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How to Litigate a Medical Malpractice Case – Part 2: Expert Selection

Materials By:
Andrew J. Smiley, Esq.

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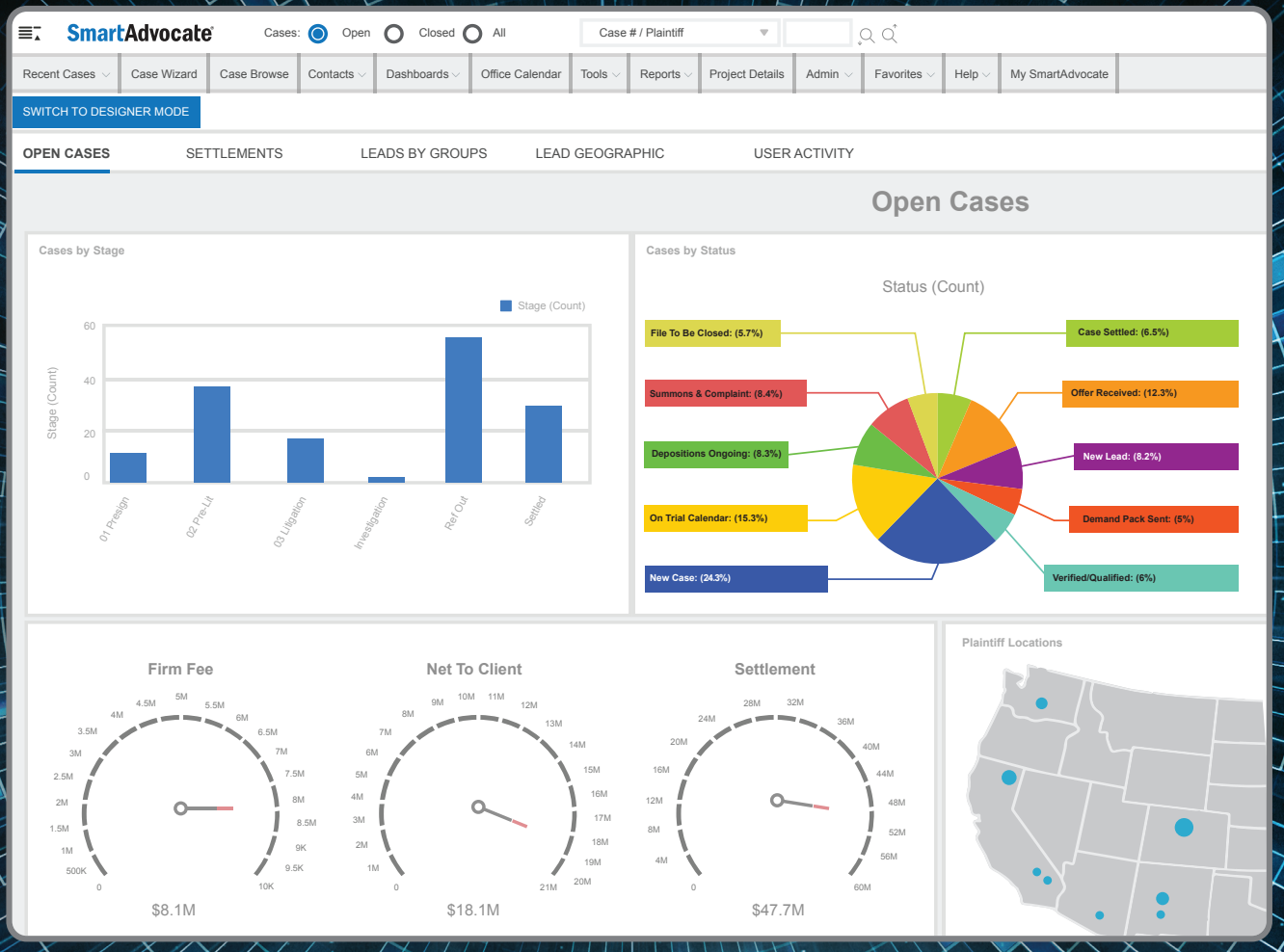

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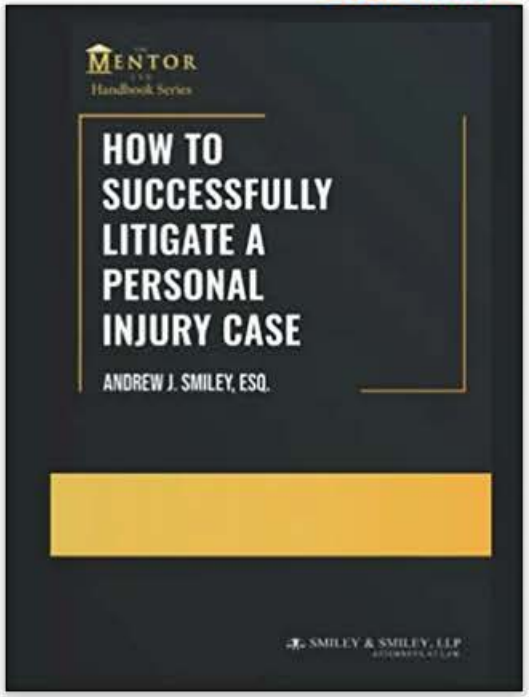


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How to Successfully Litigate a Personal Injury Case: A Practical Guide Hardcover – December 14, 2022

by Andrew J. Smiley Esq. (Author)

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Part of: The Mentor Esq. Handbook Series (1 books)

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Andrew J. Smiley, Esq is a leader in the field of personal injury law. He is a Past President of The New York State Academy of Trial Lawyers, Past President of The New York City Trial Lawyers Alliance, Master Continuing Legal Education (CLE) instructor, Lecturer, Trial Team Coach and Mentor. His podcast, *The Mentor Esq,* is listened to around the world.

In his debut book, *How to Successfully Litigate a Personal Injury Case - A Practical Guide*, Andrew shares how he has successfully litigated personal injury cases for the last few decades. This practical book is designed to break down to a granular level a plaintiff's personal injury case from start to finish. The chapters in this book outline each step in the litigation process from getting the client through settlement and trial.

If you are an attorney who wants to successfully litigate a personal injury case and obtain the best results for your clients, this step-by-step book is for you!

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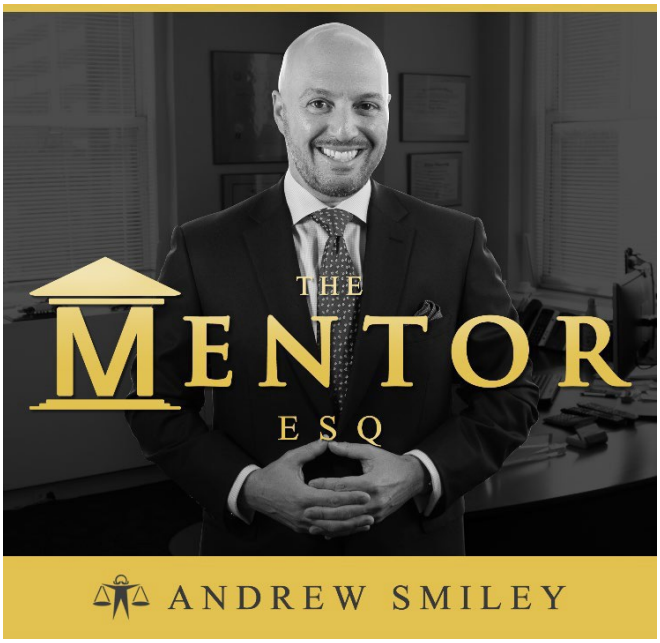

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CURRICULUM VITAE

Education:

·Brooklyn Law School - Juris Doctorate 1996

Moot Court Honor Society - Vice President/Executive Board (Chair of Trial Division)
Moot Court Honor Society - Competitor - National Appellate Trademark Competition
Moot Court Honor Society – Coach, National Trial Team – Regional Champions
CALI Excellence For The Future Award - Advanced Legal Research
Judge Edward and Doris A. Thompson Award for Excellence in Trial Advocacy

·Tulane University, New Orleans, LA - Bachelor of Arts (Honors, Psychology) 1993

Professional:

· *Smiley & Smiley, LLP*

Managing Partner & Senior Trial Attorney, January 2001 - present
Associate, June 1996 - December 2000
Law Clerk, September 1993 - June 1996
Major verdicts and settlements in plaintiffs' personal injury, medical malpractice and wrongful death litigation

· *Adjunct Clinical Instructor of Law - Brooklyn Law School*, Trial Advocacy Program (1998-2004)

· *The Mentor Esq. Podcast – A Podcast for Lawyers*

- Founder & Host (2019 – Present)

· *New York "Super Lawyer"*
2010, 2011,2012, 2013, 2014, 2015, 2016, 2017, 2018, 2019, 2020, 2021, 2022

·Bar Admissions:
- The United States Supreme Court
- New York State Courts
- United States Eastern District, Southern District & Northern District of New York
- United State District Court of Vermont

Organizations/Affiliations:

·New York State Academy of Trial Lawyers
-Immediate Past President (May 2018- May 2019)
-President (May 2017 – May 2018)
-President-Elect – (April 2016- May 2017)
-Vice President – 1st Dept. (July 2013-May 2016)
-Executive Committee (May 2019 – present)
- Board of Directors (2013- present)
- Judicial Screening Committee (2013- present)
- Master CLE Instructor (2020 – present)
- CLE Instructor (2013 – present)

· New York City Trial Lawyers Alliance
-Chairman of Board of Governors (July 2017 – July 2019)
-President (July 2015 – July 2017)
-Vice President (June 2013 – July 2015)
-Treasurer (June 2011 – June 2013)
-Secretary (June 2009- June 2011)
-Board of Directors (2000-present)

- Judicial Screening Committee, Kings County Democratic Party (2013)
- New York State Bar Association
- Brooklyn Bar Association
  Medical Malpractice Committee
  Supreme Courts Committee
- American Bar Association
- The American Association for Justice

