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JOHN ANCHEFF *v.* HARTFORD HOSPITAL ET AL.
(SC 16617)

Borden, Norcott, Palmer, Zarella and Tobin, Js.

Argued February 13—officially released July 9, 2002

Joshua D. Koskoff, with whom was *Joel Faxon*, for

the appellant (plaintiff).

Frank H. Santoro, with whom was *Robert E. Kiley*, for the appellee (named defendant).

Augustus R. Southworth III, with whom, on the brief, was *John R. Horvack, Jr.*, for the appellee (defendant Jonathan Tress).

Opinion

BORDEN, J. The principal issue in this appeal, taken from the trial court's judgment on a defendants' verdict in this medical malpractice action, is whether the trial court properly excluded from evidence a certain report of a federal commission regarding the protection of human subjects of biomedical and behavioral research.[1] The plaintiff, John Ancheff,[2] appeals[3] from the judgment of the trial court for the defendants, Hartford Hospital (hospital) and Jonathan Tress,[4] rendered following the jury verdict in their favor. The plaintiff claims that the trial court improperly: (1) excluded from evidence the Belmont Report; (2) excluded from evidence a certain medical consent form; and (3) instructed the jury on the question of the meaning of medical research. We affirm the judgment of the trial court.

The plaintiff brought this medical malpractice action against the hospital for injuries he allegedly had suffered arising out of an improperly administered program involving a drug known as Gentamicin. Insofar as is relevant to the issues on appeal, the plaintiff claimed that the hospital had improperly: conducted clinical trials and study procedures regarding Gentamicin; failed to inform the plaintiff that he was a participant in such a trial or procedure; failed to obtain his informed consent for such participation; and failed to disclose to him the experimental nature of his course of treatment with the drug. After a trial to the jury, a verdict was returned in favor of the hospital. The plaintiff then moved to set aside the verdict, which the trial court denied. This appeal followed.

The jury reasonably could have found the following facts. In January, 1993, the plaintiff underwent back surgery, after which he developed a deep wound infection reaching his spinal column. He was admitted to the hospital on February 5, 1993, where Tress was consulted as a specialist in infectious diseases. Cultures disclosed the presence of enterococcus, a difficult bacteria to eradicate. Because Tress suspected enterococcal osteomyelitis, a potentially life-threatening form of bone infection, he ordered a course of combined antibiotic therapy of Gentamicin[5] and Unasyn. Gentamicin has known nephrotoxic and ototoxic[6] effects regardless of how it is administered.

Initially, Tress ordered Gentamicin to be administered once a day in a dose of 480 milligrams. Pursuant to an inpatient dosing program previously enacted by the hospital, the hospital pharmacy increased the daily

dosage to 615 milligrams.[7] Thereafter, Tress examined the plaintiff's condition, and determined that the increased dosage was appropriate. The plaintiff received this combined dosage of drug therapy for approximately twelve days in the hospital. During that time, his kidney clearance and serum levels were monitored for signs of impaired kidney clearance and drug accumulation, with negative results during the plaintiff's stay in the hospital. The plaintiff was discharged from the hospital on February 24, 1993.

Tress prescribed a course of home intravenous antibiotic therapy of Gentamicin and Unasyn at the same levels, in order to eradicate the infection. Although the infection was successfully treated, on March 17, 1993, the plaintiff developed side effects from the Gentamicin, namely, vestibular toxicity, or poisonous effects to the inner ear, which resulted in the loss of the functioning of his inner ear, including his sense of balance. The plaintiff claimed at trial that he suffered total and permanent destruction of the functioning of his inner ear due to an excessive administration of Gentamicin.

I

THE BELMONT REPORT

The plaintiff first claims that the trial court improperly excluded from evidence the Belmont Report. Specifically, he claims that he sought to establish at trial that the hospital's program of administering Gentamicin constituted medical research, and that, therefore, the hospital was required to have that program reviewed by an institutional review board and to provide the plaintiff with a detailed written consent form outlining the risks, benefits and alternatives, as well as the experimental nature, of the program.[8] The Belmont Report, he claims, supported this claim. We conclude that, as the question was presented to the trial court, the court did not abuse its discretion in excluding the Belmont Report from evidence.

In order to analyze this claim, it is necessary to recount, first, the role that the question of medical research played in the trial. At the heart of the plaintiff's case, insofar as this appeal is concerned, was his claim that the hospital's program for administering Gentamicin, known as the once-daily aminoglycoside regimen,[9] constituted engaging in medical research. The hospital did not challenge the proposition that, *if* the Gentamicin program had constituted medical research, such a review and consent form would have been required. It vigorously contested, however, the claim that the program constituted research. The hospital claimed, to the contrary, that it constituted the implementation of a program or practice of medical therapy, which, in turn, was aimed, not at validating an untested theory or hypothesis, but at using the available literature, including prior research and clinical data, for the

improvement of patient care and safety. Thus, whether the Gentamicin program constituted medical research, as claimed by the plaintiff, or the implementation of a therapeutic program for patient care and safety, as claimed by the hospital, was litigated as a question of fact. There was conflicting evidence produced on the question.

