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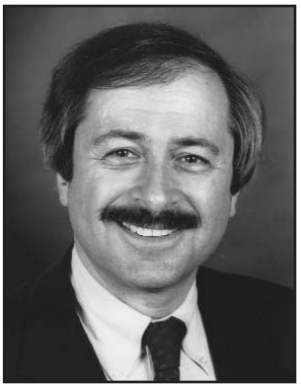
A Message from the Section Chair



This is my last letter to you as the Chair, so please bear with me for a minute or two. On November 4, 1995, **Robert Witmer**, former President of the New York State Bar Association, introduced a resolution to the House of Delegates seeking creation of a Health Law Section. It was most appropriate that Bob make the motion since the groundwork for creating the Section was laid during his administration and at his direction. While I have thanked him on a number of occasions, this is an opportunity to do so publicly.

Since the Section=s birth we have enrolled almost 1,000 members, presented a large number of successful CLE programs, published six issues of *The Health Law Journal*, rocked the NYSBA Annual Meeting with a number of outstanding programs and firmly established our presence in the health law community and with the government. A lot has happened in a brief span of time . . . and this is only the beginning.

Fall Meeting

Please mark your calendar for the Fall Meeting of the Section. Scheduled for November 12-13, 1998, in New York City, we are planning numerous committee meetings, a program on "Telemedicine" and much, much more. Watch your mail this summer for further details.

Community-State Partnership to Improve End-of-Life Care

The Robert Wood Johnson Foundation has announced a grant program aimed at creating joint public-private efforts to improve care at the end of life. I am pleased to report that your Section and a number of its committees have been selected to become an important part of the proposal submitted for the state of New York. If we are fortunate enough to receive the blessing of the Foundation, you will be hearing a lot more about this project. It will hopefully become an opportunity for many Section members to become involved.

Discharge Note

As I pass the baton to Jerry Levy, a longtime friend and your new Chair, I'd like to say "Thanks" to the Executive Committee, Committee Chairs and Section members who have worked so hard to create the Health Law Section and make it a success. You have been terrific and tireless! **Beth Krueger** at NYSBA was an invaluable resource, without whose help we never would have gotten off the ground. I'd also like to thank **Lisa Bataille** at Headquarters who took over the liaison responsibilities from Beth. She and **Kathy Plog** have helped create a seamless infrastructure for the Section. Finally, I would like to thank my partners at Thuillez, Ford, Gold & Johnson, LLP, for not complaining about the time I have spent on Section business. Their support has been extremely important to me during the past 2 1/2 years.

INSIDE THIS ISSUE

At last year's Annual Meeting, I jokingly noted three important dates in the history of our area of law: (a) 1971—creation of the National Health Lawyers Association; (b) September 18, 1994—the introduction of the first health lawyer (Alan "The Eel" Birch, in-house counsel to Chicago Hope Hospital) as a regular cast member on a major television series; and (c) November 4, 1995—the founding of the NYSBA Health Law Section.

While your Section is the youngest of the trio, it is growing the fastest and has the most impact on attorneys practicing health law in New York State. That's why your participation is so important. During the next year please plan to work on a committee, and to join us at CLE programs and meetings. If you are not a member of a committee, I encourage you to join, as our Section does much of its work through that structure. If you would like to be added, please call the appropriate chair. Also, if you have any questions, or suggestions as to how the Section might do a better job, please contact me, Jerry Levy or any member of the Executive Committee. Their names and addresses are listed in this issue.

Finally, it has been a pleasure and an honor to serve as the first Chair of this Section. I will always treasure the opportunity that it has given me to work with a great group of professionals. Please stay in touch.

Barry A. Gold

From the Editors

We begin this issue by looking at how we, as attorneys, can assist cancer survivors. L. Susan Scelzo Slavin and Lindafel Lynnette Sarno discuss the fulfillment they have experienced by providing legal advice to cancer patients on issues that may be of particular concern to them.

This issue also includes an article by Stephan Haimowitz, Susan J. Delano and John M. Oldham, discussing medical research on those who lack decision-making capacity. The article focuses on the New York case of *TD v. New York State Office of Mental Health and Department of Health*.

Our third piece, written by Claudia O. Torrey, analyzes the United States Supreme Court opinion in *Metro-North Commuter Railroad Company v. Buckley* and its impact on the doctrine of negligent infliction of emotional distress.

Finally, we include a reprint of an article by Francis J. Serbaroli that provides guidance on structuring joint ventures between nonprofit and for-profit entities.

As always, we welcome and encourage the submission of articles on timely health law topics. All articles should be submitted with accompanying floppy disks to facilitate revisions. You can reach us at the following address:

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Barbara L. Atwell and Audrey Rogers
Editors

Empowerment of Cancer Survivors

by L. Susan Scelzo Slavin and Lindafel Lynnette Sarno

Your phone messages seem endless. An order to show cause was just "hand delivered" to you on a Friday afternoon. The faxes continue to flow in. This is surely a familiar experience to all of us. But, unexpectedly you are confronted with a great opportunity to take some time out and contribute your time and knowledge to help people in need. What do you do? I'm sure we'd all love to help out. But, how can I possibly fit anything else into my already crazy schedule?

Fortunately, we have had the opportunity to conclude that our business pursuits and desires to charitably assist others need not be mutually exclusive. Once you can get beyond the hesitations of "Shouldn't I be spending this time on billing more hours or meeting my financial obligations?", it becomes obvious that donating our professional time to those in need fulfills us, both from a human and a business perspective. It is so compelling that to do otherwise would be impractical.

For a number of years, we have conducted empowerment seminars, on a *pro bono* basis, for cancer survivors and social workers. We have done this for the patient population of the American Cancer Society and Cancer Care, Inc. in the Tri-State area, as well as at major hospitals. The incredible professional and personal satisfaction of spending our time in this way for these families and professionals is unparalleled. We heartily recommend this pursuit—the catastrophically ill desperately need our help and the Bar is in the pivotal position to make effective change for this population.

