

**Cea v Silverstein**

2009 NY Slip Op 30475(U)

February 24, 2009

Supreme Court, Suffolk County

Docket Number: 07-2139

Judge: Jeffrey Arlen Spinner

Republished from New York State Unified Court System's E-Courts Service.  
Search E-Courts (<http://www.nycourts.gov/ecourts>) for any additional information on this case.

This opinion is uncorrected and not selected for official publication.

SUPREME COURT - STATE OF NEW YORK  
I.A.S. PART 21 - SUFFOLK COUNTY

**PRESENT:**

Hon. JEFFREY ARLEN SPINNER  
Justice of the Supreme Court

MOTION DATE 3-27-08 (003)  
MOTION DATE 4-17-08 (004)  
ADJ. DATE 1-7-09  
Mot. Seq. # 003 - MG  
# 004 - MD

-----X  
VALERIE CEA, as Administrator of the Estate of :  
ERNEST CEA, SR., deceased, and VALERIE :  
CEA, individually, :  
Plaintiff, :  
- against - :  
MARTIN J. SILVERSTEIN, M.D., JEFFREY :  
VACIRCA, M.D., JOSEPH CIRRONE, M.D., :  
VICTORIA NAPOLITANO, R.N., NORTH :  
SHORE HEMATOLOGY/ONCOLOGY :  
ASSOCIATES, P.C., and NORTH SHORE :  
RADIATION ONCOLOGY, :  
Defendants. :  
-----X

LEVY, PHILLIPS & KONIGSBERG, LLP  
Attorneys for Plaintiff  
800 Third Avenue, 13<sup>th</sup> Floor  
New York, New York 10022  
  
GALLAGHER, WALKER, BIANCO &  
PLASTARAS  
Attorneys for Defendants  
98 Willis Avenue --  
Mineola, New York 11501

Upon the following papers numbered 1 to 33 read on this motion to compel and cross-motion for a protective order; Notice of Motion/ Order to Show Cause and supporting papers (003) 1-12; Notice of Cross-Motion and supporting papers (004) 13-21; Answering Affidavits and supporting papers 22-32; Replying Affidavits and supporting papers    ; Other Pltff's Mem/Law 33; Defts' Mem/Law 34-35; 36-37; ~~(and after hearing counsel in support and opposed to the motion)~~ it is,

**ORDERED** that this motion (003) by the plaintiff, Valerie Cea as Administrator of the Estate of Earnest Cea, Sr., deceased, and Valerie Cea, individually, for an order pursuant to CPLR 3124 and 3126 to compel the defendants to produce discovery documents or in the alternative striking the defendants' answers, is granted to the extent the defendants are directed to comply with the Notice for Discovery and Inspection dated November 9, 2007, with the names and identifying information of other patients redacted, within thirty days of the date of this order; and it is further

**ORDERED** that this cross-motion (004) by the defendants, Martin J. Silverstein, M.D, Jeffrey Vacirca, M.D., Joseph Cirrone, M.D., Victoria Napolitano, R.N., North Shore Hematology/Oncology Associates, P.C. and North Shore Radiation Oncology, pursuant to CPLR 3103(a) for a protective order prohibiting the production of the Ethyol Study Book and other related records pursuant to the plaintiff's November 9, 2007 Demand for Discovery and Inspection, is denied.

This action was commenced on January 18, 2007 by the filing of a Summons and Complaint and arises out of claims of negligence and medical malpractice with causes of action premised upon the decedent's pain and suffering, lack of informed consent, wrongful death and negligent hiring, with a derivative claim on behalf of the plaintiff. Ernest Cea, Sr. died on April 13, 2005 and was the spouse of Valerie Cea. It is claimed that the plaintiff's decedent was treated at Mather Memorial Hospital from March 28, 2005 until his death and received an overdose of a medication, Ethyol (Amifostine) due to the negligent administration, monitoring and care and treatment by the defendants.

