

At an IAS Term, Part 4 of the
Supreme Court of the New York,
held in and for the County of New
York at the Courthouse located at 60
Centre Street, New York, New York,
on the 21st day of August, 1995.

Present:

Hon. Edward J. Greenfield, Justice

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T . D . , M . P . , M . T . , N . V . , G . P . , M . C . ,
NEW YORK LAWYERS FOR THE PUBLIC
INTEREST INC, DISABILITY ADVOCATES,
INC. AND MARVIN BERNSTEIN as Director
of Mental Hygiene Legal Service, First Department,
on behalf of all patients in facilities operated or
licensed by the New York State Office of Mental
Health,

Plaintiffs,

-against-

THE NEW YORK STATE OFFICE OF MENTAL
HEALTH, RICHARD C. SURLES, as
Commissioner of the New York State Office
of Mental Health and MARK R. CHASSIN as
Commissioner of the New York State
Department of Health,

Defendants.
-----X

ORDER TO SHOW CAUSE
WITH TEMPORARY
RESTRAINING ORDER

Index No. 5136/91

(Greenfield, J.)

ORAL ARGUMENT
REQUESTED

Upon the Affirmation of Ruth Lowenkron dated August 18, 1995, it is
ORDERED, that the defendants show cause before this court at 60 Centre Street, IAS
Part 4, Room 442, on August 24, 1995, at 2:00 p.m., or as soon thereafter as counsel can be
heard, why an order should not be entered finding the defendants in contempt of this Court's
Order dated May 30, 1995, and why an order should not be entered compelling the defendants to
comply with the May 30, 1995 Order, and for such other and further relief as the court may deem
proper; and it is further

ORDERED that service of a copy of this Order to show cause, together with a copy of the papers upon which it is granted, on the New York State Attorney General, 120 Broadway, New York, 10271, attorney for the defendants, on or before August 21, 1995 at 5:00 o'clock p.m. , by hand, shall be deemed sufficient service; and it is further

ORDERED that any opposing papers be served on or before August 23, 1995 at 5:00 o'clock p.m. on the plaintiffs' attorneys as follows; on New York Lawyers for the Public Interest, 30 West 21st street, 9th Floor, New York, New York 10010, by hand, and on Disability Advocates, Inc. 155 Washington Avenue, Suite 300, Albany, New York 12210, by overnight mail or overnight courier; and it is further

ORDERED that any reply papers be served by hand delivery to defendants' attorney in the IAS part immediately prior to the hearing on August 24, 1995 at 2:00 p.m.; and it is further

ORDERED that pending the decision in this motion, the defendants are prohibited from commencing any new non-therapeutic, greater than minimal risk experiments on incapable patients based on surrogate consent in facilities operated and licensed by Defendant New York State Office of Mental Health, and that Defendants are prohibited from adding any new incapable patients based on surrogate consent to existing non-therapeutic experiments; and it is further

ORDERED that, pursuant to New York Judiciary Law § 756, the defendants note the following:

WARNING: YOUR FAILURE TO APPEAR IN COURT MAY RESULT IN
YOUR IMMEDIATE ARREST AND IMPRISONMENT FOR CONTEMPT OF
COURT.

/s/

J.S.C.

At an IAS Term, Part 4 of the Supreme Court of the New York, held in and for the County of New York at the Courthouse located at 60 Centre Street, New York, New York, on the 18th day of August, 1995.

Present:

Hon. Edward J. Greenfield, Justice

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T . D . , M . P . , M . T . , N . V . , G . P . , M . C . ,
NEW YORK LAWYERS FOR THE PUBLIC
INTEREST INC, DISABILITY ADVOCATES,
INC. AND MARVIN BERNSTEIN as Director
of Mental Hygiene Legal Service, First Department,
on behalf of all patients in facilities operated or
licensed by the New York State Office of Mental
Health,

Plaintiffs,

-against-

THE NEW YORK STATE OFFICE OF MENTAL
HEALTH, RICHARD C. SURLES, as
Commissioner of the New York State Office
of Mental Health and MARK R. CHASSIN as
Commissioner of the New York State
Department of Health,

Defendants.
-----X

ORDER TO SHOW CAUSE
WITH TEMPORARY
RESTRAINING ORDER

Index No. 5136/91

(Greenfield, J.)