While practicing as employment discrimination attorneys, the need to educate cancer patients and survivors of their employment rights became patently obvious to us. At a time when one's first concern is for health and medical treatment, many people who have been diagnosed with cancer face an unexpected obstacle—problems with their employment. Unfortunately, discrimination against these individuals prevails in the workplace. By and large, such discrimination is a result of "cancer myths." There are three predominant myths about cancer which impact on survivors' employment opportunities. These include: (1) cancer is a death sentence; (2) cancer is a disease which is contagious; and (3) cancer survivors are an unproductive drain on the economy. However, the facts, as distinguished from the myths, are quite clear. The overall survival rates for individuals diagnosed with cancer are greater than fifty (50%) percent. Cancer is obviously not contagious and, as a group, cancer survivors have relatively the same productivity rates in the workplace as other employees. These factors are the driving force behind the need to protect the employment rights of cancer patients.

We can all take part in dispelling these myths by educating and empowering employees of their employment rights. Often, people simply need a basic knowledge of the law to empower them during difficult times. Through such knowledge, cancer survivors will have the tools and confidence to have candid discussions with their employers about their illness and their employment needs. They will know how to inform the employer of their diagnosis without causing unnecessary anxiety. They will know how to ask for an accommodation, if needed.

We firmly believe that with proper communications between the employee and the employer, much of the discrimination and adverse acts can be avoided. In brief, there is some basic information that every cancer patient or survivor should know. Federal, state and some city laws are available to protect persons with disabilities. These laws protect persons with cancer, or those who have recovered from cancer, against discrimination in the workplace. Each of these laws has specific nuances and different definitions which cause an individual's rights to differ depending upon which laws are applied. However, in general, the Americans with Disabilities Act (ADA) protects persons with disabilities nationwide. In order to determine whether an individual has a claim under the ADA, three preliminary inquiries need to be addressed. They are: (1) Are you a "disabled person"? (2) Are you "qualified" for the job and can you perform the "essential functions" of the job? and (3) Has your employer provided you with a reasonable accommodation?

Under the ADA, a disability is defined as a physical or mental impairment that substantially limits one or more major life activities, a record of such impairment or being regarded as having such an impairment (i.e., a perception of disability). Despite such disability, under the ADA and New York law, you must be able to perform an essential function of the job with or without a "reasonable accommodation." An employer is required to offer a "reasonable accommodation" for a known disability. As we all know, the most common accommodation needs of employees with a cancer history are for reduced or rescheduled work hours to accommodate medical appointments for examinations, laboratory work, chemotherapy or radiation therapy. Such requests should be made by the employee from the employer.

Be advised, however, that these protections are not a one-way street. We always advise people of the need to have a "reality check" since an employer has rights and defenses under the ADA. As such, an accommodation is not required if it would impose an "undue hardship" on the employer's business—which is generally defined as a financial expense.

Cancer survivors also have rights under the Family and Medical Leave Act (FMLA). The FMLA provides employees and family members with the opportunity to take an unpaid leave under certain circumstances. If the employee works for an employer with fifty (50) or more employees, and the employee has worked with this employer for at least one year,

he or she may be eligible for the leave. The entitlement is an unpaid leave of up to a total of 12 work weeks within one year. The unpaid leave may be available for a number of reasons. But, in terms of the cancer patient, if that person suffers from a serious health condition that makes him or her unable to perform the functions of his or her position at work, they are entitled to such leave. In addition, if the patient's spouse, child or parent wishes to take the leave to care for him or her, such leave should also be granted. Upon returning from a leave under the FMLA, such employee retains his or her employment rights as they were prior to taking the leave.

Also, many cancer survivors are quite anxious about returning to the workplace after an extended treatment period. In particular, those who have left their previous employment for health reasons and are now seeking new employment should be aware of their rights with regard to the interview process. The Equal Employment Opportunity Commission (EEOC) has set out specific guidelines as to what an employer can ask during the pre-employment stage of seeking a job. An employer may not ask disability-related questions and may not conduct medical examinations until after it makes a conditional job offer to the applicant. What is a disability-related question? Generally, these are questions that are likely to elicit information about a disability or medical information. Job applicants may not be questioned about the existence, nature or severity of a disability. They may, however, be asked about whether they are physically and mentally able to perform the "essential functions" of the position sought.

This overview is obviously a bare minimum of the legal knowledge that should be shared. However, after presenting such information, you will be able to gauge what should and should not be elaborated on. Although our audiences vary extensively, there is one prevailing experience we have observed. These incredible people, both the patients and their caretakers, as well as the health care professionals, perceive your compassion and are most appreciative of the time you have taken to help them out.

Now, why would it be impractical to avoid donating your time in this way? We simply ask, "Remember the last time someone helped you during a time of need and how wonderful it made you feel?" Of course you do. And, so will they.

Uninformed Decision-Making: The Case of Surrogate Research Consent

by Stephan Haimowitz, Susan J. Delano and John M. Oldham*

Medical researchers occupy an unusual place in our culture, viewed both as heroes vanquishing horrible illnesses and as abusers exploiting human guinea pigs. While there are examples of dramatic breakthroughs and of dreadful wrongs, such occurrences are rare. Most research produces incremental progress, which over time transforms health care, and is conducted according to established ethical principles.

Given that participants' fundamental interests are affected, it is an axiom of research that their safety and dignity must be scrupulously protected. The scope and specificity of the rules which afford these protections have greatly evolved since the infamous incidents of the past. However, as noted in the Report of the President's Advisory Committee on Human Radiation Experiments,[1] there remain issues in research which need to be addressed.

Among the most difficult of these issues are those related to the participation of individuals who lack decision-making capacity and thus are unable to give informed consent. The literature in this area reflects the complexity of the issues and the diversity of viewpoints regarding the appropriate balance between, on one hand, advancing knowledge and providing access to the newest therapies, and, on the other, the need to protect potentially vulnerable research participants.[2]

Within the research community itself, continuing efforts seek to develop principled and workable mechanisms to address these issues. Given the intricacy and importance of the matter, it seems clear that the appropriate adjudication of a legal challenge to such an effort requires a thorough understanding of these issues.

In a recent issue of the *Hastings Center Report*,[3] Alexander Morgan Capron reviewed a New York court decision *TD v. New York State Office of Mental Health and Department of Health*[4] (*TD*), concerning surrogate consent in psychiatric research, a ruling which received prominent attention in the *New York Times* and numerous professional publications. Many of these discussions include images of overzealous researchers indifferent to participants' safety and dignity. Similarly unfounded portrayals can be found in the court decision itself.