The plaintiff produced the following evidence tending to prove that the hospital's Gentamicin program constituted medical research. The hospital's program provided for a level dose of seven milligrams per kilogram of body weight (7 mg/kg), a dosage that previously had not been tested on humans. In 1993, the hospital was the only one in the country that prescribed that dosage to entire classes of patients. This dosage departed from the conventional dosage of 3 mg/kg approved by the federal Food and Drug Administration. The hospital had described both the dosage of 7 mg/kg and its method of administration, namely, one daily injection as opposed to the conventional administration of three injections per day, as ''radical.'' In addition, the hospital administered the drug to a class of patients pursuant to a ''protocol,'' which meant that, if a physician failed to prescribe the dosage of 7 mg/kg called for in the protocol, the hospital pharmacist would change the dosage automatically.

In publications to the medical community, the hospital had stated that the Gentamicin program was ''a radical change from standard aminoglycoside administration schedules,'' and that ''the [Gentamicin] program was unlike most other hospital-wide programs because it was not a conversion to a therapeutic alternative but, rather, a radical change in both the conventional dosing and administration of the aminoglycosides.'' Data was collected by the hospital on each patient apart from what was kept in the patient's medical record. In addition, the physicians responsible for enacting the Gentamicin program at the hospital, namely, Charles Nightingale, David Nicolau and Richard Quintilliani, lectured to the medical community on the findings of the program.

Furthermore, the plaintiff introduced a definition of research contained in the Code of Federal Regulations that was applicable to the hospital. That regulation defined research as ''a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. . . .'' 45 C.F.R. § 46.102 (d); see footnote 15 of this opinion for the full text of this definition. Finally, the plaintiff's expert witness, Wilmer Leigh Thompson, a physician, testified that, in his opinion, the hospital's Gentamicin program constituted medical research. In the course of rendering his opinion, Thompson, in effect, gave a definition of research that supported his opinion that the Gentamicin program

constituted research.[10]

The hospital, to the contrary, offered the following evidence tending to prove that the Gentamicin program did not constitute medical research. Before the program was enacted by the hospital in August, 1992, the physicians in the hospital's department of infectious diseases, pharmacy and therapeutics committee, antiobiotic subcommittee, and medical executive committee approved it. On the basis of the voluminous data and known principles of pharmacokinetics,[11] these committees and the physicians on them determined that the program embodied sound policy for the well-being of patients and did not constitute medical research.

In addition, the hospital introduced evidence to establish the following. The Gentamicin program had been widely studied for many years before the hospital implemented it, and it was not implemented to test the safety of Gentamicin. The program was not a clinical trial, and its implementation did not involve control groups, randomization or double blinding, which are some hallmarks of research. There was no motivation to advertise the drug, to secure funding from a drug company, or to report findings to the Federal Drug Administration. The prime considerations in the implementation of the program were efficacy of outcome and patient safety. On the basis of the scientific data, the program was implemented for inpatients at the hospital to maximize the killing of bacteria and discourage the accumulation of the drug in the patient's body. It permitted a greater drug-free interval than the conventional method of administration, and therefore resulted in less accumulation of the drug, and was at least as safe and more effective than multiple daily dosing. In addition, the hospital presented evidence that the Gentamicin program is now employed in approximately 80 percent of the hospitals in the United States.

Finally, the hospital offered the expert testimony of four witnesses that the Gentamicin program did not constitute medical research. These witnesses included David Gilbert, a physician, as well as Nightingale, Nicolau and Quintilliani. As was the case with Thompson, each of these expert witnesses gave a definition of research that supported his opinion that the Gentamicin program did not constitute research.[12]

With this background in mind, we turn to the plaintiff's evidentiary claim regarding the Belmont Report. The following additional facts, including a summary of the Belmont Report, are necessary in order to understand and evaluate this claim.

On July 30, 1992, Nightingale, who was vice president of research at the hospital, signed an agreement with the federal Office of Protection from Research Risks, an agency of the United States Department of Health

and Human Services. This agreement was a ''multiple project assurance,'' which permitted the hospital to conduct research and to receive federal funding to support its research programs. This agreement governed ''how research projects are to be conducted when one or more organizations are involved in doing that research,'' but it did not define the term ''research.'' In the agreement, however, under the heading entitled ''Ethical Principles,'' the hospital agreed to the following: ''This institution [the hospital] is guided by the ethical principles regarding all research involving humans as subjects, as set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (entitled: Ethical Principles and Guidelines for the Protection of Human Subjects of Research [the 'Belmont Report']), regardless of whether the research is subject to Federal regulation or with whom conducted or source of support (i.e., sponsorship).''

The Belmont Report consists of ten single-spaced pages. The Belmont Report's introductory passage points out that, although ''[s]cientific research has produced substantial social benefits . . . [i]t has also posed some troubling ethical questions.'' It then refers to ''reported abuses of human subjects in biomedical experiments, especially during the Second World War.'' It refers next to the ''Nuremberg War Crimes Trials,'' and to the ''Nuremberg Code . . . drafted as a set of standards for judging physicians and scientists who had conducted biomedical experiments on concentration camp prisoners.'' According to the Belmont Report, ''[t]his code became the prototype of many later codes intended to assure that research involving human subjects would be carried out in an ethical manner.'' The report then states that, because those codes that followed the Nuremberg Code ''often are inadequate to cover complex situations,'' and sometimes are conflicting and ''difficult to interpret or apply,'' the report would identify (1) ''a distinction between research and practice,'' and (2) three broader principles, or general prescriptive judgments, that are ''relevant to the ethic of research involving human subjects,'' namely, respect for person, beneficence and justice. The report acknowledged that these ''principles cannot always be applied so as to resolve beyond dispute ethical problems. The objective is to provide an analytical framework that will guide the resolution of ethical problems arising from research involving human subjects.''