ORAL ARGUMENT
REQUESTED

Upon the Affirmation of Ruth Lowenkron dated January 18, 1996, it is

ORDERED, that Defendants show cause before this court at 60 Centre Street, IAS Part 4, Room 442, on January 30, 1996, at 2:00 p.m., or as soon thereafter as counsel can be heard, why an order should not be entered finding Defendants in contempt of this Court's Decisions and Orders dated February 28, 1995, April 25, 1995, May 30, 1995 and October 13, 1995, and why an order should not be entered compelling Defendants to comply with those Decisions and Orders, and for such other and further relief as the court may deem proper; and it is further

ORDERED that service of a copy of this Order to Show Cause, together with a copy of the papers upon which it is granted, on the New York State Attorney General, 120 Broadway, New York, New York, 10271, attorney for Defendants, on or before January 18, 1996 at 5:00 o'clock p.m., by hand, shall be deemed sufficient service; and it is further

ORDERED that any opposing papers be served on or before January 22, 1995 at 5:00 o'clock p.m. on Plaintiff's attorneys as follows: on New York Lawyers for the Public Interest, Inc., 30 West 21st Street, 9th Floor, New York, New York 10010, by hand; on Disability Advocates, Inc. , 155 Washington Avenue, Suite 300, Albany, New York 12210, by facsimile transmission to 518-427-6561 and first class mail; and on Mental Hygiene Legal Service, First Department, 60 Madison Avenue, 39th Floor, New York, New York 10010, by hand; and it is further

ORDERED that any reply papers be served by hand delivery to Defendants' attorney in the IAS part immediately prior to the hearing on January 30, 1996 at 2:00 p.m.; and it is further

ORDERED that pending the decision on this motion, Defendants withdraw, in a manner consistent with good clinical practice, all incapable patients who are presently subjects of therapeutic, greater than minimal risk experiments in a facility operated and licensed by Defendant Office of Mental Health, based on surrogate consent. Defendants may, however, continue therapeutic experiments upon an individual if, within twenty days from the date of this order, Defendants provide notice to Mental Hygiene Legal Service and make application to the court to obtain authorization to continue to perform the therapeutic research; and it is further

ORDERED that pending the decision on this motion, Defendants cease, in a manner consistent with good clinical practice, all non-therapeutic greater than minimal risk experiments on incapable patients, based on surrogate consent, in facilities operated and licensed by

Defendant New York State Office of Mental Health; and it is further

ORDERED that, for purposes of this order, the term “therapeutic research” is defined as research for which an Institutional Review Board has determined that the research holds out a prospect of direct benefit that is important to the health or wellbeing of the patient and is available only in the context of the research. The term “non-therapeutic research” refers to all research which is not “therapeutic research” as that term is defined above. And it is further

ORDERED that, for purposes of this order, “prior court approval” means approval by a court of competent jurisdiction upon findings, by clear and convincing evidence, that a) the subject lacks the capacity to provide informed consent to the therapeutic research; b) the research holds out a prospect of direct benefit to the subject that is important to the health and wellbeing of the patient and is available only in the context of the research; and c) the research is in the subject’s best interests, is the least restrictive form of intervention necessary under the circumstances and is consistent with what is known of the subject’s personal wishes, preferences and desires. And it is further

ORDERED that, pursuant to New York Judiciary Law § 756, Defendants note the following:

WARNING: YOUR FAILURE TO APPEAR IN COURT MAY RESULT IN
YOUR IMMEDIATE ARREST AND IMPRISONMENT FOR CONTEMPT OF
COURT.

/s/

J.S.C.