- Brooklyn Law School Alumni Association
- National Order of Barristers
- Porsche Club of America (Connecticut Valley Region)
- Porsche Sim Racing League
- Sports Car Driving Association (SCDA)
- Just Hands Racing Foundation – Board of Directors

Publications

Smiley, Andrew J. *How to Successfully Litigate a Personal Injury Case – A Practical Guide* (2022, The Mentor Esq. Handbook Series – Available on Amazon)

Continuing Legal Education (CLE) Presentations:

(58) *How to Litigate a Construction Accident Case – Part 4:* Motion Practice, New York State Academy of Trial Lawyers, December 7, 2022

(57) *Preparing for Depositions: Best Practices for Asking and Answering Questions,* Office of The NYS Attorney General, Legislature, 2022 Legislature Program, December 6, 2022

(56) *How to Litigate a Construction Accident Case – Part 3: Depositions*, New York State Academy of Trial Lawyers, November 2, 2022

(55) *How to Litigate a Construction Accident Case – Part 2: Commencing The Action*, New York State Academy of Trial Lawyers, October 3, 2022

(54) *Trial Series: Part 2 - Opening Statement Webinar,* Queens County Bar Association, September 22, 2022

(53) *How to Litigate a Construction Accident Case – Part 1: An Overview of New York Labor Law,* New York State Academy of Trial Lawyers, September 7, 2022

(52) *How to Litigate a Catastrophic Automobile Accident Case – Part 6: The Trial,* New York State Academy of Trial Lawyers, July 6, 2022

(51) *How to Litigate a Catastrophic Automobile Accident Case – Part 5: Mediation and Settlement,* New York State Academy of Trial Lawyers, June 2, 2022

(50) *How to Litigate a Catastrophic Automobile Accident Case – Part 4: Expert Depositions,* New York State Academy of Trial Lawyers, May 4, 2022

(49) *How to Litigate a Catastrophic Automobile Accident Case – Part 3: Liability and Damages Experts,* New York State Academy of Trial Lawyers, April 6, 2022

(48) *How to Litigate a Catastrophic Automobile Accident Case – Part 2: Commencing the Action,* New York State Academy of Trial Lawyers, March 2, 2022

Continuing Legal Education (CLE) Presentations Continued*:*

(47) *How to Litigate a Catastrophic Automobile Accident Case – Part 1: The Investigation,* New York State Academy of Trial Lawyers, February 4, 2022

(46) *Anatomy of a Trial, a Trial Skills Series – Part 5: Summations,* New York State Academy of Trial Lawyers, January 5, 2022

(45) *Anatomy of a Trial, a Trial Skills Series – Part 4: Cross-Examination,* New York State Academy of Trial Lawyers, December 1, 2021

(44) *Anatomy of a Trial, a Trial Skills Series – Part 3: Direct Examination,* New York State Academy of Trial Lawyers, November 3, 2021

(43) *Anatomy of a Trial, a Trial Skills Series – Part 2: Opening Statements,* New York State Academy of Trial Lawyers, October 6, 2021

(42) *Anatomy of a Trial, a Trial Skills Series – Part 1: Jury Selection,* New York State Academy of Trial Lawyers, September 10, 2021

(41) *How to Successfully Litigate a Personal Injury Case Series - Part 7: It's a Wrap!,* New York State Academy of Trial Lawyers, July 7, 2021

(40) *How to Successfully Litigate a Personal Injury Case Series - Part 6: The Trial,* New York State Academy of Trial Lawyers, June 2, 2021

(39) *How to Successfully Litigate a Personal Injury Case Series - Part 5:Pre-Trial Disclosures and Gearing up for Trial,* New York State Academy of Trial Lawyers, May 5, 2021

(38) *How to Successfully Litigate a Personal Injury Case Series - Part 4: Depositions,* New York State Academy of Trial Lawyers, April 7, 2021

(37) *How to Successfully Litigate a Personal Injury Case Series - Part 3: Your Adversary, the Preliminary Conference and Initial Discovery,* New York State Academy of Trial Lawyers, March 3, 2021

(36) *How to Successfully Litigate a Personal Injury Case Series - Part 2: Early Settlement, Jurisdiction, Venue & Commencing The Lawsuit,* New York State Academy of Trial Lawyers, February 3, 2021

(35) *How to Successfully Litigate a Personal Injury Case Series - Part 1: Getting the Case, Investigation and Ready to File,* New York State Academy of Trial Lawyers, January 6, 2021

(34) *Brick by Brick: Building a Personal Injury Practice,* New York State Academy of Trial Lawyers, December 10, 2020

(33) *Working with Experts to Build Your Case,* New York State Academy of Trial Lawyers, October 8, 2020

Continuing Legal Education (CLE) Presentations Continued:

(32) *Fitness Industry Liability: Gyms, Trainers and Waivers*, The Mentor Esq. Podcast, September 8, 2020

(31) *Let's Make a Federal Case Out of It: Litigating Personal Injury Cases in Federal Court,* New York State Academy of Trial Lawyers, June 9, 2020

(30) *Crisis Management - The Corona Virus Pandemic,* The Mentor Esq. Podcast, April 9, 2020

(29) *Do You Have a Federal Tort Claims Act Case in Your Office,* New York State Academy of Trial Lawyers, December 10, 2019

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(25) *Trial Techniques: Interactive Lessons from the Plaintiff and Defense Perspectives*, The Defense Association of New York, September 17, 2018

(24) *Punitive Damages – What to Plead, What to Prove: Medical Malpractice*, New York State Academy of Trial Lawyers, June 8, 2017 & June 21, 2017

(23) Presenter on Evidence, *2016 Annual Update, Precedents & Statutes for Personal Injury Litigators*, New York State Academy of Trial Lawyers, September 30, 2016

(22) *Medical Malpractice in New York: A View from All Sides: The Bench, The Bar and OCA,* New York State Bar Association, October 11, 2015

(21) *Effectively Using Experts in Personal Injury Cases,* Lawline, October 8, 2015

(20) *Killer Cross Examination Strategies,* Clear Law Institute, April 21, 2015

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(15) *Personal Trainer Negligence Update,* Lawline.com, October 14, 2014

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(14) *Trial Techniques – Part 2: Cross- Examination & Closing Arguments*, Brooklyn Bar Association, May 15, 2014

(13) *Trial Techniques – Part 1: Jury Selection, Opening Statements & Direct Examination*, Brooklyn Bar Association, May 7, 2014

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(10) *Opening Statements: A Recipe for Success*, Lawline.com, August 7, 2012

(9)*"You Had Me at Hello": Delivering an Effective and Powerful Opening Statement*, New York State Academy of Trial Lawyers, April 1, 2012

(8) *Preparing the Construction Accident Case*, New York County Lawyers Association, March 26, 2012

(7) *The Nults and Bolts of a Trial*, New York State Academy of Trial Lawyers, October 24, 2011

(6) *Personal Trainer Negligence*, Lawline.com, March 22, 2011

(5) *Trial Effectively Using Experts in Personal Injury Cases*, Lawline.com, May 4, 2011
Techniques: The Tricks of the Trade, Lawline.com, February 16, 2011

(4) *Practice Makes Perfect: Learn to Practice Like a Pro*, Lawline.com, January 18, 2011

(3) *Jury Selection 101, New York State Academy of Trial Lawyers*, December 14, 2010

(2) *Practical Guidelines for Getting Items into Evidence*, Lawline.com, March, 2010

(1) *Winning Your Case: Trial Skills that Count*, Lawline.com, August 21, 2009

Television Appearances – Legal Commentary:

Fox News Channel
-The O'Reilly Factor
-What's Happening Now with Martha McCallum
- America's News Room
- Fox & Friends
-Fox Business Channel
-Neil Cavuto

-Money with Melissa Francis
CNN -Anderson Cooper 360
ET – Entertainment Tonight
Bloomberg TV
Headline News
Tru TV
Court TV
The Morning Show with Mike and Juliet

Interests, Hobbies:

Porsche Club, High Performance Driving Events, Sim Racing, Tennis, Yoga, Cooking

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK

Index No.: [redacted]

----------x

[redacted] individually and as Administrator of the Estate of [redacted], deceased,

Plaintiff,

-against-

[redacted] N.,

[redacted],

Defendants.

----------x

EXPERT AFFIDAVIT

[redacted] N, MD

STATE OF NEW YORK)
) ss:
COUNTY OF NEW YORK)

[redacted], MD., being duly sworn, deposes and states the following under penalty of perjury:

1. I am a board-certified anesthesiologist duly licensed to practice medicine in the States of New York, New Jersey, and California. I am a full-time general clinical anesthesiologist and have provided anesthesia for over 24,000 cases since graduating from residency in 2007. I obtained my medical degree from the Icahn School of Medicine at Mount Sinai in 2001. I am an Attending Physician at the Mount Sinai Hospital in New York and as well have privileges at Mount Sinai West and Mount Sinai St. Luke's Hospital in New York. I am a professor of both Anesthesiology and Psychiatry at the Icahn School of Medicine at Mount Sinai. Regarding anesthesia for orthopedic surgery, I have personally performed anesthesia for patients receiving this type of surgery many times and I am fully familiar with the standard of care as it relates to the

performance of anesthesia for this procedure. I am therefore fully familiar with the issues presented herein. My *curriculum vitae* is annexed hereto.

2. I have reviewed the depositions of [redacted], the expert affidavits of Drs. [redacted], the medical records of the [redacted] relevant to this incident, specifically the initial assessment, operative report, and anesthesia records, and the Medical Examiners report detailing Mr. [redacted] autopsy and cause of death. These records include the Plaintiff's past medical history, pre-anesthetic evaluation, anesthetic record, and post-procedure course.

3. The patient in this case, Mr. [redacted] was at the time a 177.8 cm, 178 kg 38-year-old male with a Body Mass Index of 55(super-morbidly obese) who presented to HSS for orthopedic surgery during which he experienced negative-pressure pulmonary edema requiring intubation and transfer to New York Presbyterian Hospital (NYPH) for Intensive Care Unit (ICU) level treatment, and ultimately expired.