The next part of the Belmont Report, entitled ''Boundaries Between Practice and Research,'' sought ''to distinguish between biomedical and behavioral research, on the one hand, and the practice of accepted therapy on the other, in order to know what activities ought to undergo review for the protection of human subjects of research.'' It acknowledged that the ''distinction between research and practice is blurred partly because

both often occur together (as in research designed to evaluate a therapy) and partly because notable departures from standard practice are often called 'experimental' when the terms 'experimental' and 'research' are not carefully defined.''

The Belmont Report then stated: ''For the most part, the term 'practice' refers to interventions that are designed solely to enhance the well being of an individual patient or client and that have a reasonable expectation of success. The purpose of medical or behavioral practice is to provide diagnosis, preventive treatment or therapy to particular individuals. By contrast, the term 'research' designates an activity designed to test an hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalized knowledge (expressed, for example, in theories, principles, and statements of relationships). Research is usually described in a formal protocol that sets forth an objective and a set of procedures designed to reach that objective.

''When a clinician departs in a significant way from standard or accepted practice, the innovation does not, in and of itself, constitute research. The fact that a procedure is 'experimental,' in the sense of new, untested or different, does not automatically place it in the category of research. Radically new procedures of this description should, however, be made the object of formal research at an early stage in order to determine whether they are safe and effective. Thus, it is the responsibility of medical practice committees, for example, to insist that a major innovation be incorporated into a formal research project.

''Research and practice may be carried on together when research is designed to evaluate the safety and efficacy of a therapy. This need not cause any confusion regarding whether or not the activity requires review; the general rule is that if there is any element of research in an activity, that activity should undergo review for the protection of human subjects.''

The next three pages of the Belmont Report are devoted to a discussion under the heading, ''Basic Ethical Principles.'' This discussion is, in turn, divided into three parts, entitled ''Respect for Persons,'' ''Beneficence'' and ''Justice.'' It is fair to characterize this discussion as highly abstract. The discussion refers in quite philosophical terms to subjects such as: personal autonomy; self-determination; the ethical considerations involved in using imprisoned persons as subjects of research; the Hippocratic maxim of ''do no harm'' and the Hippocratic oath's requirement that physicians benefit their patients ''according to their best judgment''; research involving children as subjects; and various meanings of the term ''justice,'' such as whether burdens are to be distributed to each person equally, to each according to his needs, to each according to his

societal contribution, or to each according to merit. In this connection, the report asserts that, during the nineteenth and twentieth centuries, the burdens of serving as subjects of medical research fell largely on ''poor ward patients,'' and noted that ''the exploitation of unwilling prisoners as research subjects in Nazi concentration camps was condemned as a particularly flagrant injustice.'' The Belmont Report also noted that, ''in the 1940s, the Tuskegee syphilis study used disadvantaged, rural black men to study the untreated course of a disease that is by no means confined to that population.''[13] The report concluded this portion by warning that ''the selection of research subjects needs to be scrutinized in order to determine whether some classes (e.g., welfare patients, particular racial and ethnic minorities, or persons confined to institutions) are being systematically selected simply because of their easy availability, their compromised position, or their manipulability, rather than for reasons directly related to the problem being studied.''

The final five pages of the Belmont Report, under the heading, ''Applications,'' are themselves divided into three categories, entitled ''Informed Consent,'' ''Assessment of Risks and Benefits'' and ''Selection of Subjects.'' The discussion contained therein is also carried on at a high level of abstraction. The first category, ''Informed Consent,'' is further subdivided into abstract discussions of ''Information,'' ''Comprehension'' and ''Voluntariness.'' The second category, ''Assessment of Risks and Benefits,'' is further subdivided into a general discussion under the headings ''The Nature and Scope of Risks and Benefits'' and ''The Systematic Assessment of Risks and Benefits.'' The third category, ''Selection of Subjects,'' focuses on the role of ''the principle of justice'' in the selection of research subjects, and concludes with the warning that ''[c]ertain groups, such as racial minorities, the economically disadvantaged, the very sick, and the institutionalized may continually be sought as research subjects, owing to their ready availability in settings where research is conducted. Given their dependent status and their frequently compromised capacity for free consent, they should be protected against the danger of being involved in research solely for administrative convenience, or because they are easy to manipulate as a result of their illness or socioeconomic condition.''

The trial court addressed the question of the admissibility of the Belmont Report on several occasions during the trial proceedings. On the first occasion, the court addressed the report only indirectly, in response to a motion in limine, dated May 5, 2000, filed by the hospital before opening arguments. The hospital alleged that, in deposition testimony, Thompson had ''testified as to 'human experimentation' and alleged violations of the Nuremberg Code, [the] Geneva Convention, Helsinki Accord, et cetera.'' The hospital moved to ''preclude

reference by the plaintiff, his attorneys or witnesses to such issues as 'human experimentation,' violations [of] the Nuremberg Code, the Geneva Convention, Helsinki Accord, et cetera, and/or making references to the Tuskegee Study, World War II experimentation, et cetera,'' on the grounds that such references were irrelevant and unduly prejudicial, and likely to inflame the jury. The court held argument on the motion on May 15. It is evident from the transcript of this argument that the court and parties considered the motion in limine to address both the plaintiff's anticipated opening argument and his evidence.