SUPREME COURT, STATE OF NEW YORK
COUNTY OF NEW YORK: IAS PART 4

-----X

T.D., M.P., M.T., N.V., G.P., M.C.,
NEW YORK LAWYERS FOR THE PUBLIC INTEREST
INC., DISABILITY ADVOCATES, INC. and
MARVIN BERNSTEIN as Director of Mental
Hygiene Legal Services, First Department,
on behalf of all patients in facilities
operated or licensed by the New York
State Office of Mental Health,

Plaintiffs,

- against -

THE NEW YORK STATE OFFICE OF MENTAL
HEALTH, RICHARD C. SURLES, as
Commissioner of the New York State Office
of Mental Health and MARK R. CHASSIN as
Commissioner of the New York State
Department of Health,

Defendants.

-----X

STIPULATION

Index No. 5136/91

(Greenfield, J.)

The parties, by their undersigned attorney's, stipulate and agree to the following:

1. The return date for Plaintiffs' motion to hold Defendants in contempt and for Defendants' cross-motion to vacate the January 18, 1996 Temporary Restraining Order is adjourned to February 23, 1996.

2. The time for Plaintiffs to reply to Defendants' opposition papers to Plaintiffs' contempt motion and to answer Defendants' Cross Motion is extended to immediately prior to the hearing on February 23, 1996.

3. The temporary restraining order dated January 18, 1996 in the above-captioned action should be modified as follows:

a.. For purposes of the January 18, 1996 order, the term “therapeutic research” is defined as research for which an Institutional Review Board has determined that the research holds out a prospect of direct benefit that is important to the health or wellbeing of the patient. The term “non-therapeutic research” refers to all research which is not “therapeutic research” as that term is defined above. If any greater than minimal risk element of an experiment is “non-therapeutic” as defined above, the entire experiment is deemed “non-therapeutic”, unless all greater than minimal risk, non-therapeutic elements are eliminated from the experiment.

b. For purposes of the January 18, 1996 order, the term “prior court approval” means approval by a court of competent jurisdiction upon findings, by clear and convincing evidence, that a) the subject lacks the capacity to provide informed consent to the therapeutic research; b) the research holds out a prospect of direct benefit to the subject that is important to the health or wellbeing of the patient; c) the research is consistent with what is known of the subject’s personal wishes, preferences and desires; d) the research is in the patients best interest; and e) the proposed experimental treatment is narrowly tailored to give substantive effect to the patient’s liberty interest, taking into consideration all relevant circumstances, including, the benefits to be gained from the treatment, the adverse side effects associated with the treatment, the risks of the treatment, and any less intrusive alternative treatments.

c. Ordered that pending the decision of Plaintiffs’ contempt motion, Defendants withdraw, in a manner consistent with good clinical practice, all incapable

patients who are presently subjects of therapeutic, greater than minimal risk experiments in a facility operated or licensed by Defendant Office of Mental Health, based on surrogate consent. Defendants may, however, continue therapeutic experiments upon an individual if, within forty five days from January 18, 1996, Defendants provide notice to Mental Hygiene Legal Service and make application to the court to obtain authorization to continue to perform the therapeutic research.

4. The temporary restraining order dated January 18, 1996 does not prohibit a parent or guardian of a minor child from consenting, without court review or approval, to therapeutic research as defined above which the parent or guardian believes is in the best interest of the child, which is recommended by a physician licensed to practice medicine and which has not been totally rejected by medical authority. Nothing in this stipulation shall be interpreted to eliminate the requirements for minor assent in applicable federal regulations, or to modify or eliminate protections for minor subjects in applicable federal or state law.

5. By agreeing to this stipulation, Defendants do not waive the right to contest any or all of the January 18, 1996 order and paragraphs 3 and 4 of this stipulation.

