.

6 Q The trial case referenced the genetic defect
7 associated with the mother's processing and
8 codeine, I believe, you discussed. Can you explain
9 again why that would not be applicable here?

10 A That genetic characteristic was responsible or, at
11 least, was described as responsible for increasing
12 the rate of metabolism of codeine to morphine.
13 There is, however, no codeine in the Greene case.
14 Codeine was not given. The metabolism of codeine
15 to morphine is irrelevant.

16 Q Can you explain for the Court why the renal failure
17 issue, we've discussed, is not a genetic defect?

18 A I'm not aware of genetic defects that would cause
19 acute renal failure at -- at about six weeks of
20 age, but I think Dr. Twombly might be better
21 prepared to answer that question.

22 Q So, in your opinion, is there any plausibility to
23 the theory that a possible genetic defect might
24 explain what happened to L.G.?

25 A No, sir. The only genetic defect that

1 theoretically could be invoked would be inability
2 to metabolize the morphine to the two glucuronides,
3 and I'm not aware that -- that such a defect has
4 been described, but even so my calculations were
5 based on morphine not on the glucuronides, because
6 morphine is the only chemical that was measured in
7 L.G.'s blood, at least the only morphine-related
8 chemical that was measured in L.G.'s blood.

9 Q Would your opinion have been the same at the time
10 of Ms. Greene's trial in 2014?

11 A Yes, sir.

12 Q Are your opinions here to a reasonable degree of
13 medical certainty?

14 A Yes, sir.

15 Q Okay. The last topic I would like to discuss with
16 you today is about your opinion on the testimony
17 from the State's witnesses and trial on synergistic
18 effect.

19 MR. WILLIAMS: And, Your Honor, I apologize.
20 I've got a lot to cite.

21 That's a transcript. First, is Quintus
22 Young, Page 148.

23 THE COURT: Yes, sir.

24 MR. WILLIAMS: We've got Dr. Bell, Pages 259
25 to 61, and then Page 265.

1 THE COURT: Two -- I'm sorry. Two-fifty what?
2 MR. WILLIAMS: 259 to 261, and then 265 for
3 her.
4 THE COURT: Okay.
5 Q All right. Dr. Kotecha, I believe that is how you
6 pronounce his name on Page 322 and 341.
7 THE COURT REPORTER: (To Mr. Williams) Can
8 you spell that name, please?
9 MR. WILLIAMS: K-o-t-e-c-h-a.
10 MR. SPENCER: What were those page numbers?
11 MR. WILLIAMS: For him, 322 and 341.
12 THE COURT: All right. Thank you.
13 MR. WILLIAMS: I've got a few more. Sorry.
14 Bear with me. Dr. Eagerton, that was 349 to
15 53.
16 THE COURT: All right.
17 MR. WILLIAMS: And 386 to 91.
18 MR. SPENCER: 386?
19 MR. WILLIAMS: Yes. To 91.
20 MR. SPENCER: Thank you.
21 THE COURT: Yes, sir.
22 MR. WILLIAMS: All right. Last batch. Dr.
23 Wren, Pages 3 -- or excuse me -- 430 to 434,
24 and then 444.
25 THE COURT: All right.

1 MR. WILLIAMS: Okay. That's everything.

2 Thank you, Your Honor.

3 **DIRECT EXAMINATION OF DR. SCIALLI CONTINUES**

4 BY MR. WILLIAMS:

5 Q Could you please describe for the Court what
6 synergistic effect or synergy means in your
7 professional opinion and experience.

8 A Synergy is a concept in toxicology where two or
9 more chemicals, including medications given
10 together, have more than additive effects meaning
11 that the effects are either different or greater
12 than you would expect from them based on their
13 individual actions.

14 Q Do you recall the testimony given by the State's
15 witnesses on this topic?

16 A Yes, sir.

17 Q And how did those witnesses describe the concept
18 with regard to the drugs found in L.G.'s system?

19 A I think they used the statement, "One plus one
20 equals three, and one plus one equals five."

21 Q And was that accurate to describe these drugs?

22 A When -- it's not accurate for these drugs. When
23 you use it for any drugs, you need to have some
24 literature to back up your conclusion that the
25 effect that you get is some multiple of what you

1 would expect from either alone.

2 Q And did you research the medical literature to see
3 if you could find anything that would support the
4 synergistic effect between any of the medications
5 at issue in this case?

6 A I did. I -- I looked in the literature and I did
7 not find any.

8 Q So do you think it was appropriate for the State's
9 witnesses to describe what happened with the drugs
10 found in L.G. as a one plus one equals three or one
11 plus one equals five situation?

12 A No, sir. I would find that misleading.

13 Q If you recall, did Dr. Karch's testimony make any
14 attempt to rebut the State's testimony about the
15 synergistic effects of the drugs found in L.G.?

16 A Not that I recall.

17 Q Okay. Finally, I want to ask about the particular
18 medications reflected on the toxicology report and
19 what sort of effects they may have had. All right.
20 Let's start first with methorphan and its
21 synergistic effect on morphine.

22 A Would you repeat the name? I'm sorry.

23 Q Methorphan.

24 A Methorphan. So methorphan is basically
25 dextromethorphan, which is sold over the counter as

1 Robitussin DM. It's a cough suppressant. It's a
2 very mild cough suppressant. In fact, some people
3 doubt it works at all. And it does not have
4 synergistic activity with morphine.

5 Q All right. And how about methorphan?
6 A Methorphan is a metabolite of dextromethorphan
7 and similarly it does not reflect a synergistic
8 interaction.

9 Q Okay. How about Clonazepam?

10 MR. SPENCER: Your Honor, if I may just
11 interrupt. Just approach Mr. Williams. I
12 think I have that slide.

13 MR. WILLIAMS: Oh, that's the Cox report.

14 MR. SPENCER: Oh, okay.

15 MR. WILLIAMS: I just haven't pulled that back
16 up.

17 MR. SPENCER: So it's just this one?

18 MR. WILLIAMS: Yeah. It's --

19 MR. SPENCER: Okay. So this is the exhibit?

20 MR. WILLIAMS: It's the -- yeah.

21 MR. SPENCER: This is actually the first
22 exhibit?

23 MR. WILLIAMS: That's right.

24 MR. SPENCER: Okay. Thank you.

25 MR. WILLIAMS: Or I think it's Number 12 now,

1 but that's the one we introduced over here.

2 MR. SPENCER: And this is -- okay. So this --

3 MR. WILLIAMS: Yeah. We just had that one on
4 the screen.

5 MR. SPENCER: Okay. Great. Thank you.

6 DIRECT EXAMINATION OF DR. SCIALLI CONTINUES

7 BY MR. WILLIAMS:

8 Q All right, Doctor. How about Clonazepam?

9 A Clonazepam is a benzodiazepine. It's used in
10 neonates for seizure control and it does not have a
11 synergistic effect with morphine. Clonazepam or
12 any benzodiazepine and morphine can have additive
13 effects on sedation, not on -- not on respiratory
14 depression, but sedation, but no synergistic
15 effect.

16 Q And you touched on this, but while we're discussing
17 this medication, are benzodiazepines prescribed
18 during pregnancy or breastfeeding?

19 A It is, yes.

20 Q And, again, how about to neonates?

21 A Yes, sir. It's prescribed particularly for seizure
22 disorders in neonates.

23 Q Okay. How about the diphenhydramine?

24 A Diphenhydramine is an over-the-counter
25 antihistamine. It's commonly marketed as Benadryl.

- 1 It's used by a lot of people for cold symptoms. In
2 fact, many obstetricians recommend diphenhydramine
3 to pregnant women who have a cold or congestion.
4 And there's no synergy with morphine.
- 5 Q Okay. Next, chlorpheniramine?
- 6 A Chlorpheniramine is another over-the-counter
7 antihistamine and it's also used for colds and
8 nasal congestion and has no synergistic interaction
9 with morphine?
- 10 Q And, finally, acetaminophen?
- 11 A Acetaminophen is Tylenol and other brands, which is
12 the preferred analgesic or pain-relieving
13 medication during pregnancy and lactation, and
14 there's no synergy with morphine.
- 15 Q Okay. So, bring that full circle, do you have an
16 opinion regarding whether these medications either
17 individually or taken together would have had a
18 synergistic effect on the morphine found in L.G.?
- 19 A My opinion is that they would not have had a
20 synergistic effect.
- 21 Q And would your opinion have been the same at the
22 time of Ms. Greene's trial in 2014?
- 23 A Yes, sir.
- 24 Q Okay. And are your opinions on this issue to a
25 reasonable degree of medical certainty?

1 A Yes, sir.

2 Q Okay. All right. That was a lot of information,
3 so in closing, would you please recap your central
4 opinions for the Court?

5 A My first opinion is that the amount of morphine
6 that was identified in L.G.'s blood could not have
7 been present to -- due to breastfeeding alone
8 without the additional factor of inability to
9 excrete morphine and its metabolites are almost
10 certainly because of renal failure.

11 The reliance of the State's witnesses on the
12 Toronto report, also called the Canadian case, was
13 not appropriate because the paper was about
14 codeine, not morphine, and because, even with
15 respect to codeine, it was not reliable as the 2020
16 paper detailed.

17 And, finally, the reference of the State's
18 witnesses to synergy was not appropriate because
19 there is no literature support for synergy in this
20 case.

21 MR. WILLIAMS: Thank you, Dr. Scialli. Please
22 answer any questions the State may have.

23 THE COURT: Lawyers approach a moment.

24 (WHEREUPON, an off-the-record bench
25 conference was held.)

1 THE COURT: We're going to take a short
2 recess. Doctor, you're still in the process
3 of giving testimony, so don't speak with
4 anyone about the substance of your testimony,
5 but you may step down. We're going to step
6 down and come back in a few minutes.

7 (Off the record from 11:24 a.m.
8 until 11:36 a.m.)

9 THE BAILIFF: Remain seated and come to order.
10 Remain seated.

11 THE COURT: Thank you. You may be seated.
12 Doctor, you want to come back.

13 Is the State ready for their cross?

14 MR. SPENCER: Yes, Your Honor.

15 THE COURT: Yes, sir?

16 **CROSS-EXAMINATION OF DR. SCIALLI**

17 BY MR. SPENCER:

18 Q Dr. Scialli, I'm sure you recall, we -- we met
19 virtually, if you will, when we -- when I took your
20 deposition several months ago; is that correct?

21 A Yes, sir.

22 Q Okay. And do you recall there was -- were several
23 articles that were discussed during the deposition
24 and they were -- and we all had copies of them and
25 I believe you had copies of them, too?

1 A There were articles. I don't know which ones you
2 mean.

3 Q Okay. Do you recall seeing this article?

4 A Yes, sir.

5 Q And is that an article you're familiar with?

6 A It's a website, but, yes, I'm familiar with it.

7 Q So a website article. And if you could just give a
8 description and title and website it's from.

9 A This is a website called "LactMed," L-a-c-t-m-e-d,
10 which is put out by the National Library of
11 Medicine. It's written by Dr. Phil Anderson.

12 Q And is it Bates-stamped?

13 A Yes, sir.

14 Q And if you can just give the first page of the
15 Bates stamp?

16 A "Greenes" -- excuse me -- "Greene 0613."

17 Q And this second article, can you give -- is this an
18 article you've saw (verbatim) before?

19 A Yes, sir.

20 Q And if you can give a name of the article and
21 source?

22 A It's an article by Hannam, H-a-n-n-a-m, and
23 Anderson, A-n-d-e-r-s-o-n, called "Contribution of
24 morphine and morphine-6-glucuronide to respiratory
25 depression in a child." And it's from a journal

1 called, "Anesthesia and Intensive Care," from 2012.

2 Q Thank you.

3 MR. SPENCER: Your Honor, I would move each of
4 these articles into evidence.

5 MR. WILLIAMS: No objection.

6 THE COURT: All right. Without objection
7 we'll do the one from the LactMed as -- (To
8 Mr. Spencer) So would it be State's 1?

9 MR. SPENCER: Yes.

10 THE COURT: And then the other one, which is
11 the Contribution of Morphine article, will be
12 the State's 2.

13 THE COURT REPORTER: Mr. Spencer, which one's
14 the LactMed?

15 MR. SPENCER: Oh.

16 THE COURT REPORTER: Can you show me which
17 one's one?

18 MR. SPENCER: Certainly. Certainly.

19 THE COURT REPORTER: This is one?

20 MR. SPENCER: This is one.

21 THE COURT REPORTER: Okay.

22 (WHEREUPON, LactMed article, it is marked
23 as State's Exhibit 1.)

24 (WHEREUPON, Contribution of Morphine
25 article, it is marked as State's Exhibit

1 2.)

2 MR. SPENCER: Thank you.

3 Q And before I get to those articles, I wanted to
4 first ask you about the -- what I believe was
5 the -- entered as Exhibit 1. If you could pull
6 that exhibit out of the pile.

7 THE COURT: (To Mr. Spencer) I think here it
8 is.

9 MR. SPENCER: Oh, I apologize. Thank you.

10 Q In that exhibit, does it indicate the sort of
11 machinery that was used to come up with these
12 toxicology results?

13 A It indicates the kind of test, it doesn't
14 indicate --

15 Q Okay.

16 A -- what machine was used.

17 Q What was the kind of test, then?

18 A Well, there were several different ones, so the
19 first one -- Item 1 has "headspace, gas
20 chromatography."

21 Q Well, let's skip ahead then to -- to the second
22 page, if that's all right? And right above --
23 sorry -- "What were the final results" -- do you
24 see that? "Analyst by gas chromatography mass
25 spectrometry"; is that how you say that?

- 1 A Mass spectrometry.
- 2 Q Mass spectrometry, okay. And is that sort of the
3 standard equipment you would use to determine blood
4 levels of a medication?
- 5 A That's the most accurate, I think. It's -- there
6 are other tests that are used for screening, but
7 this is the test that is considered the most
8 accurate.
- 9 Q Let me take that back. Okay. And as I understand
10 it, you're not here today to say that the -- that
11 particular number, that 0.52 milligrams per liter,
12 is incorrect?
- 13 A No. I have no opinion about the correctness of the
14 result.
- 15 Q Right. So my understanding is what they're saying
16 is the only way enough morphine could build up in
17 that neonate's body is if renal failure occurred
18 and that meant that the morphine couldn't be
19 eliminated?
- 20 A That would mean morphine and its metabolites could
21 not be eliminated.
- 22 Q And so, basically, you're not saying that enough of
23 that -- not enough that -- you're not saying . . .
- 24 MR. SPENCER: Beg the Court's indulgence in me
25 trying to get my phrasing right.