As the principals at the New York State Office of Mental Health (OMH) involved in the matter, we suggest that the issues of surrogate consent for research participation, as well as the court's understanding of those issues, require further examination.

The Research and Regulations at Issue

Serious mental illness inflicts enormous suffering on millions of individuals and their families, and presents a major public health problem in this country and worldwide.[5] New York is the home of some of the leading researchers working on the causes and treatment of these illnesses. Among them are researchers working at specialized OMH facilities which are affiliated with academic departments of psychiatry and major teaching hospitals.[6] Past successes of OMH research include the first chlorpromazine trials and lithium clinics in this country.

The development of chlorpromazine, as the first available antipsychotic medication, revolutionized the treatment of the most severely and chronically ill psychiatric patients, allowing many of these individuals to leave institutional care and re-join the community for the first time in years or decades. The development of lithium as a treatment for bipolar, i.e., manic-depressive illness, has been estimated to have saved more than $50 billion in what would otherwise have been the costs of the illness (e.g., treatment expense, lost occupational productivity, cost and burden to families, and the like). These are but two examples of how the work of OMH researchers has reduced individual suffering and the societal consequences of serious mental illnesses.

Research on these illnesses is conducted at both OMH inpatient and outpatient facilities, with inpatient research involving only individuals who are voluntarily hospitalized.[7] As with all areas of medicine, psychiatric research is governed by the comprehensive basic federal regulations known as the "Common Rule,"[8] as well as by the more specific Department of Health and Human Services (DHHS) and Food and Drug Administration (FDA) human subjects regulations.[9] These regulations require the voluntary, capable informed consent of the person or, if incapable, the consent of a surrogate.[10] They establish substantive rules for the conduct of research as well as specify the composition and responsibilities of local Institutional Review Boards (IRBs). These IRBs review, approve and monitor each research protocol.

In 1990, OMH adopted regulations, applicable to both state facilities and OMH-licensed general hospital units,[11] which incorporated the federal regulations but went beyond them in protecting research participants. The New York regulations required formal capacity assessments for all participants. They specified that an objection expressed at any time by a participant, regardless of their capacity, was determinative (subject to one theoretical exception that is discussed below). The regulations prohibited the involvement of incapable individuals unless the protocol could not be done without their participation, and it focused on a condition from which they suffered. Finally, the agreement of the individual's treatment team that participation in the research was consistent with his or her treatment plan was required.[12]

As elsewhere in health care, and in law, it is the situation of the individual who is incapable of understanding a personal decision which presents the most difficult consent issues. The question in the medical research context has been discussed by ethicists and policy makers for some time without resolution. The federal regulations do not address the issue of surrogate consent for incapable adults, except to refer to state law. In many states, the law is silent on the matter. Although the federal Department of Health, Education and Welfare (DHEW) proposed regulations for the "institutionalized mentally infirm" in 1978[13] the regulations were never adopted.[14] A policy adopted by the National Institutes of Health (NIH) in 1987[15] addressed some, but not all, of the issues of surrogate consent, and applied only to the Institutes' internal operations.

The OMH regulations at issue in *TD* attempted to address these consent issues for psychiatric research in New York State. The basic tenets included the assessment of capacity, informed consent from capable adults and the right of all participants to have their objection to participation honored. The regulation also provided that the objection of any person who is a member of any of the classes of authorized surrogates must also be honored even when consent has been obtained from another surrogate.[16] Surrogate consent on behalf of an incapable adult could be provided, in accordance with the person's wishes and best interests, by an individual chosen by the person, or in the absence thereof, by a family member or by a court. Since many people, including individuals with AIDS, have non-traditional relationships, consent could also be given by a "close friend" who submitted an affidavit describing his or her regular interaction with the individual and knowledge of his or her beliefs and values. For minors, consent could be obtained from parents or guardians, as provided in the federal regulations.[17]

The Lawsuit

The *TD* lawsuit was filed on behalf of six patients who, though never involved in or considered for any protocol of which we are aware, were alleged to fear that they might be "used as human guinea pigs"[18] and "forced to participate in research."[19] The case was filed by three mental health advocacy organizations and challenged the OMH regulations on a number of theories. Plaintiffs argued that a little-used state law[20] gave exclusive authority regarding human research to the state Department of Health (DOH) and, thus, the OMH regulations were invalid regardless of their content. That state law also requires certain research involving potentially vulnerable individuals to be approved by DOH, and the court interpreted this point in a way that has significant implications, as will be discussed.

Substantively, plaintiffs asserted that the surrogate consent provisions violated constitutional principles. Since virtually no court decisions had directly addressed research consent, plaintiffs extrapolated their arguments from court precedents concerning psychiatric patients' objections to psychotropic medications and decisions concerning the withholding of treatment at the end of life.

The lawyers for the Plaintiffs, and those from the Attorney General's Office, representing the Defendants, made strategic decisions to present the case as solely involving the application of these court precedents. No trial was held, no assertions scrutinized and no facts established. Consequently, in six years of litigation, the actual concepts, categories and processes related to the conduct and regulation of research were never truly examined. Moreover, plaintiffs made sensational allegations of harm to a proportionally small number of research participants[21] and, though denied by the defendants, they were never actually examined in the litigation. These claims, neither proven nor rebutted, were summarily repeated in every document filed by the plaintiffs over six years and were, over time, treated by the court as if they were facts rather than allegations.

The Court's Ruling

Underlying the court's constitutional decision are some perplexing preliminary rulings on state law concerning the DOH's jurisdiction and authority. The state law exempted research which complies with "the regulations of any federal agency" from its requirements, but the court interpreted the exemption to apply only to research which is federally funded, thus disregarding the regulatory oversight of the FDA and other federal agencies. The court then stated, confusingly, that its ruling governs only non-federally funded studies and that the ruling would have little impact on research. In reality, the court's constitutional rulings invalidate basic premises of both the federal and OMH research regulations, and impose a problematic paradigm on medical research in general.