Agreed to:

February 8, 1996

/s/
DENNIS VACCO
Attorney General of the State of
New York
Arnold Fleischer, of Counsel
Department of Law
120 Broadway
New York, New York 10271

Attorney for Defendants

February 8, 1996

/s/

DISABILITY ADVOCATES, INC.
Cliff Zucker, Esq., of Counsel
155 Washington Avenue, Suite 300
Albany, New York 12210
(518) 432-7861

February 8, 1996

/s/

NEW YORK LAWYERS FOR THE
PUBLIC INTEREST, INC.
Ruth Lowenkron, Esq., of Counsel
30 West 21st Street
New York, NY 10010
(212) 727-2270

February 8, 1996

/s/

MENTAL HYGIENE LEGAL
SERVICES, FIRST DEPARTMENT
Clifford S. Karr, Esq.
Karen Andreasian, Esq., of Counsel
60 Madison Avenue
New York, NY 10010
(212) 779-1734

Attorneys for Plaintiffs

SO ORDERED,

February 9, 1996
New York, NY

/s/

HON. EDWARD GREENFIELD,
J.S.C.

SUPREME COURT, STATE OF NEW YORK
COUNTY OF NEW YORK: IAS PART 4

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T.D., M.P., M.T., N.V., G.P., M.C.,
NEW YORK LAWYERS FOR THE PUBLIC INTEREST
INC., DISABILITY ADVOCATES, INC. and
MARVIN BERNSTEIN as Director of Mental
Hygiene Legal Services, First Department,
on behalf of all patients in facilities
operated or licensed by the New York
State Office of Mental Health,

Plaintiffs,

- against -

THE NEW YORK STATE OFFICE OF MENTAL
HEALTH, RICHARD C. SURLES, as
Commissioner of the New York State Office
of Mental Health and MARK R. CHASSIN as
Commissioner of the New York State
Department of Health,

Defendants.
-----X

STIPULATION
AND ORDER

Index No. 5136/91

(Greenfield, J.)

The parties, by their undersigned attorneys, stipulate and agree to the following:

1. The return date for Plaintiff's' motion to hold Defendants in contempt and for Defendants' cross-motion to vacate the January 18, 1996 Temporary Restraining Order is adjourned to March 22, 1996.

2. The time for Plaintiffs to reply to Defendants' opposition papers to Plaintiffs' contempt motion and to answer Defendants' Cross Motion is extended to immediately prior to the hearing on March 22, 1996.

3. The temporary restraining order dated January 18, 1996 in the above-captioned action ("the Order") does not prohibit a surrogate, who was selected by the patient for the purpose of making decisions related to therapeutic research (the "research surrogate"), from consenting,

without court review or approval, to therapeutic research, as defined in the Order, which the research surrogate believes is in accordance with the patient's wishes or, if the patient's wishes are unknown, in the best interests of the patient.

4. For purposes of the Order, a research surrogate is only designated when

- a) a psychiatrist or licensed clinical psychologist independent of the research makes a written determination that the patient has the capacity to designate the research surrogate;
- b) the document designating the research surrogate is witnessed by persons who are independent of the research;
- c) the patient is advised orally and in writing that
 - 1) s/he has the right to designate a research surrogate or not to do so;
 - 2) if s/he designates a research surrogate, s/he retains the right to object to participation in the research;
 - 3) if s/he designates a research surrogate, s/he may discharge the research surrogate at any time and withdraw from research participation at any time;
 - 4) s/he may place in the document designating the research surrogate limits on the research surrogate's authority and a statement of her/his wishes or instructions regarding participation in therapeutic research. The research surrogate may consent to research involving significant risks unless the principal limits the level of risk;
 - 5) if s/he wishes to participate in the research but does not want to designate a research surrogate, s/he may request that the facility where the

research is performed seek judicial approval for his/her participation in the research, in lieu of designating a research surrogate; and

d) the document designating the research surrogate states that provisions a through c herein have been followed, and that the research surrogate has the authority to make decisions about participation in therapeutic research.

5. All determinations of capacity for purposes of commencing the authority of the research surrogate must be made by a psychiatrist or licensed clinical psychologist independent of the research.

6. The facility where research is being performed must provide notice to Mental Hygiene Legal Service (“MHLS”) of its intent to commence the authority of the research surrogate, and MHLS may commence a proceeding as set forth in Public Health Law § 2992, if necessary.