- 1 Q What you're saying today is because of renal
2 failure, enough morphine built up in the system to
3 kill the young -- the baby A.G. (verbatim)?
- 4 A Yes, sir.
- 5 Q Okay. And so -- and the morphine caused
6 respiratory depression?
- 7 A Yes, sir.
- 8 Q And so morphine was the cause of death?
- 9 A It -- it may have been, I can't tell whether this
10 child would have died of renal failure, but it's
11 possible that it was the morphine. It's possible
12 it was the renal failure.
- 13 Q But it's possible it was the morphine?
- 14 A Yes, sir.
- 15 Q All right. And you're not challenging these
16 numbers, this 0.52 milligrams per liter number?
- 17 A I'm not rendering an opinion about the accuracy of
18 the results in the toxicology report.
- 19 Q So let me -- let me kind of go back to that if I
20 could? So, basically, what you're taped saying
21 today is the only way enough morphine could come
22 through breast milk to kill a child is if there was
23 renal failure?
- 24 A Again, it's not the morphine coming through the
25 milk. It's the inability of the child to excrete

1 it, so that it builds up in the child.

2 Q Well, that's important, right? I mean, you need to

3 be able to excrete whatever drug you're taking or

4 there could be serious consequences of -- of --

5 from that drug?

6 A Generally speaking, that's correct; certainly, with

7 respect to morphine and its metabolites, that's

8 correct.

9 Q Okay. I wanted to ask about the metabolite. Yeah.

10 I wanted to ask about the metabolites. So morphine

11 -- tell me how morphine creates metabolites.

12 A Morphine is -- is metabolized by the liver by

13 putting a small sugar-like molecule called

14 "glucuronic acid" on to the morphine at one of two

15 positions, either the Number 3 position or the

16 Number 6 position. About 60 percent of morphine is

17 metabolized to the morphine-3-glucuronide, which is

18 inactive. And something like 5 to 10 percent is

19 metabolized to the morphine-6-glucuronide, which is

20 active.

21 Q All right. And that active metabolite, how's it

22 compared in potency to morphine, itself?

23 A Morphine-6-glucuronide has similar or greater

24 activity as far as pain relief and respiratory

25 depression to the parent molecule.

- 1 Q And it's -- does the -- the metabolite commonly
2 referred to as M6G as shorthand?
- 3 A I can't speak to calling it that. I call it
4 "morphine-6-glucuronide."
- 5 Q Okay. We can keep on. I may end up, maybe,
6 calling it "M6G," because I can't pronounce those
7 words, but, yeah.
- 8 A I understand what you mean.
- 9 Q Thank you. And this M6G, does this go into the
10 central nervous system?
- 11 A Yes, sir.
- 12 Q And so this -- and I think you mentioned that it
13 not only can have an "ana-GEL-lesic" (as spoken)
14 effects, but it also can have respiratory effects?
- 15 A Yes, sir. Morphine-6-glucuronide can suppress
16 respirations as can morphine, itself.
- 17 Q Okay. Now, the M6G, that also can pass through
18 breast milk, right?
- 19 A Yes, sir.
- 20 Q And, you know, let's be straight up and get this
21 out front. The -- SLED did not test for M6G?
- 22 A The State did not test for either metabolite.
- 23 Q And particularly M6G?
- 24 A I don't know if they neglected it particularly;
25 they neglected both glucuronides equally.

1 Q Certainly. And you said there was never -- you
2 know, we don't have to really talk about the
3 Canadian study yet, but there's never been, as you
4 understand, a case where enough morphine came
5 through breast milk to kill a child that you're
6 aware of?

7 A Yes, sir. That's correct.

8 Q And Dr. Karch said the same thing at trial, too,
9 right?

10 A I don't recall.

11 Q But you did review the trial transcript?

12 A Yes, sir.

13 MR. SPENCER: Beg the Court's indulgence.

14 And I apologize, Your Honor, give me a
15 moment to take in order what I got out of
16 order.

17 Q And I want to first go to the article that -- I
18 think it's called, "Clinical Pharmacokinetics of
19 Morphine," and was Bates stamped from Pages 594.
20 Let me know when you have that article.

21 A I have it.

22 Q Okay. Can you --

23 THE COURT: Can you tell me what the Court's
24 exhibit number is?

25 MR. SPENCER: Oh, yeah. Can you tell me what

1 Court's exhibit that is?

2 THE WITNESS: This is Exhibit 4.

3 THE COURT: Four? Thank you, sir.

4 MR. WILLIAMS: Your Honor, can we get copies
5 of these four. We may have them already, but
6 not these.

7 MR. SPENCER: Sure. I think I got two copies.

8 **CROSS-EXAMINATION OF DR. SCIALLI CONTINUES**

9 BY MR. SPENCER:

10 Q All right. And if you could open to Page 599 --
11 turn to 599? And if you could review to yourself
12 under "Absorption," the second paragraph?

13 A (Reviews document.)

14 Q And just let me know when you're ready.

15 A I'm ready.

16 Q Thank you. And so morphine -- the morphine,
17 itself, acting alone is a poor analgesic, it's the
18 metabolite that helps that --

19 A This --

20 Q -- effect, correct?

21 A This paragraph implies that morphine is a poor
22 analgesic and that the analgesic activity --
23 analgesic means pain relieving -- is due to the
24 morphine-6-glucuronide.

25 Q Right. So the -- one dose isn't as -- it's not the

1 first dose that's effective, it's the repeated
2 doses?
3 A That's --
4 Q So --
5 A -- certainly what it says here. In my experience,
6 that isn't entirely the case.
7 Q But, basically, it talks about how the M6G assists
8 in that analgesic effect. Would you agree with me
9 on that?
10 A I would say that they -- they called the morphine-
11 6-glucuronide the effective metabolite of morphine.
12 Q And it also indicates that the M6G will accumulate
13 in the central nervous system with repeated doses?
14 A That's what it says, yes, sir.
15 Q And if you could turn to 602 of that article. And
16 I'm looking at sort of the bottom of that section
17 above the "Pharmacokinetics" and "Special
18 Populations." There's a sentence that says,
19 "Moreover M6G."
20 A Yes, sir.
21 Q Okay. And that says, "The M6G likely accumulates
22 in the central nervous system"?
23 A That's the first part of that sentence, yes, sir.
24 Q Right. And it would've been a good idea for SLED
25 to test the M6G so we know how much was in there,

- 1 right?
- 2 A It -- it would have been helpful.
- 3 Q Right. But it does pass through breast milk?
- 4 A Yes, sir.
- 5 Q And so there's certainly a good probability that
- 6 there was at least some M6G that passed through
- 7 breast milk?
- 8 A Yes, sir. About 5 to 10 percent of morphine is
- 9 metabolized to morphine-6-glucuronide.
- 10 Q And if the child was able to metabolize this
- 11 morphine at all the child would've created some
- 12 more M6G?
- 13 A That's possible. That depends on the age of the
- 14 child.
- 15 Q And this article seems to indicate that it likely
- 16 accumulates in the central nervous system?
- 17 A This article says, "Morphine-6-glucuronide likely
- 18 accumulates in the central nervous system."
- 19 Q Thank you. And you can -- if you could just turn
- 20 to the next page. And it's going to be the first
- 21 full sentence at that top that I'm looking at, and
- 22 indicates, "Infants have reduced capacity for
- 23 glucuridate (phonetic)" -- how do you say that
- 24 word?
- 25 A Glucuronidation.

1 Q -- "and have lower clearances particularly in the
2 first few weeks of life."
3 A Yes, sir.
4 Q So, I mean -- so a baby and neonate who's getting
5 morphine has a right off the bat, regardless of
6 renal failure, has a reduced ability to clear the
7 morphine; is that fair to say?
8 A That's what this sentence implies, yes, sir.
9 Q And, again, this is an article that we both had for
10 the deposition you had previously, right?
11 A Yes, sir.
12 Q All right. So you are aware of this science in
13 this article?
14 A Yes, sir.
15 Q Okay. I want to also turn to the -- it says, "The
16 neonates up to two months old, the half-life of
17 morphine is six and a half plus or minus 2.8
18 hours"?
19 A Yes, sir.
20 Q Okay. And how does that compare to the half-life
21 for adults?
22 A It depends on the form of the morphine. So that
23 morphine given as an immediate-release oral
24 preparation has a shorter half-life; given as MS
25 Contin has a much longer half-life.

- 1 Q All right. Because of slow-release?
- 2 A I -- I would call it "extended-release," but slow-
- 3 release sounds like it means the same thing.
- 4 Q And let's flip back real quick to five - to Page
- 5 598. And I'm looking actually at that table at the
- 6 top, when -- when you're ready. And so, in this
- 7 chart here, it talks about the half-life of
- 8 morphine being two to three and a half hours?
- 9 A Yes, sir. That's what it says.
- 10 Q So, basically a child, according to this article,
- 11 has a much longer half-life for morphine than what
- 12 I would imagine this table in the page for adults?
- 13 A No, sir. I don't agree.
- 14 Q You don't agree with what it says? You don't agree
- 15 that there's a longer half-life?
- 16 A I don't agree with the way you interpreted it.
- 17 Q Okay. If you could tell me your interpretation of
- 18 it then.
- 19 A This table shows the dose of morphine parenterally,
- 20 which means intramuscular or intravenous. The oral
- 21 dose of morphine -- or the oral administration
- 22 would have a different half-life, which is not
- 23 included in this table.
- 24 Q Well, what would the half-life be for oral
- 25 administration for an adult?

- 1 A For immediate-release, morphine, I think, it's four
2 hours. For MS Contin, it's somewhere -- anywhere
3 from 15 to 30 hours.
- 4 Q Now, by the time it reaches the child, it's -- the
5 MS Contin is just -- it's been released, right? So
6 it's just a straight-up, normal oral dose; is that
7 fair to say?
- 8 A It's been released at the -- the delay in release
9 occurs in the intestine, so by the time it hits the
10 mother's liver it's -- morphine is the -- the
11 morphine hasn't given as an immediate release
12 preparation, but lower amounts absorb more slowly.
- 13 Q Right. That's what you're talking about the 65
14 milligrams per liter in your calculations?
- 15 A I think it was 65.
- 16 Q Excuse me.
- 17 A Yeah. Sixty-five milligrams per liter, that was
18 from oral morphine as an immediate release. And
19 that was in the first two days of -- of an infant's
20 life.
- 21 Q Okay. And that -- and the morphine that we're
22 talking about coming through breast milk is --
23 obviously, it's being ingested orally, also, right?
- 24 A Yes, sir.
- 25 Q All right. Now, when an adult takes morphine

- 1 whether it's regular, short-release, long-release,
2 whatever, standard-release, they're not taking at
3 the same time ingesting M6G are they?
- 4 A I'm sorry. I don't understand the question.
- 5 Q Let's see if I can rephrase it a little bit better.
- 6 In the case of a neonate that's nursing and
7 they're taking in morphine through breast milk, and
8 they're also taking in M6G through breast milk,
9 that's what makes it different from the way an
10 adult takes morphine because an adult is just
11 taking morphine. They're not taking morphine and
12 M6G. Is that a fair characterization?
- 13 A It's -- it's correct, but, of course, once it goes
14 through the liver of the mother or the adult,
15 they're getting morphine, morphine-6-glucuronide,
16 and morphine-3-glucuronide --
- 17 Q Yeah.
- 18 A -- so what comes out of the liver after the first
19 pass effect is similar to what the baby gets from
20 drinking the milk.
- 21 Q In my own opinion, when you take that 30-milligram
22 MS Contin pill, it's morphine. It isn't MG6
23 (verbatim) yet, right?
- 24 A That's right. After the liver, about 5 to 10
25 percent of it is morphine-6-glucuronide.

- 1 Q And just the next sentence of that. It says,
2 "Morphine clearance increases literally with
3 postnatal age during the first year of life."
4 A Now, you --
5 Q Is that -- that's still -- I'm sorry. Back to 603.
6 A Yes, sir. That's what it says.
7 Q All right. So during the first weeks -- during the
8 first six weeks of life, a neonate's just not going
9 to be able to clear as much morphine as an adult.
10 Is that a fair statement?
11 A That's correct. At six weeks the -- the
12 glucuronidation is coming online, but remember that
13 most of what the infant gets is morphine-3-
14 glucuronide, which is inactive 5 to 10 percent
15 morphine-6-glucuronide, and the balance is morphine
16 and another metabolite.
17 Q Well, this is just talking about the child's
18 ability to clear morphine in this sentence.
19 A Yes, sir.
20 Q And let me ask you this: You don't actually know
21 how much morphine Ms. Greene took when, do you?
22 A If I knew, I don't recall it.
23 Q Have you spoken with Ms. Greene?
24 A No, sir.
25 Q Has anyone communicated with you as to, you know,

- 1 "Ms. Greene says this"?
- 2 A No, sir.
- 3 Q Okay. Has anyone told you Ms. Greene was taking 30
4 milligrams a day, 90 milligrams a day, or anything
5 like that?
- 6 A No, sir.
- 7 Q Okay. And looking at the transcript, you're aware
8 that she was prescribed 30 milligram tablets of MS
9 Contin?
- 10 A I just don't recall, but --
- 11 Q Okay.
- 12 A -- if you want to show me the transcript, I'd be
13 happy to answer.
- 14 Q Certainly, but I believe -- and, certainly -- have
15 you ever heard the adage, "The dose makes the
16 poison"?
- 17 A Yes, sir.
- 18 Q And that means how much you're taking determines
19 how whether it has good effects or bad effects. Is
20 that fair to say?
- 21 A That's not -- the person who said that was a -- a
22 man named Paracelsus, and that is not what he
23 actually said.
- 24 Q And so all these calculations, they don't account
25 for whether Ms. Greene was taking 30 milligrams a

1 day or 90 milligrams a day or 180 milligrams a day?

2 A Are you talking about the calculations I did?

3 Q Yes.

4 A Yes, sir. It's just based on how much morphine was

5 found in L.G.'s blood.

6 Q Right. But it's not based on how much Ms. Greene

7 may have taken?

8 A Correct.

9 Q And you don't know -- well, let's hold off on that

10 for now.

11 I want to -- we're still on Page 603. And I

12 just wanted to turn to that first paragraph --

13 excuse me -- first full paragraph. And if you

14 could just read through that.

15 A To myself or out loud?

16 Q You can read that to yourself. I think that's the

17 best way.

18 A (Reviews document.) Yes, sir. I --

19 Q And so -- and this kind of goes along with what

20 you've been saying. Someone with impaired renal

21 function is more sensitive to morphine and may

22 experience prolonged respiratory depression?

23 A I'm sorry. Were you reading from the paper or --

24 Q Yeah. The first sentence.

25 A Yes, sir. That's paraphrasing what it says.

1 Q Okay. And you would agree somebody who has a renal
2 -- impaired renal function is going to be more
3 sensitive to morphine?

4 A An individual would be less able to excrete
5 morphine and its metabolites. I wouldn't call that
6 sensitivity. It's just that there will be higher
7 levels. So if you say "sensitivity," it's not
8 milligram for milligram that they're more
9 sensitive, it's just that there are more milligrams
10 in the individual who can't excrete it.

