

2011 PENNSYLVANIA STATEWIDE HIGH SCHOOL MOCK TRIAL COMPETITION

The Estate of Simone Langston v. Dr. Lefu Harrison

SPONSORED BY THE YOUNG LAWYERS DIVISION OF THE PENNSYLVANIA BAR ASSOCIATION

Written by: Jon Grode & Paul Kaufman

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Problem Questions & Contact Information

Questions concerning these case materials should be sent to David Keller Trevaskis at the Pennsylvania Bar Association (PBA). Case material questions will be answered in cooperation with the Statewide Mock Trial Executive Committee. Questions regarding mock trial procedure, including any questions involving the Rules of Competition or Rules of Evidence (Pennsylvania. Mock Trial Version), should be directed to your District or Regional Mock Trial Coordinators.

Answers to legitimate and non-repetitive questions will be posted periodically in a supplemental memo on the mock trial website www.pabar.org under the Young Lawyer's Division (YLD) link.

You may begin submitting questions anytime. The deadline for submitting questions is 12:00 noon on January 19, 2011. The final update to the supplemental memo will be posted no later than January 21, 2011. The final memo will become the official supplemental memo and may be used in the competition. Please consult Rule of Competition 3.3 concerning the evidentiary value teams are to give the final official supplemental memo.

Questions must be sent in writing by one of the methods listed below. Please be sure to include return contact information in the event we need to reach you to clarify a question.

No questions will be considered unless submitted under this procedure.

E-mail: <u>david.trevaskis@pabar.org</u>

Fax: 717.238.7182

Regular Mail:

David Keller Trevaskis Pennsylvania Bar Association. 100 South Street PO Box 186 Harrisburg, PA 17108-0186

Introduction and Acknowledgments

Welcome to the 2011 Pennsylvania Statewide High School Mock Trial Competition - the 27th year of one of the premier secondary level academic competitions in the Commonwealth! The competition is sponsored by the Young Lawyers Division of the Pennsylvania Bar Association (PBA/YLD). It provides high school students with firsthand experience of the American judicial system. The Mock Trial Competition is one of a series of law-related and civic education programs conducted by the PBA to demystify the law for Pennsylvanians, including Freedom's Answer, I Signed the Constitution, Project PEACE, Law Day and Stepping Out for Seniors.

This year's case, *The Estate of Simone Langston v. Dr. Lefu Harrison*, is a civil action involving a pathologist who claims to have entered into a contract with a dying and impoverished elderly woman, Simone Langston, to obtain her mutated cancer cells. Ms. Langston's cells offer the promise of curing cancer as well as enriching Dr. Harrison. The central issue in the case is whether Ms. Langston had the capacity to consent to selling her cancer cells to Dr. Harrison.

The case was written by Jonathan A. Grode and Paul W. Kaufman. Mr. Grode, (Temple University James E. Beasley School of Law – 2008) wrote the 2008, 2009 and 2010 mock trial cases. He also adapted and modified the 2007 case. Mr. Grode was also the primary author of case used for the 2010 National High School Mock Trial Championship held in Philadelphia. Mr. Kaufman has been an author or editor of four mock trial cases, including the 2010 National case, and was a four time Delaware state champion mock trialer in high school. Jane E. Meyer, Esq., a current member of the National High School Mock Trial Championship Board of Directors, edited the case in collaboration with Mr. Grode and Mr. Kaufman. Our sincerest thanks go out to Mr. Grode, Mr. Kaufman and Ms. Meyer for their tireless and enthusiastic creation and editing of this year's problem.

Mr. Grode thanks Yuah Jessica Choi, Esq. (Goldblum & Hess) for reviewing various drafts of the problem, Roberta West (LEAP Program Advisor Temple University) for her ongoing and tireless support, and the entire YLD of the PBA for their valued assistance, suggestions and guidance. Mr. Kaufman thanks Dr. John Kent Northrop, M.D., Ph.D. for his wise counsel in this case and thanks his wife, Sarah, for her unflagging, irrational support of his mock trial habit. Both authors want to express their great appreciation of Henrietta Lacks and Rebecca Sklott (author of the Immortal Life of Henrietta Lacks) as the inspiration for this case.

Thanks also go to Co-Chairs of this year's Competition, Ryan Blazure, Esq. and Jennifer J. Walsh, Esq., for their efforts in organizing and implementing the many facets of this competition. The Mock Trial Committee would also like to express its appreciation to Lisa Woodburn, Esq., current PBA/YLD Chair, and Hope Guy, Esq., the PBA/YLD Chair Elect, for their continued support of the competition. Additionally, the YLD thanks David Trevaskis, PBA Pro-Bono Coordinator for his continued involvement and experienced guidance in implementing the 2011 Mock Trial Competition.

Finally, we thank the hundreds of volunteers who annually contribute their time and energy to the overall organization and running of the program. Last, but certainly not least, we thank the PBA staff, headed by Executive Director Barry Simpson and Deputy Executive Director Fran O'Rourke, and the many PBA staff members who provide valuable time and talent throughout the mock trial season. Without their assistance, this competition would not be the tremendous success that it is each year. Special thanks go to Maria Engles, the YLD Coordinator, who serves as the main point of contact for the entire program.

We hope you find these materials interesting, and wish you all the best of luck!

Case Summary

On April 11, 2009, the day before she would die, Simone Langston is alleged to have entered into an agreement with Defendant Dr. Lefu Harrison, allowing her/him to biopsy her cancer cells and to assign exclusive rights to the cells to Dr. Harrison, in exchange for \$200,000. At the time, Simone was 72 years old and suffering from advanced forms of cancer. Defendant, a pathologist at United General Hospital in Pittsburgh, discovered that Simone's metastasized colon cancer cells, which s/he named SiLa, harbored extraordinary properties. Dr. Harrison believed that through the use of genetic engineering, s/he could reprogram SiLa and create a novel cure for cancer. Shortly after Simone's death, Dr. Harrison formed SiLa, Inc. and raised in excess of \$50 million dollars of venture capital funding. Dr. Harrison is currently developing SiLa into what s/he hopes will be a revolutionary advent for scientists and medical researchers across the globe.

Plaintiff, The Estate of Simone Langston, by and through Avery Langston, Simone's daughter/son, challenges the validity of the agreement claiming Simone lacked the capacity (or competency) to enter into any kind of contract with Dr. Harrison. Avery is Simone's only surviving heir and the executor of her estate. The Estate argues that Simone's incapacity renders any agreement for the sale of her cancer cells invalid. It claims that Simone's aggressive chemotherapy scheme, high dosage morphine intake, and generally failing mental state, made it impossible for Simone to read, understand and make competent decisions regarding her medical care or to understand a complex contract concerning the rights to SiLa, as evidenced, in part, by a competency examination she badly failed a few days prior to her death. In addition, The Estate claims it unlikely that Simone would have consented to the biopsy of her cells since she was a member of the Temple of Bona Valetudo, a small but devout religious sect which believed that removal of any part of the human body, no matter how small, was a terrible sin. The Estate also denies that Avery Langston entered into a separate agreement with Dr. Harrison for the rights to SiLa as Simone's de facto legal guardian.

Defendant Dr. Harrison claims that s/he was granted permission to remove the cells and now possesses full rights to the cells through the April 11 contract. Defendant asserts that Simone was competent to enter into the agreement, as supported by a competency exam administered within an hour or so of Simone Langston's execution of the contract by which she granted SiLa rights to Defendant and provided her consent to the biopsy. Defendant also claims that first-hand witness testimony supports a finding that Simone lucidly decided to sell her tissue. Simone's medical insurer had refused to cover her huge medical bill and her only significant asset was her home, in which Avery and her/his own family lived. Simone was concerned that Avery would lose the home. According to the Defendant, Simone also felt an obligation to help humanity, and it was for these reasons that she knowingly sold her tissue. In the alternative, Defendant asserts that if Simone is found incompetent, s/he still retains the rights to SiLa as a result of a separate agreement reached between Defendant and Avery Langston.

At trial, Plaintiff will present three witnesses: (1) Avery Langston, Simone's daughter/son; (2) Dr. Tabor Caget, Simone's oncologist; and (3) Dr. Farley Davis, a competency expert. The Defense will also call three witnesses: (1) Gopi Anandganda, Simone's primary nurse; (2) Dr. Lefu Harrison, the defendant; and (3) Dr. Quincy Ebardiar, a competency expert.

THE ESTATE OF SIMONE LANGSTON, : IN THE COURT OF COMMON PLEAS : ALLEGHENY COUNTY, PENNSYLVANIA

Plaintiff

:

v. : NO. 2009 CV 011648 CV

LEFU HARRISON, M.D., SILA, INC., and : UNITED GENERAL HOSPITAL, :

:

Defendants : CIVIL ACTION – LAW AND EQUITY

COMPLAINT

1. Plaintiff the Estate of Simone Langston, by and through its Executor, Avery Langston, files this action seeking to recover damages for medical battery and unjust enrichment.

- 2. Defendant Lefu Harrison, M.D. ("Harrison") resides on 1121 Shady Avenue, Pittsburgh Pa., within the County of Allegheny, Pennsylvania.
- 3. Defendant United General Hospital ("United General") is located in Pittsburgh, Pennsylvania, which lies within the borders of Allegheny County, Pennsylvania.
- 4. Defendant SiLa, Inc. is a Pennsylvania corporation with a principal place of business in Pittsburgh, Pa., which lies within the borders of Allegheny County, Pennsylvania.
- 5. At all times relevant hereto, Harrison was an employee of United General.
- 6. At all times relevant hereto, Harrison was the President and Chief Executive Officer of SiLa, Inc.
- 7. On April 11, 2009, Harrison took a biopsy of cells from Simone Langston's terminal cancer in order to convert those cells into a highly lucrative medical treatment for cancer.
- 8. There was no diagnostic or other medical need for the biopsy, and the biopsy did not advance Simone Langston's treatment.
- 9. The sole purpose for the harvesting of Simone Langston's cells was to further the independent goal of creating a marketable cancer therapy to benefit Harrison, United General, and/or SiLa, Inc.
- 10. Simone Langston did not consent to the biopsy of cells from her cancer, which was against her will and against her long-standing religious beliefs.
- 11. At all times relevant hereto, Harrison was acting as an agent of United General acting within the scope of her/his authority.
- 12. In the alternative, at all times relevant hereto, Harrison was acting as an agent of SiLa, Inc., acting within the scope of her/his authority.

COUNT I – FAILURE TO OBTAIN INFORMED CONSENT (MEDICAL BATTERY)

- 13. The allegations of paragraphs 1-12 above are incorporated herein at though fully set forth at length.
- 14. Pursuant to 40 P.S. § 1303.504(a)(1) of the Pennsylvania MCARE Act, a physician performing a surgical procedure has a duty to obtain the informed consent of the patient before conducting the surgery.
- 15. A biopsy is a surgical procedure within the meaning of 40 P.S. § 1303.504(a)(1).
- 16. Independently, physicians have a common law duty to obtain consent before committing a technical assault such as cutting the skin or puncturing it with a needle.
- 17. Harrison did not obtain Simone Langston's consent, much less her informed consent, before harvesting cells from her body on April 11, 2009.
- 18. Accordingly, Harrison violated the MCARE Act and/or committed technical assault on Simone Langston on April 11, 2009.
- 19. United General and SiLa, Inc. are liable for the damages suffered by the decedent by virtue of *respondeat superior*.

COUNT II - UNJUST ENRICHMENT

- 20. The allegations of paragraphs 1-19 above are incorporated herein at though fully set forth at length.
- 21. Harrison's harvesting of cells from the decedent provided Harrison a benefit in the form of a line of cells that could potentially be developed into a viable treatment for cancer, which could be worth millions, if not billions, of dollars.
- 22. This potential windfall benefits Harrison, SiLa, Inc. and United General, all of which stand to profit from development of the cell line derived from decedent's cells.
- 23. Harrison harvested the cells against decedent's will and without her consent.
- 24. Under those circumstances, it would be inequitable for Harrison, SiLa, Inc., and/or United General to retain such benefits without payment of fair market value for them.

WHEREFORE, the Estate of Simone Langston prays for an award of compensatory, actual and punitive damages, in excess of the jurisdictional limit, against defendants, to be determined by a jury and to remedy the callous, heartless assault on Simone Langston's body and her dignity.

December 30, 2009	<u>/s/</u>	
Date	Attorn	ey for Plaintiffs

THE ESTATE OF SIMONE LANGSTON, : IN THE COURT OF COMMON PLEAS : ALLEGHENY COUNTY, PENNSYLVANIA

Plaintiff :

:

v. : NO. 2009 CV 011648 CV

:

LEFU HARRISON, M.D., SILA, INC., and : UNITED GENERAL HOSPITAL, :

:

Defendants : CIVIL ACTION – LAW AND EQUITY

DEFENDANTS' ANSWER TO PLAINTIFF'S COMPLAINT

- 1. Admitted in part and denied in part. It is admitted that Plaintiff filed the instant action. The remaining averments of this paragraph constitute conclusions of law to which no response is required. Those averments are therefore deemed denied.
- 2. Admitted.
- 3. Admitted.
- 4. Admitted.
- 5. Admitted.
- 6. Denied. SiLa, Inc. was not incorporated until June 10, 2009. Accordingly, on April 11, 2009, Harrison had no position with the then non-existent company.
- 7. Denied as stated. Defendants admit only that Harrison took a biopsy of cells on April 11, 2009. The remaining allegations in paragraph 7 of Plaintiff's Complaint are denied, and strict proof thereof is demanded at trial.
- 8. Admitted.
- 9. Denied.
- 10. Denied. To the contrary, by way of further response, both Simone Langston and, to the extent that Simone Langston was incompetent, Avery Langston consented to the removal of cells.
- 11. Denied. Although Defendant Harrison was acting as an employee of United General, defendants state that United General policy requires administrative approval for any non-therapeutic or research-based treatments. Because Harrison did not seek or receive administrative approval, s/he was not acting with the scope of her/his employment when s/he removed the cells from Simone Langston on April 11, 2009.
- 12. Denied. See Paragraph 6 above.

COUNT I FAILURE TO OBTAIN INFORMED CONSENT (MEDICAL BATTERY)

- 13. Defendants hereby incorporate the responses to the allegations in paragraphs 1-12 as though the same were fully set forth.
- 14. The averments in paragraph 14 of the Complaint constitute conclusions of law to which no response is required. To the extent a response is deemed required, they are admitted.
- 15. The averments in paragraph 15 of the Complaint constitute conclusions of law to which no response is required. To the extent a response is deemed required, they are admitted.
- 16. The averments in paragraph 16 of the Complaint constitute conclusions of law to which no response is required. To the extent a response is deemed required, they are admitted.
- 17. Denied. To the contrary, by way of further response, both Simone Langston and, to the extent that Simone Langston was incompetent, Avery Langston consented to the removal of cells. Both Simone and Avery Langston were informed of the nature of the procedure, its risks, and its alternatives.
- 18. Denied. Informed consent was obtained, and consent is a complete defense to technical assault.
- 19. The averments in paragraph 19 of the Complaint constitute conclusions of law to which no response is required. To the extent a response is deemed required, they are denied. By way of further response, because no assault occurred, no one is liable. Furthermore, SiLa, Inc. is not responsible for actions that occurred before its creation. United General is not responsible for Harrison's actions because they were beyond the scope of her/his employment.

COUNT II UNJUST ENRICHMENT

- 20. Defendants hereby incorporate the responses to the allegations in paragraphs 1-19 as though the same were fully set forth.
- 21. Denied. By way of further response, defendant Harrison states that the cell line in question has not been successfully commercialized and may, in fact, have little or no commercial value.
- 22. Admitted in part; denied in part. Defendants admit that defendants Harrison and SiLa, Inc. could benefit from the development of the cell line at issue. Defendant United General has no stake in SiLa, Inc. and disavows any responsibility for Harrison's actions. Accordingly, defendant United General stands no chance of profiting from the cell line's development.
- 23. Denied. To the contrary, by way of further response, both Simone Langston and, to the extent that Simone Langston was incompetent, Avery Langston consented to the removal of cells. Both Simone and Avery Langston were informed of the nature of the procedure, its risks, and its alternatives.

24. Denied. By way of further response, under the circumstances, the equitable result is the same as the legal one: Harrison and SiLa, Inc. may develop the cell line in the hope that it becomes profitable in exchange for the \$200,000 currently in escrow pursuant to the contract between Simone Langston and Dr. Lefu Harrison, which contract was reached between the two or, in the alternative, between Dr. Harrison and Avery Langston in her/his capacity as Simone Langston's legal guardian.

WHEREFORE, defendants respectfully request that the Court enter judgment in their favor and against plaintiff.

NEW MATTER

- 25. Because SiLa, Inc. did not exist at the time of the alleged torts, it cannot be held responsible for them.
- 26. Because s/he was not following United General policy and was advancing a research interest not approved by United General, Dr. Harrison was beyond the scope of her/his employment. Accordingly, United General is not liable for the alleged torts.
- 27. Alternatively, the actions of Dr. Harrison were unforeseeable, and United General is therefore not liable for the alleged torts s/he committed.
- 28. On or about April 11, 2009, Dr. Harrison entered a contract with Simone Langston in which Langston agreed to allow Dr. Harrison to remove some of her cancer cells in order to attempt to develop them into a viable cancer therapy. In consideration therefor, Dr. Harrison personally paid Simone Langston \$200,000.
- 29. The April 11, 2009 contract between Dr. Harrison and Simone Langston represents informed consent to the removal of cells and is therefore a complete defense to medical battery. In addition, because the law holds parties to a contract to the bargain they reach, any enrichment of Dr. Harrison is equitable.
- 30. In the alternative, if Simone Langston is determined to have been incompetent to enter into the April 11, 2009 agreement with Dr. Harrison, Dr. Harrison was offered a contract by Avery Langston, in her/his capacity as legal guardian of Simone Langston, when s/he left a note on her/his office door offering to consent to the removal of cells in exchange for a payment of \$200,000. Dr. Harrison accepted this offer by performance and/or by tendering a check for \$200,000 to Avery Langston.
- 31. The April 11, 2009 contract between Dr. Harrison and Avery Langston, in her/his capacity as legal guardian for Simone Langston, represents informed consent to the removal of cells and is therefore a complete defense to medical battery. In addition, because the law holds parties to a contract to the bargain they reach, any enrichment of Dr. Harrison is equitable.

	Wherefore, Defendants d	lemands iudam	ent in their favor	against Plaintiff.
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<u>January 19, 2010</u>	<u>/s/</u>
Date	Attorney for Defendant

THE ESTATE OF SIMONE LANGSTON, : IN THE COURT OF COMMON PLEAS : ALLEGHENY COUNTY, PENNSYLVANIA

Plaintiff :

:

v. : NO. 2009 CV 011648 CV

:

LEFU HARRISON, M.D., SILA, INC., and : UNITED GENERAL HOSPITAL, :

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Defendants : CIVIL ACTION – LAW AND EQUITY

PLAINTIFF'S REPLY TO NEW MATTER

- 25. Denied. It is admitted only that SiLa, Inc. was not incorporated on April 11, 2009. By way of further response, discovery will show whether defendant Harrison was acting as a promoter or sponsor for SiLa. Inc.
- 26. Denied. Discovery is necessary to determine whether defendant Harrison was acting within the scope of her/his employment.
- 27. Denied.
- 28. Denied. By way of further response, on April 11, 2009, Simone Langston was heavily medicated with painkillers that dulled her mind well beyond the point at which she was mentally incompetent. Accordingly, any agreement signed or executed by Simone Langston was void from its inception.
- 29. The averments in paragraph 19 of the Complaint constitute conclusions of law to which no response is required. To the extent a response is deemed required, they are denied. By way of further response, any contract signed by Simone Langston while she was incompetent, including any contract signed on April 11, 2009, is void and of no legal effect. Any consent given by Simone Langston while she was incompetent, including any consent given on April 11, 2009, is void and of no legal effect. In the absence of valid consent, the harvesting of cells from Simone Langston was illegal and their development to the profit of others is unjust.
- 30. Denied. By way of further response, Avery Langston never left any note for Dr. Harrison and never offered Dr. Harrison consent in exchange for a payment of \$200,000. Accordingly, no contract was ever formed.
- 31. The averments in paragraph 19 of the Complaint constitute conclusions of law to which no response is required. To the extent a response is deemed required, they are denied.

February 8, 2010	<u>/s/</u>
Date	Attorney for Plaintiffs

THE ESTATE OF SIMONE LANGSTON, : IN THE COURT OF COMMON PLEAS : ALLEGHENY COUNTY, PENNSYLVANIA

Plaintiff :

:

v. : NO. 2009 CV 011648 CV

LEFU HARRISON, M.D., SILA, INC., and : UNITED GENERAL HOSPITAL, :

:

Defendants : CIVIL ACTION – LAW AND EQUITY

November 16, 2010

OPINION

Presently before the Court are the motions for summary judgment of defendants Lefu Harrison, M.D. ("Harrison"), SiLa, Inc., and United General Hospital ("United General"). For the reasons that follow, the motions of SiLa and United General will be granted, and the motion of defendant Harrison will be denied.

Defendant Dr. Lefu Harrison, a pathologist regularly employed at all relevant times at United General, removed cells from decedent Simone Langston that may prove to have commercial worth to her/him and to the company to which s/he licensed Dr. Harrison's rights in the cell line, SiLa, Inc.¹ Harrison claims that s/he was permitted to remove the cells by a contract with Simone Langston signed or, in the alternative, by a separate agreement reached with her guardian, Avery Langston. The parties agree that there are material issues of fact regarding the circumstances in which these alleged contracts were reached, if they were reached at all.