Ethyol is a medication manufactured by MedImmune Oncology, Inc. Dr. Silverstein, a radiation oncologist treated Mr. Cea for non-small cell lung cancer with Ethyol, radiation, and chemotherapy. He is a partner with North Shore Radiation Oncology which is a division of North Shore Hematology/Oncology Associates. Both are located on Belle Meade Road, East Setauket, New York, with separate radiation and oncology offices. Dr. Silverstein testified he provides medical oncology care and radiation oncology to patients. Separate charts were maintained for Mr. Cea for radiation oncology and medical oncology. The medical oncology record contained documents relating to Ethyol, which Dr. Silverstein stated was a drug administered subcutaneously (under the skin) and is considered a radiation protector or cytoprotective agent, a cytoprotector, and which drug he prescribed to Mr. Cea in relation to his radiation treatments. A flow sheet was maintained relevant to the administration of the drug.

Dr. Silverstein testified that MedImmune, the company which manufactures Ethyol, ran a program to help defer costs of the expense of the drug if the patient's insurance denied coverage for the drug. He first learned about the drug in about 2000 and in 2003 prescribed Ethyol for intravenous use. He was paid by MedImmune to test the drug Ethyol for subcutaneous use in that it might have decreased side effects over its intravenous use. He could not remember the amount he was compensated by MedImmune. MedImmune provided the drug for free to patients for its testing. Dr. Silverstein testified that the side effects of the drug were nausea, vomiting, hypotension, rash, and anaphylactic reaction. He tested the drug for about a year or so and drafted medical literature, along with his radiation oncology associate, Dr. Joseph Cirrone, reporting his experience in that testing, but it was never published, he never submitted it for peer review, but did submit it to MedImmune. He stated the article was written into a computer and that it is filed in the radiology oncology practice office in the Ethyol study book which is located at the radiation oncology office and consists of two books: the protocol book and the patient book. He stated that Mr. Cea was not part of the study, but he felt that Mr. Cea would be a candidate for the use of Ethyol to minimize side effects of treatment, such as mucositis, esophagitis, pneumonitis.

One part of the Ethyol study book is a template of what was planned or proposed, the intent of the study and how it would be done, how the Ethyol would be administered with results logged concerning the side effects profile, antiemetics, hydration, and moderating blood pressure. The other book contained every patient by number, along with the relevant information, side effects and results with a file for each of about twelve patients in that second book. Dr. Silverstein testified that MedImmune might have provided relevant literature as to the administration of the drug, side effects, monitoring, and literature supporting its role, information valuable to them implementing the study. He also testified that Mr. Cea was treated in a fashion similar to the protocol, which treatment included hydration, Compazine an hour to an hour and a half before treatment, monitoring during the treatment by

a nurse or a physician if necessary; monitoring blood pressure prior to administration and fifteen minutes after administration; and noting side effects such as hypotension or syncopal episode (fainting spell from hypotension) He stated that because the drug can cause hypotension, he wanted to see if that was a trend that keeps on happening.

Dr. Silverstein testified that he knew the drug was not FDA approved and he believed that he told Mr. Cea, but he could not remember the specifics, but stated he would have explained that lung cancer was not a site the drug would be considered for. He could not remember if the drug was given to his office free of charge for Mr. Cea. Ethyol was administered March 17<sup>th</sup>, 18<sup>th</sup>, 21<sup>st</sup> and 23<sup>rd</sup>, but held on the 22<sup>nd</sup> but he did not know why, and held on the 24<sup>th</sup> and 25<sup>th</sup> due to Mr. Cea having low blood pressure. On March 28<sup>th</sup>, Mr. Cea was admitted to Mather Hospital with a 'stroke.' Dr. Silverstein testified that he never notified MedImmune about Mr. Cea's care.