4. Relevant points from my review of the records provided to me include the following:

- According to the [redacted] intake record Mr. [redacted] was hypertensive (158/88) and moderately hypoxic (93%) at his initial pre-operative assessment on the day of surgery.
- According to the pre-anesthesia assessment the only medical diagnosis listed for Mr. [redacted] is super-morbid obesity. Despite having a BMI>40 and a Mallampati class 3 airway there is no documented evidence that a sleep-apnea screening tool was used during this interview. It is unclear why Mr. [redacted] was designated as an ASA 2 (a patient with mild, well controlled systemic disease) using the American Society of Anesthesiologists physical classification system.

- According to the anesthetic record the plan was for spinal anesthesia. Spinal anesthesia was placed at 08:41 with 4 ml 1.5% Mepivacaine (60 mg), 55 minutes prior to the commencement of surgery which began at 09:36. Spinal anesthesia begins to wear off after 85 minutes and an LMA is placed at 10:06. Though not specifically indicated in the anesthetic record, surgery end time would presumably be prior to LMA removal at 10:51. During LMA removal the patient experiences negative-pressure pulmonary edema but does not require reintubation and is transferred to the PACU to receive diuresis and CPAP
- According to the Operative report there were no untoward intraoperative events, and the surgeon specifically states that the patient was transported from the operating room to the post-anesthesia care unit in stable condition.
- According to the [redacted] records the patient required an extended ambulatory stay due to "sleep-apnea observed in OR" and "respiratory obstruction observed in OR."
- According to the [redacted] records the patient was intubated and sedated after deteriorating in PACU.
- According to the Medical Examiner the cause of death was respiratory complications of knee surgery.

5. According to the defense expert affidavit submitted by [redacted] choice of spinal anesthesia for this case was "good" because it "avoids the very significant risk for respiratory… morbidity" in a super-morbidly obese patient such as Mr. [redacted]. While Dr. [redacted] clearly recognizes that this patient was at significantly high risk for respiratory morbidity, it does not appear that this was considered by Dr. [redacted]. Had she performed a simple sleep-apnea screening during her pre-anesthetic assessment using a tool such as the STOP-BANG

survey she would have more likely than not discovered that Mr. [redacted] was at significantly high risk for undiagnosed sleep-apnea. The STOP-BANG[1] survey is a simple assessment tool in which 8 questions are asked during the assessment and the answers used to calculate the risk for obstructive sleep apnea (OSA) with a greater number of positive responses indicating an increased risk. From the medical record alone, Mr. [redacted] falls into the high risk category and in fact, according to the deposition testimony of [redacted] Mr. [redacted] was placed on a low dose propofol infusion and became apneic to the point of oxygen desaturation. Additionally, this observed sleep-apnea and respiratory obstruction observed by CRNA [redacted] is cited in the [redacted] record as the reason for Mr. [redacted] extended post-ambulatory stay.

6. A more appropriate anesthetic choice under these circumstances would have been to either secure the airway prior to the commencement of surgery with an LMA or endotracheal tube (ETT), used a longer acting agent for the spinal anesthetic, or placing an epidural either with or without a single shot spinal. According to the deposition testimony of CRNA [redacted] none of those options were considered and while she has used bupivacaine (a longer acting local anesthetic) for this surgery before, she was told by Dr. [redacted] o use mepivacaine.

7. Regarding the choice of mepivacaine for this case, Dr. [redacted] claims that the expected duration of block with the dose administered is 203 minutes for sensory and 168 minutes for motor block. It is unclear, however, where he has obtained this information. He fails to reference any support for this opinion. According to the Mepivacaine Package Insert (the package insert for the medication that was used in this case) the manufacturer specifically states that a single dose will provide anesthesia adequate for 120 to 150 minutes and that younger patients,

[1] S (loud snoring?) T (feeling tired during the day?) O (observed sleep disordered breathing?) P (high blood pressure) B (BMI > 35?) A (Age > 50?) N (large neck size?) G (male gender?)

such as Mr. [redacted] will recover faster (that they will lie on the lower end of the duration of action curve).

8. In the Mepivacaine package insert, on page 2/14 (under the "Pharmacokinetics" heading) the manufacturer states that "the 1.5% solution will provide extensive and often complete motor block" (but not always complete motor block) and "the duration of anesthesia also varies depending upon the technique and type of block, the concentration, and the individual. Mepivacaine will normally provide anesthesia which is adequate for 2 to 2 1/2 hours of surgery." It should be noted, however, that this estimate is a mean with a wide range reported in clinical studies and as mentioned above, the patient in this case falls into the youngest age group for patients studied. On page 2/14 (under the "CLINICAL PHARMACOLOGY" heading from page 1/14) the manufacturer specifically states that with increasing age less mepivacaine is required (up to 40% less to achieve the same degree of anesthesia).

9. Additionally, a study of Mepivacaine dose response relationships specifically looked at the technique (intrathecal mepivacaine) that was used in this case for the same type of surgery.[2] According to this study, 4ml intrathecal mepivacaine 1.5% (60mg) produced a sensory block which lasted a minimum of 2 hours and 45 minutes and a motor block which lasted a minimum of 2 hours and 10 minutes in the patients who were studied. So, under ideal circumstances it is reasonable to assume that the average healthy patient (not greater than ASA 2 and not heavier than 98 Kg) would be expected to have anesthesia appropriate for this surgery provided that the surgery lasted no longer than 54 minutes. In this study 54 minutes is the maximum length of surgery (most procedures lasted around 40 minutes) and the longest period of

[2] Zayas VM, Liguori GA, Chisholm MF, Susman MH, Gordon MA. Dose response relationships for isobaric spinal mepivacaine using the combined spinal epidural technique. Anesth Analg. 1999 Nov;89(5):1167-71. PMID: 10553828.

time between initiation of the spinal anesthetic and the beginning of surgery was 30 minutes, meaning that at most 94 minutes of anesthesia appropriate for surgery was demonstrated. Things to consider include the patient population studied (these were healthy patients of normal weight, the patient in this case was not healthy and was super-morbidly obese) and the length of time between administration of the spinal anesthetic and the commencement and conclusion of surgery, both of which were much longer in this case than in the study.

10. This information from the manufacturer and from clinical studies indicate that 60 mg intrathecal mepivacaine will provide 120-150 minutes of anesthesia adequate for surgery in normal healthy people and that younger patients or patients with higher BMI will recover faster. Both Dr. [redacted] and CRNA [redacted] testified that they each expected the spinal to last for about 120 minutes.

11. Dr. [redacted] asserts that since the total time between block placement and end of surgery was only134 minutes, 60mg of mepivacaine was within the standard of care yet according to the package insert the manufacturer asserts that under ideal circumstances this dose will "provide anesthesia which is adequate for 2 to 2 1/2 hours of surgery." These circumstances were not, however, ideal. Mr. Rennie was super morbidly obese and cannot be considered "healthy" by any means, increased weight is associated with reduced duration of anesthesia, and it is not at all surprising that this spinal wore off prior to the conclusion of surgery. While Dr. [redacted] is correct in his assertion that "there is no way to know why the spinal lasted only 85 minutes" Dr. [redacted] knew, or should have known, that it was entirely within the realm of probability that this would be the case. All data from individuals in a population exists on a bell-shaped curve, with the highest number at the center (top) of the curve which represents the median. There are, necessarily, individuals who fall on either side of the median and 50% of the population will have a prolonged

response to mepivacaine but the other 50% will have a shorter duration of action. In this case, both the expert and the manufacturer provide (different) numbers for this mean, but it should be expected that not everyone is average. Factors which are known to decrease the duration of anesthesia and require increased dosing include age and weight and a patient with super-morbid obesity can be expected to experience a decreased duration of anesthesia in this circumstance.

12. Dr. [redacted] mentions "patchy anesthesia," a well-known, if not well understood, phenomenon, as the reason this spinal did not work. In this case, with a patient such as Mr. [redacted] who is at significantly increased risk for pulmonary morbidity, the possibility that the single shot spinal will not outlast the duration of surgery or be only partially effective significantly increases the risk for airway compromise by creating an urgent or emergent need to change the anesthetic plan during an ongoing operation. The prudent and safer choice would have been to secure the airway under controlled conditions prior to surgery and not risk having to do this under urgent conditions.

13. Dr. [redacted] describes the events that occurred when the LMA was removed by CRNA [redacted] as she attempted to emerge Mr. [redacted] from anesthesia. He states that a patient "coughing up the LMA" as described by CRNA [redacted] in her deposition testimony is a sign of stage 2 anesthesia. According to the detailed description of these events given by CRNA during her testimony Mr. [redacted] was clearly in stage 2 anesthesia. This is a plane of anesthesia distinct from fully conscious and completely under general anesthesia in which the patient may appear to be awake and alert but will not follow commands or respond to stimulus in the same way a fully conscious person would. This state is associated with a disinhibited state and is the highest risk state for patient injury during emergence from general anesthesia.

14. Stage 2 Anesthesia (Excitement or Delirium) is marked by features such as disinhibition, delirium, uncontrolled movements, loss of eyelash reflex, hypertension, and tachycardia. Airway reflexes remain intact during this phase and are often hypersensitive to stimulation. Airway manipulation during this stage of anesthesia should be avoided, including both the placement and removal of endotracheal tubes and deep suctioning maneuvers. There is a higher risk of laryngospasm (involuntary tonic closure of vocal cords) at this stage, which may be aggravated by any airway manipulation. Consequently, the combination of spastic movements, vomiting, and rapid, irregular respirations can compromise the patient's airway.[3]

15. During Mr. [redacted] stage 2 emergence from anesthesia, CRNA [redacted] describes suctioning the patient and removing the LMA, two maneuvers which resulted in the laryngospasm which caused the patient to experience negative pressure pulmonary edema.

16. Dr. [redacted] states that CRNA [redacted] removed the LMA while Mr. [redacted] was "coughing up the LMA" clearly during stage 2 anesthesia which is not the standard of care. If Mr. [redacted] was not in stage 2 anesthesia, he would have not had laryngospasm and would not have developed negative-pressure pulmonary edema.