Whether and when a person possesses a property interest in cells removed as part of a medical procedure is a question that has challenged lawyers, judges, scientists and bioethicists. There is no doubt that Pennsylvania law recognizes a right to bodily integrity, but when cells are taken for medical purposes, that integrity has already been invaded. Nor does the individual from whom the cells are taken exercise continuing control over them. Thus, some experts urge this Court to hold that any lingering property rights are extinguished when the cells are entrusted to medical professionals, just as the right to any other chattel property is abandoned when it is handed over to a third party. Others argue that cells and the genetic information that they contain are more a part of the personhood of a Pennsylvanian as any chattel property and should be entitled, at least, to no less protection than that afforded to a cherished trinket.

Thankfully, this Court is not writing on a blank slate. Although the Pennsylvania Supreme Court has not yet resolved this tension, other courts have, and this Court finds their reasoning persuasive. In Moore v. Regents of University of California, 51 Cal.3d 120 (1990), the California Supreme Court ruled, based in part on California law and in part on the policy interest in protecting medical research that benefits all from being controlled by individuals, that patients had no property interest in medically excised cells. The Moore case has been followed by several other distinguished jurists who concluded, as this Court does, that it correctly assesses the competing interests at stake. See Washington University v. Catalona, 427 F. Supp. 2d 985,

1 The licensed rights to develop the cell line derived from Simone Langston's cells is the only meaningful asset of SiLa, Inc., which was named for Ms. Langston.

997 (E.D. Mo. 2006); Greenberg v. Miami Children's Hospital Research Institute, Inc., 264 F. Supp. 2d 1064 (S.D. Fla. 2003).

Paradoxically, however, it is clear that under many other circumstances, there are enforceable property rights for others in cell lines, genetic sequences, and other, similar forms of biological research. The United States Supreme Court has implied that cell lines are patentable, <u>Diamond v. Chakrabarty</u>, 447 U.S. 303 (1980), and other courts have consistently held that the medical researchers working with those cell lines hold property interests that are legally enforceable, <u>see Pasteur v. United States</u>, 814 F.2d 624 (Fed.Cir.1987); <u>U.S. v. Arora</u>, 860 F. Supp. 1091 (D.Md. 1994); <u>Brotherton v. Cleveland</u>, 923 F.2d 477, 482 (6th Cir.1991) (aggregate of rights existing in body tissue of corpse is similar to property rights); <u>York v. Jones</u>, 717 F.Supp. 421, 425 (E.D.Va.1989) (couple granted property rights in their frozen embryos). The Court finds it highly peculiar that the law would suggest that the only person who cannot profit from one's cells is the person from whom they are taken.²

This Court therefore finds that there is a distinction between two circumstances in which cells could be removed by a medical practitioner based not on property rights but on the simple principles of informed consent. The first category governs cells removed as part of a regular course of medical treatment in order to better diagnose or treat the patient. If cells are taken as part of a routine diagnostic biopsy or other, similar procedure, the patient has no expectation that the cells will be retained or that they will remain in her/his control. Accordingly, the patient is considered to have abandoned them, has no further property interest in them, and the medical care provider that removed them may use any cells not destroyed in the diagnostic testing for any purpose.

By contrast, if the cells are removed without informed or presumed consent, such as when cells are removed for the sole purpose of commercializing them with no corresponding medical benefit to the patient, the patient is considered to retain whatever rights s/he does not actively surrender. The core question thus is not whether there is a property interest in the cells per se, but rather whether the "patient" consented to the "medical" treatment. Because consent is required, such consent may be limited, and a person may consent to donate cells for a limited purpose, even if s/he would have no property rights in those cells were they taken as part of a medical treatment. This common sense solution ensures that medical care providers need not fear to use the results of routine, consensual medical care, while preserving the individual right to limit the use of one's genetic and biological material.

The parties agree that cells were taken from Simone Langston's cancerous metastases on two occasions. First, cells were taken during her emergency admission, while the doctors attempted to determine the nature of her medical condition. These cells were taken for purposes of diagnosis, and because Langston was unconscious and in need of emergency care, her consent is presumed. <u>Cf.</u> 40 P.S. § 1303.504 (consent required "except in emergencies"). Thus, Langston and her estate lack any property interest in the cells removed for diagnostic

conclude that the tribe originated in Asia, which challenged long-held tribal cultural and religious beliefs. Although this settlement has no precedential force, it illustrates the perception that people have a right to control use of their genetic and biological material.

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² Others appear to be troubled by this as well. Arizona State University and forty-one members of the Havasupai tribe of Native Americans recently reached an agreement in which the University paid hundreds of thousands of dollars to resolve claims that it used DNA information collected from tribe members in research on psychiatric illness and anthropology, even though the Havasupai had unquestionably consented to scientists using that information to study the abnormal rate of diabetes in the tribe. An anthropologist obtained the Havasupai DNA and used it to conclude that the tribe originated in Asia, which challenged long-held tribal cultural and religious beliefs. Although this

purposes. However, these cells were destroyed when an autoclave at the hospital's pathology lab malfunctioned, and are not at issue here.

The second time that cells were taken from Ms. Langston was on or about April 11, 2009, after Dr. Harrison recognized the potential value of the cells.³ Because Harrison concedes that these cells were removed in order to attempt to develop a cure for others' cancer, not Ms. Langston's, Langston was entitled to refuse to have the cells removed or to condition or limit her consent in whatever manner she chose. That interest may be enforced by her estate. Accordingly, Harrison's motion must be denied.

The next question is whether United General can be held vicariously liable for Dr. Harrison's alleged misdeeds. Here again Harrison's testimony is instructive. Harrison makes it clear that s/he never intended to use the "SiLa" cell lines as a part of her/his duties as a staff pathologist at United General, a position it appears that s/he may not have held much longer in any case. Rather, Harrison's entire course of conduct suggests that s/he was acting on her/his own behalf, not United General's. For example, Harrison came in to perform the biopsy over the weekend, outside her/his usual work hours at the hospital. In addition, Harrison retained a private mental competence expert at personal expense, rather than using the hospital's, which would have been free. Moreover, Harrison consciously chose not follow United General's detailed procedures for the approval of research. Finally, testimony by United General executives confirms that United General did not approve the cell biopsy and may not have approved it had they been asked. Nor did United General executives know of or approve Harrison storing the cells at United General while s/he acquired at personal expense the means to do so elsewhere. Accordingly, the Court finds that there is no material issue of fact in this regard. Dr. Harrison was acting outside the scope of her/his employment, pursuing her/his own interest. United General does not enjoy a financial or legal interest in the development of the SiLa cell line. It should not share in the liability, if any, for the manner in which those cells were acquired. Judgment shall be entered for defendant United General Hospital.

The final motion before the Court is defendant SiLa, Inc.'s motion for summary judgment. SiLa, Inc. contends, in short, that it came into existence more than two months after the cells were taken and thus that it cannot be held liable for Dr. Harrison's actions in taking those cells. SiLa, Inc. is incorrect that there are no circumstances under which it could be held liable. There is well-developed Pennsylvania law holding that a "sponsor" or "promoter" of an as-yet-non-existent entity can nonetheless bind that entity. However, that is not the instant case. Here, the alleged contract is between Simone Langston and Dr. Harrison personally, not between Langston and SiLa. Inc. The payment for both the competency expert and the alleged payment for the cells themselves were both drawn on Dr. Harrison's personal account, not a SiLa, Inc. account or on venture capital intended to support SiLa, Inc. Nor is there evidence that SiLa, Inc. reimbursed Harrison for those costs. There is no evidence that Dr. Harrison had even conceived of SiLa, Inc. in the form it eventually took, much less that s/he represented her/himself as speaking on its behalf. Finally, Dr. Harrison has licensed the SiLa line of cells to SiLa, Inc., not transferred her/his interest to that company. Accordingly, the Court finds no material issue of fact exists. Dr. Harrison was acting on her/his own behalf on April 11, 2009, not on behalf of the non-existent SiLa, Inc. Judgment shall be entered for defendant SiLa, Inc. 4

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³ Whether this recognition was prompted by a desire to benefit all mankind, as Harrison argues, or by a crass desire for profit, as the Estate does, is irrelevant.

⁴ Plaintiff argues that the dismissal of SiLa, Inc. leaves it without a remedy. However, Harrison's ownership of the SiLa line of cells and her/his controlling interest in SiLa, Inc. are subject to legal or equitable transfer to plaintiff if plaintiff succeeds at trial. Although plaintiff is correct that SiLa, Inc. would still be allowed to develop the cells under

The Court disposes quickly of plaintiff's tenuous argument that if Simone Langston was incompetent, that Avery Langston could not contract on her behalf because Avery had not been legally appointed as Simone's guardian. The record is replete with examples of Avery exercising medical judgment on her/his mother's behalf during periods that all parties agree Simone Langston was incompetent. There is no suggestion in the record that any party, including Simone, objected to this arrangement. Having acted as Simone Langston's guardian throughout the relevant time period, Avery Langston may not rely on a technicality to evade the legal responsibility s/he undertook.

Finally, defendant Harrison argues that the Court should dismiss the unjust enrichment claim. Harrison admits having taken the second biopsy of cells from Simone Langston, and thus s/he admits that, absent informed consent, s/he committed technical assault. If there was such consent, Harrison argues, then her/his enrichment was not unjust; if there was no such consent, s/he is already liable at law. Were the Court to allow the unjust enrichment count to proceed, s/he argues, it would invite the jury to decide that there had been consent, but that the cells were worth more than s/he paid, denying her/him the benefit of her/his bargain. The Court agrees. Plaintiff's tort remedies are sufficient to provide compensation for the decedent's alleged injury. Equity will not suffer a wrong to be without a remedy, but nor will it rise to defend a plaintiff whose rights are adequately protected at law.

Accordingly, this court enters the following:

PRE-TRIAL ORDER

AND NOW, this 16th day of November, 2010, it is directed as follows:

- 1. Defendant United General Hospital's motion for summary judgment is **GRANTED**. Accordingly, judgment is entered in favor of defendant United General Hospital;
- 2. Defendant SiLa, Inc.'s motion for summary judgment is **GRANTED**. Accordingly, judgment is entered in favor of defendant SiLa, Inc.;
- 3. Defendant Lefu Harrison's motion for summary judgment is **DENIED**. Dr. Harrison shall prepare for trial on the merits of the remaining questions before the Court;
- 4. Plaintiff's unjust enrichment claim is **DISMISSED**; and
- 5. This action is hereby scheduled for a one-day jury trial during the January-March 2011 Civil Trial Term.

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FELIX HOENIKKER, J.

<u>Distribution</u>: Plaintiff's Attorney Defendants' Attorneys

the terms of its licensing agreement with Dr. Harrison regardless of plaintiff's wishes, the Court is untroubled by the possibility that a cure for cancer might emerge over plaintiff's objection.

THE ESTATE OF SIMONE LANGSTON, : IN THE COURT OF COMMON PLEAS : ALLEGHENY COUNTY, PENNSYLVANIA

Plaintiff :

:

v. : NO. 2009 CV 011648 CV

:

LEFU HARRISON, M.D.,

•

Defendant : CIVIL ACTION – LAW

STIPULATIONS

1. With the exception of Exhibits 3 and 16, all documents, signatures and exhibits, including pre-markings, included in the case materials are authentic and accurate in all respects; no objections to the authenticity of the documents or exhibits other than Exhibits 3 and 16 will be entertained. The parties reserve the right to dispute any legal or factual conclusions based on these items and to make objections other than to authenticity.

- 2. Exhibit 3 is a true and accurate copy of the document allegedly signed by Simone Langston on April 11, 2009. Either party is free to contest the authenticity or admissibility of Exhibit 3 in all other respects.
- 3. Exhibit 16 is a true and accurate copy of the document allegedly found by Lefu Harrison in her/his office. Either party is free to contest the authenticity or admissibility of Exhibit 16 in all other respects.
- 4. Jurisdiction, venue and chain of custody of the evidence are proper and may not be challenged.
- 5. All statements were notarized on the day on which they were signed.
- 6. This matter shall be bifurcated. Only the issue of whether defendant is liable is before the jury. The issue of damages is not before the jury.
- 7. With the exception of Avery Langston, all witnesses have read the decedent's medical records in their entirety and are familiar with their contents.
- 8. Avery Langston was the sole surviving child of Simone Langston at the time of Simone Langston's death. Accordingly, Avery Langston was Simone Langston's sole heir.
- 9. Simone Langston died intestate (without making a will). Her entire estate, including the family home, was consumed paying the medical bills owed to United General Hospital and other medical care providers. Her estate has no existing debts and no remaining assets.
- 10. Pursuant to the Court's decision, to the extent the fact finder might find that Simone Langston was incompetent on April 11, 2009, Avery Langston was authorized to act as her guardian and make decisions for her.

- 11. The removal of the decedent's cells on April 11, 2009, was accomplished using a cell biopsy, a surgical procedure of the type that required Dr. Lefu Harrison to obtain informed consent of Simone Langston.
- 12. The language recited in Exhibit 3 describing the cell biopsy procedure (Fine Needle Aspiration (FNA)) and the risks and alternatives thereof, contains information that a reasonably prudent patient would require to make to an informed decision as to that procedure. Whether an informed decision was made in this case is not stipulated, however.
- 13. All payments relating to the storage of the SiLa cells and the competency examination performed by Quincy Ebardiar were made from personal accounts owned by Lefu Harrison. None of these payments have been reimbursed by SiLa, Inc.
- 14. Exhibits 11 and 12 are taken from Kilgore Trout, M.D., <u>Pharmaceuticals in Hospital Practice</u> (7th Ed. 2008). "Trout's Pharmaceuticals," as it is commonly known, is a text from which medical students are taught and which is commonly used by medical professionals in hospital settings, including United General Hospital. Drs. Caget, Davis, Harrison, and Ebardiar are familiar with Trout's Pharmaceuticals.

/s/	/s/	
Plaintiff's Attorney	Defendant	s Attorney

Date: December 17, 2010

APPLICABLE LAW

FOR THE PURPOSES OF THE MOCK TRIAL COMPETITION, THE FOLLOWING SECTIONS OF THE UNIFORM HEATH-CARE DECISIONS ACT AND RESTATEMENT (SECOND) OF CONTRACTS HAVE BEEN ADOPTED, MODIFIED AS FOLLOWS:

Uniform Health-Care Decision Act § 1(3) (1993)

"Capacity" means an individual's ability to understand the significant benefits, risks, and alternatives to proposed health care and to make and communicate a health-care decision.

Restatement Second of Contracts § 12. Capacity To Contract

- (1) No one can be bound by contract who has not legal capacity to incur contractual duties. Capacity to contract may be partial and its existence in respect of a particular transaction may depend upon the nature of the transaction or upon other circumstances.
- (2) A natural person who manifests assent to a transaction has full legal capacity to incur contractual duties thereby unless he is:
 - (a) under guardianship, or
 - (b) an infant, or
 - (c) mentally ill or defective, or
 - (d) intoxicated.

Comments:

- (a) Total and partial incapacity. Capacity, as here used, means the legal power which a normal person would have under the same circumstances. Incapacity may be total, as in cases where extreme physical or mental disability prevents meaningful understanding or manifestation of assent to the transaction, or in cases of mental illness after a guardian has been appointed.
- (b) Types of incapacity. Historically, the principal categories of natural persons having no capacity or limited capacity to contract were married women, infants, and insane persons. Those formerly referred to as insane are included in the more modern phrase "mentally ill," and mentally defective persons are treated similarly. Statutes sometimes authorize the appointment of guardians for habitual drunkards, narcotics addicts, spendthrifts, aged persons or convicts as in cases of mental illness.
- (c) Inability to manifest assent. In order to incur a contractual duty, a party must make a promise, manifesting his intention; in most cases he must manifest assent to a bargain. The conduct of a party is not effective as a manifestation of his assent unless he intends to engage in the conduct. Hence if physical disability prevents a person from acting, or if mental disability is so extreme that he cannot form the necessary intent, there is no contract. Similarly, even if he intends to engage in the conduct, there is no contract if the other party knows or has reason to know that he does not intend the resulting appearance of assent. In such cases it is proper to say that incapacity prevents the formation of a contract.

Illustrations:

 X, an aged person who suffers from severe dementia, agrees with Y, a competent adult, to sell his home to Y for \$100,000. X does not have a guardian, but is shown to have been incompetent at the time of the agreement. X dies shortly after the agreement is

- made. X's estate need not sell X's home, because X was not competent to make the agreement.
- P is mentally ill and under the legal guardianship of Q. During P's hospitalization, he becomes ill, and refuses surgical treatment. Q agrees with P's doctor, R, that the procedure is advisable and agrees that R should perform it. Shortly thereafter, P is medicated and regains competency. P refuses to pay R on the grounds that he did not agree to the surgery. R has the right to be paid; P is bound by his guardian's decision, even if he would have made a different one had he been competent at the time.

Medical Care Availability and Reduction of Error (MCARE) Act

40 P.S. § 1303.504. Informed Consent

- (a) Duty of physicians. -- Except in emergencies, a physician owes a duty to a patient to obtain the informed consent of the patient or the patient's authorized representative prior to conducting the following procedures:
 - (1) Performing surgery, including the related administration of anesthesia.
 - (2) Administering radiation or chemotherapy.
 - (3) Administering a blood transfusion.
 - (4) Inserting a surgical device or appliance.
 - (5) Administering an experimental medication, using an experimental device or using an approved medication or device in an experimental manner.
- (b) Description of procedure. -- Consent is informed if the patient has been given a description of a procedure set forth in subsection (a) and the risks and alternatives that a reasonably prudent patient would require to make an informed decision as to that procedure. The physician shall be entitled to present evidence of the description of that procedure and those risks and alternatives that a physician acting in accordance with accepted medical standards of medical practice would provide.

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(d) Liability. -- A physician is liable for failure to obtain the informed consent only if the patient proves that receiving such information would have been a substantial factor in the patient's decision whether to undergo a procedure set forth in subsection (a). In that case, the physician has committed a medical battery.

ALLEGHENY COUNTY, PENNSYLVANIA

THE ESTATE OF SIMONE LANGSTON, : IN THE COURT OF COMMON PLEAS

Plaintiff :

:

v. : NO. 2009 CV 011648 CV

:

LEFU HARRISON, M.D.,

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Defendant : CIVIL ACTION – LAW

JURY INSTRUCTIONS

Before the commencement of the trial and its conclusion, the judge will instruct the jury how to apply the law to the evidence. Hypothetically, if the judge in your mock trial case were to provide instructions to the jury, they would look something like the following: (Please note: A copy of these instructions may not be used as an exhibit during the mock trial competition; however students may use these concepts in fashioning their case and making arguments to the jury.)

PRELIMINARY INSTRUCTIONS

Role of the Jury

Now that you have been sworn, I have the following preliminary instructions for your guidance as jurors in this case.

You will hear the evidence, decide what the facts are, and then apply those facts to the law that I will give to you.

You and only you will be the judges of the facts. You will have to decide what happened. I play no part in judging the facts. You should not take anything I may say or do during the trial as indicating what I think of the evidence or what your verdict should be. My role is to be the judge of the law. I make whatever legal decisions have to be made during the course of the trial, and I will explain to you the legal principles that must guide you in your decisions. You must follow that law whether you agree with it or not.

Moreover, although the lawyers may have called your attention to certain facts or factual conclusions that they thought were important, what the lawyers said is not evidence and is not binding on you. It is your own recollection and interpretation of the evidence that controls your decision in this case.

Finally, neither sympathy nor prejudice should influence your verdict. You are to apply the law as stated in these instructions to the facts as you find them, and in this way decide the case.

Sidebars

During the trial it may be necessary for me to talk with the lawyers out of your hearing by having a bench conference. If that happens, please be patient.

We are not trying to keep important information from you. These conferences are necessary for me to fulfill my responsibility, which is to be sure that evidence is presented to you correctly under the law. We will, of course, do what we can to keep the number and length of these conferences to a minimum.

I may not always grant an attorney's request for a conference. Do not consider my granting or denying a request for a conference as any indication of my opinion of the case or of what your verdict should be.

Evidence

The evidence from which you are to find the facts consists of the following:

- 1. The testimony of the witnesses;
- 2. Documents and other things received as exhibits;
- 3. Any facts that are stipulated--that is, formally agreed to by the parties; and
- 4. [Any facts that are judicially noticed--that is, facts I say you must accept as true even without other evidence.]

The following things are not evidence:

- 1. Statements, arguments, and questions of the lawyers for the parties in this case;
- 2. Objections by lawyers;
- 3. Any testimony I tell you to disregard; and
- 4. Anything you may see or hear about this case outside the courtroom.

You must make your decision based only on the evidence that you see and hear in court. Do not let rumors, suspicions, or anything else that you may see or hear outside of court influence your decision in any way.

You should use your common sense in weighing the evidence. Consider it in light of your everyday experience with people and events, and give it whatever weight you believe it deserves. If your experience tells you that certain evidence reasonably leads to a conclusion, you are free to reach that conclusion.

There are rules that control what can be received into evidence. When a lawyer asks a question or offers an exhibit into evidence, and a lawyer on the other side thinks that it is not permitted by the rules of evidence, that lawyer may object. This simply means that the lawyer is requesting that I make a decision on a particular rule of evidence. You should not be influenced by the fact that an objection is made. Objections to questions are not evidence. Lawyers have an obligation to their clients to make objections when they believe that evidence being offered is improper. You should not be influenced by the objection or by the court's ruling on it. If the objection is sustained, ignore the question. If it is overruled, treat the answer like any other.