In applying the Constitution, for example, the court essentially rejected the principle that an IRB considering a research proposal, or a court considering an individual's participation, should determine whether the overall risks to participants are reasonable in relation to the overall benefits. The court forbade the participation of an incapable adult or a minor in a protocol, regardless of the magnitude of the expected benefits to the patient and the importance of the knowledge to be obtained about the disorder, if the protocol includes even a single non-therapeutic, more than minimal risk procedure. "Therapeutic" is defined as offering a prospect of direct benefit that is important to the health or well-being of the participant, such as the amelioration of the symptoms of mental illness or a reduction in side effects compared to standard medication. "Non-therapeutic" is defined as any research that is not therapeutic, and also includes any otherwise therapeutic research that includes a non-therapeutic more than minimal risk element.

Though these concepts and the concepts of minimal risk have long been the subject of abstract arguments, the *TD* decision creates a rule with concrete consequences. For example, a patient with Alzheimer's disease who does not tolerate or benefit from the few existing treatments is now barred from receiving a new medication available solely in a research protocol if it includes a PET scan, a more-than-minimal risk procedure, performed for scientific rather than therapeutic purposes. Such a patient's relative cannot even seek authorization from a court based upon determinations that participation is in

the patient's best interests and that the patient would have consented if capable**.**

Another example of the type of research that is adversely affected by the ban on therapeutic studies that contain a non-therapeutic element concerns research on teenage suicide, a tragic occurrence which has increased by more than 200 percent since 1960.[22] Parents in New York of an adolescent who has attempted suicide can no longer consent, with their child's assent, to the child's participation in a non-federally funded protocol if the study contains a non-therapeutic element. A study[23] of this type provides, without cost, extensive inpatient and outpatient treatment of a depth available nowhere else, but it includes a lumbar puncture (spinal tap) seeking to determine suicide-predictive serotonin levels, as have been established for adults. The decision to do a lumbar puncture, a non-therapeutic element in the context of this study, is not made casually. However, this procedure is performed daily in hospitals across the country and results in bad headaches lasting 24 hours in about 10 percent of all cases.

The court ruling also addressed wholly therapeutic research. Evaluation of the individual's capacity to give consent is now required to be made by a clinician independent of the research in all protocols. As to surrogate consent for incapable individuals, the parties in the case negotiated a mechanism[24] through which an individual who lacks capacity to give or withhold consent can, if determined to have sufficient capacity, appoint a research surrogate at the time research participation is being considered.[25] Generally, the person designates a relative or "close friend." Under the agreed-upon mechanism, advance notice must be given to one of the plaintiff legal advocacy organizations which can challenge the designation in court. If the person is too incapacitated or is alone, the clinician/researcher must obtain court authorization. The court decision has prohibited family members from acting as surrogates, unless they are also patient-chosen research surrogates, even when the research is entirely therapeutic.

The *TD* decision also provides that, under state law, the state Department of Health must approve all non-federally funded research protocols involving minors, the mentally disabled and other potentially vulnerable groups,[26] with the funding source being the determinative factor, as discussed above. Thus while all the research at issue complies with the federal regulations, including, of course, review and approval by the appropriate IRB, the court added another layer of review.

Finally, while the court decision focused on psychiatric research, the rules it imposed would seem to be applicable to any medical research involving incapable individuals, including all pediatric research and research in general medicine involving incapable adults, e.g., stroke and trauma research. If this were the case, parents could not enroll their child suffering from cancer in research which provides a new and hopefully effective treatment if the protocol includes any procedure, such as a bone scan, not performed to directly benefit the child.

Inaccuracies Concerning Risk, Benefit and Capacity

The court decision is clearly predicated on the belief that standard treatments are safe and effective for all, and the belief that psychiatric research exposes participants to huge risk of grievous harm, while providing them with little or no prospect of benefit. Proceeding from this premise, the court viewed the OMH regulations as cavalier regarding participants' safety and dignity, and suggested that this research amounts to the exploitation of individuals chosen precisely because they are available and defenseless. As demonstrated below, however, the court was mistaken on these issues and was unaware of the far reaching, unintended consequences of its decision.

Developing safer and more effective treatments for the most devastating forms of mental illness is, obviously, a high priority for psychiatric research. The involvement of individuals with advanced stages of these illnesses is unavoidable. Treatments which are effective for milder forms of a disease may not be effective for more severe forms. In addition, even when some patients with severe forms of a mental illness respond to available treatments, significant percentages of such patients may not respond or may have intolerable side effects to available treatments. These patients, then, are those most disabled by illness, most likely to lack capacity and most in need of the new forms of treatment which research may produce.

Similarly, treatments which are appropriate for adults may not be appropriate for minors. For example, certain types of antidepressants that are unequivocally beneficial for adults are not effective in children and could, potentially, pose a unique risk for them.[27] This information is known only because of carefully designed research. If such research were prohibited, children who are ill could be exposed to risk because physicians may legally prescribe FDA-approved medications even though they are untested in the patient's age group. Policies designed to protect children by excluding them from research participation have had an adverse impact on treatment for children.[28] In response, the National Institutes of Health has recently issued a policy stressing the importance of the inclusion of children as subjects of clinical research.[29]

Although children are, by definition, legally incapable, adults with serious mental illnesses are not always incapable.[30] However, the inclusion of some individuals who lack decision-making capacity is unavoidable. The OMH regulations, which the court invalidated, permitted such patients to participate only if their involvement was necessary, the research focused on illnesses with which they were afflicted and participation did not conflict with their individual treatment plans.

As to the question of benefits from research, participation is increasingly recognized as an opportunity to access otherwise unavailable treatments which may be safer and/or more effective than standard treatments.[31] For example, AIDS activists protested long and successfully to get government agencies and pharmaceutical manufacturers to make new medications available faster and to more people. In addition, a variety of efforts are underway across the country to stop

health maintenance organizations and insurance companies from refusing to pay for experimental treatments for breast and other cancers.

The *TD* decision, however, suggests that the benefits of research participation are almost nil compared to those from standard treatment.[32] In fact, standard treatments are frequently unsuccessful in psychiatry, as in many other areas of medicine. On the other hand, research has begun to make great strides in developing new medications, such as clozapine and risperidone, which can provide relief to patients with schizophrenia who receive no help or experience intolerable side effects from older treatments. This court decision comes at a time of unparalleled prospects for treatment advances.