11 Q Right. So can they have -- that's why it would
12 potentially cause respiratory depression because it
13 builds up?

14 A Yes, sir.

15 Q And then we can skip ahead to two sentences to the
16 one that starts, "Patients with renal failure."

17 A Yes, sir.

18 Q And so, basically, what that sentence is saying
19 somebody with renal failure with high doses of
20 morphine will accumulate M6G and may present with
21 ox -- opioid ox -- how about this -- how about if I
22 just read that out loud to you. "Patients with
23 renal failure treated with high doses of morphine
24 will accumulate M6G and may present with opioid
25 intoxication several days after morphine

- 1 administration despite having immeasurable morphine
2 concentrations." So what this article is saying is
3 even if they have a low level of morphine, the M6G
4 will build up. Is that a fair statement?
- 5 A Yes, sir.
- 6 Q So even if we had a low morphine number, we could
7 have a whole lot more M6G involved; is that fair to
8 say?
- 9 A That could be.
- 10 Q And just kind of talk about renal failure, I mean,
11 that's not a new scientific concept, right?
- 12 A Renal failure?
- 13 Q Right.
- 14 A That's not new, no, sir.
- 15 Q And the risk of taking morphine with renal failure
16 that -- that's not a new concept, either, is it?
- 17 A That's correct. That's not a new concept.
- 18 Q And, as a doctor, that's one of the things you have
19 to be cognizant of if you're treating a patient?
- 20 A Yes, sir.
- 21 Q And the idea that neonates don't eliminate
22 morphine, as well as adults, that's not a new
23 scientific concept, either, is it?
- 24 A No, sir. They eliminate morphine more slowly.
- 25 Q And so if they're taking in more, but moving more

- 1 slowly, it can build up, right?
- 2 A Well, because it's the amount that -- let me start
- 3 over.
- 4 We give morphine postpartum to women all the
- 5 time, and those who are lactating have babies who
- 6 are experienced in seeing morphine and its
- 7 metabolites, so in spite of their renal clearance
- 8 mechanisms, they don't demonstrate toxicity as a
- 9 rule.
- 10 Q And you're talking about acute treatment?
- 11 A I'm talking about any treatment.
- 12 Q Well, what's the difference between acute and
- 13 chronic treatment?
- 14 A Acute and chronic are defined differently for
- 15 different purposes, but, in general, acute means
- 16 one time or a few times, and chronic means for some
- 17 extended period of time.
- 18 Q Right. And you usually, 'in a hospital setting,
- 19 we're talking about one or two or three days that
- 20 the mother's taking morphine?
- 21 A That's probably true.
- 22 Q All right. And those doses usually are
- 23 intravenous; is that fair to say?
- 24 A In my experience, "intramuscular" is more common,
- 25 but nowadays I think there's more oral morphine

1 being used even than intramuscular.

2 Q In a hospital setting, is there monitors that you
3 can put on a baby and make sure the -- make sure
4 there isn't any respiratory depression?

5 A You can, but I've never seen it done based on the
6 mother being treated with morphine.

7 Q When's the last time you treated with a
8 breastfeeding mother with the morphine in the
9 hospital setting?

10 A Hospital setting, probably, I would say, 2014
11 thereabouts.

12 MR. SPENCER: Beg the Court's indulgence.

13 Q Good news is we're done with that article.

14 The next article I wanted to talk to you about
15 was one of the ones I introduced. It's
16 "Contribution of morphine and morphine-6-
17 glucuronide to respiratory depression in child."
18 And I think that was -- that was -- should be
19 State's 2.

20 MR. WILLIAMS: (sotto voce.)

21 MR. SPENCER: (sotto voce.)

22 THE WITNESS: I don't have it in my
23 collection.

24 MR. WILLIAMS: Yeah.

25 THE WITNESS: Wait. No. That's not it.

1 MR. SPENCER: So let make sure I've got these
2 marked right. Yeah. This is it right here.
3 Say -- beg the Court's indulgence.

4 Let's see. I should make three copies of
5 these, so let me see what I did. (To Mr.
6 Williams) You don't have this one?

7 MR. WILLIAMS: Let me see. Oh, yeah. I think
8 we do have this somewhere.

9 MR. SPENCER: Oh, okay.

10 MR. WILLIAMS: I'm aware of them. That's
11 fine. We're good. Thank you.

12 MR. SPENCER: Okay. Great. Thank you. Give
13 me five seconds and I'll misplace something
14 every time. I misplace my glasses even.

15 **CROSS-EXAMINATION OF DR. SCIALLI CONTINUES**

16 BY MR. SPENCER:

17 Q All right. And you have State's 2 now, right?

18 A Yes, sir.

19 Q Thank you. I wanted to ask about -- there's a
20 sentence that straddles the first and second column
21 on the first Page 609.

22 A Yes, sir.

23 Q And here it indicates, "Modeling the effect on
24 morphine on respiratory rate may be improved by
25 including M6G effects."

- 1 A Yes, sir. That's what it says.
- 2 Q All right. And so that's -- because that M6G
- 3 has -- is active like the morphine, itself, so that
- 4 would be good to model those effects, too, right?
- 5 A Yes, sir, if you have the data.
- 6 Q And that's the problem, you don't have the M6G
- 7 levels?
- 8 A The State did not measure morphine-6-glucuronide.
- 9 Q Right. Now, some of your calculations were based
- 10 about the amount of morphine that might be in
- 11 breast milk, right?
- 12 A Yes, sir.
- 13 Q Okay. And so, when you were using those numbers,
- 14 you weren't using any numbers that pertain to how
- 15 much morphine actually was in Ms. Greene, right?
- 16 A I was using the concentration that was found in
- 17 L.G.
- 18 Q Well, you weren't -- you didn't -- you don't know
- 19 how much morphine was in Ms. Greene's breast milk,
- 20 right?
- 21 A That's correct. It wasn't measured.
- 22 Q And you don't how much M6G was in Ms. Greene's
- 23 breast milk, right?
- 24 A That's correct. It wasn't measured.
- 25 Q Okay. And as a matter of fact -- let me ask you

1 this: That could've -- how much morphine was in
2 her breast milk at any point in time during L.G.'s
3 life could've been measured at any time if the
4 doctor had wanted to test that number? Is that
5 fair enough? Is it fair --

6 A If -- if you --

7 Q -- fair assessment?

8 A If by "could" you mean physically, possible, yes.
9 That's -- but I don't know what was available in
10 the community where she was being treated.

11 Q But that sort of testing was out there? That's
12 available?

13 A At least for research purposes it is. I don't know
14 about a clinical test.

15 Q Now, you said you reviewed the transcript.

16 A Yes, sir.

17 Q Did you see anywhere in the transcript where it
18 indicated that there was breast milk available for
19 the coroners to test?

20 A I saw a report -- and I don't know if it was in the
21 report -- in the transcript, but there was a report
22 that two bottles of breast milk were found in the
23 refrigerator at the -- at the scene.

24 Q Are you sure it was breast milk or formula?

25 A I believe it was breast milk.

1 MR. SPENCER: Beg the Court's indulgence.

2 Q Okay. I'm gonna bring you a copy of the trial
3 transcript. If you could open up to 466. If you
4 could look at Lines 4 through 7 and read that to
5 yourself.

6 A (Reviews document.) Yes, sir.

7 Q So is it fair to say that the witness testifying
8 here was told that it was formula and not breast
9 milk?

10 A Yes, sir. That's what --

11 Q All right.

12 A -- the witness testified.

13 Q Now, has -- and you haven't spoken with Ms. Greene,
14 right?

15 A That's correct. I have not.

16 Q Okay. So you don't know whether or not Ms. Greene
17 had indicated that it was breast milk some point
18 later or whether or not that was actually formula
19 in the refrigerator?

20 A That's correct. I don't know.

21 Q All right. Do you have whatever report that
22 indicates that there was breast milk in the
23 refrigerator?

24 A I don't have it with me. I don't recall.

25 Q Do you know what that source was?

- 1 A I think it was law enforcement, but I simply don't
2 recall.
- 3 Q Do you know which agency?
- 4 A No, sir.
- 5 Q Do you know if it was in the coroner's report?
- 6 A I don't know.
- 7 Q Is it possible you just -- your memory is wrong on
8 that, and, in fact, nobody -- nobody was aware that
9 there might have been breast milk in the
10 refrigerator?
- 11 A Yes, sir. That's possible.
- 12 Q All right. So you might just be mistaken as far as
13 whether or not there were two bottles of breast
14 milk available?
- 15 A Yes, sir.
- 16 Q Thank you. If it was breast milk it would've been
17 a good idea for the coroner's deputies to go ahead
18 and take that breast milk, right?
- 19 A Yes, sir.
- 20 Q And they could've tested it, and we would know how
21 much morphine was in that breast milk, right?
- 22 A Yes, sir.
- 23 Q We would know whether it was more than 65
24 micrograms per liter, right?
- 25 A Yes, sir.

- 1 Q And we would've known whether it was less?
- 2 A Yes, sir.
- 3 Q And we wouldn't have had to put up these
- 4 calculations to say whether or not -- you -- we
- 5 wouldn't have to put up these calculations to try
- 6 and guesstimate how much morphine might've been in
- 7 Ms. Greene's milk?
- 8 A The figures that I used were the highest figures
- 9 I've seen reported in the literature. That was my
- 10 source.
- 11 Q How many women have been -- how many lactating
- 12 women that had been taking morphine have been
- 13 tested across all these studies?
- 14 A I don't know.
- 15 Q Would you say it's fair to say it's less than a
- 16 hundred, right?
- 17 A I don't know.
- 18 Q If there isn't -- in all these materials, have you
- 19 added up how many participants there are in these
- 20 studies that have had their breast milk tested
- 21 after they took morphine?
- 22 A And so the question was: Have I counted the number
- 23 of women?
- 24 Q Yes.
- 25 A I have not. My worst-case scenario was based on a

1 single woman, and so she's the -- perhaps not an
2 exemplar of what you would usually find, but she
3 seems to be a -- on the high end of what you can
4 achieve in milk with morphine.

5 Q Of those people who have been tested?

6 A Of those people who've been reported, yes, sir.

7 Q And would you agree with me that that's probably
8 less than a hundred women?

9 A It may be. I just don't know.

10 Q And it would certainly be good to have a larger
11 sample size, wouldn't it?

12 A I would still use the highest value that have been
13 reported, so this one woman at 500 would still form
14 the basis of my worst-case scenario.

15 Q What was the dose that that woman took to achieve
16 that level?

17 A I don't recall. I would have to look it up.

18 MR. SPENCER: Beg the Court's indulgence.

19 All right. And I still was on the
20 State's 2. I wanted to turn to Greene 611.

21 THE COURT: Sorry. Tell me again. Greene 2?

22 MR. SPENCER: State's Exhibit 2 --

23 THE COURT: Okay.

24 MR. SPENCER: -- and the Bates stamp, which
25 they did is -- thank goodness they did -- is

1 "Greene 611." And I don't know if that --

2 THE COURT: That's the -- the article --

3 MR. SPENCER: It says --

4 THE COURT: -- "Pharmacokinetics of morphine
5 and its metabolites in infants and young
6 children"?

7 MR. SPENCER: It's "Contribution of morphine
8 and morphine-6-glucuronide to respiratory
9 depression as a child." And that's the one I
10 don't know -- I took your copy of that, Your
11 Honor. That's State's 2.

12 THE COURT: Oh, State's 2.

13 **CROSS-EXAMINATION OF DR. SCIALLI CONTINUES**

14 BY MR. SPENCER:

15 Q And I wanted to have you look at the first
16 paragraph under "Discussion." And whenever you're
17 ready . . .

18 A (Reviews document.) Yes, sir. I've read it.

19 Q And particularly I'm focused on the sentence that
20 says -- and I'm going to read it out loud, "Peak
21 respiratory depression has been observed to occur
22 considerably later than expected from peaks and
23 morphine concentrations." And is it fair to say,
24 then, that respiratory depression can occur, you
25 know, much later than a peak level of -- of actual

- 1 morphine concentration?
- 2 A Yes, sir. Certainly, in this 12-year-old child it
3 seems to have done so.
- 4 Q And then I wanted to focus on the second paragraph
5 under "Discussion," which carries over to the next
6 column. And it's just the last sentence. But why
7 don't you read that whole paragraph to yourself, so
8 we don't get it out of context.
- 9 A (Reviews document.) Yes, sir.
- 10 Q And, in particular, what I was focused on they're
11 talking about morphine and M6G, and it says -- the
12 last sentence says, "The interaction for
13 respiratory depression is unknown."
- 14 A Yes, sir. That's what it says with respect to
15 morphine interacting with morphine-6-glucuronide.
- 16 Q And so it's fair to say in toxicology there's still
17 a lot we don't know?
- 18 A I think that's certainly fair to say.
- 19 Q And that's-- that's why doctors and pharmacists
20 are careful about what they prescribe; is that fair
21 to say?
- 22 A I'm not sure that fear of the unknown is
23 responsible. I think care and prescribing is one
24 of the things that we're taught.
- 25 Q The unknown has a lot to do with why I can't go

1 down to the drugstore and pick up morphine. That
2 has to be done under a doctor's care, right?

3 A I would disagree with that statement.

4 Q And how so?

5 A The reason that you can't go down to the drugstore
6 without a prescription and get morphine is that
7 morphine is a potentially dangerous drug even based
8 on what we know and what we're sure of.

9 Q It's not something I should just do my own research
10 on.

11 A If you can get the facilities and funding, I think
12 research is always good.

13 Q But me, personally, just a layperson, me
14 researching and deciding, okay. This is the drug
15 for me. The reason we have laws is so we're not
16 relying on what one layperson research, we're
17 relying on a doctor to make sure this is safe?

18 A I'm not sure I can comment on why we have laws.

19 Q As a doctor, you want to have all the information
20 from a patient to make a decision as to what to
21 prescribe; is that fair to say?

22 A That's always helpful.

23 Q So, for instance, if a patient of yours -- a female
24 patient of yours is breastfeeding, that's something
25 you would want to know before you'd make a decision

1 as to what to prescribe or not prescribe her?

2 A Well, if we're talking about patients of mine, and,
3 certainly, I would ask at the beginning of the
4 interview if she was breastfeeding or bottle-
5 feeding just as part of the routine history.

6 Q Certainly. Because it's true, some -- some drugs
7 pass through breast milk, right?

8 A Yes, sir.

9 MR. SPENCER: Beg the Court's indulgence. And
10 I believe this is State's Exhibit 1. This is
11 the U.S. Library Medicine article "Morphine"
12 and this subtitle "Drug Levels and Effects."

13 Q And do you have State's Exhibit 1 handy? And it
14 just so happens we have a duplicate copy. And if
15 you could open to the second page that's marked
16 "Greene 614."