Also, certain testimony or other evidence may be ordered struck from the record and you will be instructed to disregard this evidence. Do not consider any testimony or other evidence that gets struck or excluded. Do not speculate about what a witness might have said or what an exhibit might have shown.

Credibility

In deciding what the facts are, you may have to decide what testimony you believe and what testimony you do not believe. You are the sole judges of the credibility of the witnesses. "Credibility" means whether a witness is worthy of belief. You may believe everything a witness

says or only part of it or none of it. In deciding what to believe, you may consider a number of factors, including the following:

- 1. the opportunity and ability of the witness to see or hear or know the things the witness testifies to;
- 2. the quality of the witness's understanding and memory;
- 3. the witness's manner while testifying;
- 4. whether the witness has an interest in the outcome of the case or any motive, bias or prejudice;
- 5. whether the witness is contradicted by anything the witness said or wrote before trial or by other evidence;
- 6. how reasonable the witness's testimony is when considered in the light of other evidence that you believe; and
- 7. any other factors that bear on believability.

In deciding the question of credibility, remember to use your common sense, your good judgment, and your experience. Inconsistencies or discrepancies in a witness' testimony or between the testimonies of different witnesses may or may not cause you to disbelieve a witness' testimony. Two or more persons witnessing an event may simply see or hear it differently. Mistaken recollection, like failure to recall, is a common human experience. In weighing the effect of an inconsistency, you should also consider whether it was about a matter of importance or an insignificant detail. You should also consider whether the inconsistency was innocent or intentional.

After you make your own judgment about the believability of a witness, you can then attach to that witness' testimony the importance or weight that you think it deserves.

The weight of the evidence to prove a fact does not necessarily depend on the number of witnesses who testified or the quantity of evidence that was presented. What is more important than numbers or quantity is how believable the witnesses were, and how much weight you think their testimony deserves.

POST-TRIAL INSTRUCTIONS

Burden of Proof.

This is a civil case. The Estate of Simone Langston brought this lawsuit. Dr. Lefu Harrison is the person against whom the lawsuit was filed. The Estate has the burden of proving its case by what is called the "preponderance of the evidence." That means the Estate has to prove to you, in light of all the evidence, that what it claims is more likely so than not so. To say it differently: if you were to put the evidence favorable to the Estate and the evidence favorable to Harrison on opposite sides of the scales, the Estate would have to make the scales tip somewhat on its side. If the Estate fails to meet this burden, the verdict must be for Harrison. If you find after considering all the evidence that a claim or fact is more likely so than not so, then the claim or fact has been proved by a preponderance of the evidence.

Here, the Estate must prove that Harrison took cells from Simone Langston without Simone Langston's consent. The Estate can show this by showing that no one consented to the removal of cells or by showing that Simone Langston consented to the removal of cells from her body, but that she was not competent to enter into a contract at the time that the agreement was reached.

Harrison has argued that even if Simone Langston didn't reach a contract with her/him, or if she was incompetent at the time that she did reach a contract with her/him, s/he reached a contract with Avery Langston, who was Simone Langston's guardian. I am instructing you now that if and only if you find that Simone Langston was incompetent on April 11, 2009, then Avery Langston was entitled to reach an agreement on Simone Langston's behalf, and any agreement that s/he reached is binding on the Estate. Accordingly, if you find that Simone Langston was incompetent and that Avery Langston reached an agreement with Harrison on Simone Langston's behalf, you must find in favor of the defendant, Lefu Harrison. Regardless of the issue, the plaintiff, the Estate of Simone Langston, bears the burden of proof.

In determining whether any fact has been proved by a preponderance of evidence in the case, you may, unless otherwise instructed, consider the testimony of all witnesses, regardless of who may have called them, and all exhibits received in evidence, regardless of who may have produced them.

You may have heard of the term "proof beyond a reasonable doubt." That is a stricter standard of proof and it applies only to criminal cases. It does not apply in civil cases such as this, so you should put it out of your mind.

Direct and Circumstantial Evidence.

Evidence may either be direct evidence or circumstantial evidence. Direct evidence is direct proof of a fact, such as testimony by a witness about what that witness personally saw, heard, or did. Circumstantial evidence is proof of one or more facts from which you could find another fact. You should consider both kinds of evidence. The law makes no distinction between the weight to be given to either direct or circumstantial evidence. It is for you to decide how much weight to give. You may decide the case solely based on circumstantial evidence.

• Elements of the Claims

The law protects the physical integrity of every person from all unnecessary and unwarranted violation or interference. Any intentional use of force upon the person of another is a "battery." So, the least intentional touching of the person of another, if accompanied by an intentional use or display of force such as would give the victim reason to fear or expect immediate bodily harm, constitutes a "battery."

In the context of medical care, a medical care provider is only permitted to invade the body's physical integrity with the permission of the patient. That permission can be expressed in a variety of ways, and it may be given orally or in writing. Often, this permission is given as part of the regular provision of medical care. However, in some circumstances it is given exceptionally, outside of that process. Regardless, if permission is given in exchange for money or another thing of value, the law treats that agreement like any other contract.

The parties have stipulated that cells were removed from Simone Langston on two occasions. The first time, Simone Langston was unconscious. The law presumes, and you are bound to conclude, that an unconscious person has consented to regular medical treatment. The parties have stipulated that the first removal of cells was in the course of regular medical treatment. You must now treat this fact as having been proved for the purpose of this case. Accordingly, I am instructing you that the first removal of cells was legally proper and that you cannot find Dr. Harrison liable based on her/his actions removing the cells the first time.

The parties have also stipulated that the second removal of cells was not for purposes of diagnosing or providing additional medical treatment to Simone Langston. You must now treat

this fact as having been proved for the purpose of this case. Accordingly, I am instructing you that if neither Simone Langston nor, if Simone Langston was incompetent, Avery Langston acting on her behalf reached an agreement consenting to those cells being taken, you must find in favor of the Estate and against Dr. Harrison. By contrast, if you find that an agreement was reached between Dr. Harrison and Simone Langston or, if Simone Langston was incompetent, Avery Langston acting on her behalf, then you must find in favor of Dr. Harrison and against the Estate.

A contract is a promise or set of promises for the breach of which the law gives a remedy or the performance of which the law in some way recognizes a duty. To be binding, a contract must include a manifestation of mutual assent to the terms and conditions of the contract. This is referred to as the "meeting of the minds." There must be a meeting of the minds; there can be no contract if only one party intends to be bound. Likewise, there can be no contract if only one party has the mental ability to enter into the contract.

This ability is what the law calls "capacity" or "competence." "Capacity" means an individual's ability to understand the significant benefits, risks, and alternatives to proposed health care and to make and communicate a health-care decision. When someone is not able to understand any of those things, the law terms that person "incompetent." The validity of every contract is dependent upon the capacity of the parties to contract.

Under Pennsylvania law, it is presumed that an adult is competent to enter into an agreement and a signed document gives rise to the presumption that it accurately expresses the state of mind of the signing party. To rebut this presumption, The Estate of Simone Langston must present evidence of mental incompetency which demonstrates by preponderance of the evidence that Simone Langston was not mentally competent. In other words, the Estate of Simone Langston must show that it is more likely that Simone Langston was incompetent than that she was competent. Furthermore, where mental competency is at issue, the real question is the condition of the person at the very time she executed the instrument in question. Mere mental weakness, if it does not amount to inability to comprehend the contract is insufficient to set aside a contract. Lastly, a person's mental capacity is best determined by her spoken words and her conduct. and the testimony of persons who observed such conduct on the date in question outranks testimony as to observations made prior to and subsequent to that date.

Should you find that Simone Langston was incompetent and unable to provide her informed consent to the removal of her cells, you may consider that the law allows another, competent person to act on that person's behalf and to make decisions for that person. As I told you before, I am instructing you that if you find that Simone Langston was incompetent on April 11, 2009, Avery Langston was the person who was authorized to make decisions for her. Whether Simone Langston was incompetent and whether, if so, Avery Langston made any such decisions for her are matters that you and you alone must decide, and you should not take anything I say as expressing an opinion on that question. Nothing I say or do is intended to influence you in any way in reaching those decisions.

Ladies and Gentlemen of the jury: on behalf of the Court and the Commonwealth of Pennsylvania, I thank you in advance for your careful thought and consideration as you deliberate the merits of this matter.

JURY INTERROGATORIES

THE ESTATE OF SIMONE LANGSTON, : IN THE COURT OF COMMON PLEAS
ALLEGHENY COUNTY, PENNSYLVANIA

Plaintiff :

v. : NO. 2009 CV 011648 CV

LEFU HARRISON, M.D., :

Defendant : CIVIL ACTION – LAW

SPECIAL JURY INTERROGATORIES

[At many trials, the judge provides interrogatories like these to the jury at the end of the trial. The jury is instructed to reach a verdict consistent with the answers it finds to the interrogatories. A copy of these interrogatories may not be used as an exhibit during the mock trial competition.]

To the jury:

To further clarify instructions given to you by the trial judge, you are being provided with the following verdict form. At the conclusion of your deliberations, one copy of this form should be signed by your foreperson and handed to the court clerk. This will constitute your verdict.

Remember that you are applying a preponderance of the evidence standard to each question.

Question 1:

1.	Harrison on April 11, 2009, was Simone Langston competent to enter into that agreement and provide her informed consent; i.e. did she have sufficient mental capacity to do so?		
	Yes No		
	If your answer is "yes," proceed to Question 2. If your answer is "no," skip Question 2 and proceed to Question 3.		

Question 2:

2. You have concluded that Simone Langston was competent on April 11, 2009 to enter into an agreement with Defendant Harrison and provide her informed consent. Did Simone Langston in fact enter into an agreement that day with Dr. Lefu Harrison, consenting to the removal of her cells in exchange for \$200,000?

Yes	No
Langston v cells was v return to th If you answ Langston v	vered "Yes" to Question 2, Dr. Harrison's removal of cells from Simone was done with her consent and consequently, the contract to pay her for those valid. Your verdict is thus for the Defendant. Do not proceed any further and le courtroom. Vered "No" to Question 2, Dr. Harrison's removal of cells from Simone was done without her consent. Your verdict is thus for the Plaintiff. The amount is due Plaintiff, if any, will be determined at a later hearing.
Question 3:	
unable to p acting as h	concluded that Simone Langston was incompetent on April 11, 2009 and thus provide informed consent for the removal of her cells. Did Avery Langston, her guardian, grant Simone Langston's consent to Dr. Harrison, permitting remove her cells, in exchange for \$200?
Yes	No
from Simor	vered "Yes" to Question 3, you have found that Dr. Harrison's removal of cells ne Langston was done with her guardian's consent and consequently, an to pay her for those cells did exist. Your verdict is thus for the Defendant.
from Simor agreement	vered "No" to Question 3, you have found that Dr. Harrison's removal of cells ne Langston was done without her guardian's consent and consequently, any to pay her for those cells was invalid. Your verdict is thus for the Plaintiff. The damages due Plaintiff, if any, will be determined at a later hearing.
Do not pro	ceed any further and return to the courtroom.
Jury Foreperson	

Glossary of Medical Terms

- Adenocarcinoma (ad"ĕ-no-kahr"sĭ-no mah): A cancerous tumor originating in the cells of glandular tissue and forming irregular glands.
 Medical-dictionary.com http://medical-dictionary.thefreedictionary.com/adenocarcinoma
- Analgesia (an"al-je ze-ah): absence of sensibility to pain.
 Medical-dictionary.com http://medicaldictionary.thefreedictionary.com/analgesia
- Apoptosis (ap"op-to'sis): a pattern of cell death affecting single cells, marked by shrinkage of the cell and fragmentation of the cell into membrane-bound bodies that are eliminated. Often used synonymously with programmed cell death.
 Medical-dictionary.com http://medicaldictionary.thefreedictionary.com/apoptosis
- Biopsy (bi´op-se): removal and examination, usually microscopic, of tissue from the living body, performed to establish precise diagnosis.
 Medical-dictionary.com http://medicaldictionary.thefreedictionary.com/biopsy
- Cecum (se´kum): the first part of the large intestine, forming a dilated pouch proximal to the colon.
 Medical-dictionary.com http://medicaldictionary.thefreedictionary.com/cecum
- Chemotherapy: treatment of <u>cancer</u> with <u>anticancer drugs</u>. The main purpose of chemotherapy is to kill cancer cells. It usually is used to treat patients with cancer that has spread from the place in the body where it started (metastasized). Chemotherapy destroys cancer cells anywhere in the body. It even kills cells that have broken off from the main tumor and traveled through the blood or lymph systems to other parts of the body. Chemotherapy can cure some types of cancer. In some cases, it is used to slow the growth of cancer cells or to keep the cancer from spreading to other parts of the body. When a cancer has been removed by surgery, chemotherapy may be used to keep the cancer from coming back (adjuvant therapy). Chemotherapy also can ease the symptoms of cancer, helping some patients have a better quality of life.

 Medical-dictionary.com/http://medicaldictionary.thefreedictionary.com/chemotherapy
- Colonoscopy: medical procedure where a long, flexible, tubular instrument called the
 colonoscope is used to view the entire inner lining of the colon (large intestine) and the rectum. A
 colonoscopy is generally recommended when the patient complains of rectal bleeding or has a
 change in bowel habits and other unexplained abdominal symptoms. The test is frequently used
 to test for colorectal <u>cancer</u>, especially when polyps or tumor-like growths have been detected.

 Medical-dictionary.com http://medicaldictionary.thefreedictionary.com/colonoscopy
- Dementia (dě-men´shah): general loss of cognitive abilities, including impairment of memory as well as one or more of the following: disturbed planning, organizing, and abstract thinking abilities. It does not include decreased cognitive functioning due to clouding of consciousness, depression, or other functional mental disorder.
 Medical-dictionary.com http://medicaldictionary.thefreedictionary.com/dementia
- Endorphins: Pain-killing substances produced in the human body and released by stress or trauma.
 Medical-dictionary.com http://medicaldictionary.thefreedictionary.com/endorphins
- Intramuscular [IM]: administered to or occurring inside of a muscle. Medical-dictionary.com http://medicaldictionary.thefreedictionary.com/intramuscular
- Intravenous [IV]: Within or administered into a vein.
 Medical-dictionary.com http://medicaldictionary.thefreedictionary.com/intravenous
- Hilar mass: As pertains to this case, is a mass located in the center part of the lung, which lies
 directly beneath breast bone (sternum).

- Histology (histol ´¬jē): The science concerned with the minute structure of tissues and organs in relation to their function. Also called *microanatomy*. Adj. *histologic Medical-dictionary.com* http://medicaldictionary.thefreedictionary.com/histology
- Metastasis (mĕ-tas´tah-sis): transfer of disease from one organ or part of the body to another
 not directly connected with it, due either to transfer of pathogenic microorganisms or to transfer of
 cells; all malignant tumors are capable of metastasizing.

 Medical-dictionary.com http://medicaldictionary.thefreedictionary.com/metastasis
- Neurologist: A doctor who specializes in disorders of the brain and central nervous system. Medical-dictionary.com http://medicaldictionary.com/neurologist
- Neurology (noorol'əjē): the branch of medicine that deals with the nervous system, both normal
 and in disease.

Medical-dictionary.com http://medicaldictionary.com/neurology

- Oncologist: A physician specializing in the diagnosis and treatment of cancer.

 Medical-dictionary.com http://medicaldictionary.thefreedictionary.com/oncologist
- Oncology (ongkol'əjē): The branch of medicine dealing with the physical, chemical, and biological properties of tumors, including study of their development, diagnosis, treatment, and prevention.

Medical-dictionary.com http://medicaldictionary.thefreedictionary.com/oncology

 Opioid-antagonist: a drug that blocks mu, kappa, or delta opioid receptors, used primarily in the treatment of opioid-induced mu receptor-mediated respiratory depression – including those using morphine.

Medical-dictionary.com http://medicaldictionary.thefreedictionary.com/opioid

Pathologist: A doctor who specializes in the anatomic (structural) and chemical changes that
occur with diseases. These doctors function in the laboratory, examining biopsy specimens, and
regulating studies performed by the hospital laboratories (blood tests, urine tests, etc).
Pathologists also perform autopsies.

Medical-dictionary.com http://medicaldictionary.thefreedictionary.com/pathologist

- Pathology (pah-thol'ah-je): the branch of medicine dealing with the essential nature of disease, especially changes in body tissues and organs that cause or are caused by disease.
 Medical-dictionary.com http://medicaldictionary.thefreedictionary.com/pathology
- Peripheral mass: As pertains to this case, is a mass that lies on at the outer edge of the lung.
- Pericolic: located around the colon.
 Medical-dictionary.com http://medicaldictionary.thefreedictionary.com/pericolic
- Psychiatrist: a physician with additional medical training and experience in the diagnosis, prevention, and treatment of mental disorders.
 Medical-dictionary.com http://medicaldictionary.thefreedictionary.com/psychiatrist>
- Psychiatry (si-ki´ah-tre): the branch of medicine dealing with the study, treatment, and prevention of mental disorders.
 Medical-dictionary.com http://medicaldictionary.thefreedictionary.com/psychiatry
- Radiologist: A medical doctor specially trained in radiology (x ray) interpretation and its use in the diagnosis of diseases and injuries.
 Medical-dictionary.com http://medicaldictionary.thefreedictionary.com/radiologist

- Radiology (rā·dē·ð·læ·jē): that branch of the health sciences dealing with radioactive substances and radiant energy and with the diagnosis and treatment of disease by means of both ionizing (e.g., x-rays) and nonionizing (e.g., ultrasound) radiation.

 Medical-dictionary.com http://medicaldictionary.thefreedictionary.com/radiology*
- Small cell carcinoma: A highly aggressive malignancy, usually of lung, which arises in proximal bronchi and spreads early to hilar and mediastinal lymph nodes.
 Medical-dictionary.com http://medicaldictionary.thefreedictionary.com/small+cell+carcinoma
- Tumor (too'mer): neoplasm; a new growth of tissue in which cell multiplication is uncontrolled and progressive.
 Medical-dictionary.com http://medicaldictionary.thefreedictionary.com/tumor>

List of Witnesses

The Plaintiff and the Defendant must call all of their witnesses. Plaintiff Avery Langston and Defendant Dr. Lefu Harrison are permitted to sit at their respective counsel tables. All witnesses can be played by either males or females.

For the Plaintiff, The Estate of Simone Langston:

• Avery Langston: Simone Langston's daughter/son

• **Dr. Tabor Caget:** Simone's Oncologist at United General Hospital

• Dr. Farley Davis: Plaintiff's Competency Expert Witness

For the Defendant, Lefu Harrison:

• Gopi Anandganda: Simone's Primary Nurse at United General Hospital

• Dr. Lefu Harrison: Defendant, Former Pathologist at United General Hospital

• **Dr. Quincy Ebardiar:** Defendant's Competency Expert Witness

PRONUNCIATION GUIDE

Witnesses

Dr. Tabor Caget: Tay-bor Kă-jhay

Gopi Anandganda: Å-nănd-găn-da (short a's)

• Dr. Lefu Harrison: Lĕ-FOO (short e)

• Dr. Quincy Ebardiar: Ē-bar-dē-ăr (first syllable long e)

Other Terms

Bona Valetudo: Bō-na Val-ĕ-TŪ-dō

Bokonist: Bō-kĭ-nist

Papa Monzano: Mōn-zan-ō

• Gerimondlan: Jer-i-mond-lin

STATEMENT OF AVERY LANGSTON

My name is Avery Langston, and I am Simone Langston's daughter/son. I am 42 years old and currently reside at the Circle of Hope Shelter in the North Homewood section of Pittsburgh, Pennsylvania with my two kids, Nikki, who is 13, and Roger, who's 9. My wife/husband left me when we were kicked out of our home after my mother passed away about a year ago. I still pick up the odd shift at the local J-Mart and receive public assistance to make ends meet. I used to get more work there, but I think they knew that I was making some side deals with customers I knew from the neighborhood. I was never caught, but they started only giving me shifts when someone called in sick or was on vacation and they were short-handed. Really, the only thing that keeps me going are my kids and my desire to get back at that Dr. Lefu, who took advantage of my mother and caused my family's downfall. It's an American tragedy.

About two years ago, my mom just didn't seem herself anymore at all. She was tired all the time. She was 73 but looked 93. Her fingers were gnarled, and her voice was half gone from smoking. For years, she put away what seemed like ten cigarettes at a time – at least two packs a day. Even though I made her quit about seven years ago, I would still catch her sneaking one. Where she got them, I had no clue, because she had trouble getting around, a lot of trouble breathing and even more trouble remembering things. Sometimes, I would catch her talking to herself when she thought she was alone. I once heard her claim that she was still menstruating. Now, I'm no doctor, but even I knew that was not possible. I think it was her just getting older and living through more than her fair share of troubles. She was still the sweetest, most caring woman, even if I sometimes felt more like the parent. I loved her dearly.

My family lived with her in the house where I grew up, at 6902 Meade St. in Homewood. I am an only child, my father was crushed in an accident at the mill when I was only ten. I was determined never to leave my mother's side, even after I was married. We never had much money, but the mill gave my mom some settlement cash and let us stay on their health insurance plan for life. We had the house and we had each other.