As with the issues of benefit, the court failed to meaningfully address the risk issues related to research participation. No one disputes that treatments for psychiatric conditions involve risks to patients. However, to be validly assessed, research risks must be placed in the context of the risks associated with standard treatments for that illness, and to the harm from the illness itself. Medications for serious mental illness involve risks of side effects, whether provided as part of standard treatment or as part of a research protocol. In many cases the likelihood or magnitude of the risks from the medication under investigation may be less than those associated with standard treatments. In any event, research participation does not replace a risk-free treatment.

The court, however, suggests that the risk from standard treatments is small. To see the fallacy in this, one need look no further than the medication haloperidol, decried by plaintiffs as high risk, a standard treatment for schizophrenia long ago approved by the FDA. As to the risks from the illness, they are appallingly high. It is well established that the risk of suicide from affective disorders, including severe depression, is 15 percent,[33] and from schizophrenia is 10-15 percent,[34] compared to .0123 percent[35] in the general population. In addition, these illnesses can destroy a person's independence, occupational effectiveness and interpersonal relationships.

Research participation is certainly not risk-free, but the sequence of the development of new treatments is focused on preventing harm to those involved. Incapable adults or minors participate in clinical trials of new medications only after the completion of appropriate animal trials, safety trials with healthy adults and then trials with symptomatic but capable, consenting adults. The criteria for including and excluding participants, and the monitoring performed during the research, also focus on participant safety.

The *TD* court's view of research reflects the sensational allegations of risk and harm to participants made by Plaintiffs which were neither proved nor rebutted because the litigation focused on abstract legal principles. Plaintiffs based these assertions on investigations into problems, some serious and others minor, which research participants experienced. However, these same investigations determined that, while research participation could not be absolutely ruled out as a factor, it was very likely that the harms suffered by the patients resulted from their underlying illnesses, not the research.[36] Moreover, as noted above, many of the medications, such as haloperidol, a drug that Plaintiffs criticized as high risk because of its very small risk of death, were long ago approved by the FDA as safe and effective for the indicated conditions, and are often the same medications participants would have received as standard treatment if they were not participating in research.

Attention to risk is, needless to say, heightened when protocols include non-therapeutic elements, particularly when incapable adults or minors participate. However, the court took an absolutist approach and announced a prohibition which, we believe, is unwarranted for a number of reasons.

First, the non-therapeutic research elements at issue present only a minor increment over minimal risk, a concept articulated in the federal regulations.[37] Such elements usually involve a diagnostic procedure used throughout medicine, such as a PET scan or lumbar puncture. Second, even though an element of the research may be non-therapeutic, participation overall is expected to be therapeutic. In fact, the OMH regulations required the IRB to balance the risks and benefits and further required each participant's treatment team to determine that participation was not in substantial conflict with his or her treatment plan. To our knowledge, there has been no purely non-therapeutic, more-than-minimal risk research involving incapable individuals conducted in the OMH operated system or in the general hospital psychiatric units which OMH licenses. Third, the federal regulations provide specific and detailed rules permitting parents and guardians to consent to their child's participation in such therapeutic research with non-therapeutic elements.

Non-therapeutic elements are not cavalierly included in research, but they are clearly necessary if complicated diseases and the efficacy of treatments are to be understood. It seems illogical, in an age of unprecedented advances in research, that new non-invasive medical technologies, utilized daily in general medical practice, cannot be included in studies of patients who are unfortunate enough to be afflicted with illness early in life, or who have the most disabling forms of illness, because the procedure is not absolutely risk-free. It is ironic that the newest imaging techniques, which present little risk and hold great promise for understanding and developing treatments for mental illness, are prohibited as the result of a court decision seeking to ban "high-risk" non-therapeutic research, which is already prohibited by the federal and the invalidated OMH regulations and, to our knowledge, was not being conducted in any event.

A realistic and comprehensive analysis of risks and benefits is critical in the case of an individual who may be appropriate for research participation but lacks decisionmaking capacity. Capacity is, of course, a prerequisite for effective decisionmaking and thus is required for the right to self-determination to be meaningful. The definition of capacity, the procedural formality for its assessment and the designation of surrogate decision-makers should be related to the risks and benefits of research participation. In our view, the paradigm

applicable to research participation by incapable adults and minors is far closer to that of medical treatment than to the view that research represents the use of individuals to benefit others.[38] The key issue is the risk/benefit ratio to the participants, considering all the relevant factors. If that ratio is favorable, we fail to see how the goal of learning important information about the participants' illness morally invalidates their participation. Similarly, the possibility that participants, whether capable or incapable, may confuse research treatment with standard treatment is an important matter requiring researchers' best efforts to carefully discuss the issues, but it is not determinative of all the questions presented in these individuals' circumstances.

Unfortunately, the court misconstrued the OMH definition of capacity to give informed consent to research participation.[39] The court suggested that OMH set the threshold unnecessarily high as a way to ignore the individual and allow a surrogate to authorize his or her inclusion in research to which he or she would not consent.

The court's view fails to recognize that the assent of incapable persons is sought and that they must be withdrawn if any objection is expressed at any time (except with a court order as discussed below). It also ignores the prospect that, if the threshold for capacity is set too low, the person can be erroneously determined to be capable and consent to participate without understanding what that means. The definition must balance these concerns. Perhaps the regulation can be faulted for not explicitly stating that the person must be informed of the capacity determination and each step in the process, but it is the uniform practice of OMH researchers to do so. While such drafting questions could be easily corrected, the court seemed to see sinister motives in such matters.

In a similar fashion, the *TD* court focused on the issue of the person assessing the individual's capacity and ruled that he or she must possess uniform qualifications and be strictly independent of the research itself, faulting the OMH regulations (and thus the federal human subjects regulations) for failing to do so. The OMH regulations took the approach that the IRB was in the best position to determine who should conduct the capacity evaluation for a specific protocol, and this approach was appropriate. In protocols involving more than minimal risk, OMH IRBs had required a capacity assessment by a licensed clinical psychologist/psychiatrist not affiliated with the research (usually a member of the treatment team) as well as a separate assessment by a member of the research team. The reasons for an independent assessment of capacity were to avoid an appearance of conflict of interest and, when possible, to involve a member of the treatment team who is familiar with the patient. The second assessment, by a person familiar with the research, served two functions. It was intended to provide a capacity assessment for complex studies by a person with a high level of understanding of the study and it made the research team directly accountable for decisions relating to patient participation in research.