17. Lastly, Dr. [redacted] states that these events were not the proximate cause of any injury or death yet this is refuted by the Medical Examiner as the autopsy report specifically indicates the cause of death as "Respiratory complications of surgery."

18. Based on the deposition testimony provided by both Dr. [redacted] and corroborated by the medical record, the following series of events occurred, leading to the respiratory complications of surgery cited by the Medical Examiner:

[3] Siddiqui BA, Kim PY. Anesthesia Stages. [Updated 2021 Mar 7]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2021 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK557596/

- Mr. [redacted] was brought into the operating room by the nursing staff when it was believed that the surgeon was available. According to CRNA [redacted], once the patient is brought into the room its understood that everyone is ready to go, saying "that's just standard" in her deposition testimony.
- Because CRNA work is medically directed in New York state, the anesthetic plan was made by the Anesthesiologist and not the CRNA. Dr. [redacted] decided to perform a single shot spinal using 60mg mepivacaine which she expected to last roughly 120 minutes.
- Anesthesia was induced as was the customary practice at the time.
- Both the anesthesia team and the nurses were ready at 8:55 am, roughly 30 minutes after bringing the patient in the room.
- The surgeon did not arrive for 45 minutes after that. According to Dr. [redacted], she believes that about 55 minutes of surgical anesthesia time wasted waiting for surgeon.
- When the surgeon began to operate the spinal had either already begun to wear off or was not effective "patchy block" and Dr. [redacted] decided to convert to general anesthesia.
- An LMA was placed without incident.
- It was the expectation of CRNA [redacted] that when it was time for emergence Dr. [redacted] would be present as this is the standard of care in New York.
- When it was time for emergence the witness summoned Dr. [redacted] via text to return to the room, but she was giving a break to another CRNA in another operating room and could not immediately return.
- During this time, the patient began to emerge from anesthesia and became difficult to control.

- CRNA [redacted] removed the LMA while she was the only anesthesia provider in the room despite her testimony that she was aware that in New York State CRNAs are required to be supervised by physician anesthesiologists and that the attending physician must be present for all critical events.
- Mr. [redacted] immediately became obstructed, experienced laryngospasm, and developed negative-pressure pulmonary edema.
- An alert was triggered to summon help from other locations and two other attending anesthesiologists responded to assist with the management of Mr. [redacted]
- After 20 minutes Mr. [redacted] was transferred to the PACU where an attempt was made to treat his negative-pressure pulmonary edema using Bi-PAP and Lasix.
- Ultimately Mr. [redacted] was intubated and transferred to NYPH for ICU level care.

19. It is my opinion, to within a reasonable degree of medical certainty, that the actions and inactions of [redacted] directly resulted in the injury which ultimately resulted in the death of Mr. [redacted]. It is also my opinion that these actions and inactions represent a significant departure from the standard of care.

20. It is my opinion, to within a reasonable degree of medical certainty, that the defendants, [redacted] departed from the standard of care, in failing to properly pre-screen Mr. [redacted] for the risk of anesthesia and improperly categorized him as an ASA 2 patient.

21. It is my opinion, to within a reasonable degree of medical certainty, that the defendants, [redacted], departed from the standard of care, in their choice

of mepivicane, in the dose administered, knowing that there was a likelihood that it would wear off during surgery, causing an emergent event to use an LMA to secure [redacted] airway.

22. It is my opinion, to within a reasonable degree of medical certainty, that the defendants, [redacted] departed from the standard of care, in failing to have an anesthesiologist in the operating room at the time of Mr. [redacted] emergence from anesthesia.

23. It is my opinion, to within a reasonable degree of medical certainty, that the defendants, [redacted] eparted from the standard of care, when CRNA [redacted] emoved the LMA from Mr. [redacted] while he was still in stage 2, resulting in an expected anatomical response of laryngospasm which caused Mr. [redacted] to suffer from negative pressure pulmonary edema and began the chain of events that ultimately resulted in his death.

24. Dr. [redacted] was aware that an LMA should not be removed during Stage 2 as she testified on page 140 of her deposition transcript:

Q. If the LMA had not been dislodged, and [redacted] was just coughing with it in, would the standard practice be to keep the LMA in even though he was coughing, or would it be to take it out at that time?

A. You would ideally keep the LMA in until the patient is out of stage 2 and into stage 1.

Q. Why is that?

A. Because they can override the hyper- reflective airway closure, and they can force the vocal cords to open to breathe.

24. Unfortunately for Mr. [redacted] was not present at the time of Mr. [redacted] emergence (nor was any anesthesiologist present as required by HSS and as per accepted practice

in the field of anesthesiology) as she would have known to wait until Mr. [redacted] was in Stage 1 to remove the LMA and there would have been no subsequent complications.

25. The failure to have Dr. [redacted] or any other anesthesiologist present for the removal of the LMA at the time of emergence, and the removal of the LMA while Mr. [redacted] was in stage 2 anesthesia, were both departures from good and accepted practice which were each a proximate cause of Mr. [redacted] laryngospasm which resulted in respiratory complications which ultimately caused his untimely death.

I reserve the right to amend these opinions should additional information become available.

Dated: New York, NY

February 25, 2022

[redacted] MD

Sworn to before me
This 25th day of February, 2022

NOTARY PUBLIC

MADLYN I. SOLIVAN
Commissioner of Deeds
City of New York - No. 5-1071
Certificate Filed in New York County
Commission Expires 10/1/23

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK

[redacted] individually and as Administrator of the Estate of [redacted], deceased,

Plaintiff,

-against-

[redacted]

Defendants.

----------x

Index No.: [redacted]

EXPERT AFFIDAVIT
[redacted], MD

STATE OF NEW YORK)
) ss:
COUNTY OF NEW YORK)

[redacted], MD , being duly sworn, deposes and states the following under penalty of perjury:

1. I am board certified in Internal Medicine, Pulmonary Medicine, and Critical Care Medicine. I am an Associate Professor at the NYU School of Medicine, and I am the Director of Critical Care at Bellevue Hospital in New York City. Bellevue is an urban public hospital, a level I trauma center, and a tertiary referral center. As such, we care for patients with a wide variety of conditions. My clinical work consists of critical care, where I serve as the primary attending for medical ICU patients or as a critical care or pulmonary consultant to any area of the hospital. In either role, I frequently care for mechanically ventilated patients requiring sedative agents, including propofol. I am well versed with the potential adverse reactions associated with propofol, including Propofol Infusion Syndrome (PRIS), and the standard of care when this condition is suspected. My *curriculum vitae* is annexed hereto.

2. In the case of Mr. [redacted], I have reviewed in detail the medical records of [redacted] and the Report of Autopsy from the Office of the Chief Medical Examiner. I have reviewed the deposition transcripts of Drs. [redacted]. I have also reviewed the affidavits of the defense experts, [redacted]

3. It is my opinion, to within a reasonable degree of medical certainty, that there were several deviations from the standard of care by the defendants in this case and that those deviations contributed to Mr. [redacted]'s untimely death.

4. Mr. [redacted], in the postoperative period, developed severe hypoxemic respiratory failure that was most consistent with negative pressure pulmonary edema meeting the clinical criteria for Acute Respiratory Distress Syndrome (ARDS.) He required mechanical ventilation and lung protective ventilatory strategy, with deep sedation to achieve ventilator synchrony. Propofol was used at high doses to achieve deep sedation. This is a commonly used sedative agent in the critical care setting and the standard of care for a critical care physician is to know and understand its intended uses and the signs or symptoms of potential adverse reactions. Propofol is highly lipophilic. This gives it favorable properties such as crossing the blood-brain barrier quickly to cause immediate sedative effects. However, this also means that it binds to adipose tissue throughout the body. So, while propofol is considered a short acting medication, it can accumulate in adipose tissue and have a prolonged effect even after the infusion has been stopped. Therefore, blood levels of the drug are not a reliable indicator of its effects. Propofol can cause a benign green discoloration of urine in some patients, a dose-related hypotension due to direct vasodilatory effects, hypertriglyceridemia due to the lipid content of the drug, or can cause a

syndrome called Propofol Infusion Syndrome (PRIS.) Some of the findings of this syndrome include hypotension, renal injury, elevated CPK, metabolic acidosis, and bradyarrhythmia. Not all of these findings need to be present to suspect the syndrome, and there are multiple potential etiologies for these findings in a critically ill patient. However, the presence of any of these findings without an apparent alternative explanation should prompt consideration of PRIS. This syndrome is indeed rare but is associated with a high mortality if not recognized immediately and managed with immediate cessation of propofol. For the reasons described above, slow titrations of the drug will not remove it from the system quickly.

5. In this case, the patient had pressor-dependent hypotension, fever, and elevated CPK on 1/12/19. His propofol infusion rate was increased throughout that day. On 1/13/19, the ICU attending conducted an exam to rule out compartment syndrome as the cause of the CPK, found no evidence of this, and explicitly documented that this was most likely due to PRIS. The propofol drip was sequentially weaned and was discontinued by the end of that day, demonstrating further that PRIS was considered the likely diagnosis. Between 1/13/19 and 1/17/19, the patient remained off propofol, though the effects of the drug were likely still present given the dose and the duration of the drug the patient had received. On 1/14/19, Orthopedics was consulted to rule out compartment syndrome and did so. On 1/15/19, the attending physician, Dr. [redacted], described the fever as "unexplained" and considered rare diagnoses such as "malignant hyperthermia" to explain the findings. On 1/17, propofol was restarted at the direction of Dr. [redacted], with the stated plan to reduce the rate of propofol "given the possibility of PRIS." On 1/18, the patient remained on propofol and received additional boluses of the drug during a tube exchange and that same day Dr. [redacted] documented that the patient still had fevers that were

"unexplained." The propofol was discontinued that evening and remained off until the patient suffered a cardiac arrest on 1/20.