After dad died, Mom joined the Temple of Bona Valetudo. It was a stretch, because Mom was always a Bokononist, but I guess it was the only way she could cope with the loss. Anyway, she had a spiritual awakening, and pretty soon, in a lot of ways, she began to care more about the Temple than about me. She tried to get me to come to the Temple with her, but I had friends at our old church and cried my eyes out until she finally gave up. That was one thing we always disagreed about. Well that and the fact that when I was in high school, I got suspended my senior year for cheating on a mid-term, probably cost me a chance at college. Mom never let me live that one down either. Anyway, Mom believed that god created her whole and that no one should take anything from her body. So she never got her blood taken, or had surgery or even had a mole removed. To her that kind of stuff was a sin, and she could go to hell for it. However, she could still get shots, so if she got real sick, she would eventually take some antibiotics or whatever and be back on her feet. Only when things got really bad did she go to the doctor.

February 14, 2009 was the worst day of my life. It was a Sunday, and I had just gotten home from a second shift at the J-Mart around 11p.m. The kids were already in bed and my wife/husband was asleep in front of the TV, as always. And to think I thought I might get a romantic Valentine's Day dinner! I went upstairs to check on mom, but she was not in her bed. I thought she must have been sleep walking, which she had started to do more and more. I went through the entire house, but could not find her. I had just started to check the backyard when I noticed neighbors gathering at the corner and I heard sirens. I ran over and found my mother lying unconscious in a pool of blood in the middle of the street. My neighbors told me that my mom was the victim of a hit and run accident. I could barely process anything as I rode with her to United General Hospital, near Pitt's campus. After a few hours in surgery, my mom was

transferred to another wing of the hospital. She had a couple of broken ribs, a shattered leg and a mild concussion. She was still unconscious, but I was really happy that she made it through in one piece. She was lucky to be alive.

Later that day she was transferred to the oncology ward. Her doctor, Tabor Caget, explained to me that when they were operating, they found some abnormal bleeding and had to run some additional tests. I knew if mom were conscious she would never have allowed them to operate on her or take her blood because of her religious beliefs, but Dr. Caget just said it was for the best, because since she was unconscious, they were able to treat her. Turns out that mom had cancer, two cancers, really. It was bad. Colon cancer had spread throughout her body, and lung cancer was stopping her breathing. Dr. Caget explained to me the cancer was so far advanced that mom was going to have to undergo serious chemotherapy if she had any chance of surviving for more than a month or two. I got really concerned, but Dr. Caget explained to me that s/he had a new treatment regime that was promising and could really help mom. The best part was that it was non-invasive, so mom would have no religious objections. Plus, Dr. Caget convinced me that mom's health insurance would cover the cost, and if not Medicaid would certainly pick up the rest given our financial situation.

When my mom regained consciousness, she was devastated that the doctors operated on her without permission. At first, she was completely hysterical, and she kept saying that she was going to hell for it. Eventually, I couldn't take it anymore, and I just went home. When I came back in the morning, Nurse Gopi was there, and my mother was smiling ear to ear. Nurse Gopi explained that Papa Monzano, the head of the church, had said years ago that members would not go to hell if they didn't make a choice to get the medical care. Anyway, Mom was much calmer, and so I asked her what she wanted to do. She told me that she wanted to live, that the family needed her and that she didn't want to die in a hospital bed. We decided to get the experimental treatment, especially because it seemed to follow her religious beliefs. We waited a couple days for Dr. Caget to get the procedure approved by the hospital, then Dr. Caget had some expert come in on February 22 and make sure mom was competent enough to agree to the procedure, and to my surprise, even though she was too weak to fill out the paperwork, she was allowed to make medical decisions for herself. She dictated it, and I wrote it out, then she gathered her strength and signed it. I was worried that I would have to make the decision for her! And so the nightmare at United General began. Nurse Gopi and Dr. Caget became my new family. Even the pathologist, Dr. Harrison, at first seemed to genuinely care about mom.

Dr. Lefu turned out to be a complete fraud. Shortly after the treatment started, Dr. Lefu stopped by to see us. Mom was showing some signs of progress, and Dr. Lefu was downright giddy, but not about that. S/He explained that mom's colon cancer was special. S/He believed it had some magical properties that could help save millions of lives. Mom, who was a bit groggy because of all the pain medication, was really excited about the idea of being able to help others through her suffering. But when Dr. Lefu asked if s/he could take some more blood and tissue samples to confirm her/his findings, mom burst into tears. There was no way she was going to part with even the smallest cell, that's how much she believed in the teachings of the Temple. When mom explained, Dr. Lefu got really upset and yelled something like, "well then, I will just have to do it the old fashioned way and clone the ones I got." We all looked at each other like Dr. Lefu was some sort of mad scientist. I know that Dr. Lefu says I tried to negotiate a sale with her/him, but that's a lie. I wasn't concerned with money; all I wanted was my mom back. No amount of money would have changed that I think. Fortunately, Dr. Lefu was banned from visiting mom as a result of the stunt.

Just when life was settling down, it turned upside-down again. It was March 3rd. There had been a small fire in one of the labs and part of the hospital had to be evacuated. I was so

worried about mom. When they finally let us back in the building a few hours later, I found my mom in her room crying uncontrollably. She said that Dr. Lefu had come to yell at her again and tell her that no one was there to protect her from the devil. Nurse Gopi thought that mom may have had a nightmare because of the chemotherapy. Nurse Gopi said that Dr. Lefu may seem odd, but was not the kind of person who would break the rules. Anyway, Nurse Gopi got permission from Dr. Caget to up mom's pain medication to calm her down. Just as mom was about to fall asleep, Dr. Caget came and delivered the horrible news that mom's insurance had rejected payment because the chemotherapy was too experimental. Dr. Caget also told us that Medicaid refused to provide coverage for the same reason, even though we qualified financially. Dr. Caget told us it was important to see the course through to get the best results and that we could apply for charity, or, at worst, mom's estate could file for bankruptcy. Dr. Caget told us that the total bill would be less than \$200,000 and that so far the bill was around \$50,000.

After a few tear-filled minutes, Dr. Lefu seemed to appear out of nowhere. S/He must have been lying in wait nearby. Dr. Lefu offered to pay \$100,000 if mom consented to letting Dr. Lefu take additional cell samples. Mom was too groggy to respond. I knew mom wouldn't go for it and told Dr. Lefu as much. It would take a lot more than that to make things better. Dr. Lefu got this crazy look on her/his face and picked up a leftover tray of food and threw it at me. It missed, but the room was a complete mess. Dr. Lefu got very angry and started screaming, "this is the most ridiculous nonsense I've ever heard. Do you want to lose everything – your house, your family – stop being so shortsighted and stupid!" Mom was startled, and as soon as she realized Dr. Lefu was in the room, she started screaming, "the devil is here again, please protect me Avery, protect me, I don't deserve to go to hell!" I lost control of myself, and lunged at Dr. Lefu. My fist landed square on her/his face. Everyone in the hospital must have heard the commotion. Nurse Gopi, who was there the entire time, restrained me. Later, I saw Dr. Caget scolding Dr. Lefu in the hallway. Dr. Caget promised me that Dr. Lefu wouldn't press charges, but I had to agree to not come to the hospital except during standard visitor hours. We were the victims but I was the one being punished. I was devastated again. My life was falling apart.

The next month or so was a daze. I would go to work and then to the hospital during visiting hours. Mom was kept heavily sedated with medication, more so than at any time during her stay. She was herself, but not. Her senses seemed completely dulled. Whenever Dr. Caget would come in to give a report on mom's progress, I would ask her how she was feeling. She always responded the same by chanting something like, "as long as my body remains intact, heaven will take me." It was like she wasn't thinking, just reacting. I think she was coming to terms with her fate, or maybe it was just her meds, but she was eerily calm after my fight with Dr. Lefu. Her silence was really frustrating, and I sometimes yelled at her, but even then, I couldn't get a reaction. When Dr. Caget told us on April 6 that hospital charity would not pay her medical expenses, I barely reacted. But Mom, turned and looked at me right in the eyes, with tears welling and said, "maybe I should let the devil in." I knew she was referring to Dr. Lefu and her/his offer, but I also knew that it was just the pain talking. The Temple was her life. Nurse Gopi, who was also in the room changing Mom's IV, seemed to peek up when mom said this and she quickly and awkwardly left before finishing the job. It was really weird.

Mom died a week later, on April 12th, just seven weeks after she was admitted. I was holding her hand and right before she died, she looked at me and said, "Dr. Lefu, the devil, did this to me. I hope heaven and not hell awaits me. I love you, Avery!" Mom, of course, forbid an autopsy, so we don't really know what killed her, but I guess it doesn't matter. About a week after the funeral I received a check for \$200,000 from Dr. Lefu, with a letter that said it was for the hospital bill and had a copy of some contract for the rights to mom's cells that was signed by mom and Dr. Lefu and witnessed by Nurse Gopi. It was dated the day before she died, during the time I was working. I was shocked. I have seen my mom's signature a thousand times, and

this one looked like a weak version, if it was even hers at all, not traced from her consent form or something.

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I know Dr. Lefu says I made some sort of side agreement with her/him for that amount. What a liar! I hadn't even seen her/him once since the fight, and I definitely didn't place some secret note under her/his door. I was barely ever at the hospital at that point and when I was, I was always by my mom's side. I don't even know where the pathology department is. This is not my fault. What made things even worse was that the money didn't even come close to covering all of the hospital bills and hidden charges. I talked to my mom's lawyer, and he said not to cash the check, so we put it in escrow. But that meant the estate itself didn't have any money, and we had to sell the family house to cover all of the medical expenses. I had lost everything - my mother, our house and my spouse. Since then I learned that Dr. Lefu has taken mom's cells and turned it into some multimillion dollar research business. Maybe Mom was right. Maybe Dr. Lefu is the devil.

Avery Langston
Signature

September 27, 2010

STATEMENT OF DR. TABOR CAGET

My name is Dr. Tabor Caget and I'm 48 years old. I currently reside in Squirrel Hill just outside of Pittsburgh with my family. Dr. Lefu Harrison is my neighbor, which means I had to deal with that scoundrel while I was at work and at home. I've been an oncologist at United General Hospital since 1990 and I think Lefu joined the staff about a year after me as a pathologist. I attended medical school at the University of Pennsylvania, graduating Alpha Omega Alpha (1984) and completed my residency in internal medicine and residency in oncology at the University of Pittsburgh Medical Center in 1990. I have been the recipient of numerous federally funded grants for my experimental work with chemotherapy treatments and I've had several peer reviewed articles published on the subject. People say I'm cold, but it's no great sin to be more interested in the mechanisms for curing cancer than in the patients themselves. Patients die. So it goes. But cancer is eternal, until someone breaks through and eradicates it. That person will be a legend. Who wouldn't want to be Edward Jenner or Jonas Salk?

The case of Simone Langston is among the most interesting of my career. Simone's cancer was incredibly advanced when she finally appeared at the hospital. We thought she'd last a week, maybe two. I thought her case would be a great example of how life could be extended with the new chemotherapy I was developing. Unfortunately, she died just a few weeks after commencing treatment, so the data was unclear, but I'm convinced that my therapy gave her those precious extra days of life. In lay terms, Simone had two types of cancer. One was a very aggressive and previously unknown type of colon cancer that had metastasized, or spread, to all parts of her body through her blood stream, and the other was a lung cancer that was probably caused by years of smoking.

Part of what made Simone Langston's case so interesting was her religious beliefs. United General has a strict policy: we respect all religious limitations and obtain full consent for any procedures, especially from those patients who claim that religious belief prohibits certain medical actions. We pride ourselves in giving care on the patient's terms. I was really mindful of this, as well as my malpractice insurance premium, and so, on February 22, I made certain Simone signed a consent form. Consistent with hospital policy and Simone's religious beliefs, I also had her sign a denial of extraordinary treatment form. Simone was in terrible pain, so she dictated her answers to Avery, but she was able to sign it herself. Simone was on a light dose of morphine for the pain associated with injuries suffered from the car accident and was still recovering from a concussion, so to be safe, following policy, I had Dr. Davis, a staff psychologist at the hospital, perform a competency examination before the consent form was executed. In similar cases, we sometimes administer Naloxone, a drug that counteracts the effects of opiates like morphine, for consent form purposes. I think I've successfully given it to patients with similar size and weight to Simone that were on as much as 1.5 mg/1 min of morphine, but I never really pushed it much further than that. Naloxone is pretty powerful, and it can significantly improve awareness and reasoning, but we didn't even need it here at all. Davis determined that Simone was fit to consent to the treatment as she was. Avery said it was very considerate of me to be so concerned with her/his mother's religious beliefs.

Avery was always around, always in the way and often seemed to be fighting with her/his mother over religious issues. I guess I didn't care too much for Avery, but you don't get to choose your patients. So it goes. Still, I actually feel sorry about the financial mess my treatment caused. In hindsight, I was so concerned with getting Simone on my chemo regime that I may have oversold it to her and Avery. I told them that it would probably be covered by insurance or the hospital even though I knew it unlikely. In addition, I couldn't cover any costs with grant money since the clinical trial had been completed. I figured they'd get hospital charity, but it probably would not have mattered, because they were so poor. Worst case scenario, Simone's estate would have had to declare bankruptcy eventually just to cover the hospital stay. I felt

awful when I later learned that Avery and her/his kids ended up in a shelter. I guess I could've given them some money, but I've got a couple of kids of my own who want to go to college, and well, family first. I stand by my treatment. It was the best chance of slowing her cancer.

Though I may have taken advantage of Simone, it was nothing like what Lefu did. Lefu seems to have no conscience whatsoever. Lefu somehow became convinced that Simone's mutated colon cancer was destroying the lung cancer cells. Lefu told me that s/he felt s/he could reprogram the colon cancer and turn it into the ultimate cancer treatment. Just another mad scientist peddling science fiction, but like cold fusion, it has some appeal to the uneducated. Really, it was my chemo was killing the lung cancer. Lefu became obsessed with SiLa, as s/he called Simone's cancer. When Lefu found out that I had Simone sign a consent form only for my chemotherapy but not for Lefu's pathology samples, s/he was furious. S/he cornered me in the cafeteria and loudly accused me of committing a "crime against humanity" and for cutting off her/his supply to the "nectar of the gods." What a loon. Lefu was the only criminal in the room. After I refused to help Lefu get Simone's consent, s/he stormed off. That made me smile. There are few things I enjoyed more than seeing Lefu frustrated.

But, Lefu was determined. S/he started lurking around Simone's room at odd hours of the day and even sometimes at night, trying to find the right moment and courage to approach Simone about the consent form. I knew there was no way it was going to happen. The woman was devout, and watching Lefu try to fake a bedside manner was a joke. But I didn't stand in the way of her/him making a fool of her/himself. A couple of days later, on March 2, I heard Lefu berating Simone, on my unit, about not consenting to a biopsy! Even Nurse Gopi couldn't believe what was going on. I've worked with Nurse Gopi for years and I trusted her/him and her/his judgment of character implicitly. Anyway, I didn't want my treatment results affected by a stressed out patient so I told the hospital administration what had happened, and Lefu was banned from the oncology ward as a result. So it goes.

The next day, March 3, was wild. When I got to work, the Pathology lab was smoking! Apparently, Lefu had fallen asleep in the middle of an experiment. An investigation was opened, and my understanding was that if Lefu was found to have engaged in an unauthorized activity that resulted in the fire, that s/he would lose her/his job at least, and possibly her/his medical license. Later that day, I learned that Simone's insurance claim was denied and that Medicare wouldn't pick up the tab for the chemo treatment. I had no choice but to tell Simone and Avery. I hoped that they would not stop the treatment, since Simone was becoming a poster child for my chemo regime. Fortunately, on my advice, they decided to stay the course.

I told Nurse Gopi to keep an eye on Simone while I went to grab lunch, because Simone was frazzled by the fire alarms and commotion. I upped her morphine to calm her nerves. When I got back not 25 minutes later, sandwich in hand, I heard a loud crash and yelling from Simone's room. I arrived to find Nurse Gopi restraining Avery, bits of food smattered everywhere, Lefu standing there incredulously holding the side of her/his face and Simone in tears. I pulled Lefu out of the room and told her/him point blank to leave my patient alone or else I would have her/him fired. Lefu responded, "without SiLa, I don't have anything anymore anyway! Don't you see my own life also hangs in the balance?" In theory, Lefu may have been onto something, but this plea was completely pathetic. S/He was completely deranged. I then approached Avery and told her/him it was best if s/he cut down visitation to designated hours.

Over the next month or so, Simone held her own on my treatment regime, although she was experiencing typical chemo side effects associated with my method, including general malaise and depression. Certainly beats nausea and internal burns. The most recent CT Scan even showed the lung cancer was definitely shrinking in size. Without Avery there as much, Simone

seemed to be in better spirits. However, Nurse Gopi suggested that to further minimize the pain, a higher morphine dosage would be good, and it would also reduce Simone's remaining anxiety. I agreed and increased the dosage on a couple of occasions. To be honest, Simone's mental state was not my concern. As long as she was still on the chemo and physically improving, I didn't pay much attention to her mental state. Nurse Gopi spent tons of time by Simone's side when Avery was not around, and the dosage was not dangerous by any means, though I am not an expert on pain management. If I had known then that Nurse Gopi was working for Lefu, I would've paid closer attention.

Regardless of her mental state or her level of sedation, Simone remained steadfast in her religious beliefs. Numerous times, Simone told me that if she was going to die, at least she would go to heaven because no one had taken anything from her body. It was like she was mindlessly chanting some religious incantation. The only time I ever saw her waver was on April 6, when I told her and Avery that the hospital charity had refused to provide them with any financial assistance. Simone and Avery had a whispered conversation about an offer for money from Dr. Lefu in exchange for some additional SiLa samples. Simone was saying something about saving the house, and Avery was nodding. I was stunned that even Lefu would slink that low. I mean, unethical is one thing, but that's got to be criminal! I tried to ask Nurse Gopi about it, but s/he snuck out of the room before I had the chance. Still, I was very concerned that Lefu was up to something, so I decided to have Dr. Davis check Simone's mental status once again. I think Dr. Davis visited her around April 8th, but I never followed up. Life got in the way a bit, and I was working on more important things. So it goes.

Apparently, Dr. Lefu did get Simone to sign something on April 11th for the rights to her cells. I'm not surprised Lefu struck on a Saturday. We all knew Avery was working on Saturdays, and there are fewer staff around on weekends. Plus, I work Monday through Friday, so Lefu knew I would not be there to stop her/him. And of course, Nurse Gopi was a witness ... who else would do it? I'd seen Simone the day before on my normal rounds, and I'm no psychiatrist, but there's no way that she knew what she was signing. She was completely out of it. Her eyes were glazed over and it looked like her mind was a million miles away.

After this case started, I reviewed Simone's medical records. Everything pertaining to her drug regiment seemed in order except that I am listed as authorizing Nurse Gopi to administer Naloxone. I don't remember doing it, but I reviewed the patient chart and it is accurate. I trusted Nurse Gopi, and I practically signed whatever s/he asked for. I am more careful with my staff nurses now. When Simone died on April 12th, I was shocked. I really believed she was doing well. I wonder what else Lefu and Nurse Gopi gave Simone on the 11th. Unfortunately, Simone's beliefs precluded an autopsy, so the cause of death listed by the medical examiner was cancer. That was impossible. My treatment was working. Other factors were at play. Also, I'm almost 100% certain that Avery didn't make a side deal with Lefu. They hated each other and Avery's access was limited to the oncology ward. Our pathology department is pretty guarded under high security.

Lefu ended up taking the money and running, resigning before the results from the fire investigation were completed and starting up the SiLa lab with a pile of venture capital money. I hear that SiLa, Inc. is worth millions while Avery is stranded in poverty. Lefu's also claiming that SiLa, not my chemotherapy, prolonged Simone's life. What a joke. Lefu even got a job for Nurse Gopi. It certainly looks like Nurse Gopi and Lefu were in cahoots from the beginning, and I was played like a pawn. But here I am, and everything comes around. So it goes.

Dr. 7abor Caget

<u>September 28, 2010</u> DATE

STATEMENT OF DR. FARLEY DAVIS

My name is Dr. Farley Davis. I am 67 years old and I am the head of Psychiatry at United General Hospital. I have held this position on a part-time basis since unofficially retiring two years ago. I now consult with the hospital and spend most of my time working as a forensic psychiatry expert witness. I am retained generally to provide my expert opinion on matters regarding capacity for wills, contracts and consent required for medical care. I have now participated in over a hundred legal matters, about three-quarters of the time on behalf of plaintiffs. I charge \$275 per hour. I am also a member of the hospital's disciplinary board.

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I obtained my B.S. in Psychology from Temple University in 1966 graduating magna cum laude; my M.D. from the University of Pennsylvania in 1970; and completed my residency in Psychiatry from Pennsylvania Hospital in 1974, where I also served as the Chief Resident during my final year. After completing my specialty training, I took a position as a staff Psychiatrist at United General in 1975. I have received many awards and achievements, including being named a Life Fellow of the American Psychiatric Association in 2006. In addition, over the years, I've audited and taught law school classes at the University of Pittsburgh.

I first met Simone Langston at the request of Dr. Caget, her oncologist. Dr. Caget is a well-respected member of United General's staff and although I wouldn't consider her/him a close friend, we definitely respect each other. Dr. Caget sought to perform an experimental form of chemotherapy on Simone and needed to verify that Simone had the capacity to consent, pursuant to hospital policy. Simone held strong religious beliefs that precluded many forms of invasive care. While chemo is noninvasive, Dr. Caget still wanted to ensure that Simone was fully able to consent. Consent is required for all treatments and we have a special policy, which I lobbied for and drafted, to accommodate patients with strong religious beliefs. It was good for everyone: marketing loved it, patients appreciated it, and it reduced our malpractice liability.

