IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF OKLAHOMA DAWANNA ROBERTSON, et al. PLAINTIFFS,

J. MICHAEL MCGEE, M.D., F.A.C.S., et. al. DEFENDANTS
PLAINTIFFS' OPPOSITION TO DEFENDANTS' MOTIONS TO DISMISS

I. INTRODUCTION

Plaintiffs bring this action against defendants as a result of a human clinical trial that everyone agrees went awry. Virtually every aspect of this trial was contrary to the rules and standards governing such human experiments. Plaintiffs are patients in the study, as well as their spouses, children and loved ones. Defendants have each filed motions to dismiss the pleadings, essentially arguing that plaintiffs have no federal or state causes of action to remedy the harm they have suffered. These motions should be denied. Plaintiffs submit this memorandum of law in opposition.

II. STATEMENT OF FACTS

On December 30, 1996, defendant J. Michael McGee, M.D., F.A.C.S., an Assistant Professor of Medicine, Division of

Surgery, at the University of Oklahoma Health Sciences Center-Tulsa ("OUHSC-T") submitted to the Food and Drug

Administration ("FDA") an Investigational New Drug application ("IND") proposing to conduct a human clinical trial at

OUHSC-T; the drug originally named "Melanoma Vaccine" was renamed "Allogenic Melanoma Cell Line (IIB-MEL-J)

, University of Oklahoma Vaccine" ("the Vaccine"). A copy of the IND is attached as Exhibit "A." At its outset, this human

clinical trial was beset with errors. The IND was deficient and misleading; among other things, it referenced preclinical

animal studies for a vaccine other than the one which was the subject of the IND and failed to state that no preclinical

animal studies supported the injection of the Vaccine into humans. At or about this same time, Dr. McGee submitted to the

Tulsa Institutional Review Board a protocol ("the Protocol") proposing to conduct a human clinical trial of the Vaccine ("the

Trial") at OUHSC-T involving no more than 15 subjects. The Tulsa IRB approved the protocol on January 8, 1997, and

permitted Dr. McGee to begin enrolling patients shortly thereafter and well before the FDA approved the IND on March 11,

1997. A copy of the Protocol is attached as Exhibit "B." An IRB is

an institutional review board of at least five members

which is charged with knowing institutional commitments and regulations, applicable law, and standards of professional

conduct and practice. An IRB, which is mandated by federal law at institutions such as OUHSC-T, has the responsibility

pursuant to federal regulations to review and approve all aspects of a human clinical trial including the design of the

protocol, the qualifications of the investigator, the informed consent document, the selection process of participants, the

balance of risks and benefits, and the conduct of the trial. All of these functions have but one purpose: to protect the

subjects in every human experiment conducted at the institution. Included among the Tulsa IRB was defendant Dr. Donovan

who, as the Chief Bioethicist at OUHSC-T, assumed the responsibility of ensuring that this and other clinical trials at

OUHSC-T comported with generally accepted ethical standards. Plaintiffs allege, and various auditors and regulators have

found, that the IRB Defendants failed in these responsibilities in not critically examining the design of the protocol and the

qualifications of Dr. McGee, in failing to review the operation of the Trial, proposed amendments to the informed consent

forms provided to patients, the amendments to the protocol, and the advertisements for the Trial, and in failing to ensure

proper reporting. The stated purpose of the Protocol was to conduct a controlled clinical trial in a regulated environment to

determine the toxicity of the Vaccine. Thereafter, Dr. McGee revised the Protocol for a phase I/II study to determine

safety/efficacy of the Vaccine on 25 patients. Over the course of the Trial, certain other entities joined with Dr. McGee as

cosponsors. These entities, defendants St. John Medical Center, Immunex Corporation, and the Hoag Cancer Center, are

named in the Amended Complaint as the Sponsor Defendants. Throughout the course of the Trial, with the approval and

knowledge of the Tulsa IRB, and the Sponsor Defendants, Dr. McGee instead considered it "his goal" to treat patients with

a product he considered to be a cure for cancer. That "goal" was in complete disregard of the applicable federal rules and

regulations, the Protocol approved by the FDA and the Tulsa IRB, and ethical standards governing the conduct of human

clinical trials. Upon obtaining approval to begin the Trial, Dr. McGee sought to obtain patients with varying degrees of

melanoma. To that end, Dr. McGee and defendant St. John Medical Center began advertising the Trial, including buying

time for a commercial designed to look like a newscast in which the Vaccine was represented to be a cure for cancer.

Ultimately, more than 90 patients were admitted to the Trial, more than the number in the FDA approved Protocol. The

Vaccine was a biological agent prepared by Dr. McGee and his staff using human cancer cells. At a later point, defendant

Hoag Cancer Center participated in the process of manufacturing the Vaccine. For a variety of reasons as set forth in the

Amended Complaint, the Vaccine failed to meet the standards for the production of such drugs. Essentially, the Vaccine

was neither manufactured, maintained, nor tested properly. On or about February 5, 1999, defendant Immunex Corporation

agreed to cosponsor the Trial and to provide a biochemical drug to be used in the Trial in combination with the Vaccine

known as sargramostim, a recombinant human granulocyte macrophage-colony stimulating factor ("GM-CSF"), which

causes certain cells to multiply. In exchange, Immunex received a right of first negotiation to obtain a worldwide license to

any patentable drug or protocol arising out of the Trial. Immunex represented that the GM-CSF it was providing would be in

"appropriately marked containers. . . . [and] that no dosage form being part of any shipment by Immunex to the Investigator

. . . shall be adulterated or misbranded." It agreed that it would provide GM-CFS to the Trial only if Dr. McGee and others

associated with administering the Vaccine would adhere to certain requirements, including submission to Immunex any

amendments of the Protocol, that the Trial be conducted in accordance with the Protocol and the applicable requirements of

21 C.F.R., and that the Investigator obtain the informed consent of each subject/patient participating in the Trial. A copy of

the Agreement with Immunex is attached as Exhibit "C." All patients selected to participate in the Trial were provided a form

titled "Individual's Consent to Voluntary Participation in a Research Project" ("consent form"). Copies of the consent forms

are attached as Exhibit "D." Plaintiff Participants each were given the consent form and other documents, which purportedly

were to provide certain information necessary to make an informed decision as to whether they were going to take part in,

and were appropriate candidates for, the Trial. These consent forms, other documents, and discussions were materially

misleading and deceptive, as set forth in the Amended Complaint. Problems with the forms included:

a. The consent form falsely implied that the FDA approved the Trial of the Vaccine and GM-CSF and their experimental use when the Trial that was actually implemented was different than the proposed Trial submitted for approval to the FDA.

a. The consent form falsely stated that "[t]he medical and scientific basis for the use of such a vaccine comes from studies in both animals and humans showing that, from these cells, factors are obtained that appear to assist the body to reject cancer." In actuality, no proper studies were conducted on either animals or humans.

a. The consent form falsely stated that risks subjects could expect included only local skin reddening; itching, swelling, and pain; and occasional temporary fever. In addition, the consent form provided that "fever, weakness, headache, bone and muscle pain, and chills have occurred with GM-CSF and can be prevented or reduced with Tylenol or Advil. Additional side effects may include swelling in the feet and hands due to water retention, difficulty breathing and rash." In fact, Plaintiff Participants suffered through much more dangerous and painful side effects.

a. The consent form stated that "records of the Trial would be kept confidential and that the subject would not be identifiable by name or description in any reports or publications. In actuality, the records of the Trial were not kept confidential and the subjects were identified by name in reports.

a. Dr. McGee, the principal investigator, failed to adequately discuss the consent form with the plaintiffs, failed to advise them of the true nature of the Trial, and instead advised them that he had the cure for their cancer.

a. Certain versions of the consent form indicated that pregnant women were prohibited from participating in the Trial and that participants in the Trial should not become pregnant or impregnate women while in the Trial, while other drafts of the consent form did

not contain this provision.
As a result of these and other deficiencies and misrepresentations, Plaintiff Participants were led to believe the risks of the

Trial were minimal and the potential benefits of their participation for themselves and the future treatment of melanoma were

enormous. The effects of such misrepresentations and non-disclosures were that Plaintiff Participants agreed to participate

and continue in the Trial. The conduct of the Trial was in violation of federal regulations. These included faulty or nonexistent

quality control and assurance procedures with respect to the manufacture, storage and shipping of the Vaccine, inadequate

patient examinations before and after injections, serious inattention to the reporting of adverse events related to the use of

the Vaccine, over enrollment of subjects in the Trial, and the admission of subjects in the Trial who were not eligible under

the Protocol because of the severity of their illness or pregnancy. Defendants McGee, Plunket, Wortham, Brooks,

Broughan and Donovan were continually advised of the unlawful and unsafe practices in the Trial and the need to report the

errant practices to the federal regulators; yet no action was taken. In response, Dr. McGee told Nurse Cherlynn Mathias

that God guided him on a path to cure cancer and that his only concern was to give the Vaccine as a treatment for

melanoma patients. As a result of Nurse Mathias' objections to the Trial, in January 2000, OUHSC-T retained a firm to

conduct a one-day audit after which, if hired, it would conduct a full audit. At the conclusion of this initial review, the auditor

advised Dr. Broughan, Dr. Wortham, Dr. Plunket, and Dr. McGee that serious violations of the law had occurred, that

serious risks to patient safety existed, and that the FDA should be notified of the infractions. Dr. McGee then telephoned

safety officer Karen Jones of the FDA, but instead of advising Ms. Jones of the safety violations in the Trial, Dr. McGee

represented that any lack of compliance was due to faulty paperwork. A full audit occurred by a different firm in or about the

first week in March 2000. These auditors also found serious safety and other violations and recommended that the Trial

immediately terminate. Defendants thereafter decided that these findings would be distributed only on "a need to know

basis," meaning not to the FDA or the patients. By letter dated April 10, 2000, Dr. McGee, with the knowledge and approval

of others at OUHSC-T, represented to the patients that the Trial was closing due to an inadequate supply of the Vaccine;

this was false and a deliberate misrepresentation. A copy of one of these letters is attached as Exhibit "E." Neither the

patients nor the FDA was advised of the safety violations. After a rebuke by the regulators, OUHSC-T later sent a follow-up

letter to some of the subjects admitting that the first letter was false and that the Trial was closed for safety reasons. A

copy of one of these letters is attached as Exhibit "F.' Due to the failure of OUHSC-T to inform the patients and the FDA of

the serious safety infractions, Nurse Mathias contacted the Division of Human Subject Projections, Office of Protection from

Research Risks, National Institute of Health (known since June 18, 2000 as the Office of Human Research Protections in

the Office of the Secretary or "OHRP"). After receipt of a June 12, 2000, letter from Dr. Michael Carome of the OHRP,