7. A research proxy may, but need not, be in the form of the attached proxy.

8. The rights, duties and procedures set forth in Public Health Law Article 29-C, except as modified herein, are fully applicable to the appointment of a research surrogate.

9. Nothing herein authorizes a health care proxy or research surrogate to consent to non-therapeutic research. Nothing herein authorizes a health care proxy or research surrogate to consent to therapeutic research unless all the requirements herein are met.

10. If prior to the effective date of this stipulation and order, a patient executed a health care proxy in compliance with Public Health Law Article 29-C which specifically authorized the proxy to consent to therapeutic research, and the patient no longer has the capacity to designate a research surrogate as defined herein, the patient may be continued in the current therapeutic research without court approval.

11. Defendants may continue therapeutic experiments upon an incapable individual if, by March 15, 1996, Defendants provide notice to Mental Hygiene Legal Service and make application to the court to obtain authorization to continue to perform the therapeutic research.

Agreed to:

March 7, 1996

/s/
DENNIS VACCO
Attorney General of the
State of New York
Arnold Fleischer, of Counsel
Department of Law
120 Broadway
New York, New York 10271

Attorney for Defendants

March 7, 1996

/s/
DISABILITY ADVOCATES, INC.
Cliff Zucker, Esq., of Counsel
155 Washington Avenue, Suite 300
Albany, New York 12210
(518) 432-7861

March 7, 1996

/s/
NEW YORK LAWYERS FOR THE
PUBLIC INTEREST, INC.
Ruth Lowenkron, Esq., of Counsel
30 West 21st Street
New York, NY 10010
(212) 727-2270

March 7, 1996

/s/
MENTAL HYGIENE LEGAL
SERVICE, FIRST DEPARTMENT
Clifford S. Karr, Esq.
Karen Andreasian, Esq.
of Counsel
60 Madison Avenue
New York, NY 10010
(212) 779-1734

Attorneys for Plaintiffs

SO ORDERED,

March 11, 1996
New York, NY

/s/

HON. EDWARD GREENFIELD,
J.S.C.

RESEARCH PROXY

I _____ (name of principal) hereby appoint

Name: _____

Address: _____

Telephone Number: (____)____-____

as my research surrogate to make any and all decisions for me regarding my participation in research having a prospect of therapeutic benefit to me, except to the extent I state otherwise.

This research proxy shall take effect in the event I become unable to make my own decisions regarding my participation in research having a prospect of therapeutic benefit to me.

NOTE: Although not necessary, and neither encourage nor discouraged, you may wish to state instructions or wishes, and limit your surrogate's authority. If you choose to state instructions, wishes or limits, please do so below:

If you wish to participate in particular research, you may describe the research below:

If you wish to limit your participation in research to the research described above, initial here: ()

I direct my research surrogate to make any and all decisions for me regarding my participation in research having a prospect of therapeutic benefit to me in accordance with my wishes and instructions as stated above or as otherwise known to him or her. I also direct my

research surrogate to abide by any limitations on his or her authority as stated above or as otherwise known to him or her. If my wishes with respect to research are unknown, I direct my research surrogate to act in accordance with my best interests.

In the event the person I appoint above is unable, unwilling or unavailable to act as my research surrogate, I hereby appoint

Name: _____

Address: _____

Telephone Number: (____) _____ - _____

as my alternate research surrogate.

I have been advised that:

- 1) I have a right to designate a research surrogate or decline to do so.
- 2) I retain the right to object to participation in research.
- 3) I may discharge my research surrogate at any time and withdraw from research participation at any time.
- 4) I may place limits on the research surrogate's authority and may state my wishes or instructions regarding participation in therapeutic research. My research surrogate may consent to research involving significant risks, unless I limit the level of risk.
- 5) If I wish to participate in research, but do not want to designate a surrogate, I may request that the research facility seek judicial approval for my participation in the research, rather than designate a research proxy.