Dr. Caget was concerned that Simone may have some form of dementia and that Simone, who was receiving intravenous morphine, might be cognitively impaired. On February 16, 2009, I conducted a full psychiatric examination over the course of several hours. Simone denied any problems with her memory or having any other cognitive or functional problems. Although she lived with her daughter/son's family, she stated that she easily could have lived on her own.

I also interviewed Avery Langston, who revealed concern as to her/his mother's capacity. Avery indicated that s/he had been worried about Simone's mental state for years and reported that her mental state had deteriorated significantly over the past five years, manifested by Simone talking to herself. Avery also stated that her/his mother claimed that she had started menstruating again. I was surprised that this bothered Avery so much; it seemed clear to me that Simone probably confused bleeding caused by her colon cancer with menstruation, and I was frankly a little shocked that Simone was not feeling guilty for having ignored obvious warning signs. Simone and Avery reported that Simone had no prior history of mental health treatment, brain trauma, outside of her recent concussion, or evaluation for memory problems. There was no indication of formal hallucinations or delusions. While Simone did become irritated during the interview and displayed mild anxiety, this was understandable given that Simone indicated she felt under attack for her religious beliefs.

From a physiological perspective, Simone was suffering from advanced metastatic colon cancer, lung cancer and multiple broken bones. In addition, she had a mild concussion, which can affect the results of the battery of standard neuropsychological tests I administered. Simone was receiving morphine for her pain intravenously at a rate of 1 mg / 1 min. The effects of morphine on cognitive ability are widely disputed, especially over time, since patients typically develop a tolerance to opiates, which means that a higher dose is needed to obtain a beneficial

effect. In addition, weight and general health also play a factor in determining the effect of the narcotic. However, it is widely accepted that a dose of 1.6 mg / 1 min. renders a patient to have a lack of capacity for a person of Simone's weight, 60 kg.

The results of all of my testing were consistent with Simone having warning signs of dementia aggravated by the medication she was receiving and the nature of her physical ailment. However, Simone was definitively lucid, aware of her surroundings, and steadfast in her belief system. She performed well on the recognition memory, orientation to time and place, auditory comprehension, and reading ability tests administered at the time of my examination. The legal test for competence is not a high bar. We don't ask people to do calculus; they just have to be able to make a reasoned decision.

I also administered a Mini-Mental State Examination or MMSE. The MMSE is a 30 point questionnaire which it utilized to determine cognitive impairment. Simone scored a 25 on the MMSE, which is considered to be the bottom end of the effectively normal range of competency. This test has been a standard in the field for decades and is highly reliable. In every generation, someone thinks that they can do better than the MMSE, and recently some respected professionals have argued in favor of the Montreal Cognitive Assessment (MoCA). MoCA is a fine test, and it is superior in some ways to the MMSE, because it tests along broader axes of cognition. However, the MoCA test has only been in use for a decade or so, and lacks the builtup data that are so necessary for rigorous scientific comparison. I'm aware that it has been shown to provide better assessment of certain diseases in clinical studies, but so was Bertrand and Rumfoord's Summary Mental State Exam (SMSE), and later studies proved it nearly worthless for most other diseases. My own staff has from time to time urged that we move to the MoCA. When Quincy Ebardiar was here, s/he strongly preferred it, but the MMSE has beaten back every competitor so far, and Quincy will someday rue having bet on the wrong horse. MoCA is promising, the best new test I have seen in years, and it may someday become the industry standard, but right now, we're better off with the time tested, and the MMSE is old faithful. Regardless, two professionals performing similar investigations should reach similar results. The test is merely a tool, and physicians who try to apply any test too rigidly or treat the numerical results of the test as the final word on the question of competence have failed to do their jobs. Forensic psychiatry is not an arithmetic exercise.

In my opinion, based on my training, experience, and examination, on February 22, 2009, Simone possessed the capacity to enter into contracts, to make a new will, and manage her financial affairs. She certainly had the capacity to sign the consent form. However, I strongly recommended that her capacity be examined on a regular basis, as I was very concerned that the chemo regime and narcotics she was receiving could negatively impact her ability to make decisions. A startling number of Dr. Caget's experimental chemotherapy patients experienced depression and I was concerned that the chemotherapy, in combination with her physical ailments and morphine intake, would quickly and markedly degrade her mental ability.

I had no further contact with Simone until about 6 weeks later when Dr. Caget sought another evaluation. I met with her on April 8th. Once again, Avery was present. Sadly, as I had feared, Simone was a shell of her former self. For starters, she did not recognize me, despite the length of my initial examination. I reviewed her chart, paying particular attention to the progress of her chemotherapy and her morphine intake. She was 1.6 mg / 1 min., which is the maximum amount recommended for someone of Simone's size, weight and age. Physiologically, the chemotherapy was taking its toll on Simone. She was obviously weaker than before, and she had a vacant look. While recent CT scans suggested that the chemotherapy was working in reducing the size of her colon cancer, the side effects were extensive. I didn't have the time or inclination to perform a full psychiatric examination, so I only did the MMSE. Simone scored a

12, which indicates moderate to severe cognitive impairment. In my opinion, Simone clearly could no longer understand the significant benefits, risks, and alternatives to proposed health care and make or communicate a health care decision. Furthermore, I didn't feel that Simone had the capacity to execute any contract, especially if the matter was complicated.

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A patient's capacity, or competence, can fluctuate greatly, and someone displaying symptoms as severe as Simone's on April 8th can conceivably be deemed to have capacity as soon as the following day. However, Simone's mental capacity had plummeted, and the likelihood of a turnaround was vanishingly small. I recommended a full mental health examination to Avery, and s/he asked me if that meant that s/he would be in charge of all decisions from there on out regarding her/his mother's medical care. I responded affirmatively. I communicated my suggestion to Dr. Caget the next week, but Caget told me that Simone had passed away.

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I have reviewed the document entered between Simone and Dr. Harrison that was executed on April 11th. In my opinion, there is little to no chance that Simone had the capacity, from both a medical and legal perspective, to execute this agreement. I see nothing in her medical records which suggest minor changes in her medication would have drastically improved her cognitive ability. I am aware that she received a small dose of an opioid-antagonist, naloxone, on the 11th that would have nullified to some degree the effects of the morphine in her system, but considering the high levels of morphine already in her system and the wide variety of other factors leading to her diminished mental state, one injection alone would not have made her completely lucid. Could it have helped some, over a half hour or so? Sure, but that's about it. Honestly, I was surprised that Dr. Caget authorized naloxone considering the pain the patient was still experiencing. Regardless, this agreement should be deemed void in any and all courts of law. That signature alone reveals how weak Simone was.

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A full disciplinary committee investigation was underway regarding the March 3rd fire when Dr. Harrison resigned, on June 9, 2009. We intended to commence internal termination proceedings against her/him the following week, but I was pleased to be saved the aggravation. Frankly, it was just a matter of time. Dr. Harrison was the kind of doctor we don't need here. You would have thought that the incident at the Rosewater Clinic, where s/he resigned under allegations of forgery, would have scared her/him straight, but s/he cut corners, took liberties and was way too aggressive.

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Lefu knew that hospital protocol required the staff psychologist to conduct such evaluations, but it's just like her/him to have hired Ebardiar to whip up a secret MoCA exam on everyone's day off. I like Quincy, but everyone knows s/he's available at the right price; s/he had to resign from United General for allegedly selling diet pills over the internet. Regardless, I have reviewed Dr. Ebardiar's opinion. If Simone really did score a 24 on the MoCA just three days after she registered a 12 on the MMSE, it just goes to show what a flawed test MoCA is. Or what a flawed physician performed it. Naloxone is a fine pharmaceutical, but it is not a miracle drug. Simone was a very, very sick woman lying, heavily medicated, quite literally in her death bed. It is sophomoric to think that a single 6mg dose of naloxone would have brought Simone back from the near cationic state in which I saw her to the level of competence Quincy claims to have observed. This is precisely why competence determinations are best left to trained forensic specialists using established tools, not gifted amateurs test driving their pet project.

Dr. Farley Davis

October 7, 2010 DATE

Signature

STATEMENT OF GOPI ANANDGANDA

My name is Gopi Anandganda, and I am 31 years old. I currently reside at 390 Semple Street in the Oakland neighborhood of Pittsburgh. I'm a registered nurse and am currently employed as a Research Manager for ResearchPI, Inc, a company that specializes in the administration of clinical testing for new drugs on behalf of universities and pharmaceutical companies. Prior to working for ResearchPI, I was employed as a Registered Nurse by United General Hospital in the oncology ward for about six years. I got that job after completing a bachelor's degree in nursing from the University of Pittsburgh. I am so much happier now. I got the job, in part, because of Dr. Lefu's glowing recommendation and now not only do I make twice the money, but instead of watching people slowly die, I'm making a difference for millions of people across the world. When my family came here from San Lorenzo, we had nothing but a dream of a better life. Now, I am in a position to help innovations that improve the lives of millions. This is what this country is all about.

I first met Simone Langston when she was transferred to the oncology ward from the ER on February 15, 2009. I was assigned as her primary care nurse. People always think it is the doctors who need good relationships with patients, but it is the nurses who are responsible for caring them hour after hour. I always tried to keep my guard up with my patients, because the mortality on the oncology ward is so high, but Simone was different. Her cancer was very advanced, but as soon as I saw her smile, a bond formed instantly between us.

I always had tremendous respect for Dr. Caget, who was the head of our oncology ward at United General. S/He was a phenomenal doctor and pretty much taught me everything I knew about the field of oncology, even though s/he seemed to care more about her/his experimental chemo regimen than about the individual patients. I was worried when Dr. Caget wanted to put Simone on the treatment; it's very hard on patients, and it is usually reserved for younger, stronger ones. I didn't want Caget killing Simone just to get a little more data.

To get Simone on the chemotherapy, Dr. Caget brought in one of our hospital's most well-known and respected doctors, Dr. Davis, to perform a psychiatric examination. Though Simone didn't really know what she was actually signing up for, she was definitely competent. I had only been caring for her for a couple of days, but you could tell this lady was with it, even if she was nearing 80. You don't need to be a doctor to understand whether or not someone is alert and aware. I was taught from a young age to respect my elders, but that seems to be a bit lost here in the U.S. I was on the ward for six years, and I think most of our elderly patients were lucid. I wasn't surprised at all when Dr. Davis realized Simone was fit to sign the consent form.

At first, I felt sorry for Avery Langston, but the more time I spent around Avery, the more I came to understand who s/he really was. For starters, I don't think s/he respected her/his mother at all. The way Avery treated Simone bordered on mental abuse. Avery would sit by Simone's bed, scolding her about all kinds of things, from money to her religious beliefs. Religious beliefs were very important to Simone, as they are to all of us in the Temple. All other folks know about us is that we believe in body integrity, because every few years someone refuses medical treatment and makes the news, but there's so much more to our faith. If people could experience the beauty of *boko-maru*, or dance-pray with us for hours on end, they would realize that Bona Valetudo is just another way of looking at the world and finding beauty and meaning in the incomprehensible vastness of god. People think it must be strange for me to work as a nurse, taking blood samples and so on, but they miss the point: the Temple does not impose its beliefs on anyone else. We're happy to do whatever people themselves want to ease or end suffering. United General understood that, which is why so many people in the Temple go there.

 But Avery didn't get it. Avery was condescending and callous, and s/he would quickly dismiss any attempts at conversation offered by Simone. If Simone were to make a suggestion of any nature, Avery would make comments about how delusional Simone was acting or how the medication must be affecting Simone's judgment. Frankly, I didn't really understand why s/he spent so much time at the hospital anyway. Maybe Avery just wanted to get guardianship so that s/he would not have to consult her at all. S/he seemed hungry for that power.

A few days after Simone commenced her chemotherapy, Dr. Lefu (that's what we all called her/him) came down from the lab to visit with Simone. Dr. Lefu was so excited. S/he felt that Simone's genetically mutated colon cancer had special properties which could lead to a novel therapy for cancer, one that didn't involve radiation or chemotherapy. Dr. Lefu wanted to get some additional biopsy samples from Simone to confirm her/his findings. However, like I said, Simone was steadfast in her religious beliefs, and she flatly rejected Dr. Lefu's suggestion. Avery went wild. First, Avery told Simone to "shut up about all that religious nonsense!" Then Avery asked Dr. Lefu how much s/he was willing to pay for the samples. When Dr. Lefu explained that this was for the advancement of science and society and that s/he wouldn't pay a penny, Avery became belligerent and insisted that Dr. Lefu leave the room. I remember Dr. Lefu saying, "well then, I will just have to do it the old fashioned way and clone the ones I got." I stared at Avery like s/he was crazy for trying to sell off pieces of Simone.

The next day, there was a fire in Dr. Lefu's lab, and that section of the hospital was evacuated. I saw Dr. Lefu outside the building as I was arriving for my shift. S/He was definitely upset, agitated and was muttering about Simone's tissue samples having been contaminated. When I finally got up to the oncology ward and checked on Simone, s/he was crying uncontrollably and muttering that she'd seen the devil. I figured that s/he must have been having a nightmare, which is often a side effect of chemotherapy. I went to Dr. Caget and suggested that we increase Simone's morphine dose to help calm her nerves. Dr. Caget approved my recommendation, which s/he pretty much always did.

When Dr. Lefu appeared at Simone's room a couple of hours later, I was pretty surprised to see her/him. The increased morphine had just kicked in, and Simone was calmly sleeping. Dr. Lefu approached Avery and said that s/he had thought it over and that s/he was now willing to pay for what Dr. Lefu referred to as the "precious SiLa cells." Dr. Lefu offered Avery \$100,000. I remember Avery's reaction like it was yesterday. Avery said, "Well if you are willing to pay \$100,000, I bet you would pay three times that amount. I won't say a word for my mother for under \$300,000." How greedy is that?! I knew that they had just recently learned that insurance was not going to pay for Simone's treatment, but that was no excuse. Avery's comment must have struck a nerve with Dr. Lefu, because s/he picked up Simone's meal tray and flung it across the room! Avery rushed at Dr. Lefu with her/his arms flailing. The loud bang woke Simone who looked at Avery and screamed, "what has the devil gotten into you child? Stop acting like such a fool!" I restrained Simone, and Dr. Caget came in and pulled Dr. Lefu out.

The next day, Dr. Lefu approached me in the cafeteria and apologized for her/his outburst. S/He explained that the SiLa cells were so important to the future of humanity that s/he had to do everything possible to obtain another sample. Dr. Lefu explained the whole thing, and I understood why what s/he was trying to do was more important than United General, Dr. Caget's chemotherapy and even Simone's life. These cells held the key to saving thousands of lives. One of the chief tenets of the Temple is that we work to end the suffering of others, even when it means suffering ourselves. It's called *gerimondlan*, healing the world. Dr. Lefu asked me to try and explain this to Simone. Dr. Lefu then handed me a check for \$500, just for listening I guess. Dr. Lefu said I could keep the money regardless of whether or not I helped her/him. I decided to try and help. It was the right thing. It was *gerimondlan* in the truest sense.

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Over the next month, Simone and I bonded. S/He told me stories of her childhood, her loving relationship with her husband, and her fears about what would happen to her grandkids if they were left to Avery and her/his awful wife/husband. S/He explained to me how much the Temple had helped her when her days were darkest and how that support created the deepest of faith. Simone had no problems remembering things or communicating clearly, even with the extra morphine. Every word she spoke made sense, and her emotions were completely intact. It was only when Avery berated Simone that s/he would become agitated. I spent as much time as possible with Simone. I even slept in her room some nights. I eventually told her that I thought the chemo was not working and that she was going to die soon, with or without the treatment. That is how much I respected her - she deserved to know. Near the end of March, I explained to Simone about the magical cells in her body and, that even though they were killing her, she possessed a gift that would heal the entire world if she would just part with the smallest of cell samples. I told her that with Dr. Lefu's help, she could save thousands of lives. I knew Simone didn't want to betray her faith, but I also knew she understood the obligation of gerimondlan and her role in the Great Wheel. Simone became more removed, though I don't think it was due to the morphine and chemo; it was because she was deep in spiritual thought. She may have been losing her hair, but she was definitely not losing her mind.

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On April 6th, things changed dramatically. Dr. Caget told Simone and Avery that United General was not going to cover the treatment expense and that they would have to pay for everything. I think Simone then realized that her house would have to be sold. I could see the concern in her eyes, and I knew this is what motivated her to say to Avery, "I think we should consider Dr. Lefu's kind offer." I left the room to tell Dr. Lefu the good news. Dr. Lefu told me to have Dr. Caget lower Simone's morphine dosage to ensure that Simone was as lucid as possible when making this most important decision, and suggested that I have Dr. Caget sign off on a dose or two of Naloxone, a drug that counteracted the effects of morphine, just in case. I couldn't see why. Though Simone had been guiet and introspective, s/he knew what was going on.

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On April 11, Dr. Lefu came to the oncology ward in the afternoon with a psychiatrist to perform a competency exam. Simone was really not doing well at first but then Dr. Lefu told me to administer the Naloxone Dr. Caget had approved. It was a 6 mg dose. The effects of the drug were amazing. Within minutes, Simone's eves lit up and she was more talkative than she had been in weeks, though I could tell she was in considerable pain as the effects of the morphine were nullified. She squeezed my hand in a loving way and smiled at Dr. Lefu. Dr. Lefu presented Simone with a document s/he had drafted for the rights of the cells and consent for a new biopsy of her tumors. Simone read it over carefully and even asked me a few questions. Simone wanted to makes sure her family would get enough money to cover her medical bills. I told her that I thought the \$200,000 Dr. Lefu offered would more than cover it. She completely understood what she was doing. Simone looked towards the ceiling and said, "Dear lord, I know you will forgive me." She then signed the document. Dr. Lefu quickly performed the procedure and obtained the tissue sample.

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Simone died the next day as a result of the aggressive chemotherapy. I think she let herself die because she knew she had served her purpose in this world and that her family would be taken care of. Regardless, I'm just so happy that Dr. Lefu was able to get the cell samples s/he needed to start SiLa, Inc. and potentially save the world from cancer. Simone understood that SiLa was far more valuable than any one life, even her own. She was healing the world.

Gopi Anandganda
Signature

September 29, 2010 DATE

STATEMENT OF DR. LEFU HARRISON

My name is Lefu Harrison and I am 45 years old. Formerly, I was a pathologist at United General Hospital in Pittsburgh. I now serve as President and CEO of SiLa, Inc. Ever since I realized the potential housed in Simone Langston's metastasized colon cancer, my life has taken on an extraordinary course. I'm finally realizing my full potential and my ability to ultimately make a real difference in this world. However, this success has not come without my own personal pain and suffering. Sometimes, you have to hit bottom before you can reach the top. I've gone into tremendous debt, both monetarily and emotionally, to create SiLa, Inc. and I'm just now earning a return. Right now, I live by myself in Squirrel Hill. My career and my research have always been more important than family. Some people are just destined for greatness, and in that respect Simone Langston and I are the same.

Cancer is the biggest killer in the world, accounting for over 13% of all deaths. Even while I was in medical school at the University of Pittsburgh, I knew that I needed to find a way to defeat this disease. Medically, cancer is nothing more than cells that have begun multiplying abnormally until they begin to take over parts of the body, often by metastasizing, that is moving through the blood stream or the lymphatic system to other areas of the body. Because the cells are native to our body, the immune system is powerless to stop them. In fact, scientists have identified several genes that often fail in cancer, including the genes that cells use to recognize when they have mutated and to apoptose, which is like cell suicide. In other words, cancer avoids all the things that the body has to stop it, and if it goes untreated, it will almost always kill.

However, cancer's strength could also be its downfall. Just as a cell mutates in order to become cancerous, if a mutation occurs in the cancer itself, it could become a weapon against other cancers! And that's what happened to Simone Langston. She was a heavy smoker. Smoking tobacco is, medically, just about the worst thing you can do to yourself. Smoking accounts for 90% of all cases of lung cancer. It's more than a terrible habit, it's murder, and just like it killed my father when I was young, it was killing Simone. In fact, Simone had developed two types of cancer, one in her colon that ended up spreading through her entire body and one in her lung. The cancer had gone untreated for so long that, when she finally was admitted to the hospital, the colon cancer had mutated, creating a new type of cancer that had beneficial, almost magical properties, including actually attacking and killing her lung cancer cells. It was like her colon cancer was itself a treatment for her lung cancer. I named these special cells SiLa, in Simone's honor and memory. I knew that if they could be stopped from becoming malignant themselves, SiLa could be used as a base to create a cure for cancer. This is exactly why I went into pathology: cancer is a disease that has to be attacked at the cellular level.

I remember the first time I met Simone. I knew that Dr. Caget had gotten a consent form for the chemotherapy regime s/he put Simone on. A true colleague would've included my work in it as well, but Caget disliked me. I think it's because after medical school, while I was doing a year of research at the Rosewater Clinic, I was involved in some controversy where the Clinic accused me of forging a couple of informed consent signatures. I didn't do it, though my lawyer reached a settlement with the Clinic whereby it would drop the investigation if I would resign. I never admitted any guilt at any time. Caget's good friend Farley Davis was on the disciplinary board and probably told Caget about it.