17 A Yes, sir. I'm there.

18 Q And I'm just gonna go ahead and read this sentence
19 -- these first two sentences. "Morphine is
20 metabolized to inactive morphine-3-glucuronide 60
21 percent and to active morphine-6-glucuronide 10
22 percent. Morphine has an oral bioavailability of
23 about 30 percent in adults," and that actually is
24 what you were saying when you say about 30 to 40
25 percent is available when it's taken orally; is

1 that right?

2 A Yes, sir.

3 Q And then the next sentence, "Morphine-6-glucuronide
4 has an oral bioavailability of about 4 percent."

5 But then the next sentence, "but probably can be
6 converted back to morphine in the infant's gut and
7 absorbed as morphine." So basically --

8 MR. WILLIAMS: I want to -- objection, Your
9 Honor. Are we going to get to a question?

10 MR. SPENCER: Well, I was just reading it so
11 he can be looking at the same thing as me.

12 MR. WILLIAMS: Okay. Well --

13 MR. SPENCER: Plus, this is already in
14 evidence, so I'm just publishing something in
15 evidence.

16 THE COURT: All right.

17 MR. SPENCER: And, you know -- and I think the
18 reason they're objecting here is because that
19 M6G --

20 MR. WILLIAMS: That --

21 MR. SPENCER: -- is being converted back to
22 morphine. Is that a fair statement?

23 MR. WILLIAMS: Your Honor, that's not why
24 I'm --

25 THE COURT: All right.

1 MR. WILLIAMS: -- objecting. We're objecting
2 because Counsel's testifying --

3 THE COURT: All right. Let's not editorialize
4 and just -- let's move forward.

5 MR. SPENCER: Apologies, Your Honor.

6 THE COURT: All right.

7 **CROSS-EXAMINATION OF DR. SCIALLI CONTINUES**

8 Q So the M6G has an oral -- excuse me. Let me skip
9 ahead.

10 Let me ask that question. M6G, according to
11 this article, is converted to morphine in the gut?

12 A Yes, sir. It can be back converted to morphine --

13 Q Okay.

14 A -- in the intestine.

15 Q And, now, in those calculations that you have
16 there, you didn't calculate about any of the M6G
17 coming through breast milk being converted to
18 morphine in the gut, did you?

19 A No, sir. I just used the morphine concentration
20 that was found in L.G.'s blood, which would include
21 whatever morphine she got from milk and whatever
22 morphine was back --

23 Q Well, let me ask you this: Going back to the
24 Canadian article --

25 MR. WILLIAMS: Can he finish his answer, Your

1 Honor?

2 THE COURT: Yes.

3 Q Oh, I'm sorry. I didn't mean to cut you off. Go
4 ahead, please.

5 THE COURT: Yes, sir, Doctor. Go ahead and
6 finish your answer.

7 A -- whatever morphine was back and metabolized from
8 morphine-6-glucuronide.

9 Q Can you repeat that again. I'm sorry.

10 A Sure. My calculations were using the morphine
11 concentration in L.G.'s blood, which would have
12 included the morphine that she got from milk and
13 the morphine that was back-metabolized from
14 morphine-6-glucuronide.

15 Q Where's the number that comes from the morphine
16 that's metabolized from the M6G in L.G.?

17 A It's part of the total. So I looked at the total
18 morphine concentration, which is all that the State
19 provided.

20 Q So you're talking about the 0.52 milligrams per
21 liter number?

22 A Yes, sir.

23 Q All right. Now, then the other part of that was
24 you're trying to calculate how much morphine came
25 through Ms. Greene's breast milk, right?

1 A Yes, sir.

2 Q Hypothetically, based on -- on those articles?

3 A Yes, sir.

4 Q Okay. And your numbers didn't include how much M6G

5 was coming through the breast milk, did it?

6 A No, sir.

7 Q And you didn't account for the M6G that originated

8 from Ms. Greene that might've been converted to

9 morphine inside Baby L.G.?

10 MR. WILLIAMS: Your Honor, asked and answered.

11 MR. SPENCER: No. That's the first time I've

12 asked it.

13 THE COURT: All right. (To the witness) Go

14 ahead and answer the question.

15 A I used only the morphine concentration in -- in

16 L.G. because that's all that the State provided.

17 Q Now, did we provide how much morphine came through

18 the breast milk?

19 A No, sir. I believe that you --

20 Q You supplied that number, right?

21 MR. WILLIAMS: (To the State) Let him finish

22 his answer.

23 THE COURT: Sir, you --

24 THE COURT REPORTER: I'm sorry.

25 THE COURT: Let him answer the question.

- 1 Don't cut him off.
- 2 A I believe that you implied that the morphine in
- 3 L.G. came from morphine in the milk.
- 4 Q Morphine and M6G, right?
- 5 A I don't recall you having said that at the time of
- 6 trial.
- 7 Q Okay.
- 8 A And we don't even know how much back metabolism
- 9 there is. LactMed doesn't say. It says, "That it
- 10 probably can be converted."
- 11 Q Okay. Let's talk about what's happening today.
- 12 Your assessment today. You've assessed how much
- 13 morphine there might be in L.G.'s milk based on
- 14 these articles; is that correct?
- 15 A Well, I -- I would just amend your question in the
- 16 milk that L.G. drank; she wasn't producing any
- 17 milk.
- 18 Q All right. The milk that Ms. Greene was producing,
- 19 you tried to calculate what that number might've
- 20 been based on those articles?
- 21 A What I did was to introduce the highest
- 22 concentration in milk that I could find.
- 23 Q Right. But you don't know what her actual
- 24 concentration of morphine was, right?
- 25 A That's correct.

- 1 Q Okay. Thank you. And so, basically, what you did
2 is introduce the number based on the articles of
3 the morphine that might've come through her milk?
- 4 A Yes, sir.
- 5 Q All right. And that's -- that's where those milk
6 bottles come in in the presentation, right?
- 7 A Yes, sir.
- 8 Q And you're saying you've got to drink this much
9 milk to get this much morphine, right?
- 10 A Yes, sir.
- 11 Q But it doesn't have to be 60 jugs or whatever
12 you've got in there, because some of that M6G that
13 also come from her milk might've been converted to
14 morphine, right?
- 15 A That's possible.
- 16 Q And what you're saying today is there's no way
17 enough morphine could have come through the milk
18 after renal failure, right?
- 19 A Yes, sir.
- 20 Q And so you've got to get the highest number of --
21 you know, you were using the highest numbers
22 because you're trying to show it's not possible,
23 right?
- 24 A No, sir. Using the highest concentration of
25 morphine in milk is -- actually makes it more

1 difficult to show that it could not have occurred,
2 because I'm saying that there's up to 500
3 micrograms per liter when I think that's highly
4 unlikely, but that's an extreme value.

5 Q Right. And you're picking an extreme value, right?

6 A Yes, sir.

7 Q But you haven't used a number to say, "This much of
8 M6G came through her milk and was converted to
9 morphine in the baby's gut, right?

10 MR. WILLIAMS: Your Honor, again, asked and
11 answered.

12 MR. SPENCER: Your Honor, I still don't think
13 we've got a straight answer on this.

14 THE COURT: I'm -- I'm gonna let him -- I
15 think I understand, but I'm gonna let him
16 answer it one more time. I think I got it.

17 (To the witness) Go ahead, sir.

18 A Could I get the question one more time, please?

19 Q Sure. What I'm trying to ask is: You don't have
20 the number that accounts for the milk -- the
21 morphine -- excuse me -- that came through the
22 breast milk and was later converted from M6G to
23 morphine in the baby's gut?

24 A No. I don't, frankly, know the extent, if any, to
25 which that happens, and I don't have that number.

1 Q And we're talking about whether or not something is
2 possible, right?

3 A Well, to convert morphine-6-glucuronide back to
4 morphine is energetically unfavorable, and so I
5 would be surprised if it happens to any large
6 extent.

7 Q But we don't know to what extent that occurs do we?

8 A We don't know and LactMed doesn't know.

9 Q And that's the problem with taking dangerous drugs.
10 There's things that can happen that we don't expect
11 to happen?

12 A Well, I'm not sure I would agree with that. The
13 problem with taking dangerous drugs is that they
14 are dangerous for one reason or another.

15 Q Tell me about the studies where mothers have taken
16 MS Contin for several weeks and they study to see
17 how much morphine accumulated in a child that was
18 breastfeeding.

19 A I haven't found any studies that looked at that
20 question.

21 Q What studies are there out there that, for a period
22 of 24 days or longer, a woman took 90 milligrams of
23 MS Contin a day, and they tested to see what the
24 result was with the breastfeeding infant?

25 A I don't know of any.

1 Q So we don't know just how dangerous this MS --
2 excuse me -- this MS Contin is for a long chronic
3 use with a breastfeeding mother who's taking,
4 hopefully, only 90 milligrams a day, do we?

5 MR. WILLIAMS: Your Honor, can we -- on the
6 editorializing, can we both not editorialize
7 it?

8 MR. SPENCER: That's a fair question, Your
9 Honor.

10 THE COURT: (To the witness) Go ahead and
11 answer the question. I think it's a fair
12 question. Go ahead and answer it.

13 A I'm sorry. I'm gonna have to ask you to repeat it.

14 Q Sure. Absolutely. There have been no studies out
15 there, would you agree with me, where a woman took,
16 hopefully, only 90 milligrams of MS Contin a day
17 while breastfeeding? There's no studies to see how
18 much morphine ended up in the child? Is there any
19 studies like that?

20 A Not that I know of.

21 Q And so would you agree with me that would be a
22 pretty dangerous experiment to run, wouldn't it?

23 A No, sir. I wouldn't agree. First of all, that
24 would be an experiment. I think it could be done
25 as was done in -- in all of these publications

- 1 where women were given morphine and where their
2 milk concentrations were measured.
- 3 Q What was the average duration of -- first of all,
4 all those were -- tests were with morphine not MS
5 Contin specifically, right?
- 6 A Many of the studies don't specify, but they
7 would -- they may have been with -- with immediate-
8 release morphine.
- 9 Q How many of those studies was the mother taking 90
10 milligrams of morphine a day?
- 11 A I don't know, but recall (verbatim) that MS Contin
12 is not different from morphine. The kinetics are
13 different so that the concentration that the
14 patient gets in her blood is going to be lower and
15 more prolonged.
- 16 Q In the mother's blood?
- 17 A Yes, sir.
- 18 Q By the time it gets into the baby it's just plain
19 morphine, it's no longer-extended release?
- 20 A Yes, sir. That's correct.
- 21 Q Okay. Now, let's go back to that question: And
22 how many studies are you aware of where any form of
23 morphine the mother was taking 90 milligrams a day?
- 24 A I don't know of any.
- 25 Q How many studies are you aware of where duration of

1 testing with morphine was more than one week?

2 A I just don't recall. There may have been some.

3 Q And, in fact, most of those studies we're talking

4 about 24- to 48-hour periods; is that fair?

5 A I just don't recall.

6 Q Okay.

7 MR. SPENCER: Beg the Court's indulgence.

8 Q Well, actually, you've got the article right there.

9 If you could look it, State's 1, under -- the

10 heading under "Drug Levels." That gives you a

11 number of articles, doesn't it?

12 A Could you tell me the document I should look at?

13 Q Greene 614.

14 A And your question is: Whether this gives you the

15 number of articles?

16 Q Excuse me -- that was poorly -- that was misphrased

17 (phonetic). This summarizes a number of different

18 studies in this article, right?

19 A Yes, sir. It summarizes the articles that Phil

20 Anderson and his staff looked at.

21 Q Okay. And how many -- how -- take a guesstimate.

22 How many mothers are tested cumulatively across all

23 these studies that I discussed in this article?

24 A I -- I don't want to guess. I can read through it

25 and count them.

1 Q Sure. Go ahead. ;

2 A (Reviews document.)

3 THE COURT: Lawyers approach.

4 (WHEREUPON, a off-the-record bench

5 conference was held.)

6 (Off the record from 12:45 p.m. until

7 12:46 p.m.)

8 **CROSS-EXAMINATION OF DR. SCIALLI CONTINUES**

9 BY MR. SPENCER:

10 Q Well, you know, to be fair to you, because in this
11 instance I just threw that at you, would 67 total
12 be about a fair number to you?

13 A That's the number that I counted.

14 Q Great. Thank you.

15 MR. SPENCER: Your Honor, I understand you may
16 want to break for lunch now. We can do that
17 now.

18 THE COURT: Well, I'd like to get through with
19 the -- with the cross if possible.

20 MR. SPENCER: But, Your Honor, it's going to
21 last longer.

22 THE COURT: All right. Then we will take a
23 break at this time. We'll take a lunch break.

24 Doctor, you're still under oath to give
25 your testimony, so don't have any discussions

1 with anyone of the substance of your
2 testimony, but you may step down. We will get
3 back together at two o'clock.

4 (WHEREUPON, a lunch break was taken.)

5 (Off the record from 12:46 p.m.

6 until 1:59 p.m.)

7 THE BAILIFF: All rise, and come to order,
8 please. The Honorable Judge Mark Hayes
9 presiding.

10 THE COURT: You may be seated. Come on back
11 up, Doctor.

12 THE COURT: Is the State ready to continue
13 their cross?

14 MR. SPENCER: Yes, Your Honor.

15 THE COURT: Lawyers approach.

16 (WHEREUPON, an off-the-record bench

17 conference was held. Sotto voce.)

18 **CROSS-EXAMINATION OF DR. SCIALLI CONTINUES**

19 BY MR. SPENCER:

20 Q All right. Mr. Scialli, I just want to pick right
21 up on that same article, which was State's Exhibit
22 Number 1 and still on Page 614 and where it says,
23 "Maternal Levels" and it talks about five lactating
24 mothers. Do you see that paragraph?

25 A Yes, sir.

- 1 Q Okay. And they talk about the peak milk level
2 after parental morphine being 500 micrograms per
3 liter. Is that the article that you were
4 referencing for the 500-microgram number that you
5 used in your calculations?
- 6 A (Reviews document.) Yes, sir.
- 7 Q Okay. And do you know what the dose was that
8 produced that 500 microgram per liter number?
- 9 A The citation here was 5 to 15 milligrams morphine
10 every four to six hours.
- 11 Q Okay. And if you can read that sentence there,
12 where it says, "The peak milk level after
13 parenteral morphine"?
- 14 A Right.
- 15 Q And it gives the answer.
- 16 A Right. It says, "A single 15 milligram intravenous
17 -- excuse me -- 15 milligram dose, which was 10
18 milligrams intravenous and 5 milligrams
19 intramuscular."
- 20 Q Okay. So that was a 15-milligram dose in that
21 particular study -- or that particular woman?
- 22 A Yes, sir.
- 23 Q Okay. And the tablets in this case were 30
24 milligrams each, right?
- 25 A I don't recall, but I've heard you say that before.