OUHSC-T ordered another audit. By letter dated June 29, 2000, the OHRP advised OUHSC-T that it had found serious

violations with respect to the Trial and to the Tulsa IRB's review and supervision of the Trial. A copy of this letter is attached

as Exhibit "G." On June 30, 2000, OUHSC-T provided a report of the latest audit. The audit was highly critical of essentially

all aspects of the Trial. For example, the audit found serious defects with the manufacturing, testing and distribution of the

Vaccine. It also found that patients were treated in remote sites without local IRB review and approval of the Protocol. The

audit also found there was "an intent to deceive at the very time that full disclosure is most needed." A copy of the audit

report is attached as Exhibit "H." In or about July 2000, Dr. Wortham was removed from his position as Director of the Tulsa

Office of Research, Dr. Plunket was removed from his position as Chair of the Tulsa IRB, and Dr. McGee was removed as

Assistant Chair of Surgery and Research Professor and relieved of

all administrative functions. By letter dated July 20,

2000, the University of Oklahoma terminated Dr. Brooks, Dean of the College of Medicine-Tulsa, citing "professional

incompetence or dishonesty [and] substantial, manifest, or repeated failure to fulfill professional duties and responsibilities

or to adhere to University policies" due to "knowledge of multiple serious problems" with the Trial. A copy of this letter is

attached as Exhibit "I." From July 17 through August 4, 2000, the Department of Health and Human Services, Public Health

Service of the FDA audited the Trial. On August 4, 2000, the FDA, through investigators Joel Martinez and David M. Beltran,

issued a four-page report detailing its findings of numerous infractions and safety violations, including inclusion of patients

which did not meet the Protocol criteria and failure to perform all Protocol procedures as required. The report also concluded

that OUHSC-T, as the sponsor of the Trial, committed various substantive infractions. With respect to the Tulsa IRB, the

report concluded it had abrogated its responsibilities, including failing to assure proper protection of human subjects.

Additional infractions included, but were not limited to, deviating from the Protocol, missing documentation, shipping of

drugs to people's homes, allowing subjects to self-inject themselves, missing data in the case report forms, failing to report

adverse events, enrolling ineligible patients, and allowing patients to receive other treatments while enrolled in the Trial. A

copy of the HHS report is attached as Exhibit "J." On the eve of filing this response to the Defendants' Motions To Dismiss,

Plaintiffs learned that on June 21, 2001, the Department of Health and Human Services, Public Health Service of the FDA

sent to Dr. McGee a Notice of Initiation of Disqualification Proceeding and Opportunity to Explain letter, outlining in twelve

(12) pages only some of the deficiencies with his clinical studies, and the misleading manner with which Dr. McGee is

responding to these allegations. The FDA, through this process, "...asserts that [Dr. McGee] repeatedly or deliberately

failed to comply with the...regulations, and it proposes that [Dr. McGee] be disqualified as a clinical investigator." See

Exhibit "Y" attached hereto. These infractions and safety violations render the Trial void of any research, scientific or

medical value. As a result of this misconduct, and the harm it has caused, plaintiffs brought this lawsuit alleging

Constitutional, federal statutory, and state law causes of actions. Defendants McGee, Immunex, Broughan, Boren, St. John

Medical Center, The Hoag and the IRB defendants have each filed motions to dismiss the pleadings alleging plaintiffs have

failed to state claims upon which relief may be granted. As set forth below, these motions should be denied.

III. LEGAL ARGUMENT

A. STANDARD OF REVIEW

Defendants move to dismiss the Amended Complaint pursuant to Federal Rule of Civil Procedure 12(b)(1) and (6) which provides: Every defense, in law or fact, to a claim for relief in any pleading, whether a claim, counterclaim, cross-claim, or third-party claim, shall be asserted in the responsive pleading thereto if one is required, except that the following defenses may at the option of the pleader be made by motion: (1) lack of jurisdiction over the subject matter(6) failure to state a claim upon which relief can be granted.

If the complaint that is the subject of a Rule 12(b)(1) motion relies "directly upon a federal statute, so that the question of

the court's jurisdiction is intertwined with the merits of the case, the general rule is that a federal court possesses

jurisdiction and should decide the case on its merits." Bloomer v. Norman Regional Hospital, 221 F.3d 1351, 2000 WL

963336, *2 (10th Cir. July 12, 2000). The only exceptions to this rule are if the federal claim is immaterial and asserted only

to obtain jurisdiction or if the claim is "insubstantial and frivolous." Id. If the exceptions do not apply, and they are not

alleged to apply in this matter, the motion is converted into a Rule 12(b)(6) or, if appropriate, a motion for summary

judgment under Rule 56. Id. In other words, the issue is not whether there is jurisdiction over the subject matter of the

claims but whether plaintiffs failed to state a claim upon which relief can be granted. In reviewing a Rule 12(b)(6) motion, a

court accepts the allegations in the complaint as true and views them in the light most favorable to the nonmoving party. A

court, thus, does not weigh potential evidence. Aguilera v. Kirkpatrick, 241 F.3d 1286, 1292 (10th Cir. 2001). To that end, a

motion predicated on Rule 12(b)(6) shall not be granted "unless it appears beyond doubt that the plaintiff can prove no set of

facts in support of his claim which would entitle him to relief." GFF Corp. v. Assoc. Wholesale Grocers, Inc., 130 F.3d

1381, 1384 (10th Cir. 1997). The Statement of Facts is a synopsis of the Amended Complaint. Accordingly, for the purpose

of this motion, all of the facts set forth above must be accepted as true.

B. THE RIGHT TO BE TREATED WITH DIGNITY IN THE CONTEXT OF MEDICAL EXPERIMENTATION IS GUARANTEED BY THE FOURTEENTH AMENDMENT TO THE UNITED STATES CONSTITUTION.

Defendants argue that this Federal Court is no place for this litigation because no federal or Constitutional issues are at

stake. History and an emerging body of law argue otherwise. What is at stake in this litigation is whether individuals have

a Constitutional right to human dignity so as not to be the subjects of an unethical human experiment. Such a right, set

forth in the Nuremberg Code and in the federal regulations known as the Common Rule, is a fundamental right of all

citizens of the world and, thus, must be a right of the citizens of the United States, a Constitutional right.

The Fourteenth Amendment provides that no State shall "deprive any person of life, liberty, or property, without due

process of law." This clause "guarantees more than fair process, and the 'liberty' it protects includes more than the

absence of physical restraint." Washington v. Glucksberg, 521 U.S. 702, 719 (1997). Rights are protected under the Due

Process Clause of the Fourteenth Amendment if they are "so rooted in the tradition and conscience of our people as to

be ranked as fundamental" or if such rights reflect "basic values implicit in the concept of ordered liberty" such that

"neither liberty nor justice would exist if they were sacrificed." See Moore v. City of East Cleveland Ohio, 431 U.S. 494,

503 (1977) ; Griswold v. Connecticut, 381 U.S. 479, 500 (1965); Palko v. Connecticut, 302 U.S. 319, 325 (1937); Snyder

v. Massachusetts, 291 U.S. 97, 105 (1934); . The right to bodily integrity has long been recognized as a fundamental right

protected by the Constitution. See Albright v. Oliver, 510 U.S. 266 (1994) (due process accorded to matters involving

marriage, family, procreation and the right to bodily integrity); Planned Parenthood of Southeastern Pennsylvania v.

Casey, 505 U.S. 833 (1992), (Constitutional liberty interest includes right to bodily integrity, a right to control one's

person); Schmerber v. California, 384 U.S. 757 (1966) (integrity of an individual's person is cherished value of our society);

Union Pacific R. Co. v. Botsford, 141 U.S. 250 (1891) (no right held more sacred or more carefully guarded than right of

every individual to be in possession and control of his own person, free from restraint or interference of others). Courts

have particularly recognized such Constitutional autonomy rights in the medical context. See, e.g., Cruzan v. Director,

Missouri Department of Health, 497 U.S. 261 (1990) (Constitution grants competent person right to refuse lifesaving

hydration and nutrition); Roe v Wade, 410 U.S. 113 (1973) (women have Constitutional right to control decision on

whether to obtain an abortion); Griswold v. Connecticut, 381 U.S. 479 (1965) (restriction on citizens from receiving

contraceptives from their physician an unconstitutional intrusion); Rochin v. California, 342 U.S. 165 (1952) (forcible

stomach pumping of accused violates due process and is conduct which "shocks the conscience"); Skinner v. State of

Oklahoma, 316 U.S. 535 (1942) (sterilization performed without consent deprives individual of basic liberty). As Justice

Cardoza stated in Schloendorff v. The Society of New York Hospital, 211 N..Y. 125, 105 N.E. 92, 93 (1914), a case

against a surgeon for performing an operation without consent: "Every human being of adult years and sound mind has a

right to determine what shall be done with his own body." Id., 211 N.Y. at 129-130. While this Court could easily find that

the right at issue here is within the right to bodily integrity, the right to be free from unethical human experimentation,

sometimes called the right to human dignity, should be considered a distinct fundamental right of all human beings not

just citizens of the United States. To best understand the nature of this right, it is important to understand both the

historical context in which the Nuremberg Code arose and the post-Nuremberg controversies involving human subject

protection. That understanding is necessary because an examination of "our Nation's history, legal traditions and

practices" is critical in determining the scope of the right to liberty under the Due Process Clause. Washington v.