Anyway, I wanted to get additional cell samples to continue my research and assumed Simone would consent to additional biopsy samples given my reasons. I rarely visited a patient's room, since I'm more of a lab rat, but something of this magnitude was an exception. I first met her on February 22. Simone was ecstatic when I told her that even though she was dying, she would be able to save millions of lives. Although she was injured and on pain medication, she was completely lucid. She had a smile that filled a room and your heart with hope. However, her

daughter/son, Avery, was the complete opposite. Avery could only think of one thing: money. All s/he cared about was how much I would pay the family for more cell samples. Avery didn't seem to care that Simone's religious beliefs instructed that nothing be removed from her body. In any event, I got into a screaming match of sorts with Avery. I could respect a religious objection, even though it was ludicrous, but human life is not something to be sold to the highest bidder. I overreacted and may have said some things that sounded crazy. I think I told them that I was going to clone the cells, which is totally impossible. Regardless, Dr. Caget banned me from Oncology as a result of my confrontation with Avery.

I had to try something, so I stayed at the hospital late that night and tried to stimulate the culture I had into an artificial growth cycle, which would obviate the need for another biopsy. Unfortunately, sometime after 4 a.m., the coffee ran out, and I fell asleep at the autoclave. It short circuited, which caused a small fire. The sprinkler's quickly doused the room, and there was just a lot of smoke, but the few SiLa cells I had were contaminated and completely useless!

I was devastated, realizing that my carelessness could cost thousands of lives. I started seeing my patients' faces in my mind, and my father's, accusing me of wasting their lives. I almost walked into the street in front of the hospital before I realized I'd been wandering the parking lot for several hours. The fire had been put out but it wasn't safe yet to re-enter the building. I knew it could end my career, but I didn't care: I snuck back in and went to see Simone. I know I shouldn't have, but I needed to explain to Simone what her choice really meant. Simone was alone and greeted me with a smile. I found her mind was as clear as mine was cloudy. I explained to her that the sample of her cells that I had were lost. I explained again how vital it was to my research that I get some more. She told me that she understood but was unsure of what to do. She said she wanted to help, but had taken vows she could not break without endangering her soul. I begged her to think about it and she soberly said, "okay." I told her I'd be back soon to discuss it after she had more time to think.

I thought I had gotten through to Simone and that she would make the right decision on her own, but I was worried time would run out. Her colon cancer was advancing quickly, and Dr. Caget's pie-in-the-sky chemo was not stopping it. I decided my only alternative was to approach Avery; it was the only way to make sure it happened quickly. I spent a few soul-searching hours in my lab, only half paying attention to my work. I decided that I would liquidate all of my assets. if it meant being able to acquire another SiLa biopsy. So I went to Simone's room for the second time that day. I found Avery and Nurse Gopi with Simone. Simone appeared a bit out of sorts. She was not speaking, and her eyes were glazed over. What a change from a couple of hours before! I even thought for a second that maybe I had imagined my previous conversation with her. I told Avery that I would be willing to give her/him \$100,000 if s/he would get Simone to consent to a biopsy. Avery, true to form, immediately rejected the offer, telling me that if I was willing to offer \$100,000, then I would certainly offer three times that amount. I was shocked. I wasn't even 100% sure SiLa had any commercial value, and even if it did, I would have to spend years unlocking it. My anger got the best of me, and I knocked over a food tray. Avery lunged at me and caught me in the eye with her/his finger. Nurse Gopi restrained Avery, and Simone started screaming. Whatever inroads I made earlier were now destroyed. Dr. Caget, ended up chastising me, but I was so distraught I don't remember what s/he said or how I responded. My father was back again in my mind's eye, staring at me accusingly, reminding me of my failures.

I decided to do some research into the Temple of Bona Valetudo. How wrong I had been! Based on what I read, offering Simone money could be interpreted by her as a temptation by the devil. I could not afford any more missteps. I needed someone with access to Simone. Fate provided me an answer; like the whole universe realized how important this discovery was! I recalled that

Nurse Gopi was a member of the Temple as well, so the next day I approached her/him after her/his shift. Realizing that this may be my last chance, I carefully explained to Nurse Gopi what SiLa really meant and what it could mean to humanity. I used the pathology report as my evidence and by the end of a cup of coffee, I had convinced Nurse Gopi that SiLa was so important that it could be an exception to the tenets of the Temple. I was so thankful that s/he was even willing to listen to me that I gave her/him a check for \$500 to show my appreciation, even though I understood from the internet that money would not motivate Nurse Gopi to assist me. S/He really believed it was the right thing to do.

Over the next month or so, while I tried and failed to focus on my other work, I got reports from Nurse Gopi on Simone's progress on the chemo as well as her general mental state. Simone was dying, and the chemo was accelerating the process. Caget was such a fool; s/he had the key to beating the lung cancer right in front of her/him, but s/he was too blinded by the hollow promises of the chemo to see it. Nurse Gopi assured me that Simone remained lucid and that their conversations were productive, but I knew that the morphine Simone was taking was a very high dose and could affect her ability to make decisions on her own. Nurse Gopi told me that with Avery banned except during visiting hours, they talked openly about the Temple and whether or not Simone would be forgiven if she allowed the biopsy to occur. I was certain I had made the right decision in confiding in Nurse Gopi and hoped someday I could repay the favor.

On April 6, all of my prayers were answered. Nurse Gopi came running to my lab to tell me that for the first time, Simone said she would allow me to take the biopsy of the SiLa cancer. Apparently Simone was very worried that her family house was going to have to be sold to pay for her treatment. All that Simone wanted in exchange was for me to cover her medical bills. Simple enough really, since SiLa could be worth billions. It was a risk, but it was worth it! I knew I had to be extremely careful about how I set everything up. I figured it would take about a week for me to get everything in order and decided that Saturday April 11 was the perfect day. There was less staff around on weekends, and Dr. Caget never worked weekends, so I could move about freely on the oncology ward. I was also very concerned about documenting that Simone had the capacity to provide informed consent to the biopsy and to agree to the rights to SiLa she was signing over. So I hired a lawyer to draft the agreement and hired my old friend Quincy Ebardiar to check her competency to attest to the biopsy and sign the contract.

 I hadn't spoken to Quincy in months, but s/he was available, and was willing to do it that Saturday if I paid her/him one and one-half times her/his usual fee. I would've used a hospital psychiatrist, but the administration and I were not on good terms. I also had Nurse Gopi lower Simone's morphine dose on the 10th and get authorization from Dr. Caget for Naloxone, which would counteract the effect of the morphine. Even though I am not an expert in narcotics or psychiatry, I knew that both of those medication changes would help Simone with her ability to understand the agreement and competently to execute it. I wanted there to be no question as to the validity of the contract. The only thing I didn't know for sure was how much I would have to pay, so I began a radical liquidation – stocks, bonds, CDs, even my retirement accounts. Everything went into the "SiLa Fund" as I called it. I looked into a second mortgage and a quick sale of my Porsche in case I had to go to \$300,000, but fortunately, I found a post-it note from Avery on my lab door on the April 8th that said "\$200,000 and you got a deal." Simone eventually signed the agreement, but I kept Avery's note just in case.

On April 11th, after a false start on the test, Quincy re-started the MoCA almost immediately after the morphine had been discontinued and the Naloxone administered by Nurse Gopi. Dr. Caget had already signed off on the Naloxone. Simone started out real slow on the tests but then went from stoic and mildly responsive to animated and talkative. Simone was definitely of sound mind, and I wasn't surprised when she scored extremely well on the MoCA and was

deemed competent. I had her review the agreement carefully and advised her to ask Nurse Gopi or me about any questions she had. Simone did have a few general questions about the biopsy procedure, which was a fine needle aspiration, and also about the amount of money offered. Nurse Gopi assured her that \$200,000 was more than enough to cover the medical expenses. I was really glad that Avery wasn't there to try and extort more money. Simone signed the contract about an hour after receiving the Naloxone. After the morphine was readministered I performed the biopsy procedure, and SiLa was once again back in my hands. Unfortunately Simone died the next day, most certainly from the chemotherapy; but Simone will be immortal, and her contributions will be remembered long after her life! As for Avery, I feel bad that s/he is apparently living in a shelter or whatever, but Avery got the money s/he demanded.

After I got her sample and confirmed my original findings, I realized that I would need a better lab space - keeping the cells at United General was a legal mess waiting to happen. I hid them in the lab until I could pay a private facility to store them while I lined up investors. On June 1, 2009, I finally found the financing I was looking for and SiLa, Inc. was born. I quit working at United General the following week. For all of her/his hard work, I gave Nurse Gopi a good letter of recommendation to a company run by a couple of my medical school classmates. The Oncology ward has very high nursing turnover, and s/he was ready to leave United General after all of this, too. To protect my intellectual property, I obtained a patent for the SiLa cells and licensed it to the Company. To date we have raised over \$56 million dollars in venture capital and we are only a year or two away from starting trials in rats with the reprogrammed SiLa cell. What a turn around; like I said, sometimes you have to hit bottom before you rise to the top.

Lefa Harrison	<u>October 12, 2010</u>
Signature	DATE

STATEMENT OF DR. QUINCY EBARDIAR

My name is Quincy Ebardiar, I am 48 years old, and I am a psychiatrist specializing in addiction and eating disorders. I am a founder and principal of IC9 LLC, a team of nine neurologists, psychiatrists, neurosurgeons, and counselors based in downtown Pittsburgh. The "IC" stands for "Intra-Cranial," because we're all brain doctors. Catchy, isn't it? IC9 provides consulting services for a wide variety of business and research institutions. For example, lots of organizations want grant money for research or drug testing but don't have staff to perform competency examinations or administer psychiatric or neurological tests. No problem! We do, and we even have our own EEG, MRI and fMRI machines on which they can rent time. IC9 also receives grant funding of its own. In fact, I'm the lead investigator in a study funded by Castle Sugar, Inc. into whether its energy drinks are really addictive, or whether that's just a spurious rumor spread by jealous competitors. We are still collecting data.

We also frequently serve as expert witnesses in both civil and criminal cases. Dr. Woodly is the only forensic psychiatrist in the team, but she trained the rest of us in the basics, and we have all testified at least once in court. I have testified in a couple dozen cases, sometimes on addiction as a mitigating factor, but five or six times on competence issues. I charge \$350/hr for my time. I don't know which side I have testified more frequently for, because I'm focused on my issue, not what it means to the case.

I received Bachelor's and Master's degrees in anthropology from the University of Chicago, but I left the program when my doctoral thesis was rejected. Thankfully, though, I had met all kinds of interesting people abroad when I was working on my Masters. One of them had friends in Colombia and - presto! - I was in med school at the Universidad Pontificia Bolivariana in Medellín. I had a blast in South America, but after I graduated in 1990, I wanted to come back to the States. Luckily, there was an opening at the Rosewater Clinic, a prestigious medical think tank. They were doing some early studies with first-generation ADHD medication, which was basically amphetamines, and I had done research in Colombia on drug liking effects, a clinical measure of the degree to which a substance is addictive. It was a natural fit, and I started post-graduate work there just a couple weeks after my white coat ceremony.

I met Lefu Harrison in my second year at Rosewater. Lefu joined up as a pathologist. Lefu isn't exactly a people person, but if you needed something done, Lefu was the best. Rosewater had a lot of rules, and a lot of them were silly. Lefu realized that, too, and we worked together to do path breaking work in addiction physiology. It was a real downer when Lefu got the boot on some overblown forgery claim. S/he was generating the best data Rosewater had seen in years.

After a couple of years in research, in 1996 our grant ran out, and I joined Lefu at United General. Big mistake! The psych department there is run by Farley Davis, who invented half the techniques we use, but who quite frankly is older than dirt. The whole place was run like it was *Leave it to Beaver*. All the men wore ties, and the woman had to wear skirts. Everything was "sir" this and "ma'am" that. But what bothered me the most was that their practices were years out of date. Psychiatry is a fast-moving field, and we're learning more about the human mind every day. Tests that got the job done in 1980 are ancient history now, but Davis insisted on them. Like the MMSE, which is a fine test, and was state of the art in its time.

Competence is a binary question: you either are competent to make a particular decision or you're not. The level of competence we require varies based on the decision: to decide to take or refuse a Tylenol, the standard is low, but for a transplant, the bar is much higher. Regardless, every medical decision requires competence in four distinct sub-areas: understanding of what the procedure is physically, appreciation of what it means to the patient, reasoning whether to

undergo it and expression of that choice. Each of these pieces requires a different kind of mental ability, and the patient's reasoning can give insight into competence. For example, one patient may think god will heal him and may refuse surgery for that reason. That person might be wrong, but still competent, if he truly understands the procedure, appreciates the risk of nontreatments, reasons and articulates that reasoning. But if a patient doesn't want surgery because he thinks the FBI will put a tracking device in him while he's under anesthesia, his decision is not based on understanding or appreciation of the procedure itself. That said, even the paranoid person might still be competent to make a contract or write a will. You can be competent for some things and not for others, or at one time and not others.

Unfortunately, the MMSE focuses on intact verbal skills, which overvalues expression and underemphasizes the reasoning process. By contrast, the Montreal Cognitive Assessment (MoCA) also tests visuo-spatial abilities, complex attention, and executive function. Because the MMSE is testing only one thing, even if it tests it very well, it has a much narrower range of outcomes. Because MoCA tests a wider range of abilities, it is more sensitive to people who are competent but whose intact verbal skills are impaired, and, critically, it also means that MoCA locates a patient within a much wider band of possible outcomes, so a MoCA result tells you more. MoCA is simply a better tool for assessing competence, and it's been proven clinically superior in patients with Huntington's Disease, minimum cognitive impairment Alzheimer's Disease, brain tumors, and stroke. And that's just the testing that has been done so far. The trend is undeniable. Davis always said that there wasn't enough data to support MoCA. There's no question that MMSE has the best volume of research behind it, but of course there isn't as much data for MoCA, when industry thought leaders like Davis refuse to try it! By that logic, I'd have driven a shiny new horse and buggy here, instead of my Dodge Viper.

So I didn't stay too long at United General. After I started challenging Dr. Davis at medical staff meetings and secretly taught the ER staff to use MoCA, an investigation started into an "anonymous" tip that I was prescribing drugs over the internet. I let things play out a little, but when they referred me to the Board of Medical Examiners, I knew that was it. The allegations were totally false but I had gotten into a bad practice of writing prescriptions for myself, and I knew that the Board would figure that out sooner or later. It started with some diet pills, but those are basically speed, so I was having trouble sleeping. Then I prescribed myself some sleeping aids, which made me groggy, so I slipped and broke my foot. Then I needed some painkillers... anyway, long story short, I was hooked on some things. I admitted my mistake to the Board and resigned from United General. I reached out to some other folks having similar problems bringing their hospitals' gray hairs into the 21st Century, and IC9 was born. Now I'm my own boss and I'm making twice the cash. I've never looked back.

I was surprised to hear from Lefu in April 2009. It had been a while. S/he sounded really excited. S/he needed a competency exam, and s/he needed it fast. I told Lefu no problem. Then s/he said s/he needed it that Saturday, which was a huge problem, because I had tickets to see the Crystal Method that night in Philly. But Lefu offered to sweeten the deal, and since I could use the extra money to buy plane tickets, I said sure. Anything for an old friend, right?

When I got to Simone Langston's room on April 11, around 2:30 p.m., I could see immediately why Lefu wanted me there. Simone looked terrible. Her cheeks were drawn, her skin was pale, her eyes had sunk into her head, and she had trouble breathing. Even before I reviewed her chart, it was obvious that she was dying quickly from something nasty. I wasn't surprised to see that it was lung cancer. That's while you'll never see me smoking a cigarette.

Simone was too weak to go through a full psychiatric evaluation, and I had a plane to catch, so I went straight to the MoCA. At first, it was a train wreck. She drew a square instead of a cube,

drew a smiley face instead of a clock, and she called the lion a kitty cat and the rhinoceros a dinosaur. I was ready to leave then and there, but Lefu persuaded me to start over after the nurse stopped the morphine and dosed Simone with 6 mg Naloxone. The more I thought about it, the more that made sense. I mean, she wasn't in a different universe on any of her answers, and her opiate doses would be enough to make anyone a little loopy.

Sure enough, the Naloxone cleared her right up. Opiates affect different people differently, and opiate antagonists do, too. Clinical studies generally don't support Naloxone doing what I saw it do. But for Simone Langston, the impact was incredible. In a matter of minutes, life returned to her eyes and she was sharp as a tack. Even though it did take longer than normal to complete the exam, Simone scored a 24. If you simply follow the numbers and apply the MoCA guide, that means that she was Moderately Impaired and that she most likely lacked capacity. But that's why tests are administered by professionals, not robots. Two of the questions that Simone missed had to do with the day and date. In a patient who has been heavily medicated or who has been in the hospital for a long time, losing track of time is quite common. I would have been concerned if she had thought that it was still the 1980s, but she was only off by a few days. That's not a serious cause for concern, clinically. Besides, even the MoCA numbers put her at the very high end of Moderately Impaired, within the margin of error for outright competence. With that said, based on my observations, she was not impaired at all. That's why the test guide says "most likely" lacks capacity, not "lacks capacity." Some 24s are competent, and Simone wasn't even a real 24. If you count the questions she missed, she was a 26, and she acted like one. She was reasoning well and was oriented and aware. I am confident, within a reasonable degree of medical certainty, that she was competent, at least until the Naloxone wore off.

I know that Dr. Davis does not think that the MoCA result is valid, because s/he doesn't think that the Naloxone could have worked as well as it did. I have a lot of respect for Dr. Davis despite our differences, and I generally trust Farley's tests. Dr. Davis and I agree that the factors in Simone's mental state were age, illness, and medication. She was only in the hospital two months, so her age did not meaningfully change, and while she certainly got sicker, there is no evidence that the cancer spread to her brain. So that leaves medication, and morphine depresses mood and reduces competence. Moreover, over time, patients build up drug resistance, so higher and higher doses are needed to achieve pain relief. These higher doses also mean greater mental effects. But those effects only last while the drug is administered. If the drug is lessened or counteracted, its suppressive effects fade, too. A patient whose opioids are reduced or counteracted can very quickly rebound into (often painful) competence. And, of course, Dr. Davis's April 8 examination was an MMSE. If Simone Langston's intact verbal skills were suppressed by her high dose of morphine, the MMSE could give an artificially low report.

Anyway, I finished my report immediately and recall Simone looking through the consent form and agreement with a pen in her hand. This took place less than an hour after Simone took the Naloxone. Even though I wasn't paying close attention, it appeared to me that Simone remained alert and competent. When Lefu and the nurse started talking to Simone about the biopsy procedure, I was really surprised to hear that Simone was a Bona Valetudian but was consenting to a biopsy. When I was in medical school, we stood by and watched more than one Valetudian pass away because he or she refused a transfusion or didn't want a test that we needed. I thought about saying something, but Simone wasn't my patient, she was Lefu's, and anyway, I had a plane to catch. I packed my materials and took off. Can't say I'm surprised to find myself here, though. This is what happens when you mess around with people's religion.

Quincy Ebardiar
Signature

September 30, 2010
DATE

EXHIBIT LIST

Exhibit 1	Consent Form for Chemotherapy
Exhibit 2	Denial of Treatment Form
Exhibit 3	Agreement for Rights to SiLa and Consent to Biopsy
Exhibit 4	Radiology Reports
Exhibit 5	Pathologist Report
Exhibit 6	Hospital Policy: Religion
Exhibit 7	Medication Administration Record
Exhibit 8	Mini-Mental State Examination (MMSE)- February 16, 2009
Exhibit 9	Mini-Mental State Examination (MMSE)- April 8, 2009
Exhibit 10	Montreal Cognitive Assessment (MoCA)
Exhibit 11	Drug Fact Sheet – Morphine
Exhibit 12	Drug Fact Sheet – Naloxone
Exhibit 13	Letter and Check from Dr. Lefu Harrison to Avery Langston
Exhibit 14	Farley Davis, M.D., Curriculum Vitae
Exhibit 15	Quincy Ebardiar, M.D., Curriculum Vitae
Exhibit 16	Post-It Note
Exhibit 17	Check from Dr. Lefu Harrison to Nurse Gopi Anandganda



Dept. of Oncology

Oncologist:
Dr. Tabor Caget

Consent for Chemotherapy

DATE: February 22, 2009 Patient: Simone Langston DOB: 08/10/1936 ID: 0908076

READ THE FOLLOWING CAREFULLY:

- You are being asked to give your permission to participate in an experimental chemotherapy treatment that will be administered by United General Hospital through the care of Dr. Tabor Caget. Specifically, this treatment involves a combination of chemotherapy drugs that have not been used together in the past: Camptosar, Eloxatin, and Vectibix. Therefore, United General has deemed this treatment plan **experimental**. It is hoped that this chemotherapy treatment will retard the growth of your very aggressive and metastasized colon cancer.
- If you have any questions or concerns about this procedure, please ask Dr. Caget to provide further information so that you feel you are making as informed a decision as possible before signing this consent form.

GENERAL PROCEDURES:

• Over the course of the next **eight weeks**, you will be given the chemotherapy through intravenous (IV) delivery. The medication will be provided incrementally with dose depending on the schedule dictated by Dr. Caget. You will not need to ingest any pills. You will remain at United General as an inpatient until the chemotherapy schedule has been completed in full, unless unforeseen complications arise or you voluntarily withdraw from the program. No cell or tissue samples will be required, but you must have CT scans and MRIs from time to time in order to monitor the status of your colon cancer.

SIDE EFFECTS:

• As with any treatment involving chemicals, there are side-effects that may occur. Because this particular treatment plan has been deemed experimental, United General and Dr. Caget cannot guarantee what particular discomforts you may feel. However, as with most forms of chemotherapy, you may experience the following symptoms: depression of the immune system; fatigue; bruising; nausea; and hair loss. Unlike with chemotherapy of the past, there have been no reported

• instances of psychosis or night terrors with the particular combination of chemotherapy drugs associated with this treatment plan.