- 1 Q But that would be double the dose here, right?
- 2 A No, sir. I think you may have the pharmacokinetics
- 3 wrong.
- 4 Q Your -- because it's intravenous in this case?
- 5 A Not only that, but when you take morphine by any
- 6 route on a long-standing basis, you reach a steady
- 7 state, and that is the blood concentration reaches
- 8 a particular level and then stays there. That's
- 9 called "steady state" --
- 10 Q Okay.
- 11 A -- which isn't necessarily twice the blood
- 12 concentration as giving half a dose acutely.
- 13 Q This is a peak milk level, right?
- 14 A It says, "The peak milk level" -- let me find it
- 15 again -- "occurred 30 minutes after the second
- 16 dose," yes, sir.
- 17 Q So, I mean, this is before a steady-state number
- 18 would be established, wouldn't it?
- 19 A Well, probably so. It really depends on how she's
- 20 been getting or how regularly she's getting the
- 21 morphine.
- 22 Q Okay. Now, tell me what the steady-state volume of
- 23 distribution is?
- 24 A Are you saying a volume of distribution? Is that
- 25 what you're --

- 1 Q A steady-state volume of distribution. Please --
- 2 A The volume --
- 3 Q -- define that.
- 4 A -- the volume of distribution is the amount of
- 5 liquid that the drug would be distributed in to
- 6 give you a given concentration.
- 7 Q Okay. Now, what's the difference between volume of
- 8 distribution and then volume of -- a steady-state
- 9 volume of distribution?
- 10 A I haven't heard the term "steady-state volume of
- 11 distribution," but all I can answer is that it's
- 12 likely the volume that a steady-state dose would be
- 13 distributed in.
- 14 MR. SPENCER: Beg the Court's indulgence.
- 15 Q Let's move on for a bit. And I want to turn to
- 16 615, now, and I'm looking at the second paragraph.
- 17 And that discusses the study with seven women?
- 18 A Yes, sir.
- 19 Q Okay. And what I want to focus on is there is a
- 20 sentence in there -- the first sentence I want to
- 21 focus on is, "There was a high intersubject
- 22 variability with peak milk levels occurring at
- 23 different times." And in the next sentence they
- 24 say, "The peak level of the -- the M6G was 1,084
- 25 micrograms per liter." Do you see that?

- 1 A Yes, sir.
- 2 Q And I understand, of course, the M6G wasn't tested,
3 but in this case, this is double your worst-case
4 scenario; is that fair, in terms of --
- 5 A No, sir.
- 6 Q -- the amount of M6G?
- 7 A No, sir. This is morphine-6-glucuronide. What I
8 gave you was the morphine concentration in milk.
- 9 Q Fair enough. But that was 500 micrograms that you
10 gave me, right?
- 11 A I gave you 500 micrograms per liter.
- 12 Q Of morphine?
- 13 A Yes, sir.
- 14 Q And this is 1,000 micrograms per liter of M6G?
- 15 A Yes, sir.
- 16 Q And then the next sentence I wanted to -- you know,
17 if you can go ahead and you can just read it to
18 yourself first and let me know when you're ready.
- 19 A (Reviews document.) Yes, sir. I'm ready.
- 20 Q Okay. Great. And so, in that sentence it gives
21 the comparative morphine and M6G levels that are
22 reported at different times. Is that a fair
23 statement?
- 24 A Yes, sir.
- 25 Q Okay. And for instance, the first number is "34

- 1 micrograms per liter" of morphine, right?
- 2 A Thirty-four micrograms per liter, yes, sir.
- 3 Q All right. And the corresponding number for
- 4 that -- for the M6G would be "273 micrograms per
- 5 liter." Is that fair to say?
- 6 A Yes, sir.
- 7 Q Okay. And is it fair to say, if you were just
- 8 to -- that's eight times more micrograms for the
- 9 M6G than the morphine?
- 10 A No, sir. I wouldn't say that, because you -- the
- 11 morphine-6-glucuronide has a heavier molecular
- 12 weight. So if you're just talking about how many
- 13 molecules of morphine or morphine-6-glucuronide,
- 14 you have to divide by the molecular weight of each
- 15 one.
- 16 Q But you'd agree that number's eight times more,
- 17 right?
- 18 A I can agree that 273 is more than 34. I'd -- I'd
- 19 have to get out my calculator to agree that it's
- 20 eight times.
- 21 Q How about the next one, "24 and 672"?
- 22 A What's the question with respect to 24 and 672?
- 23 Q That you -- well, let's do it this way: Do you
- 24 agree that the 672 is a lot more than the 24?
- 25 A I would agree the Number 672 is higher than the

- 1 Number 24, but, again, it's morphine-6-glucuronide
2 and morphine.
- 3 Q All right. So the next number -- the next two set
4 of numbers, "7 and 426." Do you see that?
- 5 A Yes, sir.
- 6 Q And just don't draw -- just going by raw numbers,
7 that's 60 times more, right?
- 8 A Well, sir, I can do the math if you'd like, but
9 we're talking about numbers, and I wouldn't agree.
10 That applies to morphine-6-glucuronide and
11 morphine.
- 12 Q What's the difference in molecular weight between
13 the morphine and the M6G?
- 14 A I'd have to add it up. I don't know as I sit here.
- 15 Q Okay. So you haven't prepared that for today?
- 16 A No, sir. That's really not relevant.
- 17 Q Well, I mean that's all -- that's a matter of
18 opinion, isn't it?
- 19 A It's not relevant to my testimony.
- 20 Q But we established that it's at least likely that
21 some M6G gets converted to morphine, right?
- 22 A Well, some of the morphine-6-glucuronide might be
23 metabolized in the gut to morphine. It's less than
24 5 percent, so I wouldn't offer --
- 25 Q Where would the 5 percent number come from?

- 1 A From the literature.
- 2 Q Do you have that literature here today?
- 3 A No, sir.
- 4 Q Okay. Because you didn't think it was relevant?
- 5 A No, sir. Because I looked it up at lunchtime.
- 6 Q Okay. But you don't have that literature here
- 7 today?
- 8 A I looked it up on my phone, I can try to find it
- 9 again if you'd like.
- 10 Q That's all right. We're here today.
- 11 MR. WILLIAMS: (To Mr. Spencer) Is there a
- 12 question?
- 13 MR. SPENCER: Nope.
- 14 Beg the Court's indulgence.
- 15 MR. WILLIAMS: And, Your Honor, just -- if he
- 16 could please let the witness finish his
- 17 answers, we would appreciate it. There were a
- 18 couple --
- 19 MR. SPENCER: Okay.
- 20 **CROSS-EXAMINATION OF DR. SCIALLI CONTINUES**
- 21 BY MR. SPENCER:
- 22 Q Was there something you didn't answer that I cut
- 23 you off on? I apologize if I did.
- 24 A I -- I don't frankly recall what it was.
- 25 MR. WILLIAMS: Yeah. It was a few back.

1 Q And just going forward, yeah, please tell me if you
2 want to finish your answer, because I'm definitely
3 not doing that on purpose.

4 I wanted to go on to the next article, and
5 that would be the, "Pharmacokinetics of Morphine
6 and Its Metabolites." I think that was put in
7 by -- it's Greene 619, I think that was put into
8 evidence by Ms. Greene's attorneys.

9 THE COURT: (To Mr. Spencer) Applicant's 2.

10 MR. SPENCER: Thank you, Your Honor.

11 Q And I'm looking at the last paragraph on 619, kind
12 of over in the second column.

13 A Yes, sir.

14 Q And this talks about the documented range -- large
15 interindividual variability of morphine
16 disposition. In fact, there is only a few
17 individual studies in this particular case dealing
18 with heart disease and morphine pharmacokinetics.
19 But is it fair to say, there's a large
20 interindividual variability of morphine disposition
21 amongst people?

22 A Dr. Elkomy and his colleagues are talking about
23 children with cardiovascular disease who have had
24 surgery for congenital heart surgery, so I would
25 say his remarks would be limited to that

- 1 population.
- 2 Q But that seems to be the problem he's addressing.
- 3 There is a large interindividual variability and it
- 4 hasn't been studied in the context of -- of studies
- 5 with children with having heart surgery. Isn't
- 6 that a fair statement?
- 7 A What he actually says is, "Despite the documented
- 8 large interindividual variability of morphine
- 9 disposition, only a few individual studies have
- 10 addressed the effect of heart disease on morphine
- 11 pharmacokinetics in the pediatric population."
- 12 Q In this particular study, how many people were
- 13 involved -- how many children were involved? And
- 14 the answer's on 620 under, "Material and Methods."
- 15 A Twenty children.
- 16 Q Twenty children. Now, was there also a simulation
- 17 done in this study? Do you recall that?
- 18 A I don't recall that. He has a section called
- 19 "Pharmacokinetic Model," and a model is usually a
- 20 simulation or a calculation.
- 21 Q Okay. And I'm looking at 622, and I could
- 22 certainly use your help at making sure I understand
- 23 I'm reading this right. But I'm looking at the
- 24 last full paragraph before, "Results."
- 25 A I'm sorry. I don't see any bullets on --

- 1 Q And it's --
- 2 A -- 622.
- 3 Q Oh, it wouldn't be a bullet. It -- it would be a
4 paragraph, but it's on 622, and I don't know -- it
5 -- it's in the second column. It's the last
6 paragraph before, "Results." And it says, "A total
7 of 100 subjects were simulated per group."
- 8 A Yes, sir.
- 9 Q Okay. So is it -- so, basically, there's 20
10 children that are tested and then there's a hundred
11 simulations. Is that a fair way to read it?
- 12 A Yes, sir. I think it's one simulation for a
13 hundred theoretical subjects.
- 14 Q So like five simulations per subject, or is it --
15 do you know how that works?
- 16 A No. That's not how it works.
- 17 Q Okay. Now, please explain how it works to us.
- 18 A The 20 children are used to create the mathematical
19 models, which are then run for a hundred subjects.
- 20 Q Okay. Thank you. And the next thing I'm still
21 looking at on Page 619; and this is actually in the
22 first paragraph, right under, "Introduction." And
23 it's the -- the sentence I'm looking at before
24 Footnote 7 -- or Citation Footnote 7.
- 25 A I'm sorry. Did you have a question?

- 1 Q Yeah. I'm just -- I just wanted to make sure you
2 found it first.
- 3 A Oh, yes, sir. I found it.
- 4 Q Okay. And so that -- that confirms morphine
5 clearance is reduced and its effect prolonged in
6 neonates. Would you agree with that?
- 7 A Compared to older children and adults, yes, sir.
- 8 Q And now I'm going to go skip ahead to 625. And I'm
9 looking in the "Discussion" section. I'm starting
10 on Column 2, and it's the second paragraph. And,
11 actually, you could read the second and third
12 paragraphs to yourself, and just let me know when
13 you're ready.
- 14 A (Reviews document.) Yes, sir. I've read it.
- 15 Q Okay. Thank you. And, again, that talks about the
16 large between-subject variability, and it says,
17 "The morphine -- the morphine disposition is
18 extremely variable, especially in children with
19 complex pathios (phonetic)" -- I don't know how to
20 say that one -- "pathophysiology." So, again,
21 they're talking about a lot of vitreo (phonetic)
22 personal variability, though, right?
- 23 A Yes, sir, in these children with cardiovascular
24 disease and heart surgery.
- 25 Q And in that last sentence -- I'm just going to read

1 it out loud. "The relatively high residual
2 variability of morphine and its metabolite
3 concentrations" -- it references Table 2 -- "has
4 been previously documented." So would you agree
5 this article is talking about previously documented
6 variability of morphine and its metabolite
7 concentrations?

8 A Well, it says "relatively high," so that begs the
9 question of relative to what?

10 Q Certainly, out of context, but it certainly
11 indicates some interpersonal variability, doesn't
12 it?

13 A Well, yes, sir. But I think we need to read
14 Reference 24 if we want to know what the nature of
15 that variability was and what the nature of the
16 population was.

17 Q And in the next -- the next sentence in the
18 following paragraph, "Morphine clearance ontogeny
19 in children involves matter -- maturation of the
20 glucuronidation enzymes within six months of
21 birth." So is that indicating that it -- it takes
22 roughly six months for morphine clearance to
23 mature?

24 A I don't know if it means that, but certainly by six
25 months, the infant liver has similar capacity for

- 1 metabolism of morphine as does the adult liver.
- 2 Q And -- by six months?
- 3 A Yes, sir.
- 4 Q And it, also, says that for the glucuronidation
- 5 enzymes within six months; is that fair?
- 6 A Let me -- let me see where you are. I'm not sure
- 7 if I can see that, but it is the glucuronidation
- 8 that's at issue with metabolizing morphine in
- 9 the -- in the liver.
- 10 Q Okay. I just want to turn to the next Page 626.
- 11 MR. SPENCER: And, Your Honor, if I can just
- 12 have a moment that I can just locate something
- 13 I kind of misplaced. Thank you, Your Honor.
- 14 Q I'm on Greene 626, which is the same article. And
- 15 I'm in the paragraph that carries over from the
- 16 first to the second column. That first sentence,
- 17 is that where you got your volume of distribution
- 18 number for your calculations?
- 19 A Yes, sir.
- 20 Q Okay. And that says it's the steady-state volume
- 21 of distribution, right?
- 22 A Yes, sir.
- 23 Q Okay. Now, is volume of distribution constant
- 24 within a person?
- 25 A Volume of distribution will depend on the weight,

1 so to the extent that weight is constant, volume of
2 distribution will be constant. There is
3 variability with age, however. Excuse me.

4 Q Okay. Well, let me ask you this: Because you said
5 there was -- in the number we were looking at
6 before, you -- you mentioned a peak value, right?
7 Is that peak value going to occur before there's
8 any elimination of substance?

9 A I'm sorry. Excuse me. I don't remember talking
10 about peak value. Could you refresh my memory?

11 Q I believe we were looking at --

12 A This is in another article; is that right?

13 Q I think it's actually in -- yes. It was the
14 previous article. And --

15 A Okay. Now, I know what you're talking about.

16 Q -- it was Greene 615.

17 A I thought you were talking about my calculations.
18 Go ahead. I'm sorry to interrupt.

19 Q Right. Right. I -- I did kind of jump a little
20 bit. But that's where I -- you know, I had asked
21 you about the peaking level, and that was the one
22 where it was 1000 micrograms of M6G per liter. And
23 I think in that it occurred half an hour
24 afterwards.