Glucksberg, 521 U.S. 702 (1997); Collins v. Harker Heights, 503 U.S. 115, 125 (1992); Cruzan, supra, at 269-70; Moore,

supra, at 503. After the Nazi holocaust, a series of twelve unprecedented war crimes trials took place at the Palace of

Justice in Nuremberg, Germany. In the first trial, later the subject of numerous books and movies, the allies designated

four judges from the United States, Great Britain, the Soviet Union, and France to sit and render judgement under

international law on the leaders of the Third Reich. Thereafter, the United States proceeded with the other prosecutions

including with what became known as the "Doctors Trial," whose verdict included what is now known as the "Nuremberg

Code." See Jay Katz, "The Nuremberg Code and the Nuremberg Trial," JAMA 1996; 276:1662-1666, a copy of which is

attached as Exhibit "K." The Doctors Trial, captioned United States v. Karl Brandt et al., was conducted by three United

States judges, one of whom was Johnson Crawford who at the time was a United States District Court Judge for the

District of Oklahoma. The trial began on December 9, 1946, under the authority of the United States Military pursuant to

United States rules of procedure with United States lawyers as prosecutors. Karl Brandt, Hitler's personal physician, and

twenty-two other medical doctors were charged with war crimes, membership in criminal organizations, and crimes

against humanity. See "From the Indictment," United States Holocaust Memorial Museum archives, reprinted at

www.ushmm.org/research/doctors/persons.htm, a copy of which is attached as Exhibit "L." The first two charges

concerned acts intended to aid the Third Reich's military aims; the

third charged the physicians with acts undertaken

under the guise of human experimentation either in the reckless pursuit of scientific knowledge or for sadistic torture. The

experiments included studies on the tolerance of human beings to adverse conditions such as high altitudes, freezing

temperatures and ingestion of sea water, tests involving the inoculation of prisoners with infectious diseases, pathogens

and new vaccines, and gruesome physiological studies involving mutilations and transplants. See "The Brutalities of Nazi

Physicians," JAMA, 1946; 132: 714-715, Editorial, a copy of which is attached as Exhibit "M." Telford Taylor's opening

statement for the prosecution underscores the point that the wrongs at issue in the Doctors Trial were breaches of the

fundamental rights of all human beings under American jurisprudential principles. Mr. Taylor stated:

> **The charges against these defendants are brought in the name of the United States of America. They are being tried by a court of American judges. The responsibilities thus imposed upon the representatives of the United States, prosecutors, and judges alike, are grave and unusual. . . The mere punishment of the defendants, or even of thousands of others equally guilty, can never redress the terrible injuries which the Nazis visited on these unfortunate people. For them it is far more important that these incredible events be established by clear and public proof so that no one can ever doubt that they were fact and not fable; and that this Court as the agent of the United States and as the voice of humanity, stamp these acts, and the ideas which engendered them, as barbarous and criminal.**

Trials of War Criminals Before the Nuremberg Military Tribunals Under Control Council Law, Vol. I, No. 10, (Washington

D.C.: G.P.O. 1946-1949), reprinted at www.ushmm.org/research/doctors/telford.htm, a copy of which is attached as

Exhibit "N." A principal defense, as articulated by Dr. Brandt's counsel, the eminent jurist Robert Servatius of Cologne,

was that the scientific and medical community at large and particularly in the United States had long been conducting

human experiments on prisoners, vulnerable populations and uninformed subjects. Sadly, this charge was quite accurate,

though certainly never to the extreme as practiced by the Nazis. After 139 court sessions, 62 witnesses, and 901 written

exhibits, Chief Judge Walter B. Beals, who was the Chief Justice of the Supreme Court of the State of Washington,

announced the verdict of the court. Sixteen of the defendants were convicted of war crimes against humanity and seven

were condemned to death. Though nothing else was required, the court did far more, perhaps because of the troubling

defense testimony with respect to unethical scientific and medical experiments occurring outside of the Third Reich. The

court held:
The great weight of the evidence before us is to the effect that certain types of medical experiments on human beings, when kept within reasonably well defined bounds, conform to the ethics of the medical profession generally. The protagonists of the practice of human experimentation justify their views on the basis that such experiments yield results for the good of society that are unprocurable by other means of study. All agree, however, that certain basic principals must be observed in order to satisfy moral and legal concepts:

1. The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the interventions of any elements of force, fraud, deceit, duress, over reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject, there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment. The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs, or engages in the experiment. It is personal duty and responsibility which may not be delegated to another with impunity.

2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study and not random and unnecessary in nature.

3. The experiment should be so designed and based on the results of animal experimentation . . .

4. The experiment should be conducted so as to avoid all unnecessary physical and mental suffering and injury.

5. No experiment should be conducted where there is a priori reason to believe that death or disabling injury will occur. . .

6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiments.

7. Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.

8. The experiment should be conducted only by scientifically qualified persons . . .

9. During the course of the experiment the human subject should be at liberty to bring the experiment to an end . . .

10. During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of the good faith, superior skill and careful judgment required of him that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.

Id., reprinted at www.ushmm.org/research/doctors/nuremberg_code.htm, a copy of which is attached as Exhibit "O."

These ten points constitute what is now known as the Nuremberg Code. They were not promulgated as new legislation to

be applied retroactively to the defendants then in the dock. They were an articulation of what these United States judges

believed "all agree" were the fundamental rights of every human being. See Affidavit prepared for this case of Michael

Grodin, M.D., a leading authority on the Nuremberg Code. A copy of his Affidavit and C.V. is attached as Exhibit "P." The

Code set forth two equally important requirements of ethical human experimentation, both of which are at issue in this

case. The first is the requirement of voluntary consent of the subjects after being informed of all material information about

the experiment. The second, often overlooked but no less significant, is that such experiments must comport to certain

ethical and scientific standards even if subjects have given their informed consent to participate. The Code did not just

look backward at the events that gave rise to the Doctors Trial but looked forward to postwar research on human beings.

As stated by Dr. Leo Alexander, one of the prosecution's key expert witnesses and the man many credit as the author of

the Code:

> **. . . it is a useful measure by which to prevent in less blatant settings the consequences of more subtle degrees of contempt for the rights and dignity of certain classes of human beings, such as mental defectives, people presumably dying from incurable illnesses, and other people disenfranchised, such as prisoners or other inarticulate public charges whose rights might be easily disregarded for the apparently compelling reason of an urgent purpose.**

Michael Grodin, "Historical Origins of the Nuremberg Code," in Annas and Grodin, The Nazi Doctors and the Nuremberg

Code: Human Rights in Human Experimentation (1992) at p. 139, a copy of which is attached as Exhibit "Q." The World

Medical Association, which includes representatives of the American Medical Association, was founded in 1947 soon

after the Doctors Trial. In 1954, the Eighth General Assembly of the World Medical Association adopted a resolution on

human experimentation based largely on the Nuremberg Code. The resolution contained the basic principles that "it is the

duty of the physician in medical research to protect the life, health, privacy and dignity of the human subject." After

several revisions, this document now known as the Declaration of Helsinki was adopted by the 18th World Medical

Assembly in Helsinki in 1964. It was revised again in 1975 to include a requirement for ethical review committees, such

as Institutional Review Boards and adopted most recently by the 52nd General Assembly of the World Medical

Association in Edinburgh Scotland in October 2000. In the fifty years after Nuremberg, outrage over a series of public

scandals involving human experiments in the United States have reaffirmed this Nation's commitment to human subject

protection. The first two public scandals were revealed in a landmark article by Harvard physician and Medical School

Professor Henry Beecher in the New England Journal of Medicine. See H. K. Beecher, "Ethics and Clinical Research,

New England Journal of Medicine, Vol. 274 (June 16, 1966), pp. 1354-60, a copy of which is attached as Exhibit "R." One

occurred at New York's Sloan Kettering Institute for Cancer Research where a researcher working on the immune

system's ability to fight cancer convinced the director of the Jewish Chronic Disease Hospital in Brooklyn to allow him to

inject unwitting patients with live cancer cells. The second was the Willowbrook Study, in which researchers at an

institution for mentally disabled children sought to develop a hepatitis vaccine by studying children whom they had

deliberately infected with isolated strains of the virus. In the conclusion of Dr. Beecher's article, he cautioned that no

research should be conducted without the informed consent of the subject and that the risks in any experiment must be

commensurate with the benefits.

It was the third scandal, with racial overtones all too reminiscent of Nazi atrocities, that generated federal action to

regulate human subject research. The infamous Tuskeegee Syphilis Study conducted by physicians of the U.S. Public

Health Service was halted in 1972, nearly 40 years after it began while 200 African-American subjects were allowed to

remain untreated despite the availability of therapeutic measures. In 1973, the Ad Hoc Advisory Panel issued its Final

Report of Tuskeegee Syphilis Study, concluding "society can no longer afford to leave the balancing of individual rights

against scientific progress to the scientific community." See Final Report, Department of Health Education and Welfare

(Washington, D.C.: G.P.O. 1973), a copy of which is attached as Exhibit "S."

Thereafter, Congress appointed a federal commission to examine the system for protecting human research subjects.

The National Commission for the Protection of Research Subjects in Biomedical and Behavioral Research was charged

with identifying the basic ethical principles underlying research on human subjects. In 1979, it issued "The Belmont

Report," a document all research institutions, including the University of Oklahoma in this case, promise in an Assurance

Agreement to uphold in all research studies in order to be eligible for certain grant monies. After acknowledging the

influence of the Nuremberg Code, the Belmont Report sets forth three principles to guide human subject research: the

first is respect for persons, which demands that researchers fully inform their subjects of all material information about the

study and only then obtain their voluntary consent; the second is beneficence, which prohibits any experiment where the

risks are too great or are outweighed by the benefits; and the third is justice, which requires equitable selection of

research subjects. Belmont Report, DHEW Pub. No. (05) 78-0012. (Washington D.C.: G.P.O.), a copy of which is

attached as Exhibit "T."

Congress passed the National Research Act in 1974 which authorized the implementation of regulations to protect

research subjects. In 1991, the regulations were integrated into the Common Rule for 17 departments and agencies, the

most familiar of which is the Department of Health and Human Services regulations at 45 C.F.R. Part 46, a copy of which

is attached as Exhibit "U." The Common Rule is published in the Federal Register at 56 Fed. Reg. 28, 012 (June 18,

1991). These regulations, among other things, detail the conditions required for obtaining informed consent and the

information that must be provided under those conditions, restrict experiments to those in which risks are minimized,

require the equitable selection of research subjects and establish the requirement for institutional review boards to

oversee research at every institution subject to the regulations.

Public concern over the rights of research subjects has increased within the decade subsequent to the Common Rule,

and particularly within the last few years, as media reports detailed the tragic consequences of unethical human

experiments, including the one at issue here. See, e.g., "Ethics and Orphans: The Monster Study," San Jose Mercury

News, June 7, 2001 (revealing 1939 experiment inducing orphans to stutter); "Research Volunteer Dies in Hopkins

Asthma Study," Baltimore Sun, June 14, 2001 (27-year-old volunteer killed in nontherapeutic experiment); "Uninformed

Consent," The Seattle Times, March 11-15, 2001 (death of subjects in blood cancer trial at Fred Hutchinson Cancer

Research Center); "Federal Rules for Research on People Often Fail," USA Today, Feb. 26, 2001 (corneal transplant

experiment conducted without full disclosure); "Uninformed Consent," Salon Magazine, March 27, 2000 (survey article on

student research subjects at risk); "U.S. Halts Cancer Tests in Oklahoma," Washington Post, July 11, 2000 (melanoma

vaccine trial at University Oklahoma shut down for numerous violations); "Regulating Dr. Frankenstein: Money, Lax Ethics

& Clinical Trials," Legal Times, October 16, 2000 (call for stricter standards to protect research subjects); "The Ethics of

Drug Testing: Kids as Guinea Pigs," Salon Magazine, May 31, 2000 (nine-month-old killed in propulsid drug trial at

Pittsburgh Children's Hospital); "The Biotech Death of Jesse Gelsinger," New York Times Magazine, Nov. 28, 1999 (18-

year-old volunteer killed in gene therapy experiment at University of Pennsylvania); "Research Volunteers Unwittingly at

Risk," Washington Post, August 1, 1998 (survey article on research subjects at risk); "Student Dies at Rochester in MIT

Based Study," MIT Tech Talk, April 10, 1996 (19-year-old university student volunteer killed in nontherapeutic

experiment); "For the Sake of Science," Los Angeles Times Magazine, September 11, 1994 (suicide of 23-year-old UCLA

student in schizophrenia experiment). Copies of these articles are attached collectively as Exhibit "V."