Reading the *TD* decision, it appears that the court's concerns in this regard blended into images of collusion for which there is no evidence in this case. No evidence was presented to suggest that IRBs were not responsibly exercising their discretion to approve the qualifications of the person(s) who assess capacity. If there is an inherent and immutable conflict of interest, such a conflict would appear to exist whenever a clinician or lawyer provides an evaluation or recommendation which could affect that professional's practice.

Compare the situation of an individual needing heart bypass surgery. The surgeon, who has an economic interest in performing operations, generally evaluates the patient's capacity to give or withhold consent. Rarely possessing any training in this area, the surgeon makes the determination in an informal manner. If the patient is viewed as incapable, his or her relative usually gives consent. Guardianship or other formal legal proceedings are extremely rare, and are viewed as unnecessary steps which will result in delay and added costs. The contrast between research, in which consent is formally addressed, and heart bypass surgery, in which it is not, is made more vivid by the fact that this very common surgery results in serious cognitive harm in 6 percent of the cases, and studies have revealed wide variations in surgeons' assessments of the necessity and the benefits of the procedure.[40]

Overruling Patient Objections

A few other matters found to be problems by the court warrant comment. As noted above, if a potential participant is determined to be incapable, informed consent is sought from a surrogate and assent is sought from the person. If the person objects to participation at any time, their wishes are determinative, regardless of capacity and regardless of the consent of a surrogate. The OMH regulations provide for overruling a patient's objection only in a narrow circumstance which, we believe, has not yet arisen.

The unfortunate reality is that there are patients whose conditions present consistent risks of serious harm to self or others. Despite significant progress in psychiatric treatment, there remain some severely impaired individuals for whom nothing works and who may, therefore, remain on locked wards for their entire lives. Hopefully, medications will be developed which can help such patients, and their use during FDA Phase III trials may be indicated.

The OMH regulations provide that if such a situation arises and an incapable patient expresses an objection, the matter could be presented to a court, as now occurs for objections to standard treatment. Only if the court determined by clear and convincing evidence that the person was incapable and the proposed medication was, considering all the relevant factors, in his or her best interests, could treatment through research participation be authorized.

The *TD* court was dismayed that the OMH regulation on this point did not specifically require that written notice be given to the person stating that a court order was being sought. However, the regulation was silent on this point because such notice must be given at the initiation of court action, in accordance with the court's own rules of procedure.[41]

Waiver of Parental Consent

The court also took strong exception to the OMH regulation regarding waiver of parental consent as to minors' participation in research. It characterized the mechanism as permitting the unjustified and unilateral denial of the rights of natural parents. This waiver principle has long been established in the federal regulations,[42] and it allows an IRB to permit a minor to participate without parental consent only if such consent is not reasonably required to protect the child's interests (most often in abuse situations) and an alternate way of protecting the minor's interests is established. The invalidated regulation had added the requirement that the OMH commissioner approve such waivers and the alternate protective mechanisms.

Such parental waivers have been employed, in narrow circumstances, by OMH. Research was initiated to evaluate risk factors and the efficacy of different models of HIV education for gay and lesbian teenagers. Other than the potential risks associated with informing the parents or guardians, the research posed no more than minimal risk to participants. It was known that not all the teens would have discussed their sexual orientation with their parents. As part of the protective mechanism, counselors already working with the adolescents, and independent of the research, agreed to act as their advocates. The IRB determined that, if the advocate and the teen decided that involving the parent would put him or her at risk, parental consent could be waived. The advocates agreed, in writing, to assist the teens in asking questions about the research, withdrawing from the protocol if they became uncomfortable, etc. This careful approach to sensitive issues, in the context of research with life-saving potential, is hardly an assault on parental rights.

HHS Versus FDA Regulations

In the court's discussion of the federal regulations, it is unclear whether the court ignored those adopted by the FDA and other federal agencies or determined them to be substantially inferior to those of the DHHS in protecting the interests of research participants. In fact, both are governed by the "Common Rule,"[43] and the FDA, like DHHS, reviews protocols to "ensure the study poses no unacceptable risks to subjects, is ethically sound, and is likely to achieve the study objectives."[44] The court's decision showed no awareness of the oversight provided by the FDA to studies of investigational drugs and devices or of the reporting requirements imposed by the FDA for these studies, which are stricter than those required under the DHHS human subjects regulations. Similarly, there was no consideration of the system of oversight of IRBs by the FDA which, unlike DHHS, involves routine site visits to review IRB operations and procedures.

Although it never discussed the FDA regulations, the *TD* decision ends with a comment on research funded by pharmaceutical companies—which is under the FDA's jurisdiction. Never mentioned before in the litigation, the court noted the companies' motivations, suggesting that the "race to market" new medications necessitated the rules imposed by the court. Whatever else may be accurate, it is clear that the actual research these companies fund is appropriately regulated and that such research is indispensable. Without such support, the development of major psychiatric and medical treatments including clozapine—the first new antipsychotic effective in significant percentages of patients refractory to traditional treatment—would not have been possible. Once again, the court did not consider the reality of research.

Conclusion

The *TD* court applied broad legal principles to new issues amidst sensational but unsubstantiated claims. Neither those claims, the reality of the scientific enterprise nor the existing regulation of the research process were carefully examined. The ruling imposes rules and processes with unclear benefit to potential research participants. The resulting delays and prohibitions will impede access to the newest and hopefully most effective and safest treatments for desperately ill individuals. In its effort to prohibit abuses that were already prohibited by regulations, the court has impeded necessary and ethical research.

The decision is likely to divert research funding from New York, often to states that have never addressed surrogate research consent. The infrastructure which has made New York a world leader in research, a system produced by significant dedication of funding and talent, is likely to atrophy. Better justification, we believe, would seem necessary for new rules that would cause a decrease in research efforts. This is particularly true when the managed care restructuring of health care may also have a negative impact on research. [45]

The *TD* decision's implications for research may not be limited to New York. The court rejects, without analysis, a central principle of the federal research regulations. Prior to this court ruling, it was clear that an IRB considering a research proposal was expected to determine whether the overall risks to the individual from research participation were reasonable in relation to the overall benefits. That a court can summarily find such a principle to be unconstitutional, suggests that the prevailing approach to a complex bioethical question can be invalidated by rulings of courts with little grasp of the issues. Such a prospect is troubling, particularly as technically and ethically complex areas of research are emerging, such as genetics and cloning.