25 And so my question was: Is -- is that peak

- 1 level number, is that before there's any
2 elimination?
- 3 A Probably not, but it would depend on the chemical,
4 and so the distribution is generally measured --
5 the volume of distribution is generally measured at
6 steady-state.
- 7 Q And that number that you used, that 7.3 number,
8 that says it's a steady-state volume of
9 distribution, right?
- 10 A Yes, sir.
- 11 Q And so what is steady-state distribution, again?
- 12 A So, again, it's a term I don't use, because volume
13 of distribution is typically measured at steady-
14 state, but I don't know if they're distinguishing
15 it here from some other way of measuring volume of
16 distribution.
- 17 Q But when you calculate the volume of
18 distribution -- the steady-state volume of
19 distribution, that's to kind of calculate the
20 loading dose of the drug, isn't it?
- 21 A No, sir.
- 22 Q Well, what is -- what is it used for then?
- 23 A It's used for any scenario where you want to
24 indicate how the medication is dissolved in liquid
25 or in compartments that simulate liquid within the

- 1 body.
- 2 Q All right. And does part of that calculation
- 3 include the elimination rate?
- 4 A That calculation is only based on a measurement of
- 5 the concentration at steady-state. It depends on
- 6 the drug as to how much elimination has occurred.
- 7 So steady-state means that the amount being
- 8 absorbed and the amount being excreted are the
- 9 same, so the --
- 10 Q Okay.
- 11 A -- level doesn't change.
- 12 Q So that steady-state number, you're talking about
- 13 the amount absorbed and the amount excreted being
- 14 the same, sort of a pairing, right?
- 15 A Being offsetting, is what I meant.
- 16 Q Right. So that number contemplates elimination?
- 17 A And -- and it depends on the drug, how much
- 18 elimination there is at -- at the time of steady
- 19 state.
- 20 Q Now, the volume of distribution amongst different
- 21 individuals, that can have a variation, right?
- 22 A It will vary depending on weight, but the amount
- 23 per kilogram is relatively constant at the same
- 24 age. There will be some variability as there is in
- 25 all measurements in -- in biological systems.

- 1 Q Now, let me ask you this way: The -- that 7.3
2 number, did every single patient in this study have
3 that 7.3 number, or is some going to have more;
4 some going to have less?
- 5 A I would think some would have more and some would
6 have less.
- 7 Q Do you know what the lowest number was?
- 8 A No, sir. But their graphs suggest that these
9 numbers are all within two standard deviations of
10 the mean, which is typical for biological systems,
11 including human beings.
- 12 Q Which graph are you looking at?
- 13 A If you look at Figure 6, for example.
- 14 Q Okay. Are you looking at -- which ones are you
15 looking at then -- which --
- 16 A Well, all them --
- 17 Q -- set of panels?
- 18 A For all of them, the data points are largely within
19 two standard deviations.
- 20 Q And how much would be two standard deviations?
- 21 A It would depend on what you're measuring.
- 22 Q What percent would it be?
- 23 A So, typically, that's -- goes from about the 3rd to
24 the 97th percentile.
- 25 Q So 33 percent to 97 percent?

- 1 A No. Third percentile to 97th percentile.
- 2 Q So you're saying it would be like 97 percent, 103
- 3 or -- I'm -- I'm not following you.
- 4 A That means 97 percentile includes 97 percent of the
- 5 population.
- 6 Q Okay.
- 7 A The 3rd percentile includes 3 percent of the
- 8 population.
- 9 Q Okay. So you -- the 3 percent would be outside of
- 10 that range? Is that how --
- 11 A Somewhat, right.
- 12 Q Okay.
- 13 A Not quite 3 percent. It's actually -- I think it's
- 14 2.5 something percent.
- 15 Q 2.5 percent, but there would be somebody outside of
- 16 that range then.
- 17 A Yes, sir.
- 18 Q And do you know how far outside of that range?
- 19 A No, sir. But they -- they show the -- the data
- 20 points here for these calculations, and -- let's
- 21 see if I can read it. So it looks like up to three
- 22 standard deviations, which is about the 99th
- 23 percentile.
- 24 Q So what would be the volume of distribution for
- 25 that person that's outside?

- 1 A I don't know. I can read through the paper, again,
2 and see if they give that distribution, but as --
- 3 Q No.
- 4 A -- I sit here, I don't know.
- 5 Q Because the lower the volume of distribution then
6 would be the lower the amount of morphine that
7 would need to be in the system to get to that
8 number; is that fair?
- 9 A Yes, sir. If it's a low volume of distribution,
10 then less morphine will give you the same
11 concentration as a high volume of distribution.
- 12 Q Right. So, in this instance, your number was 7.3,
13 and that led to your conclusion that it would take,
14 I think, 12 milligrams per liter to get to the
15 level that we found in the baby. Is that fair to
16 say?
- 17 A It was -- it was, as I recall, 12 and a fraction
18 milligram; it's not milligram per liter. That's
19 the total dose.
- 20 Q It would be milligrams?
- 21 A Yes, sir.
- 22 Q Thank you. But if that volume of distribution was,
23 say, 25 percent lower, then it would only be 9-
24 point-something milligrams?
- 25 A If it were how many -- how much lower?

- 1 Q Twenty-five percent.
- 2 A If it were that much, that would surprise me, but
3 yes, 25 percent of 12 would be 3, so then it would
4 be 9 milligrams.
- 5 Q And I think what we were talking about before
6 lunch, what we're trying to figure out, is it
7 possible that there was this high level of
8 morphine, right?
- 9 A I wasn't trying to figure it out, but I think you
10 were challenging my conclusion that it is
11 impossible.
- 12 Q Right. Well, that your calculation was supposed to
13 show it was impossible, right?
- 14 A Yes, sir.
- 15 Q And that's why you chose that 500 micrograms per
16 liter number, right?
- 17 A Yes, sir.
- 18 Q In fairness to the State, right?
- 19 A I don't know if "fairness" is the right word to
20 use, but to -- to show the -- the range of possible
21 values under extreme circumstances.
- 22 Q And I guess that's what I'm asking for today. What
23 is the low number in that study where -- where we
24 have 7.3 liters per kilogram as the volume of
25 distribution? What is the lowest number?

- 1 A I don't know as I sit here, but I'd be happy to
2 read through this paper and see if they give it.
- 3 Q Whatever that number is, it's going to lower the
4 volume -- it's going to lower the amount of
5 morphine necessary to have been ingested to get to
6 that .52 number, though, right?
- 7 A Yeah. And if we use your 25 percent, it would
8 change the 6 gallons of milk a day to 4 gallons of
9 milk a day. And we doubt that it is that much of a
10 variation, but that's what a 25 percent difference
11 would do.
- 12 Q But today -- I mean, right now, you aren't prepared
13 to give me that answer.
- 14 A I'd be happy to sit here and read this if you have
15 the time.
- 16 Q Thank you. Okay. I want to look at Greene 625.
17 There's -- it's still the same article; it's a page
18 earlier than what we were just talking about. And
19 what I'm looking at would be four paragraphs down
20 in the "Discussion."
- 21 A Could you give me the page number, again, please?
- 22 Q Oh, certainly, 625.
- 23 A 625. Yes, sir. I'm there.
- 24 Q Okay. And you may read that fourth paragraph to
25 yourself when you can. Just let me know when

1 you're ready.

2 A (Reviews document.) Yes, sir. I've read it.

3 Q Okay. And what that article is saying, is in that

4 particular study, they overpredicted the morphine

5 clearance in neonates?

6 A Yes, sir.

7 Q Okay. And that's because there's only -- a part of

8 the reason they explained is probably because

9 there's only three -- excuse me -- three neonates

10 in the study?

11 A That was their explanation.

12 Q So this study, which we're relying on for the

13 volume of distribution, is the study that -- of 20

14 subjects, only three were neonates, right?

15 A Yes, sir.

16 Q Thank you.

17 A I should add that L.G. was not a neonate.

18 Q The baby? How would you define a neonate?

19 A Neonate is the first 30 days of life. Which --

20 Q Do you know how much morphine that Ms. Greene might

21 have been taking in the first 30 days of L.G.'s

22 life?

23 A No, sir.

24 Q Thank you. Okay. If you can go to Greene 627, and

25 I'm looking at the carryover paragraph, so if you

- 1 want to flip back, you can --- you can if you want
2 to, but I'm looking at the last sentence of that
3 carryover paragraph.
- 4 A Yes, sir.
- 5 Q And I'm just -- I'm just going to read it to you.
6 "Due to immaturity of the glucuronidation enzymes
7 in newborns, the influence of age on morphine
8 exposure as predicted by our model may not be valid
9 for this age group." And so that acknowledges the
10 immaturity of glucuronidation enzymes in newborns,
11 right?
- 12 A Yes, sir. And as they say in the preceding
13 sentence, "up to one month of age."
- 14 Q And this child lived for 46 days?
- 15 A The child was more than six weeks of age, and so
16 the glucuronidation enzymes had -- had come on by
17 the time this child passed away.
- 18 Q But you aren't aware as to how much morphine Ms.
19 Greene might have consumed while she was
20 breastfeeding the baby in the first 30 days of her
21 life, right?
- 22 A Correct. I only based my calculations on the
23 concentration in the baby after death at six plus
24 weeks of life.
- 25 Q And at six plus weeks of life, roughly two-thirds

1 of her life was -- she was a baby under 30 days
2 old, right?

3 A For 30 days out of 46.

4 Q Good news is I think I'm done with all of those
5 particular articles.

6 MR. SPENCER: Beg the Court's indulgence.
7 Your Honor, I have an article -- well, let me
8 do this. Let me . . .

9 Q If you could tell me what the name of that article
10 is?

11 A It's called "Opioids and the Immune System."

12 Q And what's the publication?

13 A *U.S. Pharmacist*.

14 MR. SPENCER: And, Your Honor, I would move
15 this exhibit, this is a online publication --
16 oh, just one more thing.

17 Q Could you tell me who the -- indicate who the
18 authors of this article are?

19 A Bean M. -- I'm sorry. Breanne, B-r-e-a-n-e,
20 Mefford, M-e-f-f-o-r-d.

21 THE COURT REPORTER: (To the witness) I'm
22 sorry, sir. Can you slow down? Can you start
23 over, again. B-r-e --

24 THE WITNESS: B-r-e-a-n-n-e, Mefford, M-e-f-f-
25 o-r-d, and Chris, C-h-r-i-s, Donaldson, D-o-n-

1 a-l-d-s-o-n.

2 THE COURT REPORTER: Thank you.

3 Q What organizations does it indicate those two
4 doctors are from?

5 A The Department of Pharmacy at University of
6 Kentucky Medical Center for Mr. Donaldson, and the
7 Department of Pharmacy, I presume at the same
8 medical center, for Ms. Mefford.

9 MR. SPENCER: Your Honor, I would move this
10 article into evidence.

11 MR. WILLIAMS: Your Honor -- (To Mr. Spencer)
12 was this on y'all's exhibit list?

13 MR. SPENCER: Yeah. I think this -- this one
14 should be Number 21.

15 MR. WILLIAMS: And is it a medical -- a
16 published article or just a website?

17 MR. SPENCER: It is a website article.

18 MR. WILLIAMS: Okay. Yeah. I mean, I -- we
19 object to -- to the extent there's not
20 sufficient foundation for it, and, I mean,
21 hearsay. It's just a website article,
22 but . . .

23 THE COURT: All right. I'm going to have to
24 sustain the objection unless you can lay a
25 better foundation for it being admitted into

1 evidence for a -- as a reliable medical
2 document.

3 MR. SPENCER: Certainly, Your Honor. (To the
4 witness) I'll take that back from you.

5 **CROSS-EXAMINATION OF DR. SCIALLI CONTINUES**

6 BY MR. SPENCER:

7 Q Are you aware of any articles that discuss how
8 morphine affects the immune system?

9 A No, sir.

10 Q Do you know how morphine might affect an immune
11 system?

12 A No, sir.

13 Q Is that something you have done any research on?

14 A No, sir.

15 Q Do you know the effect morphine might have on NK
16 cells?

17 A No, sir.

18 Q And what's the role of NK cells?

19 A NK cells are part of the cellular immune system.
20 They're what are called "natural killer cells."
21 That's what the NK stands for.

22 Q Have you -- something that affects the immune
23 system would -- negatively would potentially create
24 the likelihood of a virus or something like that,
25 wouldn't it?

- 1 A Perhaps.
- 2 Q But you aren't familiar, yourself, as to the
3 effects of morphine on the immune system?
- 4 A I am not.
- 5 Q I wanted to ask you about the synergistic effects
6 testimony you gave earlier. And, basically, your
7 problem with the testimony is there's no studies
8 showing the -- that there were synergistic effects
9 between the various drugs?
- 10 A Yes, sir.
- 11 Q Now, explain, again, what your definition of
12 synergistic is?
- 13 A Synergism in toxicology is where one or more
14 chemicals or medications given together has a
15 greater effect or different effect than would be
16 predicted by the sum of either one given alone.
- 17 Q An example would be, like, caffeine and aspirin?
- 18 A I don't know if caffeine and aspirin have
19 synergistic effects.
- 20 Q Uh-huh.
- 21 A I suspect if they have any interaction, it's
22 additive, but an example -- well, I can give you an
23 example if you'd like.
- 24 Q I would like that, thank you.
- 25 A So an example would be carbamazepine and

- 1 phenobarbital, where phenobarbital interferes with
2 the metabolism of carbamazepine, which is usually
3 how synergy works. So that when you give the two
4 together, the effect is like you have a higher
5 concentration of carbamazepine.
- 6 Q Okay. Now, let me ask you this about
7 acetaminophen. Now, an overdose of the
8 acetaminophen can be -- cause renal failure; is
9 that correct?
- 10 A An over -- say that, again. I just didn't hear it.
- 11 Q Can an overdose of acetaminophen cause renal
12 failure?
- 13 A Not to my knowledge, but I would ask Dr. Twombly.
- 14 Q Certainly. And so, if, for example, it did cause
15 renal failure, though, and that causes morphine to
16 accumulate, that would be an example of synergistic
17 effect?
- 18 A Not necessarily. It depends on how the -- the
19 prediction based on dose would work out. So that
20 when you're talking about a synergistic effect,
21 you're talking about an alteration in metabolism,
22 and, generally, not an alteration in excretion.
- 23 Q All right. Now, let me ask you this: What is an
24 additive effect?
- 25 A An additive effect is where you get a -- an

- 1 interaction that can be predicted by the individual
2 effects of each of the components.
- 3 Q Now, is the FDA a good source to find out if
4 there's any warnings about the possible effects of
5 multiple drug -- combinations of --
- 6 A It depends what you mean by the FDA. If you mean
7 the FDA-approved product labeling, that's a result
8 of negotiations between the sponsor and the agency.
9 And sometimes the wording in the -- in the labeling
10 is not optimum as far as conveying the science.
- 11 Q Concerning the website, is that a good place to
12 look and see if there's any warnings --
- 13 A I don't know --
- 14 Q -- in combination of medications?
- 15 A -- I don't know what you mean about the website,
16 but warnings typically appear in the approved
17 product labeling.
- 18 Q What's your understanding of -- well, broadly
19 speaking -- what the FDA does?
- 20 A Yes, sir. I know certainly with respect to drug
21 labeling.
- 22 Q And is it fair to say drug warnings?
- 23 A I beg your pardon?
- 24 Q And fair to say drug warnings, also.
- 25 A Drug warnings are product -- part of the drug

1 labeling.