In response to the trial court's initial indication that such references would constitute ''unfair argument,'' the plaintiff's initial position was that *all* of the references, with the sole exception of the reference to Nazi Germany, were relevant to the standard of care. He represented that he would not use the terms ''Nazi Germany'' or ''human experimentation,'' but he insisted that he be permitted to refer to the Tuskegee study because ''the foundation of [the] regulations'' about using humans as subjects of human research was ''the Belmont Report, and that's where all these regulations . . . come from,'' and that ''out of Tuskegee came the Belmont Report.'' The court granted the motion in limine.

The next instance occurred on May 22, 2000, when, prior to opening arguments, the trial court and counsel conferred preliminarily regarding certain documents, including the Belmont Report, which had been filed by the plaintiff as proposed exhibits, as to some of which the hospital objected. In response to the hospital's objection to the report, including its references to human experimentation, the Nuremberg Code and the Tuskegee study, and recalling ''the same issues . . . which we hashed through the other day,'' the plaintiff claimed that the Belmont Report was admissible because ''the standards that I'm going to be claiming were violated are contained in'' the report, and the report ''is the best evidence of what [the hospital was] required to do.'' The plaintiff argued that the Belmont Report ''is evidence of what the standard of care was in conducting any research involving humans.'' He contended further that his expert witnesses would testify that the hospital was ''required to get, pursuant to [the report] the informed consent of the [plaintiff] if [it] wanted to continue with research or include him in the research,'' and to submit the research to an institutional review board. He then repeated his claim that the Belmont Report contained the standards to which the hospital was to be held in treating the plaintiff, and that it was ''absolutely essential that [he] be able to introduce [the report] and show [it] to the jury, [and] explain what the standards are.''

The plaintiff also asserted that the Belmont Report

was admissible because the hospital had represented in the July 30, 1992 agreement with the federal government that ''we want to be able to advertise and to reap the benefits of assuring people that we're going to do research the right way, and here's the standards that we're going to live up to in conducting this research,'' that those standards ''define research as this,'' and that the jury ''should see the standards . . . .'' Although the court suggested that the plaintiff's own expert could testify ''what the standard'' was, the plaintiff insisted that he was also entitled ''to get the standard of care from the [hospital],'' and to ''explore what the standards were . . . with the [hospital].'' He contended further that he would be ''asking the court for an instruction on violation of the standard of care in conducting what [he contended was] research,'' which was ''defined in the [report] as [the hospital] assured the government [it] would follow. So if [the hospital says] research is one thing, I should be able to show the jury . . . what [the report] say[s]. I'm sorry that [it] say[s] human experimentation, but it's not . . . inflammatory, it's necessary . . . .'' At the conclusion of this proceeding, the plaintiff delivered a copy of the Belmont Report to the court. The court postponed ruling on its admissibility until the following day.

The next day, May 23, the trial court ruled that the Belmont Report was inadmissible. The basis of its ruling was that the report constituted a statement of ethical principles and guidelines for the protection of human research subjects, and that, although it distinguished between practice and research, it did not address the issue before the jury, namely, the standard of care applicable to the hospital.

The plaintiff then contended that, on the issue of the standard of care for informed consent applicable to the hospital, the treatment by the hospital was in fact ''research and that one of the ways we are going to establish that is through the . . . report which defines [research], and it was the standard that the [hospital] acknowledged as the standard.'' Therefore, he argued, the Belmont Report was evidence of the applicable standard of care ''that was embraced by the [hospital].'' The plaintiff then asked the court whether he would be permitted to pursue the matter further ''with either my experts or [the hospital's experts].'' The court responded that he could ''ask them . . . in [his] exploration of the standard of care . . . what they rely on in . . . reaching their understanding [of] what the standard of care is and then it's possible we may get into this . . . .''[14]

Subsequently, during the plaintiff's direct examination of Nightingale, whom the plaintiff had called as his witness, the plaintiff again offered the Belmont Report, along with certain federal regulations, which are discussed in footnote 15 of this opinion, without further

elaboration or qualification. The hospital objected to both the report and the regulations, and the court sustained the objection to the report and overruled the objection to the regulations.[15]

The plaintiff next attempted to offer the Belmont Report through the direct testimony of Thompson. The plaintiff represented that Thompson would testify that one of the bases of his opinion that the hospital violated the applicable standard of care, ''may or is likely to be the standards as set forth in the Belmont Report.'' The court responded: ''The Belmont Report is not getting in. I've ruled on it several times. Even in this context, it's not getting in. . . . He can testify about the regulations. We've resolved that.''

Thereafter, the plaintiff made one final offer of the Belmont Report, and at the same time asked the court to reconsider its rulings and to articulate the basis for its exclusion. The plaintiff repeated his earlier claim that the report was ''relevant because it is a standard that was required to be followed by hospitals [that] assured the government that they would follow the standard . . . .'' He then read that part of the report that differentiated between the terms ''practice'' and ''research.'' He then asserted: ''*The entirety of the Belmont Report is relevant*. I read that portion because of the court's concern [at] the time of my argument. I claim it is absolutely relevant in this case. . . . It's in evidence that it was assured by the hospital. [Thompson] . . . will testify that it's a standard that was required of participants . . . in conducting any research involving humans. That is the relevance of it in this case.'' (Emphasis added.)