6. It is my opinion that there were deviations from the standard of care for critical care physicians in this case. It is widely known within the critical care medical community that the standard of care requires that propofol be discontinued upon any clinical indication that a patient may be suffering from propofol infusion syndrome. Additionally, the standard of care requires that propofol should not be re-administered to a patient who is potentially suffering from PRIS. The defense expert, Dr. [redacted], does not dispute this. Indeed, Dr. [redacted] states in paragraph 46 of his affidavit that "**If there is a suspicion that a patient has propofol infusion syndrome, the standard of care is to stop administering propofol."** NYPH attending physicians, Drs. [redacted] were both aware of these standards of care based upon their deposition testimony. Unfortunately, however, [redacted], was unaware that the standard of care requires the discontinuation of propofol upon a suspicion of PRIS. On pages 51-52 of his deposition transcript, Dr. [redacted] testified as follows:

Q. Would you agree, Doctor, that if there is a serious suspicion that a patient in ICU care is suffering from propofol infusion syndrome, that the standard of care requires that the propofol be immediately stopped from being administered to that patient?

[redacted]*: Objection to form. You can answer it.*

A. I can't answer a theoretical question with no clinical details.

Q. If you considered a patient to be suffering from propofol infusion syndrome, would you agree that once you had that consideration that the standard of care would require for you to stop the administration of propofol?

A. If I -- can you repeat the question. If I considered? Is that what you said that?

MR. SMILEY: Marni, can you read back that back, please.(Whereupon, the referred-to question was read back by the Reporter.)

THE WITNESS: No. Just from a consideration, I don't think there's any mandated steps. I think we always have to be very thoughtful and consider multiple possibilities and always weigh the risks and benefits of making any medical intervention, starting or stopping anything.

It was clearly a departure from good and accepted practice for Dr. [redacted] to continue to administer propofol via intravenous bolus injections and constant intravenous drip after it was well documented by his colleagues, and himself, that Mr. [redacted] was previously taken off propofol out of concern for PRIS.

7. When PRIS was considered the most likely diagnosis on 1/13/19, the propofol should have been stopped immediately as opposed to gradually weaned. The propofol should not have been restarted during the hospitalization in a patient in whom a clinical diagnosis of PRIS had been made. Both of these departures from the standard of care resulted in longer exposure to propofol. To a reasonable degree of medical certainty, these departures by the defendants from the accepted standard of care directly contributed to an unexpected and otherwise unexplained cardiac arrest in a patient who was otherwise improving and were a proximate cause of Mr. [redacted] s death.

Dated: New York, NY
February 28, 2022

_____
[redacted], MD

Sworn to before me
This 28th day of February, 2022

Madlyn I. Solivan
NOTARY PUBLIC

MADLYN I. SOLIVAN
Commissioner of Deeds
City of New York - No. 5-1071
Certificate Filed in New York County
Commission Expires 10/1/23

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK

[redacted]

----------x

[redacted] individually and as Administrator of the Estate of [redacted] deceased,

Plaintiff,

-against-

[redacted]

Defendants.

----------x

EXPERT AFFIDAVIT
JOHN [redacted]
Pharm. D.,

STATE OF MASSACHUSETTS

COUNTY OF SUFFOLK

JOHN [redacted] Pharm. D., being duly sworn, deposes and states the following under penalty of perjury:

1. I am a pharmacist duly licensed to practice pharmacy in the State of Massachusetts since 2003. I have worked as a critical care pharmacist since 1989, and have been Board certified as a critical care pharmacist by American Board of Pharmaceutical Specialties since 2016, three years after this board certification become available. I completed a Bachelor of Science in Pharmacy in 1998 and a Doctor of Pharmacy in 1996 (three years after this degree became available) from the University of Toronto. I completed a residency in Hospital Pharmacy from the Victoria Hospital, London, Ontario, Canada in 1989 and a critical care research fellowship from Henry Ford Hospital in 1997. I am presently a Professor of Pharmacy at Northeastern University, an Associate Scientist in the Division of Pulmonary and Critical Care Medicine at Brigham and Women's Hospital and a lecturer in medicine at Harvard Medical School. I have published more

than 200 peer-reviewed publications on ICU sedation and delirium and have an H-index of 52. I am fully familiar with the use of Propofol in the ICU and the Propofol-Related Infusion Syndrome (PRIS). I chaired the 2018 Society of Critical Care Medicine Clinical Practice Guidelines that define how IV sedatives, including propofol, should be used in the ICU. I have conducted (and am conducting) numerous ICU propofol randomized controlled trials including the National Institute of Health MENDS2 trial that was published in the New England Journal of Medicine in 2021. I have published two high-impact publications that define the risks and mortality associated with PRIS. A 2008 publication by Fong J et al. (my graduate student at the time) in Crit Care Medicine on PRIS-associated mortality has since been cited in 130 other papers. A 2010 publication by Roberts et al (my graduate student at the time) in Crit Care on PRIS-related risk factors has since been cited in 211 other papers. I am invited to lecture around the world at Critical Care meetings on ICU sedation and I consider myself to be an international expert in the field. As a practicing critical care pharmacist in the Medical ICU at Brigham and Women's Hospital, I am familiar with the applicable standards of pharmacological care as it pertains to sedative use. My complete *curriculum vitae* is annexed hereto.

2. My opinions set forth in this Affidavit are based upon my education and years of training and experience in the field of critical care pharmacy. All of my opinions are made to a reasonable degree of pharmacological certainty.

3. I have reviewed the medical records pertaining to Mr. [redacted] from the [redacted]. I have reviewed the Report of Autopsy from the Office of the Chief Medical Examiner. I have reviewed the deposition transcripts of Drs. [redacted]. I have also reviewed the affidavits of the defense experts, [redacted].

4. Based on my review of the aforementioned records and documents, and based on my research and training, it is my opinion to a reasonable degree of medical certainty that the Defendants' treatment of the decedent was not within the accepted standards of care and that the Defendants' alleged acts and/or omissions were a proximate cause of the decedent's death.

5. According to the decedent's records from [redacted], then 39-year old [redacted] presented to [redacted] on January 10, 2019 to undergo an anterior cruciate ligament ("ACL") repair to be performed by orthopedic surgeon, [redacted]. The decedent reported no significant past medical history, aside from his right knee injury (sustained because of a fall at work). Of note, he was morbidly obese (174 kg, BMI 54.95 kg) and drank alcohol but had no smoking history.

6. Dr. [redacted] performed a knee arthroscopy, a reconstruction of the decedent's ACL, and a left hamstring graft. Anesthesiologist Dr. [redacted] and Nurse Anesthetist [redacted], positioned the decedent and started anesthesia at 8:13 am. According to the [redacted] Anesthesia Record, the decedent was given a neuraxial block. Dr. [redacted] started the ACL repair at 9:36 am.

7. At 10:06 am, it was noted the decedent was awake, complaining of mild pain, and moving his legs, and the decision was made to convert to general anesthesia. A laryngeal mask airway (LMA) was placed without incident. Nurse [redacted] administered propofol.

8. At 10:51 am, it was noted that the decedent's anesthesia was tapered down, he became agitated and tried to cough out the LMA. The LMA was removed, and it was noted that the decedent "immediately obstructed with likely laryngospasm with subsequent desaturation. We suspected the patient inhaled against closed glottis and had negative pressure pulmonary edema." The decedent was re-sedated with Propofol and ventilated with a two-handed mask vent with good

airflow, but his oxygen saturation only partially improved to the 80s. Dr. [redacted] completed the ACL repair at 10:54 am. The decedent left the Operating Room and was taken to the PACU at 11:10am. Anesthesia ended at 11:31 am.

9. While he was in the PACU, IV furosemide and CPAP were administered. A chest x-ray and bedside lung ultrasound revealed fluid in the lung. The decedent's blood pressure was 157/87 and is oxygen level was 88%. By 3:00 pm, his oxygen saturation improved to 93%, but his blood pressure was now 115/61. The plan was to admit the decedent overnight for continued CPAP and diuresis.

10. By 5:54 pm, the decedent complained of shortness of breath and remained on CPAP. His blood pressures were between 91/57 and 142/84 and his oxygenation saturations were between 67% and 96%. By 7:27 pm, his arterial oxygen saturation was 63.9%. At 7:47 pm, a Propofol infusion was started at 25 mcg/kg/min.

11. The decedent underwent a chest x-ray at 8:29 pm, which revealed bilateral pulmonary infiltrates with air bronchograms, suggestive of pulmonary edema. Lab's revealed elevated levels of potassium, creatinine, venous lactate (indicating lactic acidosis), and an elevated white blood count. The decedent's arterial pH, PO2 levels and arterial base excess were low. The decedent was intubated and sedated with propofol.

12. At 11:40 pm, the decedent was transferred to [redacted] with monitor, portable ventilator and life pack and was on continuous infusions of Norepinephrine, Phenylephrine, Vecuronium, Furosemide, Propofol and Lactated Ringers. He was diagnosed with acute hypoxic respiratory failure potentially related to negative pressure pulmonary edema, Acute Respiratory Distress Syndrome (ARDS), Aspiration Pneumonia (or a combination of all three).

13. Despite administration of a Phenylephrine infusion at 70 mcg/min and Norepinephrine infusion at 12 mcg/min, his blood pressure was 101/70. Despite administration of a vecuronium, fentanyl and a propofol infusion (titrated to 50 mcg/kg/min), and a PEEP of 28 and Fi02 of 100% on a low-tidal mode of controlled ventilation, over his first 24 hours of admission at NYPH (Jan 12-13, 2019), his oxygenation saturation did not exceed 95%. Of note, during this period, his serum chemistry revealed clinically significant elevations in potassium (6.4), creatine (1.78), creatinine kinase (> 2000), AST (55), and ALT (64).

14. On January 13, 2019, the Propofol infusion dose was increased from 50 mcg/kg/min (54.54 ml/hr) at 7:00am, to 55 mcg/kg/min (59.99 mL/hr) at 8:00 am, and to 60 mcg/kg/min (65.45 mL/hr) at 9:00am. At or around 12:12 pm, Dr. [redacted] documented that the decedent's urine was green and that he had hypertriglyceridemia, both of which he noted in the chart as 'likely to propofol'. Dr. [redacted] planned to add Dexmedetomidine, reduce propofol, continue weaning off vecuronium, and wean PEEP by 2 mmHg every 8 hours if there was no evidence of desaturation or hemodynamic compromise. Subsequently, at 11:00am, the Propofol was reduced to 50 mcg/kg/min (54.54 mL/hr), at 12:00 pm to 40 mcg/kg/min (43.63 mL/hr), at 2:33 pm to 30 mcg/kg/min (32.72 mL/hr, at 3:00 pm to 10 mcg/kg/min (10.91mL/hr) until it was discontinued entirely by 9:00 pm.