2 Q Are you aware as to whether or not they have a
3 website?

4 A I know FDA has a website; I don't know the content
5 of the website.

6 MR. SPENCER: Your Honor, this wasn't on the
7 original exhibit list, but I did email this to
8 them, I believe, early in the week. This
9 is --

10 MR. WILLIAMS: That's right, I agree. Yeah.
11 You emailed it.

12 MR. SPENCER: Your Honor, I have a website
13 from this. This is something Your Honor could
14 take judicial notice of, which is the warning
15 that can be found; it's at the FDA website.
16 It's slash -- it's "ww fda.gov/drugs/drug
17 safety and availability" hyphens between each
18 of these numbers --

19 THE COURT REPORTER: I'm sorry. Can you say
20 that again, please?

21 MR. SPENCER: Okay. Let me start right over.
22 The website is www.fda.gov/drugs/drug safety
23 and availability. "FDA drug safety
24 communication, FDA warns about severe risks
25 and death when combining opioid, pain, or" and

1 it just ends right there, but it's out there
2 on the website and I have these articles. And
3 I would seek to admit them into evidence.

4 MR. WILLIAMS: Your Honor, we object under the
5 rules of evidence on the same issues as
6 before, foundation and the fact that it's a
7 web publication and judicial notice, and it's
8 your prerogative, obviously, but to the extent
9 it's offered in the rules of evidence, we
10 object on that basis.

11 THE COURT: All right. I am uncomfortable
12 accepting them into evidence without some kind
13 of foundation being laid other than that
14 there's a website out there.

15 MR. SPENCER: Certainly, Your Honor. Do you
16 know the way to -- I apologize, I didn't mean
17 to cut you off.

18 THE COURT: I mean, you know, we've got a
19 witness on the witness stand. You're cross-
20 examining the -- the witness. I mean, the
21 witness, he's already testified he doesn't
22 know about the website; he just knows it
23 exists. I don't feel that it's proper to then
24 admit evidence through a website that this
25 witness does not have any knowledge about

1 other than that it exists. You can try to get
2 it in through some other witness.

3 MR. SPENCER: I understand what you're saying,
4 Your Honor. And, Your Honor, I mean, this is
5 -- and, granted, we've been putting in
6 articles all day. Yeah. It is a website
7 article that could simply be cited as
8 authority in future briefing or whatever.

9 I mean, we're talking about the FDA
10 website, Your Honor. Certainly that's --
11 might be what I do, but it just seems we could
12 have a productive conversation about it, and
13 it seems, Your Honor, I would just argue --
14 postulate that it is admissible as something
15 you could take judicial notice of, which is
16 why I tried to read the -- the website into
17 the record.

18 THE COURT: He says I can take judicial notice
19 of a website that I've never been on, that I
20 don't know anything about, and this witness
21 has testified that he knows it exists, but
22 does not know much about it. Do you agree
23 with that?

24 MR. WILLIAMS: No, Your Honor. I mean, as I
25 said judicial notice is the Court's

1 prerogative, but if -- if you have no
2 familiarity with the website and you're not
3 sure of its reliability or who published it,
4 if it's an authorized government report, then
5 we object on that basis, and you take judicial
6 notice.

7 THE COURT: I mean, you're more than -- you're
8 more than -- you can proffer it for purposes
9 of this record, but I do not feel comfortable,
10 especially when it -- what you're reading to
11 me indicates that it is a substance matter
12 that deals with medicines --

13 MR. SPENCER: Certainly.

14 THE COURT: -- and I'm not a medically-trained
15 person to say that I should take judicial -- I
16 mean, I can take judicial notice of the
17 websites out there, but then for me to
18 actually go to the website and read something
19 that I can't rely on or have a witness explain
20 to me what the terminology is or what it
21 means. I'm uncomfortable making a decision in
22 this case based on anything that I would read
23 from that website.

24 MR. SPENCER: I understand, Your Honor. We
25 can just proceed, Your Honor.

1 THE COURT: Okay. Do you want to offer --
2 proffer that?
3 MR. SPENCER: I'm sorry?
4 THE COURT: Do you want to -- well, you --
5 you've stated the website's --
6 MR. SPENCER: Yeah. I proffer.
7 THE COURT: -- address. Okay.
8 MR. SPENCER: Well, that's -- you know, yeah.
9 What I can do is I can make it as -- I don't
10 know, in jury trial we would call it a
11 "Court's exhibit." I mean -- but just an
12 exhibit for the record.
13 THE COURT: Okay. You can do that, yeah.
14 MR. SPENCER: I guess, is that the way to mark
15 it, as Court's exhibit, I think, in this --
16 THE COURT: That's fine. Proffer as a Court's
17 exhibit.
18 THE COURT REPORTER: Okay. This will be
19 Court's Exhibit 1.
20 (WHEREUPON, the website article, it is
21 marked into evidence as Court's Exhibit
22 No. 1.)
23 THE COURT: Okay.
24 MR. SPENCER: Thank you, Your Honor. And
25 this --

1 THE COURT: You can just give it to her.

2 MR. SPENCER: I will do that. That's the --
3 certainly.

4 CROSS-EXAMINATION OF DR. SCIALLI CONTINUES

5 BY MR. SPENCER:

6 Q So, Your Honor -- excuse me -- Dr. Scialli, so of
7 your own knowledge, are you aware if there's any --
8 of whether or not there's any FDA warnings about
9 the risk of combining opioids and benzodiazepines?

10 A I know what's in the 2016 labeling.

11 Q Okay. Tell me about the -- what you know about the
12 2016 labeling?

13 A It says something about benzodiazepines should not
14 be given with opioids -- or opioids should not be
15 given with benzodiazepines. I believe that's
16 referring to an additive effect that they have on
17 sedation.

18 Q So in that particular case there's an additive
19 effect, and that's something they feel needs to be
20 warned about, right?

21 A I, frankly, don't know. I don't know if the FDA
22 feels that way or the sponsor feels that way or
23 there was some negotiation for that language, but
24 that's not with respect to respiratory depression;
25 that's sedation.

- 1 Q And so you've reviewed that August 2016 labeling?
- 2 A I -- I read that portion of the labeling.
- 3 Q Now, are opioids and benzodiazepines something that
- 4 both can depress the central nervous system?
- 5 A They both have activity in the central nervous
- 6 system, so morphine affects the new receptor, which
- 7 is a specific receptor in the central nervous
- 8 system. Benzodiazepines affect the GABA A
- 9 receptor, and both of those receptors can cause
- 10 sedation. When you stimulate both together, you
- 11 get an additive effect; that is an effect of one
- 12 plus an effect of the other.
- 13 Q And are you aware of whether or not benzodiazepines
- 14 such as Klonopin can cause respiratory depression
- 15 on their own?
- 16 A I don't know if they can cause respiratory
- 17 depression at some dose. I -- I think probably not
- 18 or not readily. Benzodiazepines were introduced to
- 19 replace barbiturates, which had a overdose
- 20 liability with death, and benzodiazepines were
- 21 introduced as a replacement, because they are much
- 22 safer in overdose.
- 23 Q But this article has -- I mean -- excuse me -- this
- 24 August 2016 warning is saying there is some dangers
- 25 combining opioids and benzodiazepines?

- 1 A If you're pointing to the document on your podium,
2 I think that's the -- the website excerpt, which --
3 with which I'm not familiar.
- 4 Q But in your understanding of the 2016, is there was
5 -- there's a warning about a danger using these two
6 kinds of drugs?
- 7 A If you're talking about the labeling, then yes.
8 I'm not sure if you're pointing to the labeling on
9 the podium.
- 10 Q Sure. I wasn't, but -- you know, but that's what I
11 was asking about, so I appreciate it. Now, are you
12 aware of any research that talks about the dangers
13 of both Klonopin and MS Contin being ingested by a
14 neonate?
- 15 A No, sir.
- 16 Q Okay. And in terms of these other drugs, are you
17 aware of any research about the effects of taking
18 any of those other drugs and morphine by neonates?
- 19 A No, sir. But, of course, all of these other drugs,
20 including the clonazepam were present at
21 therapeutic concentrations. So if you were
22 intentionally giving clonazepam to an infant to
23 treat a seizure disorder, this is the concentration
24 you would try to achieve.
- 25 Q Now, one of the drugs that was found was

- 1 essentially Benadryl, right?
- 2 A Benadryl is the brand-name for diphenhydramine.
- 3 Q Do you give Benadryl to children under, let's say,
- 4 two months old?
- 5 A I don't personally treat children under two months
- 6 old, so I -- I can't really answer that question.
- 7 Q Are you aware of whether or not that's an
- 8 appropriate medication to give a neonate?
- 9 A No, sir. I'm not aware.
- 10 Q Or a child under two months?
- 11 A Again, I'm not aware.
- 12 Q What are some of the side effects, though, of
- 13 Benadryl, potentially?
- 14 A The most common side effect is sedation, and then
- 15 there are anticholinergic side effects.
- 16 Anticholinergic is a -- a kind of effect on the
- 17 sympathetic nervous system, so a dry mouth would be
- 18 one example.
- 19 Q Is it something that could lead to CNS depression?
- 20 A To my knowledge, except for sedation,
- 21 diphenhydramine does not produce CNS depression.
- 22 Q Is that something you've researched?
- 23 A It's part of my general medical training, and to
- 24 the extent that I've recommended Benadryl, I'm
- 25 familiar with it.

1 Q Are you familiar with the term "opioid potentiation"
2 (phonetic)? Did I say that right?
3 A Say that term, again, please?
4 Q It's opioid potentiation.
5 A Potentiation, yes, sir.
6 Q Okay. Are you aware of whether -- first of all,
7 can you explain what that is?
8 A So potentiation would be making the opioid more
9 effective, generally, in pain relief.
10 Q Can that also refer to increasing the side -- the
11 risk -- increasing the side effects?
12 A But that's not the -- my understanding of how the
13 term is used.
14 Q Are you aware of whether or not Benadryl is a
15 opioid --
16 A I --
17 Q -- potentiator?
18 A -- I'm not. I've never used Benadryl as an opioid
19 potentiator, neither have I been taught that
20 Benadryl is useful as an opioid potentiator.
21 Q Are you aware of whether or not it can also
22 increase the side effects of opioids?
23 A The side effects, no, sir. The -- the extent of my
24 research for this case was to look for evidence
25 that there was synergistic effects of Benadryl and

- 1 -- and morphine.
- 2 Q So you didn't check and see if there was any of
- 3 these substances created a risk of opioid
- 4 potentiation in the sense of increasing side
- 5 effects?
- 6 A Well, potentiation, as I use the term, is
- 7 increasing the analgesic effect of morphine or
- 8 whatever opioid you're trying to potentiate.
- 9 Q But you didn't do any research to see if it also
- 10 would increase the side effects of opioids?
- 11 A Only with respect to synergism.
- 12 Q Which is different from the concept of --
- 13 A Whether there are --
- 14 Q -- what we were just talking about?
- 15 A -- whether there are additive effects on side
- 16 effects I didn't research. I haven't learned about
- 17 them in my -- in my training or my practice.
- 18 Q In terms of combining the effects of drugs --
- 19 knowing what the effect of combining drugs is
- 20 something that you should be aware of as a doctor;
- 21 is that correct?
- 22 A Yes, sir. I should be aware of it for sure.
- 23 Q And, you know, practicing doctors, too, right?
- 24 A I would hope so.
- 25 Q And, again, that's one of the reasons why it's

1 important for doctors to know all the medications a
2 patient is on; isn't it?

3 A It's a good idea for doctors to know all the
4 medications that a patient takes.

5 Q And it's a good idea of a patient -- that you are
6 treating a patient for them to let you know all the
7 medications they might be taking from other
8 doctors. Is that fair to say?

9 A That would be ideal.

10 MR. SPENCER: Beg the Court's indulgence.

11 Q Now, I want to just talk about the Canadian study a
12 little bit. And did you happen to see the
13 "MOTHERISK" article in which Dr. Koren and Dr.
14 Chitayat has responded to the -- I believe it was
15 the Zipursky article?

16 A I think I probably have, but perhaps you could show
17 it to me and refresh my recollection.

18 Q Absolutely. (Shows document.)

19 A Thank you.

20 Q Okay. Let me -- you know, take your time, and let
21 me know if that's something you've seen.

22 A (Reviews document.) I've looked at it.

23 Q Okay. Is that an article that you were familiar
24 with?

25 A I have seen this paper.

1 Q Okay. And that obviously deals with their
2 commentary on the Zipursky article you spoke about,
3 right?

4 A Yes, sir.

5 Q All right.

6 MR. SPENCER: And, Your Honor, with that I
7 would move the article into evidence.

8 MR. WILLIAMS: No objection.

9 THE COURT: Without objection. It would be
10 State's --

11 MR. SPENCER: Three?

12 THE COURT REPORTER: Yes. That's correct.

13 (WHEREUPON, the Motherisk article, it is
14 marked into evidence as State's Exhibit
15 No. 3.)

16 Q Okay. And, actually, what I did want to talk to
17 you about, though, was this Zipursky article,
18 itself. And in that article, they reported that
19 there was a higher codeine concentration in the
20 child's postmortem blood. Is that a fair
21 assessment? And if it helps, I found it on 571.

22 A (Reviews document.) And I'm sorry. I don't see
23 what you're saying. The codeine concentration?

24 Q It's on 571. This is the abstract. They list the
25 implausibility based on several factors, and I'm

1 looking at the third one.

2 A Okay. I see that. Thank you.

3 Q Okay. And is it a fair statement to say the reason

4 they were concerned about the codeine that they

5 found in the baby was -- because that might

6 indicate some of the morphine was from the baby

7 metabolizing the codeine to morphine?

8 A I -- I don't get that from this statement.

9 Q All right. Did you read that article over?

10 A Yes, sir.

11 Q Okay.

12 MR. SPENCER: I beg the Court's indulgence.

13 Q I mean, while I try and find what I'm looking

14 for -- it is true that, though -- that there is

15 such a thing as rapid metabolizers of codeine,

16 right?

17 A Yes, sir.

18 Q And codeine is metabolized to morphine and a

19 metabolite called, I think, "codeine 6."

20 A I don't remember the name of the other codeine

21 metabolite, but it is metabolized to morphine.

22 Q But it's a different -- the metabolite is a

23 different metabolite than the M6G?

24 A My understanding is that codeine is metabolized to

25 morphine.