The court then responded by articulating the basis of its ruling. The court stated: ''I've read the Belmont Report. In its summary it states [that it] is a statement of basic ethical principles and guidelines that should assist in resolving the ethical problems that surround the conduct of research with human subjects. It sets forth principles and guidelines. It refers to the Nuremberg War Crime trials, Nuremberg Code, judging physicians, scientists who conducted biomedical experiments on concentration camp prisoners. It also references the exploitation of unwilling prison[ers] as research subjects in Nazi concentration camps was condemned as a particularly flagrant injustice. In this country in the 1940s [the] Tuskegee syphilis study used rural black men to study the untreated course of a disease. It also talks about justice arrives from social, racial, sexual and cultural biases, institutionalize[d] in society. Its prejudicial effect greatly outweighs its very limited evidentiary value.''

The plaintiff then stated: ''Then, Your Honor, I would offer the evidence redacted to the portions Your Honor has cited.'' The court responded: ''That's it. I've rule[d] on it three times. You can mark it'' as an exhibit for

identification. The plaintiff then repeated that, regarding ''each of the court's concerns I would . . . offer it in redaction.'' The court stated: ''I don't want to hear another word about it.''

It is clear from the trial court's articulation that the basis of its ruling[16] was that the Belmont Report's probative value was outweighed by its likely unfair prejudicial effect. The court acted in accord with § 4-3 of the Connecticut Code of Evidence, which provides: ''Relevant evidence may be excluded if its probative value is outweighed by the danger of unfair prejudice or surprise, confusion of the issues, or misleading the jury, or by considerations of undue delay, waste of time or needless presentation of cumulative evidence.'' In this context, unfair prejudice is that which ''unduly arouse[s] the jury's emotions of prejudice, hostility or sympathy; *State* v. *Wilson*, 180 Conn. 481, 490, 429 A.2d 931 (1980); or tends to have some adverse effect upon [the party against whom the evidence is offered] beyond tending to prove the fact or issue that justified its admission into evidence. *State* v. *Graham*, 200 Conn. 9, 12, 509 A.2d 493 (1986), quoting *United States* v. *Figueroa*, 618 F.2d 934, 943 (2d Cir. 1980). . . . Section 4-3 also recognizes the court's authority to exclude relevant evidence when its probative value is outweighed by factors such as confusion of the issues or misleading the jury; *Farrell* v. *St. Vincent's Hospital*, [203 Conn. 554, 563, 525 A.2d 954 (1987)] . . . .'' (Citations omitted; internal quotation marks omitted.) Connecticut Code of Evidence § 4-3 (2000), commentary.

In such a case, our scope of review is limited to determining whether the court clearly abused its discretion. *State* v. *Wargo*, 255 Conn. 113, 123, 763 A.2d 1 (2000). ''We will make every reasonable presumption in favor of upholding the trial court's ruling, and only upset it for a manifest abuse of discretion. . . . [Thus, our] review of such rulings is limited to the questions of whether the trial court correctly applied the law and reasonably could have reached the conclusion that it did.'' (Internal quotation marks omitted.) Id. Applying this standard, we conclude that the trial court did not abuse its discretion in excluding the Belmont Report.

We first note that, with two exceptions—one that we discuss now, and one that we discuss later in this opinion—throughout the proceedings the plaintiff consistently offered the entire Belmont Report into evidence. The first exception was the plaintiff's representation, in the argument on the motion in limine, that he would not refer to either ''Nazi Germany'' or use the term ''human experimentation.''[17] We consider this representation, therefore, as the functional equivalent of an offer to redact from the report the references to the ''reported abuses of human subjects in biomedical experiments, especially during the Second World War,'' and to ''the exploitation of unwilling prisoners as

research subjects in Nazi concentration camps . . . ." See footnote 17 of this opinion. Thus, we review the trial court's ruling on the basis on which the question was presented to it, namely, as an offer of the report in its entirety, shorn only of those two references.

As our earlier summary of the Belmont Report indicates, it contained a great deal of material that the trial court reasonably could have considered as unfairly prejudicial. First, it purported to be, for the most part, a statement of basic ethical principles, and not to be a statement of the legal standard for securing informed consent. Moreover, it invited the jury, in deciding whether the hospital's Gentamicin program constituted research or medical practice, to think about the Nuremberg War Crimes Trials and the Nuremberg Code, the substance of which the report did not describe, and thus, implicitly, to compare the hospital's conduct with whatever the jurors may have understood those terms to mean. It also invited the jury to engage in a highly abstract and philosophical level of inquiry into such subjects as respect for the autonomy of persons, the notion of self-determination, the concept of beneficence, and the various theories of justice. It invited the jury to think about using children and criminal prisoners as subjects of medical research. It invited the jury to think about the meaning of the physician's Hippocratic oath, which was neither given in full nor explained in any detail. It invited the jury to compare the hospital's conduct to the infamous Tuskegee study. It invited the jury to compare the hospital's conduct regarding the plaintiff to the complexities of securing informed consent from vulnerable groups such as racial minorities, the economically disadvantaged, the very ill, and the institutionalized. We cannot fault the trial court, as the plaintiff would have it, for determining that submitting this material to the jury would unduly arouse its emotions of prejudice, hostility or sympathy, and would tend to confuse the issues and mislead the jury.