15. Dr. Kel[redacted] documented in her January 13, 2019 9:08 pm note that the decedent's elevated creatinine kinase was "most likely rhabo[myolosis] due to Propofol infusion syndrome". She evaluated the decedent for compartment syndrome but found no clinical suggestion of this condition.

16. In Dr. [redacted] note dated January 14, 2019 at 2:01 pm, she documented that the decedent remained dyssynchronous with the ventilator overnight, and his oxygen

saturation dropped to the mid-70s. She noted there was a lower concern for Propofol-related infusion syndrome given the relative low rates of Propofol (by this time, Propofol has already been discontinued).

17. Dr. [redacted] note reflected continuing challenges in optimizing mechanical ventilation for the decedent. Given the decedent's body habitus, he could only tolerate low tidal volumes if he was paralyzed and a high PEEP was delivered. The plan was to liberalize his tidal volumes up to 8 mL/kg/IBW. Dr. [redacted] wrote, 'We will accept higher plateau pressures as this does not truly reflect excessive stretch. Will continue and sedatives and paralytics today as he re-recruits. Hopefully when he is recruited and defervesced he will tolerate stopping sedatives and lowering PEEP (since his tidal volumes will be larger)." He also wrote, "Unfortunately, we are using BZD (benzodiazepines) as cannot get Propofol given TG (triglycerides elevation).

18. According to Dr. [redacted] January 16, 2019 note, the decedent remained extremely ill, in respiratory failure, on ventilator support, with intermitted fever, and with massive fluid overload. However, his serum creatine had plateaued, he was out of shock, he was not oliguric, he was following commands, and he was improving. Dr. [redacted] attempted to stop fentanyl, but the decedent became severely distressed and dyssynchronous with the ventilator, resulting in hypoxia. His hypoxia improved when fentanyl was reinstituted.

19. On January 17, 2019 at 9:00 am Propofol was administered for the first time since January 13th at a dosage of 25 mcg/kg/min (27.27 mL/hr). From 12:35 pm until 2:00 pm, the Propofol dosage was increased to 40 mcg/kg/min (43.63 mL/hr) because the decedent underwent a bronchoscopy for which he required increased sedation. Dr. [redacted] planned to get "off this dose of Propofol given the possibility of Propofol infusion syndrome" and to diurese the decedent more aggressively for significant volume overload. As such the Propofol infusion was titrated down to

35 mcg/kg/min (38.18 mL/hr) at 2:00 pm; 30 mcg/kg/min (32.72 mL/hr) at 3:00 pm, 20 mcg/kg/min (21.82 mL/hr) at 4:00 pm; 15 mcg/kg/min (16.36 mL/hr) at 5:00 pm; and 10 mcg/kg/min (10.91 mL/hr) at 6:00pm. After stopping sedation, the decedent became extremely distressed, experienced ventilator dyssynchrony, and had to be sedated again. At the 6:45 pm, the decedent was restarted on Propofol at an infusion dose of 25 mcg/kg/min (27.27 mL/hr) until 4:00 am on January 18, 2019, when the infusion rate was decreased to 20 mcg/kg/min (21.7 mL/hr).

20. On January 18, 2019 at 1:21 pm, the decedent was given an IV bolus dose of Propofol 30 mcg and at 1:47pm a second IV bolus dose of Propofol 60 mcg [on top of the continuing Propofol 25 mcg/kg/min (27.27 mL/hr) continuous infusion] to provide additional sedation during an endotracheal tube change. The Propofol infusion was subsequently weaned until it was discontinued entirely at 4:24 pm. According to the [redacted] chart, this was the last time the decedent received Propofol.

21. On January 19, 2019, a Lorazepam infusion was started due to agitation on the Fentanyl and Dexmedetomidine infusions. It was noted he should be not be given any further Propofol because of hypertriglyceredemia. With larger ETT allowing greater tidal volumes, the inspiratory pressure decreased, respiratory distress decreased and both the PEEP and Fi02 were able to be reduced.

22. According to the [redacted] chart, on January 20, 2019 at 2:23pm it was noted that overnight the decedent had been given Fentanyl IV boluses for agitation, but was currently awake, interactive, able to follow commands, and wiggle his toes. Dr. [redacted] noted the decedent was "approaching extubation."

23. According to the decedent's "Cardiac Arrest Note" (written on January 20, 2019 at 11:05pm), the decedent had been agitated trying to pull off his cooling pads and was tolerating

mechanical ventilation on a pressure support mode of 20/5 and a FiO2 of 40%. His mechanical ventilation was switched to an AC mode and became hypotensive after the administration of IV boluses of Fentanyl and Lorazepam. The ECG revealed the decedent to be in a narrow complex supraventricular tachycardia with a HR in the 100s. The decedent subsequently became bradycardic. Subsequently, when no pulse was palpable, a code was called and advanced cardiac life support (ACLS) was emergently commenced. The antecedent suffered a cardiac arrest. Despite approximately 1.5 hours of ACLS, he could not be revised.

24. According to the death certificate and the Report of Autopsy from the Office of the Chief Medical Examiner, the decedent's immediate cause of death was respiratory complications of the surgical reconstruction of the cruciate ligaments and meniscal tears of the right knee. Obesity was listed as another condition contributing to death. The manner of death was listed as a "therapeutic complication."

OPINIONS

25. It is my opinion to a reasonable degree of pharmacological certainty that the defendants administered the decedent an excessively high dose of Propofol, failed to recognize Propofol-related Infusion Syndrome (PRIS) when established symptoms of PRIS were apparent, and continued to administer Propofol after PRIS was apparent.

26. Dosing of propofol using actual body weight (ABW) may result in supratherapeutic propofol concentrations in morbidly obese patients (defined as a BMI $\geq$ 40). Weight-based dosing using either IBW or adjusted body weight is therefore preferred.[1] This is particularly important in clinical situations where the patient's response to propofol therapy (i.e., level of sedation) cannot be evaluated. An ICU scenario where level of sedation cannot be

[1] Erstad BL, et al. Drug dosing in the critically ill obese patient – a focus on sedation, analgesia and delirium. Crit Care 2020; 24:315.

evaluated is during continuous neuromuscular blocker therapy unless Bispectral (BIS) monitoring is employed. At the 14-hospital, Harvard University-affiliated, Mass General Brigham Health System, a warning is in place to alert critical care pharmacists (when validating physician orders) when maximum hourly propofol infusion rate (in the order) exceed 300 mg/hr. Importantly, a rigorous evaluation of 153 PRIS cases, concluded that 'dose-related signs of PRIS occur more frequently with higher infusion rates, irrespective of the duration of propofol infusion".[2] The decedent had a BMI of 54.95 on admission to the MICU at NYPH. On January 13, 2019 his propofol infusion was titrated to 60 mcg/kg/min (an infusion rate of 65.45 mL). With a bottle of propofol having a concentration of 10 mg/mL, the decedent at this time was receiving propofol at a dose of 654.5 mg/hr. This is more than twice the hourly dose that would be allowed in a morbidly obese patient at the Mass General Brigham Health System and is a departure from the accepted standard of care. At this time, the decedent was also receiving a continuous infusion of the neuromuscular blocking agent, vecuronium. However, BIS monitoring was not employed, a standard sedation monitoring practice during continuous neuromuscular infusion use, so the level of sedation was not able to be monitored during this period by MICU clinicians at [redacted]. As the defense expert, Dr. [redacted], highlights in his affidavit, the single most-important risk factor for PRIS is the dose of propofol administered. Yet, the decedent received an infusion dose of propofol that was more than twice as high as the accepted maximum. The failure of the defendants to consider the decedent's morbid obesity when dosing propofol and to evaluate the therapeutic response to this extraordinary high propofol dose by using BIS monitoring (in the face of continuous vecuronium use) is breach of accepted pharmacologic practice.

[2] Krajcova A, et al. Propofol infusion syndrome: a structured review of experimental studies and 153 published case reports. Crit Care 2015; 19:398

27. While published PRIS literature highlights the time from first propofol exposure to the onset of PRIS is variable, one analysis of 1017 critically ill adults receiving continuous propofol found that the first two PRIS-defining clinical manifestations (i.e., metabolic acidosis, cardiac dysfunction, and renal failure) occurred in the first 24 hours after propofol initiation.[3] Detailed research surrounding the mechanisms of PRIS, and importantly, the mitochondrial uncoupling that initiates this syndrome, highlight the importance of a priming exposure to propofol followed by a second exposure to propofol. The decedent received two hours of low-dose propofol at [redacted] on January 10, 2019 during his surgical procedure that was then followed by the initiation of a high-dose infusion of propofol in the MICU at [redacted] on January 13, 2019 – three days later. Beyond a pharmacologic doubt, decedent was exposed to propofol over a three-day period and thus was at high risk for PRIS based on published evidence.

28. Based on current evidence, the most accepted minimal clinical definition for PRIS is: metabolic acidosis (arterial pH ≤ 7.30 AND serum bicarbonate ≤ 18 mg/dL) AND cardiac dysfunction (SPB ≤90 + use of 1 or more vasopressors) AND ≥1 of: rhabdomyolysis (CPK ≥ 10,000), hypertriglyceridemia (serum triglyceride ≥400 mg/dL) and renal failure (oliguria and/or a serum creatinine that increases ≥1 mg/dL in 24 hours) (*See*, footnotes 2, 3). At the time of transfer to [redacted] on January 12, 2019 (2 days after first being exposed to Propofol), and for 24 hours after, the decedent clearly met the definition of PRIS using the above well-accepted definition, since:

a. He was receiving a very high dose propofol infusion (please see paragraph 26-above);

b. He had a metabolic acidosis.