I understand that, unless I revoke it, this research proxy will remain in effect indefinitely or until the date or occurrence of the condition I have stated below:

(Please complete the following if you do not want this health care proxy to be in effect indefinitely):

This proxy shall expire: (Specify date or condition) _____

Signature of Principal

Signature: _____

Print Name: _____

Address: _____

Date: _____

Witnesses

I declare that the person who signed or asked another to sign this document is personally known to me and appears to be of sound mind and acting willing and free from duress. He or she signed (or asked another to sign for him or her) this document in my presence and that person signed in my presence. I am not the person appointed as agent by this document. I am not associated in any way with any research in which this patient, is or is likely to be a subject.

NOTE: For patients residing in a mental hygiene legal facility, at least one witness must be an individual not affiliated with the facility and at least one witness shall be a physician certified by the American Board of psychiatry and Neurology.

Witness Signature: _____

Print Name: _____

Address: _____

Telephone Number: (____) ____ - _____

Witness Signature: _____

Print Name: _____

Address: _____

Telephone Number: (____) ____ - _____

Determination of Capacity

I am a (psychiatrist certified by the American Board of Psychiatry and Neurology)
(licensed clinical psychologist). I examined _____ on (date)
_____ and determined that s/he has the capacity to designate a
research surrogate. I am not associated in any way with any research in which this patient is, or
is likely to be, a subject.

Signature: _____

Print Name: _____

Address: _____

Telephone Number: (____) ____ - _____

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK : IAS PART 4

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T.D. , M.P., M.T., N.V., G.P., M.C.,
NEW YORK LAWYERS FOR THE PUBLIC INTEREST, INC.,
DISABILITY ADVOCATES, INC. and MARVIN BERNSTEIN
as Director of Mental Hygiene Legal Service, First
Department, on behalf of all patients in facilities
operated or licensed by the New York State Office
of Mental Health,

Index No.
5136/91
(Greenfield, J.)

Plaintiffs,

- against -

THE NEW YORK STATE OFFICE OF MENTAL
HEALTH, RICHARD C. SURLES, as Commissioner
of the New York State Office of Mental
Health and MARK R. CHASSIN as Commissioner
of the New York State Department of Health,

STIPULATION OF
WITHDRAWAL WITHOUT
PREJUDICE

Defendants.

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IT IS HEREBY STIPULATED AND AGREED, by and between the
undersigned, attorneys for the parties, that:

1. Plaintiffs withdraw, without prejudice to renewal, their pending motion for contempt brought on by Order to Show Cause dated August 21, 1995, and their pending motion for contempt brought on by Order to Show Cause dated January 18, 1996.

2. Defendants withdraw, without prejudice to renewal, their pending cross-motion to vacate the Temporary Restraining Order dated January 18, 1996.

3. The Temporary Restraining Order dated August 21, 1995, and the Temporary Restraining Order dated January 18, 1996, as modified by the parties' Stipulations dated February 8, 1996, and March 7, 1996, continue in full force and effect.

Dated:

March 12, 1996

/s/
DENNIS VACCO
Attorney General of the
State of New York
Attorney for Defendants
Arnold Fleischer, of Counsel
Department of Law
120 Broadway
New York, New York 10271

March 12, 1996

/s/
DISABILITY ADVOCATES, INC.
Cliff Zucker, Esq., of Counsel
155 Washington Avenue, Suite 300
Albany, New York 12210
(518) 432-7861

March 12, 1996

/s/
NEW YORK LAWYERS FOR THE
PUBLIC INTEREST, INC.
Ruth Lowenkron, Esq., of Counsel
30 West 21st Street
New York, NY 10010
(212) 727-2270

March 12, 1996

/s/
MENTAL HYGIENE LEGAL
SERVICE, FIRST DEPARTMENT
Clifford S. Karr, Esq.
Karen Andreasian, Esq.
of Counsel
60 Madison Avenue
New York, NY 10010
(212) 779-1734

So Ordered:

/s/

HON. EDWARD GREENFIELD, J.S.C.