COSTS

• This treatment is not part of a formal clinical trial and United General Hospital is in no way or form responsible for the cost associated with this treatment. You or your insurance company will be responsible for medical costs associated with receiving this chemotherapy. If you have insurance, your insurance company may or may not pay for these costs. If you do not have insurance, or if your insurance company refuses to pay, you will be required to pay.

VOLUNTARY PARTICIPATION / WITHDRAWAL FROM TREATMENT

• Participation in this treatment is voluntary. While it is strongly recommended that you do not stop the chemotherapy once the course has started, you will, at all times, retain the ability to cease participation for any reason. Written notification must be provided to hospital staff if you no longer wish to continue to receive treatment.

AGREEMENT OF DECISION TO PARTICIPATE

I have read and comprehended this consent form. This experimental treatment plan has been explained to my satisfaction and all of my questions relating to the proposed chemotherapy, including the risks and discomforts, and side effects have been answered. I also affirmatively state that I have the capacity and ability to enter into this treatment plan willfully and knowingly. Based on this information, I voluntarily agree to give permission (consent) for me to take part in the proposed experimental chemotherapy treatment.

Simone Langston	Feb. 22 2009
Signature of Participant	Date
Simone Langston	
Printed Name of Participant	

Fxhibit 2



Dept. of Oncology

Oncologist: Dr. Tabor Caget

Simone Langeton

NAME

Denial of Treatment Form DATE: February 22, 2009 Patient: Simone Langston DOB: 08/10/1936 ID: 0908076 PLEASE COMPLETE THE FOLLOWING IN YOUR OWN WORDS DESCRIBING THE TYPES OF TREATMENT AND PROCESSES YOU **DO NOT** WISH TO RECEIVE. THIS FORM CAN BE COMPLETED IN ANY LANGUAGE. IF YOU NEED A TRANSLATOR ONE WILL BE PROVIDED FREE OF CHARGE BY UNITED GENERAL HOSPITAL. I, <u>Simone Langston</u>, do NOT wish to receive the following types of treatments and procedures associated with the medical care I am receiving from United General Hospital with respect to my colon and lung cancer because of my religious beliefs in the Temple of Bono Valetuda : the taking of anything from my body
 any tests that require blood
 any other tests that use needles of any kind My physician explained to me the benefits of receiving such treatment which include: being able to better monitor my sickness and the effects of the treatment I did consent to Despite any recommendations made by my physician, I freely and or sound mind refuse to consent to any of the treatments listed above. Feb. 22, 2009
DATE

Signature

Signature

AGREEMENT FOR RIGHTS TO SILA AND CONSENT TO BIOPSY

This Agreement shall be deemed effective as of April 11, 2009 by and between Simone Langston ("Seller") and Dr. Lefu Harrison ("Buyer").

RECITALS

WHEREAS: Seller possesses a special type of colon cancer, whereby the tumor cells have mutated and metastasized (such mutated and metastasized cells are herein referred to as "SiLa");

WHEREAS: SiLa has been determined to have the ability to attack and destroy other cancer cells located in Seller's body;

WHEREAS: Buyer seeks to obtain the rights to SiLa in order to conduct additional research in the hopes of reprogramming SiLa so that it can used and marketed as a novel cancer fighting drug; and

WHEREAS: In order ensure that the Seller (patient) provides to Buyer (physician) her full and informed consent to the biopsies required in order to obtain SiLa, Buyer hereby informs Seller of the following:

- The procedure to be performed is a Fine Needle Aspiration (FNA) biopsy of Seller's left lung. This is a routine procedure whereby a 22 gauge needle will be inserted into the core of your tumor under fluoroscopic (light) guidance, and a tissue sample will be obtained. This procedure will be done while you are mildly sedated with morphine but remain awake. You may feel pressure, and a brief sharp pain when the needle touches the lung tissue. Most patients do not experience severe pain. The needle is withdrawn when enough tissue has been obtained. The entire procedure takes 30 to 60 minutes.
- All alternatives to obtaining the tissue samples as needed to provide Buyer/physician with SiLa involve procedures which are more invasive than this FNA procedure and involve more significant complications.
- If you have any questions or concerns about this procedure or with any issue discussed today, please ask Buyer/physician to provide further information so that you feel you are making as informed a decision as possible before signing this Agreement and providing your consent at the end of this document.

NOW THEREFORE, in consideration of the mutual covenants, conditions, and promises herein contained, and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties hereto, intending to be legally bound hereby, agree as follows:

- 1. <u>Seller's Obligations</u>. Seller agrees to allow Buyer to have the exclusive rights to SiLa for the purposes of medical research and commercial distribution. Seller, in full awareness of her religious beliefs, agrees to allow Buyer to obtain biopsies of the tumors located in her lung which possess SiLa. In addition, this agreement provides full and informed medical consent for the aforementioned biopsies. Seller agrees that the biopsies are to occur immediately after executing this agreement. Seller agrees to allow Buyer to perform said biopsy.
- 2. <u>Buyer's Obligations</u>. Buyer agrees to purchase rights to SiLa for \$200,000 to be paid directly to Simone Langston, or if Simone Langston dies, to her sole heir, Avery Langston, within in 10 days of the execution of this agreement. If Buyer fails to provide full payment within the proscribed period of time, this agreement will be deemed null and void.
- 3. Term. The term of this Agreement shall be indefinite from date of execution.
- 4. <u>Royalties and Dividends</u>. No royalties or dividends will be paid to Seller at any point now or in the future for any and all financial gain realized through the commercial marketing, sale, and distribution of SiLa by Buyer.
- 5. <u>Entire Agreement</u>. This Agreement constitutes the complete and exclusive statement of all mutual understandings between the parties with respect to the subject matter hereof, superseding all prior or contemporaneous proposals, communications and understandings, oral or written. In addition, this Agreement supersedes any and all agreements, waivers, refusals and consent forms executed by Seller to any medical care provider that contradict the terms of this Agreement. This Agreement may be amended only in writing by an instrument signed by each party.
- 6. <u>No Partnership</u>. Nothing contained in this Agreement shall constitute or be construed to be or create a partnership or joint venture between the parties or their respective successors or assigns.
- 7. <u>Section Headings</u>. The section headings contained herein are for convenience of reference only and are not intended to define, limit or describe the scope or intent of any provision of this Agreement.
- 8. Governing Law and Dispute Resolution. This Agreement shall be deemed to have been made and shall be construed and interpreted in accordance with the laws of the Commonwealth of Pennsylvania and any and all disputes that may arise hereunder shall be resolved in a court of competent jurisdiction sitting in Allegheny County, Pennsylvania. In the event of any dispute under this Agreement, the non-prevailing party shall pay to the prevailing (or substantially prevailing) party all costs of dispute, including without limitation its reasonable attorney's fees and court costs.
- 9. <u>Waiver</u>. No waiver of any provision hereof or of any right or remedy hereunder shall be effective unless in writing and signed by the party against whom such waiver is sought to be enforced. No delay in exercising, no course of dealing with respect to, or no partial exercise of any right or remedy hereunder shall constitute a waiver of any

other right or remedy, or future exercise thereof.

10. <u>Force Majeure</u>. If the performance of any part of this Agreement by either party is prevented, hindered, delayed or otherwise made impracticable by reason of any flood, riot, fire, judicial or governmental action, labor disputes, act of nature or any other causes beyond the control of either party, that party shall be excused from such to the extent that it is prevented, hindered or delayed by such causes.

IN WITNESS WHEREOF, the parties hereto have executed this Agreement and/or have caused this Agreement to be executed by their duly authorized officers effective as of the Effective Date.

Lefu Harrison

Seller: Simone Langston Buyer: Dr. Lefu Harrison

Simone Lungston

Witness: Gopi Anandganda

Jopi Anandzanda



Dept. of Radiology

Radiologist: <u>Dr. Jayne Ratkin</u>

Radiology Report

DATE: February 15, 2009 Patient: Simone Langston DOB: 08/10/1936 ID: 0908076

A. Procedure

- a. Spiral CT Scan Abdomen/Pelvis and Lung
 - Use of X-rays to visualize the internal organs of the body. This is a non-invasive, fairly low-risk imaging modality that is tolerated well by patients.

B. Radiologic Findings

- a. No obvious organ damage or source of internal bleeding; however, there is marked circumferential thickening of the cecum (Figure 1). The bowel wall has a lowattenuation component (Figure 1), which is due to necrosis. There is also stranding of the pericolic fat, a finding suggestive of tumor invasion through the wall. Biopsy, via colonoscopy is needed to confirm the diagnosis of colon cancer.
- b. In addition to the lesion identified in the colon, two nodules were discovered in the lungs (Figures 2 and 3, below). The hilar mass (Fig 2) is estimated to be approximately 7.42 cm in greatest dimension. The peripheral mass (Fig 3) is estimated to be approximately 4 cm in greatest dimension. These opacities seem to suggest metastatic cancer; biopsy via fine needle aspiration (FNA) is needed to confirm the diagnosis.

C. Diagnosis

- a. Colon cancer biopsy needed to confirm diagnosis.
- b. Several lung tumors, suggestive of metastatic cancer biopsy needed to confirm diagnosis.

D. Recommendations

- a. Colonoscopy with biopsy
- b. Lung FNA biopsy

Radiologist: Jayne Ratkin

CT Scans



Figure 1. Spiral CT scan of the ascending colon, suggestive of adenocarcinoma. COLON CANCER

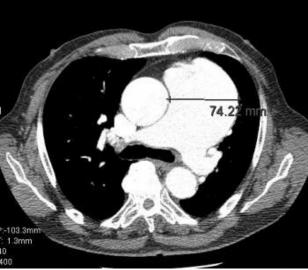


Figure 2. CT scans of the chest showing a tumor in the left hilum. LUNG CANCER

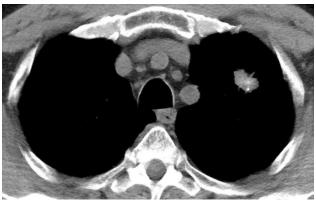


Figure 3. CT scans of the chest showing another tumor in the periphery of the left upper lobe. LUNG CANCER



Dept. of Radiology

Radiologist: Dr. Jayne Ratkin

Pittsburgh, Pennsylvania

Radiology Report

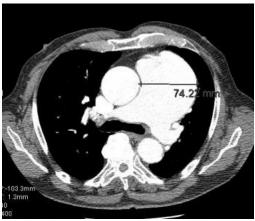
DATE: March 31, 2009 Patient: Simone Langston DOB: 08/10/1936 ID: 0908076

A. Procedure

- a. Spiral CT Scan Lung
 - Use of X-rays to visualize the internal organs of the body. This is a non-invasive, fairly low-risk imaging modality that is tolerated well by patients.

B. Radiologic Findings

a. A repeat CT scan of the lung was performed to evaluate the size of the hilar mass discovered on February 14, 2009. The tumor was originally estimated to measure 7.42 cm in greatest dimension (Fig 1 – below right). The latest CT scan shows that the left hilar tumor has shrunk considerably, now measuring 2 cm in greatest dimension (Fig 1 – below left).



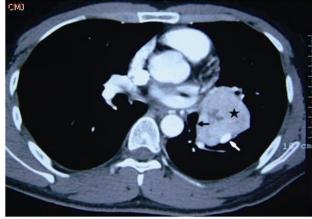


Figure 1. Comparison CT scans of the chest showing a left hilar mass (Feb 14, 2009) measuring 5 cm, and the same hilar mass measuring 2 cm 1.5 months later (Mar 31, 2009). LUNG CANCER IS REDUCING IN SIZE.

C. Diagnosis

a. Possible diminishing lung cancer.

D. Recommendations

a. Lung FNA biopsy.

Radiologist: Jayne Ratkin



Dept. of Pathology

Pathologist: Dr. Lefu Harrison

Pathologist Report

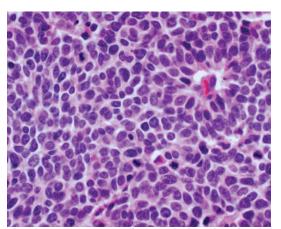
DATE: February 22, 2009 Patient: Simone Langston DOB: 08/10/1936 ID: 0908076

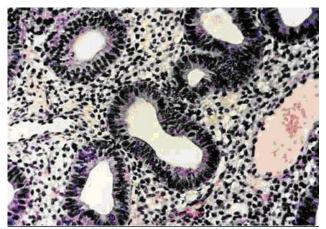
A. Procedure

- a. Fine Needle Aspiration (FNA) of the lung
 - A routine procedure with very little risk to the patient. A 22 gauge needle is inserted
 into the core of the tumor under fluoroscopic (light) guidance, and a tissue sample is
 obtained. In this case, two tissue samples were obtained from two different regions
 of the left lung.

B. Pathologic Findings

a. Two tissue samples were obtained from the left lung. The first biopsy was taken from a hilar mass approximately 7 cm in diameter as measured by radiology. The second biopsy was taken from a 8 cm mass, as measured by radiology, in the periphery of the left upper lobe. The histologic findings from the biopsies, using light microscopy, are shown in Figures 1 and 2. The biopsies showed two different types of lung cancer invading the lung. One type was small cell carcinoma, which was the predominant cell in the hilar lung mass. The second type of cell was metastatic adenocarcinoma from the colon, which was found predominantly in the peripheral mass; however, several adenocarcinoma (colon cancer) cells were noted in the hilar mass.





Figures 1, 2. Hematoxylin – Eosin (H&E) stain of the cells from the left hilar lung mass showing high cellularity, frequent mitoses, and small cells with scant cytoplasm, demonstrating small cell carcinoma (Fig 1) LUNG CANCER. H&E stain of cells from the peripheral nodule in the left upper lobe showing somewhat enlarged glandular cells with slightly enlarged nuclei exhibiting moderate pleomorphism and hyperchromasia, indicating adenocarcinoma (Fig 2).

b. Using electron microscopy (EM), the FNA tissue sample from the hilar mass was inspected with greater scrutiny. With this modality, it appeared as if the adenocarcinoma cells were inducing apoptosis ("cellular suicide") of the small cell cancer cells, shown in Figure 3 below.

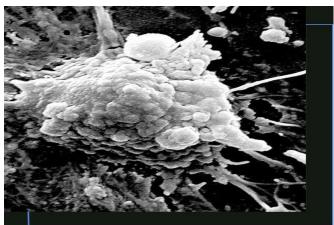


Figure 3. Electron Microscopy (EM) of SiLa cells causing apoptosis ("cell suicide") of small cell carcinoma cells of the lung.

C. Diagnosis

a. This is an interesting and rare case of two types of lung cancer co-existing simultaneously. The primary cancer of the lung is small cell carcinoma, which exists solely in the left hilar mass. The secondary cancer of the lung is metastatic colon cancer, which exists predominantly in the periphery of the lung, but also seems to be resulting in apoptosis ("cell suicide") of the primary cancer cells in the hilar mass. This level of advanced cancer is the direct result of far advancement of the disease.

D. Prognosis

- a. Both metastatic colon cancer and small cell carcinoma of the lung carry a poor prognosis with expected lifespan of only a few months from time of diagnosis. However, in evaluating the unusual and unexpected activity of the adenocarcinoma cells against the small cell carcinoma cells, the prognosis of the patient seems slightly improved. It seems as if the one cancer is attacking and killing the other.
- b. In reviewing the literature on lung cancer, there are no prior case reports of cancer cells from one type of cancer destroying the cancer cells of another type of cancer, making this a unique and unprecedented case. As such, these cancer-killing cells, or SiLa cells, as they should be referred to in all future research, represent a very important discovery. SiLa could possibly be a breakthrough for research pertaining to a noninvasive cure for cancer. A vaccination could also be derived.

E. Recommendations

- a. Obtain additional tissue samples via FNA from the hilar mass to evaluate the regression of the tumor and the depletion of the small cell carcinoma cells. More importantly, these samples can be used by researchers across the globe to find a novel cure for cancer.
- b. Obtain additional radiologic images to evaluate the reduction in size of the hilar mass.

Pathologist: Lefu



Hospital Policies and Employee Manual 2009

Hospital Policy: Religion

Page 10

Section 3.0: Religion

United General was founded on the historical and truly American tenet of religious freedom. Hand in hand with this right comes the right of separation of church and state. United General prides itself on the fact that we are not associated with any religious denomination nor any government or municipal entity. United General willingly accepts all patients regardless of their belief systems and is an equal opportunity employer. United General believes that religious freedom ultimately leads to an environment where both our employees and patients feel comfortable giving and receiving care.

Therefore, United General has indoctrinated the following general policies of the American Medical Association, as modified and as follows:

- Continued Support of Human Rights and Freedom: United General affirms (1) to support the dignity of the individual, human rights and the sanctity of human life, and (2) to oppose any discrimination based on an individual's sex, sexual orientation, gender identity, race, religion, disability, ethnic origin, national origin or age and any other such reprehensible policies.
- Nondiscrimination Policy. United General affirms that it has not been its policy now or in the past to discriminate with religious belief and/or identity.
- **Civil Rights Restoration**. United General reaffirms its long-standing policy that there is no basis for the denial to any human being of equal rights, privileges, and responsibilities commensurate with his or her individual capabilities and ethical character because of an individual's sex, sexual orientation, gender identity, race, religion, disability, ethnic origin, national origin, or age.

In addition, United General has mandated the following requirements for all physicians when providing care to patients who hold any religious beliefs that prevent or inhibit certain types of medical treatment:

- 1. Obtain patient consent for medical treatment by using the United General Standard Consent Form. This form should be modified according to department, physician and treatment sought before being signed by a patient.
- 2. Have patient complete a United General Standard Denial of Treatment Form. This form should be modified according to department and physician, but must be completed by the patient using her/his own words to ensuring full comprehension of the denial of treatment. All fields must be completed before the form is signed by a patient.
- 3. Have a member of the United General Psychiatric Department perform a full competency exam to ensure that the patient has the legal capacity to execute the United General Standard Consent Form and the United General Standard Denial of Treatment Form. This exam must be completed before any forms are completed and/or signed.

1. Please note that United General does receive grant funding from the federal and state government for medical research endeavors.