One question for this Court is, in light of this history, whether the principles of the Nuremberg Code have any present day

applicability to American law and the rights of American citizens or whether they are simply wartime relics applicable only

to understanding the Nazi horrors. Given that the Code emerged from the judgment of United States judges in a United

States military tribunal, if any country is bound by the legal precepts of the Nuremberg Code, it is the United States. As

George Annas, one of the leading authorities on the Nuremberg Code, has opined,

> **The most complete and authoritative statement of the law of informed consent to human experimentation is the Nuremberg Code...This Code is part of international common law and may be applied in both civil and criminal cases covered by state, federal**

and municipal courts in the United States. George J. Annas, et al., Informed Consent to Human Experimentation: The Subject's Dilemma 21 at 1 (1997). A

number of evolving opinions support this view; none has rejected it.

The first opinion to suggest that the Nuremberg Code has a place in American jurisprudence is the dissent in the

Kentucky case of Strunk v. Strunk, 445 S.W. 2D 145 (Court of Appeals of Kentucky, 1969), in which the court by a vote

of four to three authorized the removal of a kidney from a mentally retarded institutionalized adult for transplantation into

his ailing mentally sound brother. In an eloquent dissent, Justice Samuel Steinfield wrote:

> Apparently because of my indelible recollection of a government which, to the everlasting shame of its citizens, embarked on a program of genocide and experimentation with human bodies, I have been more troubled in reaching a decision in this case than in any other. My sympathies and emotions are torn between a compassion to aid an ailing young man and a duty to fully protect unfortunate members of society.... Regretfully, I must say, no."

445 S.W.2d at 149.

In Whitlock v. Duke University, 637 F. Supp. 1463 (M.D.N.C., 1986), aff'd, 829 F. 2d 1340 (4th Cir. 1987), a subject in a nontherapeutic, deep-diving experiment sustained severe brain damage. In dismissing the action because of a finding that the plaintiff had consented to participate in the experiment with full knowledge of the risks, the court stated that the Nuremberg Code provided persuasive guidance on the standard of care in the context of human experimentation. The court stated:

> The United States Military Tribunal at Nuremberg adopted the Nuremberg Code as a proper statement of the law of informed consent in connection with the trials of German scientists for human experimentation after World War II.

Id. at 1471.

One year later, the United States Supreme Court considered the case of James B. Stanley, a Master Sergeant who

had been surreptitiously dosed with LSD as part of a mind control experiment conducted by the United States Army.

United States v. Stanley, 483 U.S. 669 (1987). Mr. Stanley became aware that he had been a guinea pig in such an

experiment when he received a letter almost 20 years later soliciting his cooperation in a study of the long-term

effects on such "volunteers." The Supreme Court in a narrow five to four ruling reaffirmed the decision dismissing the

plaintiff's complaint under the Feres Doctrine which holds that a serviceman cannot sue the government for putting

him in harm's way. In so holding, the Court impliedly acknowledged that Stanley would have had a constitutional

claim, if not for the Feres Doctrine and Stanley's status as a serviceman during the experiment.

> **In dissent, Justice Brennan noted the importance of placing the government's conduct in historical context: The medical trials at Nuremberg in 1947 deeply impressed upon the world that experimentation with unknowing human subjects is morally and legally unacceptable. The United States Military Tribunal established the Nuremberg Code as a standard against which to judge German scientists who experimented with human subjects. Its first principle was: the voluntary consent of the human subject is absolutely essential.**

Id. at 687.

Justice Brennan then concluded that "the United States Military developed the Code which applies to all citizens--soldiers as well as civilians." Id.

Justice Brennan characterized the government's experimentation on an unknown human subject as "an intentional Constitutional tort" and ended his opinion with a phrase that would thereafter be associated with the right to be free from unethical experimentation: "Soldiers ought not be asked to defend a Constitution indifferent to their essential human dignity." Id.

Justice O'Connor, also dissenting, stated: "No judicially crafted rule should insulate from liability the involuntary and unknowing human experimentation alleged to have occurred in this case." Id.

at 709-10. Justice O'Connor noted that the United States Military played an instrumental role "in the criminal prosecution of Nazi officials who experimented with human subjects during the Second World War...and the standards of the Nuremberg Military Tribunal used to judge the behavior of the defendants stated that the 'voluntary consent of a human subject is absolutely essential...to satisfy moral, ethical and legal concepts'". Accordingly, Justice O'Connor reasoned:

> **If this principle is violated the very least that society can do is to see that the victims are compensated, as best they can be, by the perpetrators. I am prepared to say that our Constitution's promise of due process of law guarantees this much.**

Id. at 711. In re Cincinnati Radiation Litigation, 874 F. Supp. 796 (S.D. Ohio 1995), is the first case to expressly hold that the Nuremberg Code may be applied in the courts of the United States. Plaintiffs who had been the unknowing subjects in experiments on radiation exposure brought suit against investigators and institutions involved in the study. In rejecting a motion for summary judgment, the court held that such claims were cognizable under the Due Process Clause of the United States

Constitution. In a section titled, "The Nuremberg Code," the court examined the history of the Doctors Trial, stating: The judges appointed by President Truman to hear the medical case were all American judges and lawyers...The Nuremberg tribunal was asked to determine culpability . . . under "the principles of the laws of nations as a result from the usages established among civilized people, from the laws of humanity, and from the dictates of public conscience. . . Throughout the trial, the question of what were or should be the universal standards for justifying human experimentation recurred. "The lack of a universal principle for carrying out human experimentation was the central issue pressed by the defendant physicians throughout their testimony". Id. , quoting, United States of America v. Karl Brandt, et al., I Trials of War Criminals, Vo., Il at 181 (1947). After quoting the first principle of the Nuremberg Code, the court concluded: "The Nuremberg Code is part of the law of humanity. It may be applied in both civil and criminal cases by the federal courts in the United States." The court thus held: If the Constitution has not clearly established a right under which these clients may attempt to prove their case, then a gaping hole in that document has been exposed. The subject of experimentation who has not volunteered is merely an object. The plaintiffs in this case must be afforded at least the opportunity to present their case. Id. The next case to invoke Nuremberg was Stadt v. University of Rochester, 921 F.Supp. 1023 (W.D.N.Y. 1996). In this case, plaintiff brought an action under the Federal Tort Claims Act claiming she had been the subject of testing by physicians who had injected her with plutonium without her informed consent. In rejecting a motion that the Constitutional claims should be dismissed, the court stated: "This case does not involve the right to refuse medical treatment, but instead the right to be free from non-consensual experimentation on one's body...the right to bodily integrity...a right which has been recognized throughout this nation's history." Id. In support, the court reviewed the long line of cases holding that the right to bodily integrity, which would include the right to be free from unethical human experimentation, was a fundamental right under the United States Constitution. Id., citing Albright v. Oliver, 510 U.S. 266 (1994); Schmerber v. California, 384 U.S. 757 (1966); Skinner v. State of Oklahoma, 316 U.S. 535 (1942); Union Pacific R. Co. v. Botsford, 141 U.S. 250 (1891). The court thus held: "The Constitution and, more specifically, the due process clause of the Fifth Amendment, clearly established the right to be free from non-consensual government experimentation on one's body." Id. The last case and the one most similar to the factual issues here is Heinrich v. Sweet, 62 F. Supp. 2d 282 (D. Mass., 1999), where family members brought an action based on allegations that various government doctors conspired to conduct extensive, unproven, and dangerous medical experimentation on 140 terminally ill patients without their informed consent. The court stated that the issues presented must be understood in their historical context and then proceeded to describe the background of the Doctors Trial and the Nuremberg Code. The court then adopted the reasoning and holding of In re Cincinnati Radiation Litigation that a breach of the principles of the Nuremberg Code by a government actor would violate the Due Process Clause of the United States

Constitution. In language particularly relevant here, the court stated: "Similar conduct that "shocks the conscience" includes the use of false promises of therapeutic hope to terminally ill patients in order to lure them into becoming human subjects...for the benefit of curious scientists rather than the health of test subjects." 62 F. Supp. 2d at 287. As these cases and history make clear, and as "all agree" in the words of the Nuremberg judges, the right to essential human dignity in the context of medical experimentation as expressed in the Nuremberg Code is a fundamental right rooted in the conscience and history of the people of the world, in general, and of the United States, in particular. It is a right reflecting basic human values essential to any "concept of ordered liberty" and, if it is sacrificed, neither liberty nor justice can exist. It is, thus, a right guaranteed by the Fourteenth Amendment to the United States Constitution and its violation will give rise to liability under 42 U.S.C. 1983. The case law and arguments submitted by defendants in opposition are unpersuasive and do not address the claim at issue here. For example, Dr. McGee contends that "the law of nations does not create private causes of action in this country." McGee Brief, Page 5. Dr. McGee further claims that "[n]either the Nuremberg Code, nor the Helsinki Accords, provide a private right of action," Brief, page 5, citing Tel-Oren v. Libyan Arab Republic, 726 F.2d 772 (D.C. Cir. 1984), cert. denied, 470 U.S. 1003 (1985) and Hoover v. West Virginia Dep't of Health and Human Services, 984 F. Supp. 978 (S.D.W.Va. 1997), aff'd, 129 F.3d 1259 (11th Cir. 1997). This argument misses the point. Plaintiffs assert claims under the United States Constitution not the Nuremberg Code or the Declaration of Helsinki. As set forth above, these documents, primarily the Nuremberg Code, are mere expressions and reflections of the essential rights of all citizens of the world, rights which predate the documents themselves and have their origins in the conscience and values of the people of any nation founded on the principles of liberty and justice. The issue in Tel-Oren was whether plaintiffs, predominantly Israeli citizens, could maintain an action against defendants Libyan Arab Republic and others for damages resulting from an armed attack on a civilian bus in Israel. In a per curiam decision, the United States Court of Appeals, District of Columbia Circuit affirmed the district court's decision to dismiss the action for lack of subject matter jurisdiction. Dr. McGee relies heavily on Judge Bork's concurring opinion which does not address the issue of whether claims for violations of the right to bodily integrity and the right to dignity can be brought pursuant to the Constitution. Rather, the opinion is based generally upon a hesitancy to adjudicate issues between individuals in other lands in general and the situation surrounding the Middle East conflict in particular. These are certainly not the facts here. In Hoover, the plaintiff was a physician who sued the state Board of Medicine due to an investigation it conducted concerning whether she over-prescribed narcotics for a patient. The plaintiff, acting pro se, sought relief under the American with Disabilities Act and the Declaration of Helsinki. The court granted the defendant's motion to dismiss, holding that because the administrative proceeding by the defendant was still pending it should abstain from deciding this action. As dicta, the court also stated, "Secondly, the Helsinki Accords do not create a private right of action in U.S. federal courts