In addition, the *TD* decision's focus on psychiatric research perpetuates the stigma that surrounds people with mental illness and mental health professionals, in contrast to the rest of medicine. Such regression, cast as progress, is all the more ironic when other recent developments are considered. Long overdue federal laws will go into effect in 1998 which seek to end the disparate treatment between mental illness and other illnesses in health insurance coverage and cost. Similarly, the federal government has recently published rules concerning employment discrimination which make clear that the Americans with Disabilities Act protections cover individuals with both physical and mental infirmities. Mental illness

is not, in the context of social policy, different from other illnesses and disabilities.

In terms of treatment, the pace of improvements in medications for the treatment of mental illness are approaching the progress previously achieved in treating other diseases. As a result, patients are receiving better treatment with more outpatient care and less involuntary commitment. The implications of the *TD* decision stands in stark contrast to these various developments.

Among the most mystifying aspects of the ruling itself are the court's simultaneous statements that it was setting fundamental minimums for research involving vulnerable people, and that those minimums only apply to some (non-federally funded) research. The plaintiffs have appealed on this point to the state's highest court, the Court of Appeals, which will decide whether to extend the rules announced by the intermediate appellate court to federally funded research. Since the case was litigated without a careful examination of the reality of research, it will be difficult to alert the court to the factual errors, analytical deficiencies and practical problems related to expanding the ruling.

Fortunately for the rest of the nation, litigation is not the only forum for considering such matters. In Maryland, a diverse task force of advocates and researchers has been considering the issues of surrogate consent for the participation of incapable adults in medical research. The group, created by the state's attorney general, has struggled with many of the same questions which have been litigated in New York for six years. It appears that, with thorough consideration, it is possible to reach consensus if not unanimity as to the appropriate principles and mechanisms to guide such research.

After two years of work, the Maryland group issued a report which includes proposed legislation addressing the issues across medical research.[46] Among its broad scope are provisions which authorize an IRB to determine that a protocol with both therapeutic and non-therapeutic elements is overall therapeutic, that is, consider each protocol as a whole, in accordance with the federal regulations. It also permits informed consent for an incapable person's participation from his or her relative or close friend based on the best interests of the person.

Although still a bill which has not yet been considered by the Maryland legislature, the recommendations are certain to receive serious attention given the group's diverse and highly respected membership. Since the National Institutes of Health are located in Maryland, the approach adopted there is likely to have national implications for research.

Like all endeavors, medical research is not problem-free. The *TD* decision, however, maligns and singles out psychiatric research without justification. The published media and professional reactions to the ruling reflect this distorted and incomplete portrayal of regulated psychiatric research in New York state. Such skewing of the perceptions of potential participants, policy makers and the public is most unfortunate, particularly when it results from a decision rendered by a court which, we believe, did not have before it the facts needed to truly understand the reality of research.

Endnotes

1. Advisory Committee on Human Radiation Experiments, *Final Report*, Washington, DC: US Government Printing Office, 1995.
2. See, for example, Rebecca Dresser and Peter Whitehouse, "Emergency Research and Research Involving Subjects with Cognitive Impairment: Ethical Connections and Contrasts," *Journal American Geriatrics Society,* 45 (1997) 521-523; Richard J. Bonnie, "Research with Cognitively Impaired Subjects: Unfinished Business in the Regulation of Human Research," *Archives of General Psychiatry*, 54 (1997) 105-111; Jessica Wilen Berg, "Legal and Ethical Complexities of Consent with Cognitively Impaired Research Subjects: Proposed Guidelines," *Journal Law, Medicine and Ethics*, 24 (1996) 18-35; Robert J. Levine, "Proposed Regulations for Research Involving Those Institutionalized as Mentally Infirm: A Consideration of Their Relevance in 1996," *IRB: Review of Human Subjects Research,* Vol. 18, No. 5, 1-5 (Sept.-Oct. 1996); Jay Katz, "Human Experimentation and Human Rights," *St. Louis University Law Journal*, Vol. 38, No. 1 (Fall, 1993) 7-54.
3. "Incapacitated *Research*," *Hastings Center Report,* Vol. 27, No. 2 (1997) 25-27.
4. *TD v. New York State Office of Mental Health and Department of Health*, 228 A.D.2d 95 (1st Dep't, Dec. 5, 1996) (hereafter A*TD* ").
5. *The Global Burden of Disease,* World Health Organization, 1996.
6. The New York Psychiatric Institute is affiliated with Columbia University's College of Physicians and Surgeons and Presbyterian Hospital. The Nathan Kline Institute is affiliated with New York University.
7. It is possible that an involuntarily committed patient could, in order to gain access to an investigational medication, be enrolled in a open label study.
8. Federal Policy for the Protection of Human Subjects, *Federal Register*, Vol. 56, No. 117, June 18, 1991, p2806-2832.
9. 45 CFR 46, 21 CFR 50 and 56.
10. The federal regulations, 45 CFR 46.116, state that consent on behalf of an incapable person must be provided by a legally authorized representative, and while the regulations identify the parents or guardian of a minor as being authorized to provide consent, they are silent as to who can serve as a surrogate for an incapable adult.
11. Research is also conducted at OMH licensed psychiatric units in general hospitals. Authorized by the general hospital's IRB and usually that of an affiliated medical school, OMH does not monitor this research.
12. For a discussion of the underlying rationale and features of the OMH regulations see Susan J. Delano, Jay L. Zucker, "Protecting Mental Health Research Subjects Without Prohibiting Progress," *Hospital and Community Psychiatry*, Vol. 45, No. 6, 601-603, June 1994.
13. Department of Health, Education and Welfare, "Protection of Human Subjects: Proposed Regulations of Research Involving Those Institutionalized as Mentally Infirm," *Federal Register* 43(223) (Nov. 17, 1978) 53950-53956.
14. Robert J. Levine, "Proposed Regulations for Research Involving Those Institutionalized as Mentally Infirm: A Consideration of Their Relevance in 1996," *IRB: Review of Human Subjects Research,* Vol. 18, No. 5 (Sept.-Oct. 1996)
15. John C. Fletcher and Alison Wichman, "A New Consent Policy for Research with Impaired Human Subjects," *Psychopharmacology Bulletin,* Vol. 23, No. 3 (1987) 382-385.
16. One possible, but to our knowledge never used, provision is discussed later in this article and applies to situations where necessary treatment is available only in the context of research and a court order is obtained to override an objection of an incapable person.
17. 45 CFR 46.408.
18. *TD v. OMH*, Complaint, (February 21, 1991) Par. 1.