[3] Roberts R, et al. Incidence of propofol-related infusion syndrome in critically ill adults: a prospective, multicenter study. Crit Care 2009; 13:R169.

c. He had cardiac failure requiring the administration of n=3 high-dose vasopressors to maintain a SPB ≥90 mmHg; and

d. His serum creatine was 1.78 mg/dL (more than twice his baseline when he presented to HSS for surgery).

Of importance, at this time, his liver transaminases (ALT/AST) had increased to a level twice above normal and his serum CK was ≥ 2,000 mg/dL, despite the later confirmation by the MICU team he did not have compartment syndrome.

29. Predictors of mortality in patients with suspected PRIS are well-established.[4] Cardiac arrest is the most common clinical scenario associated with PRIS-associated death. Importantly, PRIS-associated mortality has been reported to occur in patients where propofol was stopped prior to cardiac arrest death (and where one or more PRIS symptoms had started to dissipate) (*See*, footnote 4). In one evaluation of 1139 adults (*See*, footnote 4) with suspected PRIS, death was significantly more likely in each of the following patient subgroups: patients who were younger [Odds Ratio (OR) 2.3; 95% CI 2.3 (1.7-2.3)]; male (OR 1.2, 1.1-1.7); received a vasopressor (OR 1.8, 1.3, 2.5); had cardiac failure (OR 3.8, 2.88-4.91); had metabolic acidosis (OR 2.7, 2.7-5.0); had renal failure (OR 1.9, 1.4-2.6); had hypotension (OR 1.8, 1.3-2.3); rhabdomyolysis (OR 1.8, 1.3-2.3); or hypertriglyceridemia (OR 2.0, 1.2-3.4). Over his first three days of admission in the MICU at [redacted], where propofol continued to be administered, the decedent experienced virtually each and every one of these known risk factors for PRIS-associated mortality. The failure of the defendants to be aware of the symptoms of PRIS known to each increase mortality, and the failure to stop Propofol in a timely fashion, was a proximate cause of the decedent's death.

[4] Fong J, et al. Predictors of mortality in patients with propofol infusion syndrome. Critical Care Medicine 36:2281-7.

30. When sedation is required to optimize mechanical ventilation and patient comfort and safety in critically ill adults like the decedent, there are multiple different pharmacological sedative strategies that can be employed[5][6][7]. International practice guidelines recommend when PRIS is proven, or even suspected, that propofol should be immediately stopped, and never restarted. Dexmedetomidine was shown in a recent large New England Journal of Medicine trial to be as effective as propofol in patients like the decedent (*See*, footnote 6) yet was not initiated until more than 24 hours after the decedent met all criteria for PRIS (*See*, footnote 3). Benzodiazepines, like midazolam, while not recommended in ICU practice guidelines as sedation strategy (*See*, footnote 5) compared to propofol or dexmedetomidine, are routinely used in patients like decedent when deep sedation is required to optimize mechanical ventilation and patient safety, and if propofol use is contraindicated.

31. Critical care pharmacists are experts in medication optimization and safety in the ICU. Critical care pharmacists are particularly attuned to working with the rest of the ICU team to optimize sedation strategies to optimize defined goals and to avoid safety concerns. There is a team of board-certified critical care pharmacists in the [redacted] medical ICU, one of whom is a longstanding board member of the Society of Critical Care Medicine, and who has published extensively on ICU sedation practices. It is unfortunate, these expert pharmacists were not consulted to optimize the sedative care of the decedent.

CONCLUSIONS

[5]Devlin JW, et al. Clinical practice guidelines for the prevention and management of pain, agitation/sedation, delirium, immobility, and sleep disruption in adult patients in the intensive care unit. Crit Care 2018; 46(9):e825-e873.

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32. Based upon my review of the decedent's records at HSS and his January 11-20, 2019 admission to [redacted] it is my opinion, to within a reasonable degree of pharmacological certainty, that the defendant's departed from accepted standards of care to avoid PRIS, recognize PRIS, administer alternatives to propofol, re-administer propofol after it was discontinued, and avoid the untimely death of the decedent.

33. It is further my opinion, to within a reasonable degree of pharmacological certainty, that [redacted] was suffering from propofol infusion syndrome at the time of transfer to [redacted] on January 12, 2019 (2 days after first being exposed to Propofol), and for 24 hours after, the decedent clearly met the definition of PRIS. Although the defendants initially discontinued propofol upon concern for PRIS, Dr. [redacted] and the staff at [redacted] departed from the accepted standard of care when they re-administered high doses of propofol to the decedent during his admission.

34. It is my opinion, to within a reasonable degree of pharmacological certainty, that [redacted], died as a result of cardiac complications known to be caused by PRIS and that the defendants' failure to timely diagnose PRIS and discontinue propofol was a proximate cause of Mr. [redacted] death.

Dated: Boston, MA
February 26, 2022

John [redacted], PharmD, BCCCP, MCCM

Sworn to before me
This ~~20th~~ day of February, 2022

NOTARY PUBLIC

CHRISTOPHER ANTOINE
Notary Public
Commonwealth of Massachusetts
My Commission Expires January 18, 2024

ECONOMIC LOSSES

TO THE SURVIVORS OF

[redacted]

SUBMITTED TO:
SMILEY & SMILEY, LLP
December 16, 2019

[redacted] **PH.D.**

[redacted]

ECONOMIC LOSSES

TO THE SURVIVORS OF

[redacted]

---PRESENT VALUES---

---SUMMARY---

I. NET HOUSEHOLD INCOME WITHOUT PASSING OF MR. [redacted] (TABLE I)		
TOTAL	**$**	**2,654,426**
II. HOUSEHOLD INCOME WITH PASSING OF MR. [redacted]: (TABLE II)		
TOTAL	**$**	**- 1,414,271**
III. NET HOUSEHOLD PRODUCTION LOSS: (TABLE III)		
TOTAL	**$**	**412,177**
IV. TOTAL NET ECONOMIC LOSS	**$**	**1,652,332**

ECONOMIC LOSSES TO THE SURVIVORS OF KWAME OLA RENNIE

SUMMARY OF ECONOMIC ANALYSIS

1. Worklife and Life Expectancy – At the time of his death, Mr. [redacted] was 38.9 years of age. He had a worklife expectancy of 25.4 years to an age of 64.3. Ms. [redacted] was 35.9 years of age at the time of his death and had a worklife expectancy of 22.1 years. His life expectancy was 36.6 years to an age of 75.5 while her life expectancy was 44.3 years to an age of 80.2. This analysis will be conducted to the end of Mr. [redacted]s life expectancy. The reference for worklife expectancy is the Skoog, Ciecka and Krueger study while the reference for life expectancy is the Arias, et al study.

2. Baseline Earnings – According to the information provided to me, Mr. [redacted] earned $75,569, $85,835, $87,282, $96,050 and $95,119 in the years from 2014-18. His earnings in 2018 will be adjusted for inflation and will be used as a baseline earnings estimate in this analysis. In the years from 2015-17, he had employee business expenses that were 7.49% of earnings. This will be assumed to continue in the future at this rate and will be deducted from his earnings.

It is my understanding that Ms. [redacted] annual salary at the time of his passing was $45,000 per year and this will be used as a baseline earnings estimate for her earnings.

3. Wage and Price Inflation – In the period from 2014-18, Mr. [redacted] had earnings that increased at the rate of 5.92%. Overall wage inflation over the past 20 years has been 2.53% and this will be applied to both Mr. and Ms. [redacted] earnings. Over the past 20 years, the Consumer Price Index (CPI) has increased at 2.19%. These data are taken from the website for the U.S. Bureau of Labor Statistics.

4. Personal Consumption – The portion of total household income that would have been spent on the decedent's own food, clothing, automobiles, etc. is not a loss to the survivors and needs to be deducted from earnings to calculate the net economic loss. The study by Krueger will be used to calculate this percentage. The personal consumption rate is based upon income, gender, and number of dependents in the household.

5. Social Security Benefits – There are three benefits that are candidates for valuation:
a) Health Insurance – It is my understanding that Ms. [redacted] and her children currently have health insurance so this benefit will not be valued in this analysis.
b) 401/K Retirement Plan – It is my understanding that Mr. [redacted] had a 401/k plan where the employer matched his contribution up to 5% of his earnings. The percentage he contributed to this plan is not currently available. This will be added to the report once this information becomes known.
c) Social Security Benefits –
i) Survivors – It is my understanding that [redacted] and [redacted] currently receive $1,068 per month in social security survivors benefits and that these benefits are available until they finish high school or an age of 19. These will be adjusted by CPI inflation of 2.19% per annum.
ii) Retirement – The website for the social security administration, www.ssa.gov, provides an opportunity to calculate what social security retirement benefits would have been for both Mr. and Ms. [redacted]. He would have received $5,381 per month at his retirement age and she would

have received $3,095 per month but she would have had to wait until age 62 in order to start collecting this benefit. These benefits are also adjusted by the CPI inflation rate for future years.

6. Household Services – The value of the work performed around the home is obtained from the study The Dollar Value of a Day. The number of hours is reduced by the number of hours spent on household activities that would only benefit the decedent, although most of the hours are for the benefit of the entire household. These are conservatively valued at the minimum wage that exists for New York City. This is conservative since hiring someone to perform these jobs around the home will often require paying more than the minimum wage. It is assumed that, in the future, the minimum wage increases at 2% per year, less than the inflation rate in the CPI.

7. Income Taxes – It is my understanding that taxes are to be calculated and deducted to arrive at a net economic loss in this case. All of the federal and state income taxes that are due on their earnings and benefits are calculated and deducted from household income to arrive at the net economic loss. The tax calculator at smartasset.com was consulted to help calculate these taxes.

8. Present Value – It is also my understanding that present value is to be obtained in this case. The present value is obtained using a discount rate of 2.06%. This represents the average of the yields on 10, 20 and 30 year Treasury bonds which were 1.82%, 2.11% and 2.26%, respectively. These were obtained from the website for the U.S. Department of the Treasury.