and do not have the force of law." Id. at 979. That was the full extent of a reference to or analysis of plaintiff's claim under the Declaration of Helsinki. No reference was made as to what portion of the Declaration was alleged to be applicable to plaintiff's claims or for what reason plaintiff believed it applied, nor was there mention that plaintiff sought a cause of action under the United States Constitution. This decision can hardly be viewed as pertinent to the issues here. The other cases cited by defendants, including United States v. Noriega, 746 F.Supp. 1506 (S.D.Fla. 1990), aff'd, 117 F.3d 1206 (11th Cir. 1997), cert. denied, 523 U.S. 1060 (1998), Handel v. Artukovic, 601 F.Supp. 1421 (C.D.Ca. 1985), Princz v. Federal Republic of Germany, 26 F.3d 1166 (D.C.Cir. 1994), cert denied, 513 U.S. 1121 (1995), do not apply as they concern doctrines setting forth "broad general principles governing the conduct of nations toward each other." United States v. Noriega, supra, 746 F.Supp at 1533. That is simply not the situation here. Dr. McGee acknowledges that "[i]t is undisputed that non-consensual medical experimentation violates the law of nations and, therefore, the laws of the United States." Dr. McGee Brief, Page 7. The issue to him thus appears to be which laws have been violated by the conduct set forth in the Amended Complaint and whether the wrongs committed by these state actors are mere garden variety torts such as negligence and battery. (Curiously, Dr. McGee later argues plaintiffs can not bring these claims either.) But when such individuals under color of state law trample on rights so fundamental to this Nation's concept of ordered liberty, when the right of these plaintiffs to essential human dignity has been breached, then this Federal Court is the proper forum to address those wrongs with the Constitution as its guide.

C. THERE IS AN IMPLIED PRIVATE CAUSE OF ACTION UNDER 45 C.F.R. PART 46

The Amended Complaint asserts a claim under 45 C.F.R. Part 46, which establishes the law of the United States with respect to the protection of human research subjects at institutions such as OUHSC-T. These regulations require: Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subject to risk. . . . Risks to subjects are reasonable in relation to anticipated benefits . . . . Selection of subjects is equitable. . . . Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by §46.116. . . . Informed consent will be appropriately documented, in accordance with, and to the extent required by §46.117. . . . Where appropriate, the research plan makes adequate provision for monitoring the data collected to insure the safety of subjects. . . . Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data. . . . Where some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as persons with acute or severe physical or mental illness, or persons who are economically or educationally disadvantaged, appropriate additional safeguards have been included in the study to protect the rights and welfare of these subjects. These regulations also require institutions such as OUHSC-T to appoint an IRB to review the design of any clinical trial protocol and to

ensure that the conduct of any clinical trial at the institution is consistent with the requirements of the regulations. For purposes of this motion, this Court must accept as true that defendants violated these and several other provisions of the federal regulations. Defendants contend no private right of action exists under these regulations, and that they create enforcement rights only for the OHRP and the FDA. The regulations for which plaintiffs bring causes of action are silent as to whether a claimant may assert a private cause of action. Thus, for plaintiffs to be able to assert such a claim, Congress or an administrative agency must have implicitly intended to have individuals use them to litigate. 24 Hour Fuel Oil Corp v. Long Island Rail Road Company, 903 F.Supp. 393, 397 (E.D.N.Y. 1995). In Cort v. Ash, 422 U.S. 66 (1975), the United States Supreme Court set forth a four part test to determine the availability of an implied private cause of action: (1) whether the plaintiff is one of the class for whose benefit the statute was enacted; (2) whether there is any indication of legislative intent, explicit or implicit, to create or deny such a remedy; (3) whether the private right of action would be consistent with or frustrate the purposes of the legislative scheme; and (4) whether the cause of action is traditionally relegated to state law remedies, so that it would be inappropriate to infer a cause of action based solely on federal law. The primary factor in this analysis is whether there is any indication, one way or another, of legislative intent. Olmsted v. Pruco Life Insurance Company of New Jersey, 134 F.Supp.2d 508, 512 (E.D.N.Y. 2000). A review of the Cort factors demonstrates that there is an implied private cause of action under 45 C.F.R. Part 46, the federal regulations addressing human experimentation. First, plaintiffs are obviously in the class for whose benefit the regulations were enacted. The regulations are intended for one purpose: to protect human subjects in clinical trials such as the one at issue here. As the Memorandum titled "Review of Federal policy for the Protection of Human Subjects" reflects, 45 C.F.R. Part 46 provides that review by the IRB for all research protocols involving human subjects to ensure that "(1) risks are minimized and reasonable in relation to anticipated benefits; (2) there is informed consent; and (3) the rights and welfare of the subjects are maintained." A copy of the February 17, 1994, Memorandum is attached hereto as Exhibit "W." These regulations are designed to protect substantive rights, not simply to set forth procedures by which certain actions are to be efficiently performed. Stated differently, this is not a statute focusing on spending directives or conditions for government grants. See Rapid Transit Advocates v. Southern California Rapid Transit Dist., 752 F.2d 373, 377 (9th Cir. 1985). Second, there certainly is no legislative history expressing an intent to deny individuals subjected to unlawful human experimentation the ability to seek redress. Had a bar to private actions been contemplated, Congress would have so stated. On the other hand, the legislative history surrounding these regulations reflects Congressional intent to protect to the fullest extent subjects in human experiments. As set forth in Section B above, the legislative history is principally the hearings conducted in response to the Tuskeegee scandal. These gave rise to the National Research Act which authorized the implementation of the regulations. The hope was that, if the regulations were followed,

there would be no more Tuskeegees or Willowbrooks, no deaths like that of Jesse Gelsinger, no tragedies like that at Johns Hopkins or the Fred Hutchinson Center, no melanoma trials like that which occurred at OUHSC-T. And what if the regulations were ignored either because of self-interest or sheer ignorance? Surely if such substantive rights were created, then the breach of those rights must have a remedy. Third, it follows that a private right of action is consistent with and does not frustrate the purpose of the regulations. If the goal is to protect human subjects from injury and harm, then certainly those who suffer as a result of the failure to abide by such protections should have redress when such injury and harm occur. Finally, the protection of human subjects to which 45 C.F.R. Part 46 applies is an appropriate federal cause of action. As set forth in Section B above, the rights at issue here are Constitutional rights rooted in this Nation's history and conscience. That there are state causes of action applicable to defendants' conduct does not negate the viability of a federal cause of action. As the court stated in In re Cincinnati Radiation Litigation, 874 F.Supp. 796, 817 (S.D.Ohio 1995), a case also involving unethical human experimentation,"[t]he distinction between this case and an ordinary tort case is not one of degree, but rather, of kind." Thus, a private right of action exists for the failure to abide by 45 C.F.R. Part 46 when such failure causes harm to human subjects. Defendants contend that a private cause of action can not be brought by the plaintiffs under the Food, Drug and Cosmetic Act ("FCA") for unlawful human experimentation . In support, defendants cite cases including Merrell Dow Pharmaceuticals, Inc. v. Thompson, 478 U.S. 804, 106 S.Ct. 3229 (1986), and Kemp v. Medtronic, Inc., 231 F.3d 216 (6th Cir. 2000). These cases do hold that a private cause of action cannot be brought under the FCA, but are not factually applicable here As the plaintiffs' claim in this matter is predicated on federal claims, e.g., the Code of Federal Regulations, defendants' reliance on Merrell Dow Pharmaceuticals is misplaced, in addition to being irrelevant.. Plaintiffs do not dispute that the FCA does not provide a private cause of action. Defendants also cite Buckman Company v. Plaintiffs' Legal Committee, 531 U.S. 341, (2001) for the proposition that a fraud on the agency claim cannot be made. Again, Buckman Company specifically concerned the FCA, not any other agency or department of the government. Thus, that case has no relevance to this matter. Plaintiffs do not seek a private cause of action under the FCA and have never sought such relief. While the defendants may have violated the provisions of the FCA and 21 C.F.R. Part 312, the plaintiffs claims are for violations of 45 C.F.R. Part 46. It also appears that defendants including Immunex may have violated the provisions of 21 U.S.C. § 331. These provisions are not part of plaintiffs' causes of action. Rather, the provisions relating to drugs concern the process of disseminating a drug into the marketplace. A violation of this section is not alleged here although it is certainly possible that defendant Immunex violated provisions of this Act also. Thus, defendants' reliance on precedent that there is no private cause of action under the FCA while correct is irrelevant.

D. PLAINTIFFS HAVE SET FORTH A VALID CAUSE OF ACTION UNDER 42 U.S.C. §1983

Defendants next argue that plaintiffs have not stated a cause of

action under 42 U.S.C. §1983. Plaintiffs have alleged a "deprivation of ... rights, privileges, or immunities secured by the Constitution and laws§." as set forth in 42 U.S.C. §1983. Thus, if plaintiffs have set forth a valid cause of action under the Constitution or the Code of Federal Regulations, they are able to assert a 1983 action. As set forth in the sections above, plaintiffs have alleged valid claims under the Fourteenth Amendment and under 45 C.F.R. Part 46. Defendants contend, however, that they are immune to a civil rights claim pursuant to 42 U.S.C. §1983, although even Dr. McGee acknowledges he is a state actor for purposes of civil rights liability. Dr. McGee attempts to distinguish various United States Supreme Court cases but these cases do not support defendants' contentions; they disprove them. For example, Washington v. Harper, 494 U.S. 210 (1990), involved a mentally ill state prisoner who filed a civil rights action against a prison warden contending that he should not have received antipsychotic drugs against his will. The Supreme Court held that the Due Process Clause permits the State to treat a prison inmate with serious mental illness against his will if he is dangerous to himself or others and if the treatment is in his medical interest. Id. at 222-23. The converse of this holding is that a doctor could not subject a competent individual to a procedure without his or her informed consent. To that end, in Washington v. Harper, Justice Kennedy concluded that "[t]he forcible injection of medication into a nonconsenting person's body represents a substantial interference with that person's liberty." Id. at 229. Similarly, in Riggins v. Nevada, 504 U.S. 127 (1992), the United States Supreme Court held that a prisoner's Fourteenth Amendment rights were violated when he was forced to ingest anti-psychotic drugs during his trial without the state demonstrating that the medication was medically appropriate and there were not less intrusive alternatives. Defendant McGee also seeks to distinguish United States v. Stanley, 483 U.S. 669 (1987), discussed above at length. This case only stands for the inequitable holding that, under the Feres Doctrine, a serviceman can not sue the military even if it subjects him to an unethical experiment without his informed consent. Implied in this ruling is the holding that a Constitutional claim could be asserted for such conduct but for the Feres Doctrine and Stanley's status as a serviceman. Defendant McGee cites Collins v. City of Harker Heights, 502 U.S. 115, 127, n.10 (1992), to advance the argument that the guarantee of due process applies to "deliberate" or willful decisions to deprive a person of "life, liberty, or property." The Amended Complaint sets forth in great detail the deliberate process engaged by Dr. McGee and the other defendants to administer rogue medicine under the guise of a clinical trial in violation of the ethical rules, standards, regulations and internal protocol governing such conduct. There is no allegation that defendants' conduct with respect to the Trial was anything but deliberate. Defendants also contend they are either not "state actors" or not proper parties for the purpose of liability under this section. At this stage of the litigation, defendants' arguments must be rejected. The allegations in the Amended Complaint are that the defendants all were involved in the conduct of this Trial. Contrary to defendants' statements, there is no claim of respondeat superior . Rather, all defendants, state and otherwise private actors, worked together to