An Agreement, entitled Clinical Data Collection and Analysis Agreement, was signed June 27, 2003 by Robert L. Hirsch, PhD, Vice President of Medical Affairs, MedImmune, Inc. and April 30, 2003 by Martin J. Silverstein, M.D. The agreement provides that MedImmune is in the business of developing, manufacturing and selling biologics and pharmaceuticals, and in consideration of the mutual promises and for other good and valuable consideration.<sup>1</sup> At paragraph 106 it sets forth that - "Investigator" shall mean Martin Silverstein, M.D. in his/her capacity as an employee of the Institution.<sup>2</sup> The agreement provided for a study which was defined as the collection, presentation and analysis of the data as set forth in the proposal concerning the study compound, Ethyol, and which study was to be conducted by Dr. Silverstein who was to be responsible for identifying and recruiting patients, employing personnel, obtaining all equipment and supplies including the Ethyol.

Dr. Silverstein was to be paid \$40,000.00 in installments, plus reimbursement for IRB fees by MedImmune pursuant to this agreement. MedImmune was obligated to pay the costs of the study and set forth that the data shall be the property of MedImmune to use for any and all purposes. Dr. Silverstein (North Shore Radiology Oncology) shall use the data only for the purposes of conducting the study, writing the reports required in paragraphs 5.01 and 5.02 and writing academic publications as permitted in Article V, which provides that only data, analyses and conclusions presented in the reports required in paragraphs 5.01 and 5.02 shall be presented in such publications. Paragraph 5.04 provides reporting will include the details of the duration and intensity of each episode, the action taken with respect to (drug) and the patient outcome, and all serious adverse events were to be reported to Pharmacovigilance with supporting documentation.

Article IX-Confidentiality contained in the agreement provides that during the term of the agreement and for ten years thereafter, irrespective of any termination earlier than the expiration of the term of the agreement, that Dr. Silverstein and his support staff shall maintain the information in

---

<sup>1</sup> The mutual promises and other good and valuable consideration have not been set forth.

<sup>2</sup> Institution is set forth as North Shore Radiation Oncology.

confidentiality and shall not reveal the information to third parties without the written consent of MedImmune, except as required by law. These restrictions do not apply to information that, inter alia, becomes public knowledge without the fault of the institution.

By way of a Demand for Discovery and Inspected dated November 9, 2007, the plaintiffs requested, inter alia, (2) All records reflecting promotional materials, gifts and incentives received from MedImmune Oncology, Inc. regarding the use of Ethyol. This demand shall be deemed to permit the redaction of names and identifying information of patients other than Ernest Cea; (3) All medical literature received from MedImmune Oncology, Inc. regarding the use of Ethyol. This demand shall be deemed to permit the redaction of names and identifying information of patients other than Ernest Cea; (4) All written agreements between defendants and MedImmune Oncology, Inc. regarding the testing or use of Ethyol for subcutaneous use. This demand shall be deemed to permit the redaction of names and identifying information of patients other than Ernest Cea; (5) All correspondence between defendants and MedImmune Oncology, Inc. regarding the testing or use of Ethyol for subcutaneous use. This demand shall be deemed to permit the redaction of names and identifying information of patients other than Ernest Cea; (6) All records reflecting the receipt of money from MedImmune Oncology, Inc. regarding the testing or use of Ethyol for subcutaneous use. This demand shall be deemed to permit the redaction of names and identifying information of patients other than Ernest Cea; (7) All articles and/or writings in any other form, including but not limited to drafts and materials submitted to MedImmune Oncology, Inc. created by any named defendant regarding Ethyol for subcutaneous use. This demand shall be deemed to permit the redaction of names and identifying information of patients other than Ernest Cea; (8) The Ethyol Study Book, as testified to by defendant Martin J. Silverstein, M.D., except that such demand shall not include the names or other identifying information about patients other than decedent Ernest Cea; (9) All documents related to Ernest Cea's participation in the Ethyol Protect Program, including, but not limited to: supporting documentation submitted to his insurance carrier (Aetna US Healthcare) or to MedImmune Oncology, Inc., as well as any and all letters of medical necessity; (10) The results of the tests of Ethyol for subcutaneous use by defendants and their patients. This demand shall be deemed to permit the redaction of names and identifying information of patients other than Ernest Cea. (11) Copies of all medical literature reviewed by defendant Silverstein in preparation for his deposition.