On the probative side of the scale, the Belmont Report did contain a definition of research, and an explanation of the line between practice and research, which the hospital, by signing the July 30, 1992 agreement, which in turn incorporated the report by reference, could be considered to have adopted. Nonetheless, the trial court, in deciding whether the report was more prejudicial than probative, was confronted by the plaintiff's consistent offer of the report as a whole, rather than with a clear choice of admitting only the probative part and excluding the rest, which constituted much the greater portion of the report. We ordinarily leave that balancing function to the broad discretion of the trial court, and see no basis for concluding that the court abused that discretion in this case.

This brings us to the second exception noted previously, namely, the plaintiff's final offer of redaction.

That offer can best be characterized as too little and too late. It was too little because it left to the trial court the task of deciding precisely what portions of the ten single-spaced page report were to be redacted. ''It [was] not the trial court's responsibility to attempt to separate the admissible and inadmissible portions of the [Belmont Report].'' *Calcano* v. *Calcano*, 257 Conn. 230, 243, 777 A.2d 633 (2001). It was too late because it came, not during any of the plaintiff's offers of the report, but after the court had ruled three times on the report as offered in an essentially unredacted form, and after the court had completed delivering its articulation of the basis of its ruling. We therefore decline to give any determinative weight to the plaintiff's final offer of redaction.

II

MEDICAL CONSENT FORM

The plaintiff next claims that the trial court improperly excluded from evidence a certain medical consent form used by Gilbert in a research program at his hospital in Portland, Oregon. Specifically, the plaintiff claims that that medical consent form ''was strong evidence relevant to prove that the [h]ospital [in the present case] was required to get informed consent'' from the plaintiff ''because of the compelling similarities demonstrated in the consent form between . . . Gilbert's study and the [hospital's Gentamicin] program . . . .'' We disagree.

The following facts underpin this claim. Gilbert testified on direct examination that, beginning in 1988, he and his colleagues at the hospital in Portland had conducted a program involving a 5 mg/kg once-daily dose of Gentamicin and another antibiotic, Timentin, which is similar to Unasyn, for small groups of patients. This was done based on the state of knowledge of the drugs as it existed at the time. From 1988 to 1993, that program was conducted pursuant to approval of the hospital's infectious disease and pharmacy committees, but without review by the hospital's institutional review board. He described this program as an ''off label use'' of the drugs involved. In 1993, however, they decided to turn this program into a formal research project, comparing two different regimes of dosing—once daily and three times per day, at different dosages, and involving randomization.[18] At that time, they sought and obtained permission to do so from the hospital's institutional review board and drafted a formal written consent form for the patients to be enrolled in the research project.

On cross-examination, the plaintiff sought to introduce the medical consent form used by Gilbert. The court sustained the hospital's objection, ruling that the form was irrelevant because there was no claim by the hospital that it had supplied any consent form, and the dispute in the case was whether the hospital was

required to provide a consent form, not what such a consent form would contain. Therefore, the court ruled, ''[w]hat was contained in [the form] is not relevant . . . .''

''Upon review of a trial court's decision, we will set aside an evidentiary ruling only when there has been a clear abuse of discretion. *State* v. *Provost*, 251 Conn. 252, 257, 741 A.2d 295 (1999), cert. denied, 531 U.S. 822, 121 S. Ct. 65, 148 L. Ed. 2d 30 (2000); *State* v. *Thomas*, 205 Conn. 279, 283, 533 A.2d 553 (1987). The trial court has wide discretion in determining the relevancy of evidence and the scope of cross-examination and [e]very reasonable presumption should be made in favor of the correctness of the court's ruling in determining whether there has been an abuse of discretion. . . . To establish an abuse of discretion, [the plaintiff] must show that the restrictions imposed upon [the] cross-examination were clearly prejudicial. . . . *State* v. *Casanova*, 255 Conn. 581, 591, 767 A.2d 1189 (2001).'' (Internal quotation marks omitted.) *State* v. *Rolon*, 257 Conn. 156, 173, 777 A.2d 604 (2001).[19]

In the present case, the critical issue was *whether* the hospital was required to secure written consent from the plaintiff because, as he claimed, the Gentamicin program of medication constituted medical research. It was not what the contents of any such form would be. Moreover, the plaintiff was not inhibited in any way from cross-examining Gilbert regarding his opinion that the hospital's Gentamicin program here did not constitute research, or regarding the similarities and differences, if any, between his program in Oregon and that of the hospital here, and why his program constituted research but the hospital's here did not. It is difficult, therefore, to see why the contents of the medical consent form used by Gilbert were relevant to the issues in the case. We conclude that the trial court did not abuse its discretion in sustaining the hospital's objection to the form.

III

INSTRUCTION ON MEDICAL RESEARCH

The plaintiff's final claim is that the trial court improperly instructed the jury on the meaning of the term medical research. Specifically, the plaintiff claims that the trial court improperly: (1) declined to follow his request to charge on the meaning of the term; and (2) instructed the jury that research ''was that which was not substantiated by the [medical] literature.'' This claim is without merit.

In the course of charging the jury on the standard of care in administering Gentamicin, the court stated: ''What is in dispute is what was the proper dosage of Gentamicin, was the seven milligrams per kilogram within the standard of care and an alternative within the standard of care.