deprive plaintiffs of their constitutional rights. An otherwise private entity, such as Immunex, will be held liable under §1983 if it engaged in joint activity with the state actor defendants. Storck v. Suffolk County Department of Social Services, 62 F.Supp.2d 927, 940 (E.D.N.Y. 1999). A "state actor" is one who receives governmental assistance and performs a traditional governmental function , and if the injury is caused as an incident of the governmental authority. Id. at 939-40. In Downs v. Sawtelle, 574 F.2d 1 (5th Cir. 1978), plaintiff, a deaf mute, brought a civil rights action against a community hospital and operating physician for conspiring to sterilize her against her will. The court held that determining a state actor is a factual intensive procedure and that, in this instance, the hospital and physician were state actors. Id. at 10. At this stage of the litigation, there is not enough evidence to determine that any of the defendants is not a state actor. In fact, the allegations in the Amended Complaint are that all defendants participated in this state sponsored clinical trial and all either knew or should have known of the unlawful manner in which it was conducted. Taking these allegations as true, the defendants are to be considered state actors for purposes of §1983 liability.

E. DEFENDANTS ARE NOT ENTITLED TO QUALIFIED IMMUNITY " \l 2

Defendants all contend they are entitled to qualified immunity and cite numerous cases for general though nonapplicable legal theories. Defendants omit any discussion of In re Cincinnati Radiation Litigation, 874 F.Supp. 796 (S.D.Ohio 1995), one of the few cases on point. In that matter: Defendants engaged in the design and implementation of experiments from 1960 to 1972 to study the effects of massive doses of radiation on human beings in preparation for a possible nuclear war. The experiments utilized terminal cancer patients who were not informed of the consequences of their participation nor, indeed, informed of the existence or purpose of the experiments. Id. at 800. Plaintiffs were the subjects of the study and set forth various causes of action including a Section 1983 claim. Among the defenses raised by defendants was the defense of qualified immunity. The court explained this judicially created doctrine: The qualified immunity defense operates as an affirmative defense protecting officials from liability for any damages caused by their performance of discretionary functions. Importantly, the defense is not effective when plaintiffs can demonstrate that an official's conduct violated a plaintiff's clearly established statutory or constitutional rights. Id. at 807. To that end, the court stated, "[c]ourts are charged with the responsibility of ensuring that the defense of qualified immunity gives no more protection than is necessary for the official in question to effectively fulfill his duties." Id. at 807. The court in In re Cincinnati Radiation Litigation noted that plaintiffs alleged they were not informed that the radiation they received was not for the treatment of their cancer, and they were not informed of the effects of the radiation. Id. at 812. Based on these factors, the defendants were denied the ability to seek shelter behind the qualified immunity defense. Id. at 814. The court stated, "The Constitution never authorizes government officials, regardless of their specific responsibilities, to arbitrarily deprive ordinary citizens of liberty and life." Id. Further, as the court held in Downs, the case in which

the deaf mute plaintiff was sterilized against her will: [I]f a jury could reasonably conclude that [defendant] determined that sterilizing the plaintiff was for her own good or the good of society and as a consequence of that belief ignored indications from the plaintiff that she did not consent to the operation, or if it could conclude that he attempted to take advantage of her mental and communication limitations to unduly influence her decision, he would be liable�He should reasonably have known that such conduct amounted to an unconstitutional deprivation and he would be acting with a malicious motive. The fact that the doctor thought he had the plaintiff's best interests at heart would not justify a qualified immunity for constitutional purposes any more than would the belief, if asserted by a discriminatory employer or educator, that minority group members are happier and more productive in a segregated environment. Id. at 12. The court also stated that a private individual acted in concert with a state actor cannot rely upon any type of qualified immunity. Id. The holdings in In re Cincinnati Radiation Litigation and Downs apply to this matter. These defendants committed acts of grave injustice to desperate people who were misled into believing the Trial was their only source of hope. Defendants' claims that they did not know that such human experimentation without informed consent and in violation of the regulations and rules governing such conduct was unlawful simply cannot be believed. At the very least, at this stage of the litigation, plaintiffs should be permitted to move forward with their claims. Certain defendants also contend there is no liability because the theory of respondeat superior does not apply under §1983. But as the court stated in In re Cincinnati Radiation Litigation, "a plaintiff must allege and prove that the supervisors in question condoned, encouraged, or knowingly acquiesced in the alleged misconduct." There is no requirement that the supervisor had to actually engage in the conduct challenged. To that end, the court stated, "[a] supervisor may be liable for violations of clearly established constitutional rights, even if the violations were directly carried out by others." Id. at 806-807. Plaintiffs will prove such facts in this case. In any event, for the purpose of this motion, this Court must accept such allegations as true.

F. PLAINTIFFS ARE THIRD-PARTY BENEFICIARIES TO THE ASSURANCE AGREEMENT IN WHICH DEFENDANTS PROMISE TO ABIDE BY THE BELMONT REPORT

As stated in the Amended Complaint, Dr. Wortham, on behalf of OUHSC-Tulsa, entered into a written agreement known as the "Multiple Project Assurance of Compliance with DHHS Regulations for Protection of Human Research Subjects" ("Assurance Agreement"). A copy of the Assurance Agreement is attached as Exhibit "X." The Assurance Agreement provides that OUHSC-T will adhere to the Belmont Report and to the Common Rule. Plaintiffs allege that defendants breached the provisions of the Assurance Agreement by conducting human experimentation in violation of the principles of the Belmont Report and the federal regulations. Plaintiffs' cause of action is premised on their third-party beneficiary status. Dr. McGee, who as chief investigator of the Trial is bound by the provisions of the Assurance Agreement, argues no

such claim has been stated upon which relief may be granted. 15 Okl.St.Ann. §29 provides, "A contract, made expressly for the benefit of a third person, may be enforced by him at any time before the parties thereto rescind it." A contract does not have to expressly state that a beneficiary may enforce it; rather, it must appear that the contract was "expressly made for the benefit of a class of persons to which group the party seeking enforcement belongs." Oil Capital Racing Ass'n, Inc. v. Speedway, Inc., 628 P.2d 1176, 1179 (Okla. Ct. App. 1981). A third-party need not be named specifically as a beneficiary. Keel v. Titan Const. Corp., 639 P.2d 1228, 1231 (Okl. 1981). The terms of the contract are the means to determine the intent of the parties contracting, the primary question in this analysis. Shebester v. Triple Crown Insurers, 974 F.2d 135, 138 (10th Cir. 1992). The following questions are thus at issue: 1) Is the Assurance Agreement an Agreement? 2) Does it bind the defendants? 3) Does it provide that defendants promise to conduct all clinical trials in accordance with the Belmont Report and 45 C.F.R. Part 46? 4) Have defendants breached that promise in the manner in which the Trial was conducted? 5) Were plaintiffs in the class of persons the Assurance Agreement was intended to benefit? 6) Have plaintiffs been damaged as a result of defendants' breach? Plaintiffs have alleged facts which answer each of these questions in the affirmative, facts which defendants' own auditors have found to be true. In any event, for the purpose of this motion, this Court must answer each of these questions in favor of plaintiffs and deny defendants' motion to dismiss the claim.

G. PLAINTIFFS HAVE ASSERTED CAUSES OF ACTION FOR INTENTIONAL AND NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS, AND NEGLIGENCE

Defendants contend that plaintiffs are unable to pursue causes of action for intentional and negligent infliction of emotional distress. Again, the allegations in the Amended Complaint, which must be taken as true, set forth a cause of action for these claims. In Oklahoma, "to establish a cause of action for intentional infliction of emotional distress, a plaintiff must prove extreme and outrageous conduct done intentionally or recklessly by the defendant which resulted in severe emotional distress in the plaintiff." Mason v. The Board of Regents of the University of Oklahoma, 23 P.3d 964, 969 (Okla. Ct. App. 2001). The Comment to the Restatement (Second) of Torts §46 provides that conduct within this section is such that "upon hearing of it, a reasonable member of the community might exclaim 'outrageous!'" See Comment d to the Restatement (Second) of Torts §46. Defendants' own auditors have all but so exclaimed, as have the federal regulators and the national media. This Court must now allow a jury to give its response. A claim for negligent infliction of emotional distress is not an independent tort but an extension of a claim for negligence. See Lockhart v. Loosen, 943 P.2d 1074, 1081 (Okla. 1997). To pursue such a claim, plaintiffs must establish a duty on the part of a defendant to protect plaintiffs from injury, a failure of the defendant to protect plaintiffs from that injury, and injuries resulting from that failure. Kraszewski v. Baptist Medical Center of Oklahoma, Inc., 916 P.2d 24, n.1 (Okla. 1996). Plaintiffs have alleged each of these facts and will establish them at trial. Nor can there be debate that defendants owed plaintiffs a duty to protect them from

the harm they suffered. Dr. McGee's contention that plaintiffs did not allege a duty of care is absurd. Could he or his counsel possibly believe that he did not owe patients under his care a duty to treat them in accordance with professional standards? The allegation that Dr. McGee and other defendants had a duty to plaintiffs to render proper care and treatment, and breached that duty causing damages, is sufficiently alleged.