TABLE I - NET HOUSEHOLD INCOME WITHOUT PASSING OF MR. RENNIE

YEAR	HIS NET OF EXPENSES EARNINGS	HER EARNINGS	HIS SOCIAL SECURITY	HER SOCIAL SECURITY	TOTAL HOUSEHOLD INCOME
2018	90,221	45,000			135,221
2019	92,503	46,139			138,642
2020	94,844	47,306			142,150
2021	97,243	48,503			145,746
2022	99,704	49,730			149,433
2023	102,226	50,988			153,214
2024	104,812	52,278			157,090
2025	107,464	53,601			161,065
2026	110,183	54,957			165,140
2027	112,971	56,347			169,318
2028	115,829	57,773			173,601
2029	118,759	59,234			177,994
2030	121,764	60,733			182,497
2031	124,844	62,269			187,114
2032	128,003	63,845			191,848
2033	131,242	65,460			196,702
2034	134,562	67,116			201,678
2035	137,966	68,814			206,781
2036	141,457	70,555			212,012
2037	145,036	72,340			217,376
2038	148,705	74,171			222,876
2039	152,467	76,047			228,515
2040	156,325	7,797			164,122
2041	160,280				160,280
2042	164,335				164,335
2043	67,397		38,743		106,140
2044			64,572		64,572
2045			65,986	27,855	93,841
2046			67,431	37,140	104,571
2047			68,908	37,953	106,861
2048			70,417	38,785	109,202
2049			71,959	39,634	111,593
2050			73,535	40,502	114,037
2051			75,146	41,389	116,534
2052			76,791	42,295	119,087
2053			78,473	43,222	121,695
2054			48,115	26,501	74,616
	$ 3,161,142	$ 1,311,002	$ 800,076	$ 375,275	$ 5,647,496

TABLE I - CONTINUED

NET OF TAX INCOME	PERSONAL CONSUMPTION RATE	PERSONAL CONSUMPTION AMOUNT	NET OF TAX AND PERS. CON.	DISCOUNT FACTOR	PRESENT VALUE
97,859	10.1%	13,657	84,202	1.0000	84,202
100,335	10.1%	14,003	86,332	1.0000	86,332
102,874	10.1%	14,357	88,517	0.9798	86,730
105,476	9.7%	14,137	91,339	0.9600	87,689
108,145	9.7%	14,495	93,650	0.9407	88,093
110,881	9.7%	14,862	96,019	0.9217	88,498
113,686	9.3%	14,609	99,077	0.9031	89,473
116,563	9.3%	14,979	101,584	0.8848	89,886
119,512	9.0%	14,863	104,649	0.8670	90,729
122,535	9.0%	15,239	107,297	0.8495	91,147
125,635	9.0%	15,624	110,011	0.8323	91,567
128,814	8.6%	15,307	113,506	0.8155	92,569
132,073	8.6%	15,695	116,378	0.7991	92,995
135,414	8.3%	15,530	119,884	0.7829	93,863
138,840	8.3%	15,923	122,917	0.7671	94,295
142,353	8.0%	15,736	126,617	0.7517	95,173
145,955	8.0%	16,134	129,820	0.7365	95,611
149,647	9.7%	20,058	129,589	0.7216	93,515
153,433	9.7%	20,565	132,868	0.7071	93,946
157,315	9.5%	20,651	136,664	0.6928	94,679
161,295	9.5%	21,173	140,122	0.6788	95,115
165,376	9.5%	21,709	143,667	0.6651	95,553
118,775	11.0%	18,053	100,722	0.6517	65,638
115,995	11.0%	17,631	98,364	0.6385	62,808
118,929	11.0%	18,077	100,852	0.6256	63,097
84,615	13.2%	14,011	70,604	0.6130	43,281
51,477	17.4%	11,236	40,241	0.6006	24,170
74,810	14.2%	13,325	61,485	0.5885	36,184
83,364	13.8%	14,431	68,933	0.5766	39,749
85,190	13.2%	14,106	71,084	0.5650	40,162
87,056	13.2%	14,415	72,641	0.5536	40,213
88,962	13.2%	14,730	74,232	0.5424	40,265
90,910	13.2%	15,053	75,857	0.5315	40,316
92,901	12.6%	14,683	78,218	0.5207	40,731
94,936	12.6%	15,005	79,931	0.5102	40,783
97,015	12.6%	15,334	81,681	0.4999	40,835
59,484	12.6%	9,402	50,082	0.4898	24,532
$ 4,178,435		$ 578,797	$ 3,599,638		$ 2,654,426

TABLE II - NET HOUSEHOLD INCOME WITH PASSING OF MR. [redacted]

YEAR	HER EARNINGS	[redacted] SOCIAL SECURITY	SOCIAL SECURITY	[redacted] SOCIAL SECURITY	TOTAL HOUSEHOLD INCOME	NET OF TAX INCOME	DISCOUNT FACTOR	PRESENT VALUE
2018	45,000	12,816	12,816		70,632	63,032	1.0000	63,032
2019	46,139	13,097	13,097		72,332	64,539	1.0000	64,539
2020	47,306	13,383	13,383		74,073	66,083	0.9798	64,749
2021	48,503	13,677	13,677		75,856	67,664	0.9600	64,960
2022	49,730	13,976	13,976		77,682	69,283	0.9407	65,171
2023	50,988	14,282	14,282		79,552	70,940	0.9217	65,384
2024	52,278	14,595	14,595		81,468	72,638	0.9031	65,597
2025	53,601	14,915	14,915		83,430	74,377	0.8848	65,812
2026	54,957	15,241	15,241		85,439	76,157	0.8670	66,027
2027	56,347	3,115	15,575		75,037	65,520	0.8495	55,658
2028	57,773		15,916		73,689	63,931	0.8323	53,212
2029	59,234		16,265		75,499	65,494	0.8155	53,413
2030	60,733		16,621		77,354	67,096	0.7991	53,615
2031	62,269		16,985		79,254	68,737	0.7829	53,818
2032	63,845		17,357		81,202	70,418	0.7671	54,021
2033	65,460		12,416		77,876	66,820	0.7517	50,226
2034	67,116				67,116	55,780	0.7365	41,082
2035	68,814				68,814	57,192	0.7216	41,271
2036	70,555				70,555	58,639	0.7071	41,461
2037	72,340				72,340	60,122	0.6928	41,652
2038	74,171				74,171	61,643	0.6788	41,844
2039	76,047				76,047	63,203	0.6651	42,036
2040	7,797				7,797	6,480	0.6517	4,223
2041					-	-	0.6385	-
2042					-	-	0.6256	-
2043					-	-	0.6130	-
2044					-	-	0.6006	-
2045				27,855	27,855	27,855	0.5885	16,393
2046				37,140	37,140	37,140	0.5766	21,416
2047				37,953	37,953	37,953	0.5650	21,443
2048				38,785	38,785	38,785	0.5536	21,471
2049				39,634	39,634	39,634	0.5424	21,498
2050				40,502	40,502	40,502	0.5315	21,525
2051				41,389	41,389	41,389	0.5207	21,553
2052				42,295	42,295	42,295	0.5102	21,580
2053				43,222	43,222	43,222	0.4999	21,608
2054				26,501	26,501	26,501	0.4898	12,981
	$ 1,311,002	$ 129,097	$ 237,116	$ 375,275	$ 2,052,490	$ 1,831,062		$ 1,414,271

TABLE III - NET HOUSEHOLD PRODUCTION						
	HOURS	NET HOURS				
	PER	PER	MINIMUM	TOTAL	DISCOUNT	PRESENT
YEAR	WEEK	WEEK	WAGE	VALUE	FACTOR	VALUE
2018	13.43	12.17	15.00	9,493	1.0000	9,493
2019	13.43	12.17	15.30	9,682	1.0000	9,682
2020	13.43	12.17	15.61	9,876	0.9795	9,674
2021	13.43	12.17	15.92	10,074	0.9595	9,665
2022	13.43	12.17	16.24	10,275	0.9398	9,657
2023	13.43	12.17	16.56	10,481	0.9206	9,648
2024	13.43	12.17	16.89	10,690	0.9017	9,640
2025	13.43	12.17	17.23	10,904	0.8833	9,631
2026	13.43	12.17	17.57	11,122	0.8652	9,623
2027	13.43	12.17	17.93	11,345	0.8475	9,614
2028	13.43	12.17	18.28	11,571	0.8301	9,606
2029	14.41	13.00	18.65	12,608	0.8131	10,252
2030	14.41	13.00	19.02	12,860	0.7965	10,243
2031	14.41	13.00	19.40	13,117	0.7802	10,234
2032	14.41	13.00	19.79	13,380	0.7642	10,225
2033	14.41	13.00	20.19	13,647	0.7486	10,216
2034	14.08	12.38	20.59	13,256	0.7332	9,720
2035	14.08	12.38	21.00	13,521	0.7182	9,712
2036	14.08	12.38	21.42	13,792	0.7035	9,703
2037	14.08	12.38	21.85	14,068	0.6891	9,694
2038	14.08	12.38	22.29	14,349	0.6750	9,686
2039	14.08	12.38	22.73	14,636	0.6612	9,677
2040	14.08	12.38	23.19	14,929	0.6477	9,669
2041	14.08	12.38	23.65	15,227	0.6344	9,660
2042	13.01	11.45	24.13	14,365	0.6214	8,927
2043	13.01	11.45	24.61	14,652	0.6087	8,919
2044	13.01	11.45	25.10	14,945	0.5962	8,911
2045	13.01	11.45	25.60	15,244	0.5840	8,903
2046	21.41	19.08	26.12	25,911	0.5721	14,823
2047	19.39	16.49	26.64	22,841	0.5604	12,799
2048	19.39	16.49	27.17	23,298	0.5489	12,788
2049	19.39	16.49	27.71	23,764	0.5377	12,777
2050	29.58	24.95	28.27	36,675	0.5266	19,315
2051	29.58	24.95	28.83	37,409	0.5159	19,298
2052	29.58	24.95	29.41	38,157	0.5053	19,281
2053	29.58	24.95	30.00	38,920	0.4950	19,264
2054	29.58	24.95	30.60	23,819	0.4848	11,548
				$ 624,901		$ 412,177

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