- 1 Q And -- but there's more than one metabolite, right?
- 2 A There's -- so on Page 588 they have a figure
- 3 showing codeine being metabolized to morphine,
- 4 which is active and to codeine-6-glucuronide, which
- 5 is inactive (as spoken).
- 6 Q So codeine doesn't metabolize to M6G, does it?
- 7 A Not directly, no, sir.
- 8 Q Does codeine pass itself through breast milk?
- 9 A Does codeine -- I didn't hear the rest of the
- 10 question.
- 11 Q Does codeine pass through breast milk
- 12 unmetabolized?
- 13 A I -- I don't know the extent to which codeine gets
- 14 into milk without metabolism.
- 15 MR. SPENCER: Beg the Court's indulgence.
- 16 Q Do you know why there would be concern about the
- 17 high level of codeine in the baby in this article?
- 18 A As I recall, their concern was whether the baby in
- 19 this article had been treated directly with the
- 20 codeine containing pain medication.
- 21 Q And so in this case they were concerned about
- 22 whether codeine came from some other source?
- 23 A Well, from the tablets, but rather than being
- 24 transmitted through milk being given directly to
- 25 the baby.

1 Q I just want to turn to the testimony that you
2 referenced at the trial. Let me bring you up a
3 page of the transcripts. The first page I want you
4 to open to would be 148. And this is where they
5 reference synergistic effects for the first time.

6 What did the witness say what -- about whether
7 or not the drugs could have a synergistic effect on
8 each other?

9 A Well, I'm not sure there's a direct statement by
10 the witness, but rather the witness is substituting
11 synergistic for a term that was supplied by
12 counsel. It says, "All of these drugs together, do
13 they have a century, dash, I call it one plus one
14 equals three?"

15 And the witness responds, "Synergistic."

16 Q All right.

17 A And then subsequently when asked if they could have
18 an effect on each other, the witness said, "They
19 could. They could."

20 Q So he's not saying they definitely do, right?

21 A I -- I don't know that he was doing anything but
22 supplying a word for what he felt was being
23 described by counsel.

24 Q All right. And then referencing Page 216.

25 MR. WILLIAMS: I believe, Your Honor, the

1 transcript speaks for itself. Dr. Scialli
2 didn't testify at trial. Those references
3 were for Your Honor to know what his testimony
4 -- the issue it was tied to.

5 THE COURT: Okay. The transcript does speak
6 for itself, so if you have any questions for
7 this witness, go ahead.

8 MR. SPENCER: Certainly. Certainly.

9 CROSS-EXAMINATION OF DR. SCIALLI CONTINUES

10 BY MR. SPENCER:

11 Q And you said you reviewed the transcript?

12 A Yes, sir.

13 Q Is there anywhere in that transcript that they say,
14 "This drug acted synergistically with that drug to
15 a degree of medical certainty"?

16 A I don't recall.

17 Q Concerning the toxicology results, what was the
18 number that stood out as the most problematic in
19 your mind?

20 A I'm not sure what you mean by "problematic."

21 Q What --

22 A All of the drug concentrations were within the
23 therapeutic range, except for morphine, which was
24 higher than I would expect could be delivered by
25 milk through lactation -- excuse me -- without

- 1 renal excretion being blocked or --
- 2 Q Does --
- 3 A -- being absent.
- 4 Q Finish your answer, please.
- 5 A I just added "or being absent."
- 6 Q That's the number that's in the lethal range,
- 7 right?
- 8 A That's the number that?
- 9 Q Is in the lethal range?
- 10 A Yes, sir. That's listed on this report as in the
- 11 lethal range. .
- 12 Q Okay. So I want to circle back to what your
- 13 conclusion was. And your conclusion is that the
- 14 reason that morphine level was so high was because
- 15 there was renal failure.
- 16 A Yes, sir. I believe that renal failure is almost
- 17 certainly the reason why the morphine was elevated.
- 18 Q And that morphine level was high enough to cause
- 19 respiratory depression?
- 20 A I think it could have been.
- 21 Q And so, basically, if there's renal failure, it is
- 22 possible for enough morphine to buildup to kill a
- 23 child?
- 24 A Yes, sir. It is possible.
- 25 Q And that's something you can say to a reasonable

1 degree of medical certainty?

2 A Yes, sir. Although, I can't exclude that the renal
3 failure would have caused death of the child absent
4 the morphine exposure.

5 Q But you don't have a separate cause of death
6 from -- from renal failure?

7 A I can't state to a reasonable degree of medical
8 certainty that renal failure would have caused this
9 child's death, although, I certainly think it might
10 have.

11 Q Do you realize that near the course of the trial
12 and appeal -- let me circle back.

13 Have you ever read the Supreme Court's opinion
14 on this case?

15 A No, sir.

16 Q Okay. So you wouldn't be aware of Justice Few's
17 dissent in that case?

18 A No, sir. I'm not aware of that case at all.

19 Q Do you realize you're the first expert to say to a
20 degree of reasonable medical certainty, in fact,
21 enough morphine could accumulate in that child to
22 cause that morphine level?

23 A I'm not aware of that, but I'll accept your
24 representation.

25 MR. SPENCER: (To the witness) Thank you. I

1 have no further questions.

2 THE COURT: (To Mr. Williams) Any redirect?

3 MR. WILLIAMS: Briefly.

4 REDIRECT EXAMINATION OF DR. SCIALLI

5 BY MR. WILLIAMS:

6 Q Dr. Scialli, did anything you discussed today with
7 the State change your opinions?

8 A No, sir.

9 Q Does it change your opinion about whether the
10 morphine level was transmitted to L.G. through
11 breast milk?

12 A No, sir.

13 Q In your opinion, what caused the morphine to build
14 up to that level?

15 A It was almost certainly renal failure.

16 Q Can it be explained by a genetic defect?

17 A I didn't hear the end of the question.

18 Q Can it be explained by a genetic defect?

19 A No, sir.

20 Q Is there any support for the applicability of
21 synergy in this case?

22 A No, sir.

23 Q The warning labels, have you ever prescribed
24 medications to pregnant or breastfeeding women,
25 despite a warning label regarding taking the drug

- 1 while breastfeeding?
- 2 A Yes, sir.
- 3 Q Does the fact that a drug could have some potential
4 for being harmful mean it should never be
5 prescribed?
- 6 A No, sir.
- 7 Q The State asked you about a lot of numbers and
8 measurements that could have been done. Why don't
9 you have those before you?
- 10 A I -- I don't have the morphine-6-glucuronide
11 levels, because the State didn't measure them.
- 12 Q Could the State have measured those?
- 13 A Yes, sir.
- 14 Q Could they have tested Ms. Greene's breast milk?
- 15 A Yes, sir.
- 16 Q And are you aware of how the State presented its
17 argument at trial with regard to the morphine?
- 18 A You have to be more specific.
- 19 Q All right. At -- well, I think I'll rephrase this.
20 Did the State advance any argument about the
21 impact of the morphine-6-glucuronide with regard to
22 what caused L.G.'s death?
- 23 A No, sir.
- 24 Q Okay. All right. Was it just the morphine level
25 itself?

- 1 A It was just the morphine.
- 2 Q Okay. Is there anything you discussed with the
3 State regarding the MG3 and MG6 glucuronides change
4 your opinion?
- 5 A No, sir. Again, the -- the theoretical or possible
6 active metabolism in the infant's gut would account
7 for, at most, 5 percent. So perhaps I would
8 decrease my estimates from 6.6 gallons a day to 6.2
9 gallons a day.
- 10 Q And for the 51.5?
- 11 A Right. I didn't do that mathematics, but it
12 wouldn't reduce it much lower.
- 13 Q By 5 or 10 percent?
- 14 A By 5 percent, yes, sir.
- 15 Q Okay. And you were asked a lot about the data
16 points that you used in the developing of your
17 calculation. Did you already account for the
18 worst-case scenario you found in the context?
- 19 A Yes, sir. I purposely used that single high value
20 that I found in the literature, although it wasn't,
21 in fact, the way that Ms. Greene was taking the --
22 the morphine.
- 23 Q That was my next question. So that was a different
24 context?
- 25 A Yes, sir. That was intravenous and intramuscular.

- 1 Q And would intravenous have a higher effect, I
2 guess, as it's processed?
- 3 A You -- you would get a higher concentration,
4 because there's no first pass effect in the liver.
- 5 Q Okay. And the calculation we walked through, was
6 that just an illustration of your opinion?
- 7 A Yes, sir. That's -- that gives some flesh to my
8 opinion.
- 9 Q But your opinion, was it based on your expertise,
10 knowledge, and review of the medical literature?
- 11 A Yes, sir.
- 12 Q So your opinion that you offer today is not
13 dependent solely on the calculation that you
14 provided?
- 15 A It's not, but I still think the calculation is
16 informative.
- 17 Q And would you describe the 65 amount as a generous
18 amount already?
- 19 A Yes, sir. That was an amount from the first two
20 days of life, and after that it's generally cited
21 as 20 to 40 micrograms per liter, not 65.
- 22 Q Does it mean that it would require an even higher
23 milk consumption to reach the level that was found
24 in L.G.?
- 25 A Yes, sir.

- 1 Q Why wouldn't you use the 1000 number of the MG6
2 glucuronide that the State referenced in doing your
3 calculation?
- 4 A I didn't have any morphine-6-glucuronide data. The
5 State only provided the concentration of morphine.
- 6 Q And is the comparison of morphine to morphine-6-
7 glucuronide an apples-to-apples comparison in terms
8 of molecular weight?
- 9 A No, sir. Morphine-6-glucuronide is heavier.
- 10 Q Okay. And can you describe for the Court what
11 exactly you mean by that?
- 12 A If morphine is glucuronidated by attaching a
13 glucose-like acid to either the 3 or the 6
14 position, then that attachment has additional
15 weight over and above the weight of the morphine
16 itself.
- 17 Q And would that explain the higher number that you
18 see on the MG6?
- 19 A It would explain some of it. I would have to
20 calculate what the molecular weight comparison is.
- 21 Q Okay. And the morphine and its effects on viral
22 susceptibility issue that the State asked you
23 about, does that change your opinion that you gave
24 today?
- 25 A No, sir.

- 1 Q Okay. Can you explain why?
- 2 A The possibility of infection with a virus or
3 otherwise, and the possibility of interference with
4 the immune system is not relevant to my opinion
5 about whether enough morphine could have
6 accumulated in this child without renal failure.
- 7 Q Can you explain the difference and the importance
8 of sedation as opposed to respiratory depression?
- 9 A Sedation is sleepiness, and so if you're going to
10 breastfeed while you're taking Benadryl, for
11 example, we advise women to look for signs of
12 excessive sleepiness in the baby.
- 13 Q Did the potential additive effect of morphine and
14 benzodiazepines that you discussed involve sedation
15 or respiratory depression?
- 16 A It involves sedation.
- 17 Q And to clarify, that was not a synergistic
18 effect --
- 19 A Correct.
- 20 Q -- that you were referencing? Okay.
- 21 And, finally, did Dr. Koren's response to the
22 Zipursky study change your opinion about anything?
- 23 A No, sir.
- 24 Q And can you clarify why if you're able?
- 25 A Dr. Koren is somewhat typical for his responses.

1 He thinks a good defense is an offense, and so he
2 has some not very polite remarks about his critics.
3 He doesn't really provide substantive information
4 showing that Zipursky and Juurlink were mistaken in
5 their criticisms.

6 Q So Dr. Koren's response didn't dispute any of the
7 calculations that were performed. Is that what
8 you're saying?

9 A That's correct. They -- they -- and they have --
10 excuse me -- nothing to do with the calculations I
11 performed.

12 Q Okay.

13 MR. WILLIAMS: Beg the Court's indulgence.

14 THE COURT: That's it?

15 MR. WILLIAMS: One second. (To the Court)

16 All right. No further questions.

17 THE COURT: Thank you, sir. You may step
18 down. Lawyers approach a moment. (To the
19 witness) Watch your step.

20 (WHEREUPON, the witness was excused.)

21 (WHEREUPON, an off-the-record bench
22 conference was held. Sotto voce.)

23 THE COURT: All right. We're going to step
24 down for five minutes. We'll come right back.

25 (Off the record from 3:33 p.m. until

1 3:41 p.m.)

2 THE BAILIFF: You may be seated.

3 THE COURT: Is the applicant ready to call
4 their next witness?

5 MR. WESTBROOK: Yes, Your Honor.

6 THE COURT: Yes, sir.

7 MR. WESTBROOK: The Applicant would call as
8 its next witness, Dr. Katherine Twombley.

9 THE COURT: Just come right up here, and there
10 is a Bible on the ledge. Place your left hand
11 on the Bible, and raise your right hand.

12 (WHEREUPON, the witness was sworn.)

13 THE COURT: Just watch your step as you're
14 stepping up and have a seat in the chair and
15 move the chair up to the microphone.

16 MR. WESTBROOK: May it please the Court. I'm
17 Dan Westbrook. I'm here on behalf of the
18 applicant, and I'd like to start.

19 **VOIR DIRE EXAMINATION OF DR. TWOMBLEY**

20 BY MR. WESTBROOK:

21 Q Dr. Twombley, would you please introduce yourself
22 to the Court.

23 A My name is Katherine Twombley.

24 Q And, Dr. Twombley, what do you do for a living?

25 A I am a pediatric nephrologist.

- 1 Q And where do you work? Who is your employer?
- 2 A Medical University of South Carolina.
- 3 Q All right. Now, I'm going to refer to that as
- 4 MUSC, if that's okay?
- 5 A Yes.
- 6 Q So where do you live, Dr. Twombley?
- 7 A In Mount Pleasant, South Carolina.
- 8 Q I'm sorry. Say that, again.
- 9 A In Mount Pleasant, South Carolina.
- 10 Q All right. And that's right outside of Charleston,
- 11 right?
- 12 A Yes.
- 13 Q All right. Dr. Twombley, let me hand you up
- 14 something -- or, actually, I'm going to let you
- 15 look at the screen, if that's all right.
- 16 MR. WESTBROOK: If Mr. Buck, our able
- 17 assistant over there, will put something up on
- 18 the screen. I'm going to hand this out. (To
- 19 the State) Here you go. (To the Court) And
- 20 this, Your Honor.
- 21 And I would ask that this be
- 22 identified -- as it already is identified, but
- 23 made as Applicant's Exhibit 9, please.
- 24 THE COURT: Without objection?
- 25 MR. SPENCER: I have no objection, Your Honor.

1 THE COURT: Without objections.

2 (WHEREUPON, Dr. Katherine Twombly's CV,
3 it is marked for identification as
4 Applicant's Exhibit No. 9.)

5 Q All right. Dr. Twombly, can you identify what
6 Applicant's Exhibit 9 is? Can you see the
7 beginning of it right there? What is this?

8 A Yes. This is my curriculum vitae, or my CV.

9 Q All right. Your CV. Is this CV accurate,
10 reasonably up-to-date?

11 A Yes.

12 Q All right. And did you oversee the creation of
13 this document?

14 A I made it, yes.

15 Q All right. So let's -- we're not going to go
16 through this entire thing, it's pretty long, but
17 just a -- a few things I want to ask you about.
18 And we'll ask Mr. Buck to put it on the screen for
19 those who can see it, the points we're talking
20 about -- the places we're talking about.

21 So undergraduate school, where did you go,
22 please?

23 A I went to the College of Charleston.

24 Q All right. And when did you graduate from the
25 College --