"Also in this dispute, and this is what you'll have to determine with respect to the research question, what the state of medicine was in 1993 as to whether such a dose was experimental or research or substantiated by medical literature and not something that was research.

"You will have to decide whether the [plaintiff has] proved that the standard of care was that a health care provider, a hospital, having the data available in 1993, the [hospital] would be required to get the institutional review board approval of this change in dosing regimen from three times a day one milligram per kilogram to seven milligrams per kilogram once daily dosing, and written informed consent from [the plaintiff]."

"Our analysis begins with a well established standard of review. When reviewing [a] challenged jury instruction . . . we must adhere to the well settled rule that a charge to the jury is to be considered in its entirety, read as a whole, and judged by its total effect rather than by its individual component parts. . . . [T]he test of a court's charge is not whether it is as accurate upon legal principles as the opinions of a court of last resort but whether it fairly presents the case to the jury in such a way that injustice is not done to either party under the established rules of law. . . . As long as [the instructions] are correct in law, adapted to the issues and sufficient for the guidance of the jury . . . we will not view the instructions as improper." (Internal quotation marks omitted.) *Godwin* v. *Danbury Eye Physicians & Surgeons, P.C.*, 254 Conn. 131, 142–43, 757 A.2d 516 (2000). We do not critically dissect a jury instruction. *State* v. *Davis*, 255 Conn. 782, 798, 772 A.2d 559 (2001).

The plaintiff submitted a request to charge that defined medical research in essentially the same language as that contained in the opening paragraphs of the Belmont Report. The trial court was correct in declining to give this instruction because the Belmont Report properly had been excluded from evidence. Therefore, there was no basis in the evidence for that definition. Furthermore, giving any instruction precisely defining the term medical research as a matter of law would have been contrary to how the case had been tried, namely, that the question of whether the hospital's Gentamicin program constituted medical research had been presented as a question of fact and, accordingly, various witnesses had given various definitions of the term for the jury's consideration.

The plaintiff also took exception to the instruction as given. He contended that the instruction permitted the jury to find that what the hospital had done would not be research "if the jury finds that there's some support [for it] in the medical literature . . . ." He now claims that, "[u]nder the [c]ourt's charge, experimentation or research was that which was not substantiated

by the [medical] literature. This could not have been further from the truth. In order for a research program to even pass muster with an Institutional Review Board, there *must be* substantiation in the medical literature for performing the research.'' (Emphasis in original.)

We conclude that the trial court's instruction, viewed as a whole and not subjected to critical dissection, was adequately adapted to the issues and sufficient for the guidance of the jury. It appropriately submitted the question of whether the Gentamicin program constituted research to the jury as a matter of fact. There were, as we have noted, several different versions presented to the jury of what research involved and did not involve. The court's passing reference to the medical literature, which was but one factor in determining whether a program constituted research, did not, as the plaintiff suggests, inform the jury that it could not find that the program constituted research if there was some support for it in the medical literature.

The judgment is affirmed.

In this opinion the other justices concurred.

[1] In July, 1974, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research was created under the United States Department of Health, Education, and Welfare. The purpose of the commission was to identify basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects and to develop guidelines that should be followed to assure that such research is conducted in accordance with those principles. On April 18, 1979, the commission set forth its findings in a statement entitled, ''The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research'' (Belmont Report).

[2] There were two intervening plaintiffs, namely, Environmental Construction Services, Inc., and the second injury fund, which asserted claims for workers' compensation reimbursement. Neither of these parties is involved in this appeal. Accordingly, we refer to Ancheff as the plaintiff.

[3] The plaintiff appealed from the judgment of the trial court to the Appellate Court, and we transferred the appeal to this court pursuant to Practice Book § 65-1 and General Statutes § 51-199 (c).

[4] Although Tress was named as a defendant in the appeal, none of the issues raised on appeal involves the claims or evidence against him, as the plaintiff has conceded at oral argument and in a subsequent letter to this court. In addition, there was a third defendant, Gerald Becker, with respect to whom the complaint ultimately was withdrawn. Therefore, we consider the claims on appeal only against the hospital, and we summarily affirm the judgment in favor of Tress. Accordingly, all references are to the hospital as the defendant.

[5] Gentamicin is one of the class of drugs known as aminoglycosides.

[6] The term ''nephrotoxic'' means poisonous to the kidneys and the term ''ototoxic'' means poisonous to the ear.

[7] We discuss later in this opinion the evidence regarding this program.

[8] It is undisputed that the hospital did not inform the plaintiff that he was part of a program that constituted medical research, and that he was not asked to give informed consent to being the subject of a program of medical research.

[9] For convenience, we refer to this as the Gentamicin program.

[10] Thompson gave four reasons for his conclusion that the Gentamicin program constituted research: (1) it was ''a systematic application to many patients of a given regime, rather than individualization for the patient and the infection''; (2) it involved ''the systematic collection of data''; (3) the data was collected ''not in the [patient's medical] chart, but in a research office''; and (4) the purpose of the program ''was to be able to publish [its results] in the medical literature and in newsletters for the hospital staff . . . .''

[11] The term ''pharmacokinetics'' refers to the ''[m]ovements of drugs within

biological systems, as affected by uptake, distribution, elimination, and biotransformation.'' Stedman's Medical Dictionary (24th Ed. 1982).