H. PLAINTIFFS HAVE SET FORTH PARTICULAR ALLEGATIONS OF FRAUD

Defendants also contend that plaintiffs have not set forth with particularity allegations of fraud. Rule 9(b) of the Federal Rules of Civil Procedure does not require the kind of detail plaintiffs provided in the Amended Complaint. Rather, the rule "merely requires that the circumstances constituting fraud shall be pleaded with particularity." Nolan Bros., Inc. v. United States for the Use of Fox Bros. Construction Co., 266 F.2d 143, 145-46 (10th Cir. 1959), cited by Resler v. Financial Group, Inc., 668 F.Supp. 1454, 1457 (W.D.Okla. 1985). Rule 9(b) is to be read in conjunction with Rule 8, which calls for "'a short and plain statement of the claim' which presents 'simple, concise, and direct' allegations." Cayman Exploration Corp. v. United Gas Pipe Line Co., 873 F.2d 1357, 1362 (10th Cir. 1989). A court will not dismiss a pleading of fraud "unless absolutely necessary�." Resler,, 668 F.Supp. at 1457. If the pleading sets forth the facts in detail, the claim should proceed. As the court stated in Scheidt v. Klein, 956 F.2d 963 (10th Cir. 1992), "a lengthy and detailed factual recitation thoroughly setting out the circumstances giving rise to" fraud claims does not provide a basis for relief under Rule 9(b). In addition, as in this case, when plaintiffs' "allegations involve multiple defendants engaging in the same fraudulent conduct over an extended period of time, and that conduct and the defendants' alleged role in that conduct is clearly identified in the pleadings, the Court will not dismiss the complaint if defendants have received fair notice of the claims against them." United States v. Medical Consultants, 170 F.R.D. 490, 497 (W.D. Okla. 1997). Plaintiffs have met their burden in alleging fraud. The Amended Complaint details the numerous misrepresentations made by Dr. McGee and the other defendants with respect to the risks of participating in the Trial, the nature, scope and legitimacy of the Trial, and the reasons for terminating the Trial . Defendants were more than aware of what this case is about even before plaintiffs filed the complaint. Defendants have more than enough information to provide them with fair notice of plaintiffs' claims. Nowhere in the Briefs of defendants seeking to dismiss the fraud counts is it alleged that they do not know or understand the charge of fraud brought against them. Rather, they generally contend that the Amended Complaint does not indicate what risks were misrepresented or how the nature, scope and legitimacy of the Trial were falsified, and that plaintiffs do not allege how they were caused harm. See McGee Brief, page 23. This is simply inaccurate. The plaintiffs' pleading goes into specific detail about defendants' misrepresentations and the harm plaintiffs sustained. At this stage of the litigation, defendants should be able to respond to the allegations.

I. PLAINTIFFS HAVE ASSERTED A PROPER CAUSE OF

ACTION FOR INTENTIONAL ASSAULT AND BATTERY/LACK OF INFORMED CONSENT

Dr. McGee claims that the causes of action for "Intentional Assault and Battery/Lack of Informed Consent" should be dismissed because plaintiffs did not allege all criteria necessary for each tort. As already stated, the purpose of the pleading requirements in this Court is to put defendants on notice of the claims against them. The Amended Complaint does this. Similarly, Dr. McGee argues that the battery and informed consent portions of the claim fail because there is no allegation plaintiffs would not have become subjects of a human experiment if there was no benefit to them and if, in fact, they would be harmed. A battery occurs if the treatment provided was "completely unauthorized." Scott v. Bradford, 606 P.2d 554, 557 (1980). A cause of action based on lack of informed consent is comprised of three parts: "the duty to inform being the first, the second is causation, and the third is injury. The second element, that of causation, requires that plaintiff patient would have chosen no treatment or a different course of treatment had the alternatives and material risks of each had been made known to him." Scott v. Bradford, supra, 606 P.2d at 558. Common sense should tell the defendants that plaintiffs would not have agreed to become subjects of an experiment that had no value, medically or otherwise, that placed them at great risk, that caused them severe discomfort and pain, that gave them false hope in their time of great illness, and that robbed them of human dignity.

J. PLAINTIFFS HAVE STATED A CLAIM FOR STRICT PRODUCTS LIABILITY AGAINST DR. MCGEE AND IMMUNEX

Dr. McGee contends that because he is a "research scientist" he cannot be held liable under Oklahoma's products liability doctrine. Immunex, a drug company whose sole purpose is to sell its product, also seeks dismissal of these counts. To hold Dr. McGee and Immunex liable under this theory, plaintiffs must show (1) the product caused plaintiffs' injuries; (2) the defect existed in the product at the time it left Dr. McGee's and/or Immunex's possession and control; and (3) the defect rendered the product unreasonably dangerous. Kirkland v. General Motors Corp., 521 P.2d 1353, 1363 (Okla. 1974). A product is "unreasonably dangerous" when it is "beyond that which would be contemplated by the ordinary customer who purchases it, with the ordinary knowledge common to the community as to its characteristics." Alexander v. Smith & Nephew, P.L.C., 98 F.Supp.2d 1299, 1307 (N.D. Okla. 2000). Per the allegations in the Amended Complaint, the Vaccine caused substantial physical and emotional damages to the plaintiffs, the defect in the Vaccine at all times existed as it never left defendants' possession and control, and the product was unreasonably dangerous. At this point it is too early to determine what benefits Dr. McGee would receive from the Trial, including whether he would have received any benefit from the sale of the Vaccine and what role he would have in such sales. What is clear is the Dr. McGee developed, manufactured, distributed and sold the Vaccine, and advertized its benefits over the airways. At this stage, plaintiffs have stated a claim against him. Similarly, these counts against Immunex are viable. That Immunex contends it should not

be liable does not make it so. Contrary to Immunex's arguments, the claims for strict products liability concern all the drugs distributed to plaintiffs, including the drug manufactured by Immunex.

K. DEFENDANTS ARE NOT EXEMPT FROM PUNITIVE DAMAGES

Contrary to defendants' representations, plaintiffs are entitled to seek and obtain punitive damages under Oklahoma's Governmental Tort Claims Act, provided defendants were not acting within the scope of their employment. See 51 Okl.St.Ann. ¬152.1. If Dr. McGee or the other defendants are found to not have acted within the scope of their employment, they may be liable for punitive damages. See DeCorte v. Robinson, 969 P.2d 358 (Okla. 1998). Moreover, plaintiffs are entitled to claim punitive damages under their federal claims. Accordingly, plaintiffs' claim for punitive damages, which applies to all claims, not simply the state law claims, should not be dismissed.

L. SHIRLEY AND BOB ROGERS ARE PROPER PARTIES

Dr. McGee contends that because there is no statement of citizenship for Shirley and Bob Rogers they may not pursue their causes of action. Due to the oversight of not listing their citizenship, plaintiffs seek to move to amend the Amended Complaint or, rather, to present evidence during discovery of citizenship so that the claims of Shirley and Bob Rogers will not be barred.

M. PLAINTIFFS' CLAIM FOR MEDICAL MONITORING IS AN ELEMENT OF THEIR DAMAGES

Defendants contend there is no specific cause of action for medical monitoring in Oklahoma but, rather, it is an element of damages. Plaintiffs agree.

N. ALL STATE CLAIMS SHOULD REMAIN IN THIS COURT UNDER THE DOCTRINE OF SUPPLEMENTAL JURISDICTION

It appears that Dr. McGee is claiming there is no supplemental jurisdiction because there is no federal question jurisdiction. As explained above, there are valid federal causes of action. Accordingly, the remaining claims should be heard by this Court. The United States Supreme Court has held that supplemental jurisdiction's justification: lies in consideration of judicial economy, convenience and fairness to litigants; if these are not present a federal court should hesitate to exercise jurisdiction over state claims¬Needless decisions of state law should be avoided both as a matter of comity and to promote justice between the parties, by procuring for them a surer footed reading of applicable law. United Mine Workers v. Gibbs, 383 U.S. 715, 726 (1966). There is no reason for the claims to be divided between the state court and this Court. All the causes of action are created by the same set of facts and involve the same defendants. To sever the causes of action would serve no purpose.

O. OKLAHOMA'S TORT CLAIMS ACT DOES NOT PROHIBIT PLAINTIFFS' CLAIMS

Plaintiffs' claims against Dr. McGee do not fall under the Oklahoma Governmental Tort Claims Act, 51 Okla. Stat. ¬151 et seq. ("the

Act"). Plaintiffs, thus, have no duty to comply, nor to allege compliance, with the notice requirements of the Act, nor does the Act limit plaintiffs' claims in any manner. Under the Act, employees of the State of Oklahoma, acting within the scope of their employment, are immune from personal tort liability. 51 Okla. Stat. §152.1(A) The State of Oklahoma has waived its immunity for "...its torts or the torts of its employees acting within the scope of their employment subject to the limitations and exceptions specified in this act..." 51 Okla. Stat. §153(A). Section 152 (5) defines an employee for the purposes of the Act, and states clearly that, "Physician faculty members and staff of the University of Oklahoma Health Sciences Center...not acting in an administrative capacity or engaged in teaching duties are not employees or agents of the state." (Emphasis added.) Dr. McGee cites the case of Anderson vs. Eichner, 890 P.2d 1329 (Okla. 1994), 1994 OK 136, in support of his position that the claims made by plaintiffs are covered by the Act. Anderson, however, stands for precisely the opposite point. In Anderson , the Oklahoma Supreme Court ruled that the Act created a "dichotomous division of physicians [employed by the State of Oklahoma] into two distinct categories: (a) teachers or students and (b) practitioners of medicine. For their tortious conduct as teachers or students the state is liable; for their like acts or omissions as practitioners the state is not." Id. at 1337. See also, Bivens vs. State ex rel. Oklahoma Memorial Hospital, 917 P.2d 456 (Okla. 1996), 1996 OK 5, and Lykins vs. Saint Francis Hosp., 917 P.2d 1 (Okla. 1995), 1995 OK 135. In Lykins , the Supreme Court of Oklahoma established that the notice-of-claim and related procedural provisions of the Act do not apply in actions against physicians who, although employees of the State, are not immune from liability under the Act. Id., at 4, 5. Plaintiffs' state law claims against Dr. McGee are for acts that fall under the distinct category of practicing medicine. Under no interpretation, no matter how stretched or strained, can defendants argue that plaintiffs' causes of action against Dr. McGee are for his acts as a teacher, student or in an administrative capacity. Dr. McGee is a physician member of the University of Oklahoma Health Science Center. He was conducting an experiment of a biochemical agent by injecting it into human research subjects. He was not teaching students or acting as an administrator for the State of Oklahoma. He was engaged in the practice of medicine in the field of clinical research, and Dr. McGee considered his research to be a treatment for a terminal illness. It is important to again note that, for the purposes of these motions, the facts as stated in the Amended Complaint are to be taken as true. The Amended Complaint states in paragraph no. 39 that, "...Dr. McGee...considered it 'his goal' to treat patients with a product he considered to be a cure for cancer." (Emphasis added.) Therefore, the acts complained of in the Amended Complaint against Dr. McGee are not the type of acts or omissions within the purview of the Act. The acts complained of are not administrative in nature, and are not acts of Dr. McGee while he was engaged in teaching. They are acts and omissions while practicing medicine and delivering medical services to patients. The fact that the acts and omissions occurred during the course of a human experiment does not bring the claims within the purview of the Act. Defendants cannot create a category of immunity under