By way of the Defendants' Response to Discovery Demand dated December 14, 2007, the defendants objected to the plaintiff's Notice as seeking information which is irrelevant and immaterial to the issues, states there are no records reflecting promotional materials, gifts and incentives received from MedImmune Oncology, Inc. regarding the use of Ethyol; provided a copy of literature received from MedImmune which the defendant reviewed in preparation of his deposition; provided a copy of the written agreement; objects to providing all correspondence between defendants and MedImmune Oncology, Inc. regarding the testing or use of Ethyol for subcutaneous use as not in the control of the defendants and that the information and documents sought are privileged, and further are irrelevant and immaterial; objected to providing all articles and/or writings in any other form, including but not limited to drafts and materials submitted to MedImmune Oncology, Inc. created by any named defendant regarding Ethyol for subcutaneous use as these are not within the control of the defendants and are irrelevant and immaterial; objects to producing the Ethyol Study Book, as testified to by defendant Martin J. Silverstein, M.D., as not within the control of the defendants, are privileged, and are irrelevant

Cea v Silverstein et al  
 Index No. 07-02139  
 Page No. 5

and immaterial; objects to providing the results of the tests of Ethylol for subcutaneous use by defendants and their patients as they are not within the control of the defendants, are privileged, and are irrelevant and immaterial. Dr. Silverstein, did, however, provide a copy of the literature reviewed by him.

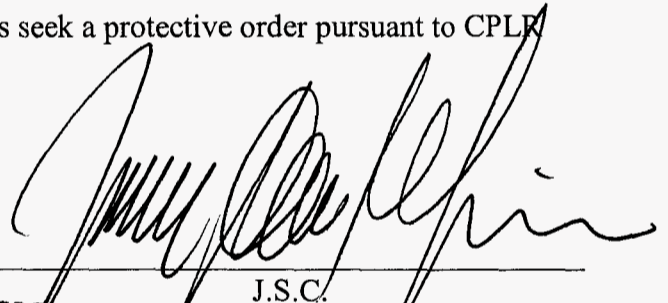
CPLR 3101(a) provides that there shall be full disclosure of all evidence material and necessary in the prosecution or defense of an action, regardless of the burden of proof. The words "material and necessary" found in CPLR 3101(a) are to be interpreted liberally to require disclosure, upon request, of any facts bearing on the controversy which will assist preparation for trial by sharpening the issues and reducing delay and prolixity. The test is one of usefulness and reason. Rule 3101(a) should be construed to permit discovery of testimony that is sufficiently related to the issues in litigation to make the effort to obtain it in preparation for trial reasonable. The purpose of disclosure procedures is to advance the function of a trial to ascertain truth and to accelerate the disposition of actions. If there is any possibility that the information is sought in good faith for possible use as evidence-in-chief or in rebuttal or for cross-examination, it should be considered as evidence material in the prosecution or defense. (*see, generally, Allen v Crowell-Collier Publishing Company*, 21 NY2d 403, 288 NYS2d 449 [1968]).

It is determined that the information sought by the plaintiff by way of the Notice for Discovery and Inspection served dated November 9, 2007 is deemed material and necessary, useful and reasonable, and sufficiently related to the litigation and is sought in good faith.

Accordingly, motion (003) is granted and the defendants are directed to comply with the Notice for Discovery and Inspection dated November 9, 2007, with the names and identifying information of other patients redacted, within thirty days of the date of this order.

Accordingly, motion (004) wherein the defendants seek a protective order pursuant to CPLR 3103(a) prohibiting the requested disclosure is denied.

Dated: FEB 24 2009



J.S.C.

**HON. JEFFREY ARLEN SPINNER**

         FINAL DISPOSITION   X   NON-FINAL DISPOSITION