Dept. of Oncology

Oncologist: <u>Dr. Tabor Caget</u>

Medication Administration Record

Patient: Simone Langston Medical Record #: 0908076 DOB: 08/10/1936

Wt: 60 kg Ht: 65 in

DATE	TIME	MEDICATION	DOSE	ROUTE	RATE	AUTHORIZED
2/15/09	13:00	Morphine Sulfate	2000 mg/1 bag NS*	IV	1 mg/1 min	Dr. Caget
2/17/09	01:00	Morphine Sulfate	2000 mg/1 bag NS*	IV	1 mg/1 min	Dr. Caget
2/19/09	13:00	Morphine Sulfate	2000 mg/1 bag NS*	IV	1 mg/ 1 min	Dr. Caget
2/21/09	01:00	Morphine Sulfate	2000 mg/1 bag NS*	IV	1 mg/ 1 min	Dr. Caget
2/23/09	13:00	Morphine Sulfate	2000 mg/1 bag NS*	IV	1 mg/1 min	Dr. Caget
2/25/09	01:00	Morphine Sulfate	2000 mg/1 bag NS*	IV	1 mg/1 min	Dr. Caget
2/27/09	13:00	Morphine Sulfate	2000 mg/1 bag NS*	IV	1 mg/ 1 min	Dr. Caget
3/01/09	01:00	Morphine Sulfate	2000 mg/1 bag NS*	IV	1 mg/1 min	Dr. Caget
3/03/09	01:00	Morphine Sulfate	2000 mg/1 bag NS*	IV	1.3 mg/1 min	Dr. Caget
3/04/09	01:00	Morphine Sulfate	2000 mg/1 bag NS*	IV	1.3 mg/1 min	Dr. Caget
3/05/09	01:00	Morphine Sulfate	2000 mg/1 bag NS*	IV	1.3 mg/1 min	Dr. Caget
3/06/09	01:00	Morphine Sulfate	2000 mg/1 bag NS*	IV	1.3 mg/1 min	Dr. Caget
3/07/09	01:00	Morphine Sulfate	2000 mg/1 bag NS*	IV	1.3 mg/1 min	Dr. Caget
3/08/09	01:00	Morphine Sulfate	2000 mg/1 bag NS*	IV	1.3 mg/1 min	Dr. Caget
3/09/09	00:00	Morphine Sulfate	2000 mg/1 bag NS*	IV	1.3 mg/1 min	Dr. Caget
3/10/09	22:00	Morphine Sulfate	2000 mg/1 bag NS*	IV	1.4 mg/1 min	Dr. Caget
3/11/09	21:00	Morphine Sulfate	2000 mg/1 bag NS*	IV	1.4 mg/1 min	Dr. Caget
3/12/09	20:00	Morphine Sulfate	2000 mg/1 bag NS*	IV	1.4 mg/1 min	Dr. Caget
3/13/09	19:00	Morphine Sulfate	2000 mg/1 bag NS*	IV	1.4 mg/1 min	Dr. Caget
3/14/09	18:00	Morphine Sulfate	2000 mg/1 bag NS*	IV	1.4 mg/1 min	Dr. Caget
3/15/09	16:00	Morphine Sulfate	2000 mg/1 bag NS*	IV	1.5 mg/1 min	Dr. Caget

DATE	TIME	MEDICATION	DOSE	ROUTE	RATE	AUTHORIZED
3/16/09	14:00	Morphine Sulfate	2000 mg/1 bag NS*	IV	1.5 mg/1 min	Dr. Caget
3/17/09	12:00	Morphine Sulfate	2000 mg/1 bag NS*	IV	1.5 mg/1 min	Dr. Caget
3/18/09	10:00	Morphine Sulfate	2000 mg/1 bag NS*	IV	1.5 mg/1 min	Dr. Caget
3/19/09	08:00	Morphine Sulfate	2000 mg/1 bag NS*	IV	1.5 mg/1 min	Dr. Caget
3/20/09	06:00	Morphine Sulfate	2000 mg/1 bag NS*	IV	1.5 mg/1 min	Dr. Caget
3/21/09	03:00	Morphine Sulfate	2000 mg/1 bag NS*	IV	1.6 mg/1 min	Dr. Caget
3/22/09	00:00	Morphine Sulfate	2000 mg/1 bag NS*	IV	1.6 mg/1 min	Dr. Caget
3/22/09	21:00	Morphine Sulfate	2000 mg/1 bag NS*	IV	1.6 mg/1 min	Dr. Caget
3/23/09	18:00	Morphine Sulfate	2000 mg/1 bag NS*	IV	1.6 mg/1 min	Dr. Caget
3/24/09	15:00	Morphine Sulfate	2000 mg/1 bag NS*	IV	1.6 mg/1 min	Dr. Caget
3/25/09	12:00	Morphine Sulfate	2000 mg/1 bag NS*	IV	1.6 mg/1 min	Dr. Caget
3/26/09	09:00	Morphine Sulfate	2000 mg/1 bag NS*	IV	1.6 mg/1 min	Dr. Caget
3/27/09	06:00	Morphine Sulfate	2000 mg/1 bag NS*	IV	1.6 mg/1 min	Dr. Caget
3/28/09	03:00	Morphine Sulfate	2000 mg/1 bag NS*	IV	1.6 mg/1 min	Dr. Caget
3/29/09	00:00	Morphine Sulfate	2000 mg/1 bag NS*	IV	1.6 mg/1 min	Dr. Caget
3/29/09	21:00	Morphine Sulfate	2000 mg/1 bag NS*	IV	1.6 mg/1 min	Dr. Caget
3/30/09	18:00	Morphine Sulfate	2000 mg/1 bag NS*	IV	1.6 mg/1 min	Dr. Caget
3/31/09	15:00	Morphine Sulfate	2000 mg/1 bag NS*	IV	1.6 mg/1 min	Dr. Caget
4/01/09	12:00	Morphine Sulfate	2000 mg/1 bag NS*	IV	1.6 mg/1 min	Dr. Caget
4/02/09	09:00	Morphine Sulfate	2000 mg/1 bag NS*	IV	1.6 mg/1 min	Dr. Caget
4/03/09	06:00	Morphine Sulfate	2000 mg/1 bag NS*	IV	1.6 mg/1 min	Dr. Caget
4/04/09	03:00	Morphine Sulfate	2000 mg/1 bag NS*	IV	1.6 mg/1 min	Dr. Caget
4/05/09	00:00	Morphine Sulfate	2000 mg/1 bag NS*	IV	1.6 mg/1 min	Dr. Caget
4/05/09	21:00	Morphine Sulfate	2000 mg/1 bag NS*	IV	1.6 mg/1 min	Dr. Caget
4/06/09	18:00	Morphine Sulfate	2000 mg/1 bag NS*	IV	1.6 mg/1 min	Dr. Caget
4/07/09	15:00	Morphine Sulfate	2000 mg/1 bag NS*	IV	1.6 mg/1 min	Dr. Caget
4/08/09	12:00	Morphine Sulfate	2000 mg/1 bag NS*	IV	1.6 mg/1 min	Dr. Caget
4/10/09	00:00	Morphine Sulfate	2000 mg/1 bag NS*	IV	1 mg/1 min	Dr. Caget
4/11/09	15:00	Morphine Sulfate	Discontinued	****	******	Anandganda RN
4/11/09	15:00	Naloxone	6 mg	IM	n/a	Dr. Caget
4/11/09	16:00	Morphine Sulfate	2000 mg/1bag NS*	IV	1 mg/1 min	Dr. Caget



Dept. of Psychiatry

Psychiatrist: <u>Dr. Farley Davis</u>

Mini-Mental State Examination (MSSE)

DATE: February 22, 2009
Patient: Simone Langston
DOB: 08/10/1936
ID: 0908076

Category	Possible Points	Score	Comments	
Orientation to Time	5	4	Patient was able to identify the year, season, month, day, but not date.	
Orientation to Place	5	5	Perfect identification of location of residence.	
Registration	3	3	Perfect registration of three items located in room.	
Attention and calculation	5	4	Patient had minimal difficulty on reverse spelling exercises.	
Recall	3	2	Patient had minimal difficulty remembering registration items.	
Language	2	2	Perfect understanding of language examples.	
Repetition	1	1	Perfect ability to repeat phrases as stated.	
Complex Commands	6	4	Patient had moderate difficulty with complex commands including object drawing.	
TOTAL SCORE: 25	COMMENTS: Patient, while struggling with complex commands aspect of the test, appears to have full command of mental faculties. Patient, however, did display warning signs of potential future problems, especially when accounting for current illness (advanced cancers) as well as current medication (morphine) and proposed aggressive chemotherapy. Patient currently has legal mental capacity to make decisions regarding medical care. It is recommended that the patient's mental state be monitored closely over the coming weeks to ensure capacity remains intact.			

STANDARD SCORE KEY				
25-30	Effectively Normal – Legal Capacity			
21-24	Slightly Impaired – Most Likely Lacks Legal Capacity			
10-20	Mostly to Moderately Impaired – Lacks Legal Capacity			
≤ 9	Severely Impaired – Lacks Legal Capacity			

Attestation: I, the undersigned, having followed all United General Hospital procedures, hereby attest that the above results of the administered Mini-Mental State Examination are true and accurate to the best of my professional ability.

<u>Dr. Farley Davis</u>

Signature



Dept. of Psychiatry

Psychiatrist: <u>Dr. Farley Davis</u>

Mini-Mental State Examination (MSSE)

DATE: April 8, 2009
Patient: Simone Langston
DOB: 08/10/1936
ID: 0908076

Category	Possible Points	Score	Comments	
Orientation to Time	5	0	Patient was not able to identify time at all.	
Orientation to Place	5	2	Patient was only able to state that she was in a hospital in Pittsburgh.	
Registration	3	2	Patient had difficulty identifying items in room. Took extended period of time to generate 2 correct answers.	
Attention and calculation	5	2	Patient had moderate to severe difficulty in reverse spelling exercise.	
Recall	3	2	Patient had moderate difficulty remembering items.	
Language	2	1	Patient displayed moderate difficulty understanding of language examples.	
Repetition	1	1	Perfect ability to repeat phrases as stated.	
Complex Commands	6	2	Patient had extreme difficulty with complex commands including object drawing.	
TOTAL SCORE: 12	tremendous previous ass legal capacit results are r chemothera	COMMENTS: Patient, unfortunately, over the course of seven weeks has shown a tremendous depletion of mental capacity. Patient was not even able to recall my previous assessment of her mental capacity. Patient categorically no longer has the legal capacity required to make decisions regarding her medical treatment. Such results are most likely the effect of the heavy morphine regiment and aggressive chemotherapy. Prognosis of patient's ability to regain capacity prior to imminent death highly unlikely, if not impossible. Appointment of quardian recommended.		

STANDARD SCORE KEY				
25-30	Effectively Normal – Legal Capacity			
21-24	Slightly Impaired – Most Likely Lacks Legal Capacity			
10-20	Mostly to Moderately Impaired – Lacks Legal Capacity			
≤ 9	Severely Impaired – Lacks Legal Capacity			

Attestation: I, the undersigned, having followed all United General Hospital procedures, hereby attest that the above results of the administered Mini-Mental State Examination are true and accurate to the best of my professional ability.

<u>Dr. Farley Davis</u>

Signature



312 Blvd. of the Allies Suite 718 Pittsburgh, Pennsylvania | 15422





Montreal Cognitive Assessment (MoCA)

Date: April 11, 2009 Subject: Simone Langstone

DOB: 08/10/1936 Gender: Female

Location: United General Hospital – Pittsburgh Education: Some High School

Category		Possible Points	Score	Comments
Visuospatial	Visuospatial / Executive		4	Subject was able to execute line sequencing drawing task, draw a cube, and a clock. Handwriting was weak and wavering.
Naming		3	2	Subject was able to identify all animals, except for llama, mistake for an alpaca.
Attention		6	5	Flawless ability to repeat numerical sequences backwards and forwards. Read letters adequately. Moderate difficulty with subtraction exercise.
Language 3 3		3	Subject displayed full command over ability to repeat phrase read by tester. Strong letter fluency.	
Abstraction	Abstraction 2 1 Subject had some problems associating a watch to a rul		Subject had some problems associating a watch to a ruler.	
Delayed Recall		5	5	Subject displayed minimal difficulty recalling word list from the beginning of examination.
Orientation	Orientation 6 4 Subject was able to identify the year, month, city and		Subject was able to identify the year, month, city and place. Unable to state date or day.	
TOTAL SCORE: 24	COMMENTS: Test subject upon initial contact appeared borderline catatonic. Hospital staff administered 6mg of Naloxone to counteract effects of morphine. After effects of Naloxone were realized, I administered the MoCA. Such course of action ensured that the mental state of the subject was accurate and not masked by narcotics. Subject displayed amazing clarity and cognitive ability, especially when considering advanced stage of cancer. Understandably, subject had a difficulty with orientation to time considering weeks of morphine course administered intravenously. Therefore, subject would most likely have scored a 26 on the MoCA. As a result, I have no issues deeming this individual competent to make decisions regarding medical care and execute complex agreements.			

STANDARD SCORE KEY			
26-30	Effectively Normal – Legal Capacity		
19-25	Moderately Impaired – Most Likely Lacks Legal Capacity		
0-19	Greatly Impaired – Lacks Legal Capacity (i.e. Alzheimer's)		

Attestation: I, the undersigned, hereby attest that the above results of the administered MoCA are true and accurate to the best of my professional ability.

M	Ebar	
W,	<i>EDAN</i>	aiar

Drug Fact Sheet - Morphine Sulfate

- Origin -most common alkaloid obtained from opium, which is the dried sap of unripe poppy seeds. Though it was officially discovered in 1804, historical records indicate that people have known about the effects of opium since Byzantine times. Morphine was first manufactured for commercial sale and medical use in 1827.
- Indications –prototypical analgesic medication that serves as a benchmark for which other analgesic medications are compared for potency. It is used medically to reduce severe pain and suffering (i.e., promotes analgesia). Other indications include cough suppression and anti-diarrheal.
- Mechanism of Action acts directly on the central nervous system (CNS) by binding to mu receptors on neurons and inhibiting the release of stimulating neurotransmitters. Morphine acts similarly to the natural endorphins found in the body by promoting decreased sensation of pain.
- Uses mainly for palliation of pain, including pain associated with myocardial infarction (heart attack), kidney stones, severe back pain, sickle cell crisis, cancer, etc. Morphine has also been used as a vehicle for physician-assisted suicide (legal only in Oregon) in patients with terminal illness.
- Recommended Dosage based on weight in kg and intravenous (IV) rate of administration. Standard dose = 2000mg/1 bag normal saline (NS)

Weight (kg)	Recommended Rate - IV (mg/min)	Maximum Rate- IV (mg/min)
40	0.5	1.1
60	1	1.6
80	1.5	2.1

- Side Effects very high potential for addiction both physically and psychologically. Additionally, patients quickly develop tolerance to the drug and require increasing doses in order to maintain the analgesic effects. Morphine is associated with a severe but non-lethal withdrawal syndrome involving diarrhea, cravings, goose bumps, tears, yawning, perspiration, runny nose, achy bones and muscles, etc. Constipation is a less severe but highly unpleasant side effect associated with being on the drug. Altered mental status and diminished mental capacity likely with high doses. Can make user more susceptible to suggested actions by others.
- *Metabolism* largely metabolized by the liver. The half-life of morphine is 120 minutes, meaning that half of the original dose of morphine that was administered will be degraded after 120 minutes. Morphine is highly fat soluble, which is why it has such a long half life. Morphine will be effectively eliminated from the body after 480 minutes.

Drug Fact Sheet - Naloxone

- Origin –synthetic opioid receptor antagonist. It was developed in the 1960s in order to combat the effects of opioid ingestion (such as morphine). It has recently been suggested that it may also have some benefit when administered to a patient in septic shock.
- Indications –reversal of life-threatening central nervous system (CNS) and respiratory drive depression caused by opioid overdose. Also used for the complete or partial reversal from the effects of physician-administered opioid regimens (i.e., after surgery) in order to provide patient lucidity and clarity.
- Mechanism of Action its chemical structure is similar to that of morphine and thus it acts as a competitive antagonist of morphine at the mu receptors in the CNS. It prevents morphine from binding to the receptor; therefore, morphine is unable to produce its effects on the body (i.e., analgesia).
- Uses –frequently used in the emergency department in order to reverse opioid overdoses in patients. Naloxone is also used on the wards in the hospital to quickly reverse the effects of morphine in patients being managed on long-term pain control regimens. This drug is also used by anesthesiologists following surgery to awake a patient out of a sedated state.
- Recommended Dosage based on intramuscular (IM) dosage administration; weight is not a
 factor. Standard dose = 4mg/injection. Do not exceed 2 standard doses in one hour period. If
 reversal of opioid effects are not seen after 10 mg administered over a 2 hour period, opioidinduced toxicity should be suspected.

Weight (kg)	Standard Dose – IM (mg)	Maximum Dose - IM (mg)
40	4	8
60	4	8
80	4	8

- Side Effects -change in mood, nausea, vomiting, sweating, restlessness, increased sensation
 of pain, headache, seizure, chest pain, allergic reaction, fast heart rate, high blood pressure,
 etc.
- Metabolism –The half-life of each dose of naloxone is approximately 30 minutes, meaning that
 half of the original dose of naloxone that was administered will be degraded after 30 minutes.
 One standard dose of naloxone (i.e. 4mg IM) generally lasts about 120 minutes before it is
 effectively eliminated from the body. A standard single dose of naloxone generally remains
 effective for 45 mins. As the naloxone degrades, its beneficial effects will also diminish
 correspondingly. Therefore, because the half-life of morphine is 120 minutes and the effective
 elimination of morphine takes 480 minutes, several 4mg injections may be needed in order to
 completely reverse morphine's effects.





FOUNDED 2009 PITTSBURGH, PENNSYLVANIA

April 16, 2009

Avery Langston 6002 Meade St. Pittsburgh, Pennsylvania 15208

Re: Payment for Purchase of Rights to SiLa

Dear Avery:

It is with a heavy hand and heart that I write this letter to you. All of us who had your mother touch our lives will mourn her for years to come. Although I cannot say that I really knew her well as a person, the limited interaction I had with her leaves me with an impression of a devote, caring and loving mother. I hope that your time of grieving allows you to celebrate the time you had with her amongst the sorry her loss will certainly cause.

However, you should appreciate the fact that because your mother allowed me to biopsy her cells and obtain the rights to SiLa, she will actually live on for decades, if not centuries to come. As much as she was a special person, her cells were and will always remain magical. The future of cancer research and medicine will never be the same. It is my hope and intention, as I write on my fist page of new letterhead for SiLa, Inc., that my efforts will not be in vain and that SiLa will realize its full potential and defeat the world's greatest killer.

Per the agreement I made with your mother on April 11, 2009 (and as specifically requested by you), please find enclosed a personal check in the amount of \$200,000. I hope that it more than covers any medical expenses incurred and allows you to take a break and enjoy life as your mother would have wanted you to. I also hope you can forgive me for any disagreements we had in the past and take pride in my future work with SiLa. Maybe if I had agreed to pay your family earlier, a lot of unnecessary pain, mistrust and misdeeds could have been avoided. For this, I am truly sorry.

When SiLa becomes a household word in a few years and cancer becomes as easy to cure as the common cold, I hope you will smile every time "SiLa" is echoed. Your mother's cancer was actually a blessing in disguise.

Best regards,

Lefu Harrison, M.D.

Chief Researcher, President & CEO

Dr. Lefu Harrison 6875 Douglas Street Pittsburgh, PA 15217 DATE _	666 April 16, 2009
PAY TO THE ORDER OF Avery Langston	\$ 200,000.00
Two hundred thousand and zero cents XXX	, DOLLARS
FBDA FOR <u>rights to Sila</u> [: 885112745 : 12966685931 12 : 666	

Note: check is not original size. Enlarged for demonstrative purposes.

Farley C. Davis, M.D.

United General Hospital • Suite 320A • Pittsburgh, PA 15261

EDUCATION

Pennsylvania Hospital, Residency, Psychiatry (1970-1973); Chief Resident with Distinction (1974)

University of Pennsylvania, Philadelphia, PA, M.D., 1970

High honors in psychiatry

Departmental honors in neurology, internal medicine

Temple University, Philadelphia, PA, B.S. Psychology, magna cum laude

Teodoro Donoso Prize - Awarded to best bachelor's thesis in the biological sciences

EXPERIENCE

United General Hospital, Pittsburgh, PA, 1975-Present

Chief of Psychiatry, 1982-Present Staff Psychiatrist, 1975-1982 Chair of Medicine, 1993-96

Farley Davis Consulting Psychiatry, L.L.C., 2002-Present

Provides forensic and therapeutic psychiatric consulting services to individuals and organizations in need of same, leveraging three decades of professional experience to solve problems and provide reliable, expert testimony in state and federal courts.

University of Pittsburgh School of Medicine, Adjunct Professor of Psychiatry, 1994-2004

PROFESSIONAL ASSOCIATIONS

American Psychiatric Association, Fellow, 1971-Present; Life Fellow, 2006-Present

Board Certified, Forensic Psychiatry, 1976-Present

Chair, Forensic Psychiatry Working Group, 1989-91

Editor, Journal of Forensic Psychiatry, 1987-2001 - Editor in Chief, 1999-2001

American Board of Forensic Examiners, 1983-Present

Chairman, Board of Governors, 1995-1997

William C. Pilgrim Award for Exceptional Contribution, 2003

American Board of Psychiatry and Neurology, 1992-Present

REPRESENTATIVE PUBLICATIONS

Capacity to Contract: A Growing Problem in an Aging Population, Psychology Today, June 2001 Dynamics of Competence and the Mini-Mental State Exam, Journal of Forensic Psychiatry, Summer 1994 The Mini-Mental State Exam: In Defense of an Old Friend, American Journal of Psychiatry, Jan. 2009

A complete list of publications and presentations is available upon request.

Quincy Ebardiar, M.D. 15 Horlick Minton Way • Pittsburgh, PA 15217

EDUCATION

United General Hospital, Residency, Psychiatry, 1992-1996

Honors: Asa Breed Honors Fellowship in Clinical Psychiatry, 1995-96

Universidad Pontificia Bolivariana, Medellín, Colombia, M.D. cum laude, 1990

Honors: Von Koenigswald Prize for Experimental Biopsychology for research into differential physiological impact of variations in benzoylmethylecgonine administration and concentration.

University of Chicago,

Master's Degree in Anthropology, 1976

Thesis: Wampeters, Granfalloons and Foma: Comparative Views of the Divine in the Southern Caribbean Islands

Bachelor's of Science in Anthropology, 1974

President, Inter-Fraternity Council

EXPERIENCE

IC9, L.L.C., Founder and Principal, 1998-Present

Provide addiction and eating disorder counseling and treatment in conjunction with the University of Pittsburgh's student health center and in private professional counseling facility. Consult with mental health professionals nationwide on addiction issues. Research addiction and eating disorder issues pursuant to grants from National Institutes of Health and private companies. Provide testimony on addiction, eating disorder and competence issues in state and federal courts and to other individuals and companies for grant acquisition and maintenance.

United General Hospital, Staff Psychiatrist, 1996-1998

Provided range of psychiatric diagnostic and treatment services to diverse patient population. Worked closely with nationally-recognized faculty to provide first-rate patient services.

Rosewater Clinic, Researcher in Clinical Psychiatry, 1990-1992

Researched effects of amphetamine compounds on muscular and skeletal formation and growth in anorexic and bulimic population. Published findings in *Nature*.

PUBLICATIONS

With Dr. Lefu Harrison, Vicious Cycles: Multiform Analysis of Parasympathetic Effects of Amphetamine Use in Patients Compromised by Eating Disorders, Nature, 21 June 1992.

Competence and Testimony in the Narcotic Drug Abuser: Beware the Changes in Mental State, American Journal of Psychiatry, September 1998

The Silent Killer: What to Do With Your Anorexic Teen, Redbook, August 2002

The Montreal Cognitive Assessment: A Better Way to Quickly Assess Competence to Refuse Medical Treatment in Emergent Care Settings, Emergency Medicine Journal, December 2007

PROFESSIONAL ASSOCIATIONS

American Psychiatric Association, Fellow, 1996-Present

Drug Abuse Working Group, 1997-2004

Eating Disorder Working Group, 1998-Present

Montreal Cognitive Assessment Advisory Council, 2008-Present

The Association for Addiction Professionals, 1992-Present

National Eating Disorders Association, Board Member, 2001-Present; Honored Clinician, 2008

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Dr. Lefu Harrison 6875 Douglas Street Pittsburgh, PA 15217	659 DATE <u>March 4, 2009</u>
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