[12] Gilbert specifically disagreed with Thompson's opinion that the Gentamicin program constituted research. He characterized it as ''implementing a program rather than a research protocol.'' He based this opinion on the fact that the hospital had ''reviewed all the literature that was available at the time, what had been done in the laboratory, what had been [done] in animals, [and] the published information on clinical trials [and] research trials that had been done in Europe and were starting to be done in the United States.'' Indeed, he testified that one of the clinical trials that Thompson had performed indicated that the program was ''ready for patient use.''

Nightingale testified that the Gentamicin program did not constitute research. He testified that, when conducting research, one would usually employ control groups, and double blinding and randomization, none of which was employed in this case. He explained that, in a research project, control groups were used in order to compare ''the new therapy or one therapy to a standard,'' represented by the control group; and that the assignment of patients to either the research group or the control group would be accomplished on a random basis.

In addition, Nightingale characterized the Gentamicin program, not as a research project, but as an aspect of clinical practice, which he defined as ''understanding . . . what work was done in the past and how this will affect the patients, especially their outcome in the treatment of diseases, and . . . adopting what was done by others and applying that to the care of patients. That's what clinical practice basically is. This differs from research in that if you have a question that you can't find an answer to in the literature of sufficient magnitude that you want to find out what the answer to the question is, then you have to in a systematic, organized way investigate that issue and find out the answer to the question. They're two completely separate things.''

Nicolau testified that the Gentamicin program was not a research project or clinical trial, in that it did not involve setting up different administration regimes for different groups of patients and comparing their results.

Quintilliani testified that none of the members of the various committees of the hospital that had approved of the Gentamicin program considered it to be a research program or a ''clinical trial where [they would be] comparing specific methods against each other.''

[13] Although not discussed further in the record, the infamous Tuskegee Study is a matter of common knowledge. It has been described as follows: ''For forty years, from 1932 to 1972, 399 African-American males were denied treatment for syphilis and deceived by officials of the United States Public Health Service. As part of a study conducted in Macon County, Alabama, poor sharecroppers were told that they were being treated for 'bad blood.' In fact, the physicians in charge of the study ensured that these men went untreated. In the 25 years since its details first were revealed, the study has become a powerful symbol of racism in medicine, ethical misconduct in human research, and governmental abuse of the vulnerable.'' University of Virginia Health System, ''The Troubling Legacy of the Tuskegee Syphilis Study,'' (May 16, 1997) at http://www.med.virginia.edu/hs-library/historical/apology/index.html.

[14] Our review of the record discloses that the plaintiff was unsuccessful in eliciting any such testimony from the hospital's experts. For example, Nightingale testified that the hospital was not required to follow any recommendations of the Belmont Report, that it did not constitute a regulation governing research on humans, and that such research was regulated by the Federal Drug Administration and the federal Office for Protection of Research Risks. We discuss later in this opinion the effect of the court's ruling regarding Thompson.

[15] The plaintiff stated: ''Let me just introduce the Belmont Report and the federal regulations that were the standards that applied for the assurance in 1993.'' Upon objection by the hospital, the court stated: ''The objection to the introduction of the Belmont Report is sustained.''

As to the regulations, the plaintiff claimed: ''The regulations establish the definition of research. They establish the regulations that the hospital has testified they were bound by . . . the standards of care in conducting research and providing informed consent.'' The regulation in question, issued by the federal Office for Protection from Research Risks, of the United States Department of Health and Human Services, is entitled: ''Federal Policy for the Protection of Human Subjects (Basic DHHS Policy for Protection of Human Research Subjects).'' The regulation, which was effective August,

19, 1991, contained the following definition: ''*Research* means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.'' (Emphasis in original.) 45 C.F.R. § 46.102 (d).

[16] Although the trial court was required to address the admissibility of the Belmont Report several times, we treat all of those instances collectively as one process and, accordingly, we refer to the trial court's ruling in the singular.

[17] In this connection, we note that nowhere does the Belmont Report use the term ''human experimentation.'' The closest language is the reference to ''reported abuses of human subjects in biomedical experiments, especially during the Second World War.'' We also note that there is no specific reference in the report to ''Nazi Germany.'' The closest, however, is one reference, in the section entitled ''Justice,'' to ''the exploitation of unwilling prisoners as research subjects in Nazi concentration camps . . . .'' We take the plaintiff's representation, therefore, to mean those references.

[18] Gilbert described the research program as follows. They randomly divided patients into three groups. One group received Timentin only; one received Timentin and Gentamicin in their traditional dosages, three times per day; and the third group received Gentamicin and Timentin once per day, in a dosage of 5 mg/kg. Gilbert also, as explained previously, differentiated this formal research program from the Gentamicin program conducted by the hospital in this case.

[19] The plaintiff claims that ''the exercise of discretion to omit evidence in a civil case should be viewed more critically than the exercise of discretion to include evidence,'' relying for that proposition on *Martins* v. *Connecticut Light & Power Co.*, 35 Conn. App. 212, 217, 645 A.2d 557, cert. denied, 231 Conn. 915, 648 A.2d 154 (1994). We have specifically disclaimed any such bifurcation in our scope of review of evidentiary rulings. See *Claveloux* v. *Downtown Racquet Club Associates*, 246 Conn. 626, 629–30, 717 A.2d 1205 (1998).