the Act that is not specifically and explicitly contained therein. As one court has stated, "A statutory grant of immunity must be explicit--immunity will not be divined from a legislative text that is silent, doubtful or ambiguous." Anderson vs. Eichner, 890 P.2d 1329, at 1339, (Okla. 1994), 1994 OK 136. Plaintiffs' claims against Dr. Broughan also fall outside the scope of the Act on the same grounds as do the claims against Dr. McGee. The Amended Complaint clearly alleges that Dr. Broughan is the supervisor of Dr. McGee. In that capacity, Dr. Broughan has individual tort liability for his acts and omissions in negligently supervising McGee. In Anderson, Dr. Eichner's individual tort liability arose from negligent supervision of two residents who were treating a patient while they were all three employed by the State. Anderson vs. Eichner, 890 P.2d 1329, 1333, (Okla. 1994), 1994 OK 136. The claims against Dr. Broughan are indistinguishable from the claims in Anderson and are, therefore, properly made. Dr. McGee's brief in support of his Motion To Dismiss admits that the Act does not apply to plaintiffs' federal causes of action. As to the state law tort claims against the individual IRB members, plaintiffs agree that these claims are subject to the provisions of the Act. Defendants claims that the Act prohibits plaintiffs' state law tort claims against Drs. McGee and Broughan should, thus, be denied.

P. PLAINTIFFS HAVE ASSERTED A CLAIM FOR SYDNEE ROBERTSON

Dr. McGee's motion is the only one out of seven motions to dismiss that takes the position that the Amended Complaint does not state a cause of action for Sydnee Robertson. Dr. McGee argues that Sydnee Robertson has stated no claim in this case, and that she must be stricken from the caption. Dr. McGee also states in his Motion that, "The minor Plaintiff, Sydnee Robertson, attempts to bring a claim through her mother, the patient Dawanna Robertson." What Defendant, McGee actually identifies in the very first sentence in Section "O" on page 35 of his Motion To Dismiss is that Dawanna Robertson is making claims for her minor daughter as her parent and next friend. This is not only a proper method of bringing a claim for a minor child, it is the only way a minor can make a claim. FRCP, Rule 17(b) & (c). Plaintiffs' First Amended Complaint ("Complaint") states in Paragraph No. 3, "Plaintiff Sydnee Robertson is a minor and a citizen of the United States and the State of Oklahoma and is a resident of the County of Okmulgee. This action is brought on behalf of Sydnee Robertson by her mother, Dawanna Robertson." The Complaint goes on to identify the factual basis for inclusion of Sydnee Robertson as a Plaintiff in Paragraph Nos. 95, 96 & 97. "95. Sometime during the course of her treatment with the Vaccine, Dawanna Robertson learned she was pregnant and, shortly thereafter, advised Dr. McGee that she was pregnant and asked whether she could remain in the Trial. 96. Dr. McGee advised her that she could remain an active participant in the Trial as the risks were minimal and did not advise her the FDA approved protocol expressly excluded any pregnant participant. 97. Dawanna Robertson's daughter, Sydnee Robertson, was born on January 30, 2000." Following these allegations, plaintiff makes foundational allegations that will establish at trial the duty of the defendants to all patients involved in the subject human experiment. In Paragraph No. 103, plaintiff alleges that the

defendants' actions fell below the standards of conduct and were a breach of the duty the defendants' owed to plaintiff and, in Paragraph No. 104, plaintiff alleges damages. In each succeeding cause of action, plaintiff incorporates the allegations described above. It should be quite clear to Dr. McGee that during the course of Dawanna Robertson's participation in this experiment, he injected into her body a biochemical agent called the Vaccine, all while Sydnee Robertson was growing and developing inside of her. Therefore, each and every act or omission complained of by Dawanna Robertson in the Complaint, each and every claim she makes, she makes not only for herself, but as the parent and next friend of her minor daughter, Sydnee Robertson. The fact that each of Dawanna Robertson's claims in the First Amended Complaint only reference Dawanna Robertson by name, does not support dismissal of Sydnee Robertson's claims. Rule 8(a)(2) and (3) of the Federal Rules of Civil Procedure only require that a complaint contain, "(2) a short and plain statement of the claim showing that the pleader is entitled to relief, and (3) a demand for judgment for the relief the pleader seeks." As the United States Supreme Court has stated, "The Federal Rules reject the approach that pleading is a game of skill in which one misstep by counsel may be decisive to the outcome and accept the principle that the purpose of pleading is to facilitate a proper decision on the merits." Conely vs. Gibson, 335 U.S. 41, 48 (1957); see also FDIC vs. Grant, 8 F.Supp 2d., 1275, at 1286 (N.D. Okla. 1998). The purpose of a complaint is to give the defendants fair notice of the claims plaintiff is making and grounds upon which they rest. Conley, at 47. Defendants have fair notice of the claims plaintiff is making. Not only is this quite clearly set out in Paragraph Nos. 95, 96 and 97 of the First Amended Complaint, it is also demonstrated by Dr. McGee's own statement in his Motion that the minor Plaintiff, "...attempts to bring a claim through her mother..." McGee's Motion, Pg. 35. They obviously are aware that plaintiffs' claims for Dawanna and Sydnee Robertson are the same federal and state causes of action for each. Sydnee's claims are merely being brought by her mother on her behalf. From this, defendants can formulate an answer, conduct discovery to further frame the issues and proceed without prejudice to them for lack of notice of claims. Therefore, defendants Motion To Dismiss on this ground should be denied. In the alternative, if the Court decides that in order for Dawanna Robertson to continue pursuing claims on behalf of her daughter, the First Amended Complaint should read, after every reference to Dawanna Robertson, "Individually and as mother and next friend of Sydnee Robertson," Plaintiffs move this Court for an order allowing them to amend the First Amended Complaint to include such language. It is well settled that leave to amend a complaint in our Federal Courts should be freely granted. McGoffin v. Sun Oil Co., 539 F.2d 1245, C.A.10 (Okla.) 1976.

Q. THE STATUTE OF LIMITATIONS HAS NOT EXPIRED

Dr. McGee next contends that the two year statute of limitations for tort claims has expired because plaintiffs met with Dr. McGee at least two years prior to filing this action. The issue, however, is not when the plaintiffs met with Dr. McGee but when they knew or should have known of the offenses, as Dr. McGee implies in his Brief. The Amended Complaint makes it clear that none of the plaintiffs knew of the problems with the Trial giving rise to their

causes of action until, at the earliest, April 3, 2000. It was on that date that Dr. McGee, with the knowledge and approval of others at OUHSC-T, represented to the patients in the Trial that it was closing due to an inadequate supply of the Vaccine. Plaintiffs further allege that they were not advised of the true reasons the Trial ended. Accordingly, the statute of limitations for the tort claims have not expired.

R. PLAINTIFFS ARE PROPERLY JOINED

Dr. McGee contends that each plaintiff must file a separate action, despite all claims occurring in the same time period against the same defendants alleging the same causes of action. F.R.C.P. 20(a) provides, in part,: All persons may join in one action as plaintiffs if they assert any right to relief jointly, severally, or in the alternative in respect of or arising out of the same transaction, occurrence, or series of transactions or occurrences and if any question of aw or fact common to all these persons will arise in the action.A plaintiff or defendant need not be interested in obtaining or defending against all the relief demanded. Judgment may be given for one or more of the plaintiffs according to their respective rights to relief, and against one or more defendants according to their respective liabilities. The rule of joinder is construed liberally to "promote trial convenience and to expedite the final determination of disputes, all with a view to preventing multiple lawsuits." A-Plus Janitorial & Carpet Cleaning v. Employers' Workers' Compensation Association, 936 P.2d 916, 926 (Okla. 1997) (applying federal law). Joinder of all plaintiffs is appropriate. The issue is not, as Dr. McGee claims, a question as to which plaintiff was in what stage of the disease or what prognosis applies to each plaintiff, or even what reaction to the Vaccine each plaintiff suffered. A jury will be able to sort out these issues. It would serve no efficient purpose to litigate these matters separately.

S. THE SPOUSES HAVE A VALID CLAIM FOR LOSS OF CONSORTIUM

Defendants accurately point out that there is no loss of consortium claim available for a claim made pursuant to 42 U.S.C. 1983. However, Defendants miss the mark when they argue that Plaintiffs fail to state a claim for loss of consortium in connection with their other claims. The case law on this point is voluminous, and the point is unmistakable. Plaintiffs state a claim for loss of consortium for their state law causes of action. "In Oklahoma, a person is legally entitled to recover damages for the loss of spousal consortium." Littlefield v. State Farm Fire and Casualty Company, 857 P.2d 65, 68 (Okla. 1993), 1993 OK 102. The IRB Defendants, Boren and Broughan argue that the Plaintiffs' loss of consortium must fail because, under the Governmental Tort Claims Act, a claimant, "shall aggregate in his claim the losses of all other persons which are derivative of his loss." 51 Okla. Stat. 152(4)(b). This is absolutely absurd and far from the state of the law. First and foremost, Plaintiffs have already demonstrated why the Governmental Tort Claims Act does not control the claims made by Plaintiffs. Secondly, the term "aggregate" merely means to unite or combine into a complete whole. See Black's Law Dictionary Sixth Edition, 1990. The term as used in the Governmental Tort Claims Act does not mean that a spouse cannot state a claim for loss of consortium. It means that the spouses claims for loss of

consortium unite or combine together, also known as aggregate, with the primary claims under one statutory liability limit, if there is one. See Walker vs. City of Moore, 836 P.2d 1289 (Okla. 1992), 1992 OK 112. Simply stated, to the extent the Governmental Tort Claims Act even applies, both claims, although quite viable and maintainable, cannot exceed the liability limits for one claim. Therefore, Defendants' Motions to Dismiss Plaintiffs' state law claims for loss of consortium, should be overruled.

IV. CONCLUSION

For the above stated reasons, defendants' motions to dismiss should be denied.

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CERTIFICATE OF MAILING I, Robert V. Seacat, hereby certifies that on the __ day of _____, 2001, I mailed a true and correct copy of the above and foregoing document, with postage thereon fully prepaid, to the following:

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