19. *TD v. OMH*, Complaint, (February 21, 1991) Par. 9.

20. N.Y. Public Health Law, Article 24-A (McKinney's, 1993)

21. *TD v. OMH*, Motion for Summary Judgment, Affidavit of Ruth Lowenkron (Sept. 9, 1992).

22. National Center for Health Statistics, Vital Statistics of the United States, 1993, Vol. 2. Parts A&B, Hyattsville, MD: Mortality Branch, US Department of Health and Human Services, 1993.

23. This particular study was halted for a significant period of time by temporary restraining orders issued by the court, and has been resumed only because of the exemption in the Appellate Division Decision for federally funded research. The exemption for federally funded research is the subject of a challenge before the State Court of Appeals.

24. *TD v. OMH*, Stipulation and Order, March 11, 1996.

25. Formal advance directives, which are rarely executed for standard health care, are even less useful in the research context given any individual's inability to anticipate, when capable, the specific issues which may be involved in a research protocol developed some time later.

26. "...the consent of the committee and the commissioner shall be required with relation to the conduct of human research involving minors, incompetent persons, mentally disabled persons and prisoners." N.Y. Public Health Law Section 2444(2), (McKinney's 1993).

27. P. Jensen "Psychopharmacology of Children and Adolescents with Major Depression: Present Status and Future Directions," *Journal of Child and Adolescent Psychopharmacology,* Vol. 2 (1992) 31.

28. *See, e.g.*, H.C. Shirkey, *Therapeutic Orphans*, *Journal of Pediatrics* 1968, Vol. 72, 119-120.

29. Policy on the Inclusion of Children as Subjects in Clinical Research, NIH Guide, Vol. 26, No 3, Jan. 31, 1997.

30. *Rivers v. Katz*, 67 N.Y.2d 485 (1986).

31. Charo, "Protecting Us to Death: Women, Pregnancy, and Clinical Research: A Consideration of Their Relevance in 1996," 38 *St. Louis University Law Review*, 135 (1993) See also OPRR Report No. 94-01, April 25, 1994.

32. *TD* at 113.

33. C. Miles, "Conditions Predisposing to Suicide: A Review," *J. Nerv. Ment. Dis.* 64:231-246, 1997.

34. C.B. Caldwell, D. Gottesman, "Schizophrenia—A High Risk Factor for Suicide: Clues to Risk Reduction," *Suicide and Life Threatening Behavior* 22(4): 479-493.

35. Centers for Disease Control 1985 Suicide Surveillance Report, U.S. Department of Health and Human Services, Public Health Service, Atlanta, GA, 1970-1980.

36. Note that research has indicated the risks of participation in therapeutic research may be no greater than those of treatment in other settings and the risks of non-therapeutic research may be no greater than those of everyday life. See Philippe V. Cardon, F. William Dommel, Jr., and Robert R. Trumble, "Injuries to Research Subjects: A Survey of Investigators," *New England Journal of Medicine,* Vol. 295, No 12 (Sept. 16, 1976) 650-654.

37. 45 CFR 406.

38. Jay Katz, "Human Experimentation and Human Rights," *St. Louis University Law Review,* 38 (1993) 7-54.

39. ACapacity means the patient's ability to understand the purpose, nature, risks, benefits and alternatives (including nonparticipation) of the research, to make a decision about participation, and to understand that the decision about participation will involve no penalty or loss of benefits to which the patient is otherwise entitled." 14 New York Code of Rules and Regulations 527.10 (c) (2).

40. Gary W. Roach, Marc Kanchuger, Christina Mora Mangano, Mark Newman, Nancy Nussmeier, Richard Wolman, Anil Aggarwal, Katherin Marschall, Steven H. Graham, Catherine Ley, Gerard Ozanne and Dennis T. Mangano, "Adverse Cerebral Outcomes After Coronary Bypass Surgery," *New England Journal of Medicine,* Vol. 335 No. 25 (Dec. 19, 1996) 1857-1863.

41. N.Y. Civil Practice Law and Rules Section 308, (McKinney's 1993).

42. 45 CFR 46.408(c).

43. Federal Policy for the Protection of Human Subjects, *Federal Register* Vol. 56, No. 117, June 18, 1991, p2806-2832.

44. United States Government Accounting Office, "Scientific Research: Continued Vigilance Critical to Protecting Human Subjects," GA0/HEHS-96-72 (March, 1996) at page 9.

45. Ernest Moy, Anthony J. Mazzaschi, Rebecca J. Levin, David A. Blake and Paul F. Griner, "Relationship Between National Institutes of Health Research Awards to U.S. Medical Schools and Managed Care Market Penetration," *Journal of the American Medical Association*, Vol. 278, No. 3 (July 16, 1997) 217-221.

46. Office of the Maryland Attorney General, *Second Report of the Attorney General's Research Working Group,* Annapolis, Md., May 5, 1997.

Update—Litigation Concerning Research

January, 1998

New York's highest Court issued a brief, narrow decision in the research case (*TD v. OMH)* which nullifies the lower court's lengthy constitutional rulings on surrogate consent. The high Court ruled that, having invalidated the OMH regulation on grounds that the Department of Health (DOH) had sole authority regarding research, the lower court's further rulings on constitutional issues were "inappropriate" and "unnecessary under the circumstances."

By deciding the case on this technical basis, the high Court summarily set aside the constitutional rulings which we had argued were thoroughly flawed. Those arguments are summarized in this article.

The substantive issues concerning the research participation of incapable individuals are now being reviewed by an advisory committee established by DOH and will be formally addressed by that agency's commissioner. Proposals on these matters are also being drafted by the President's National Bioethics Advisory Commission and by the National Institutes of Health. OMH has been involved with both efforts and we anticipate that new guidelines will be issued shortly. However, further litigation in New York on the issues discussed in the article appears likely.

Please contact me if you would like more information on these matters.

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The Legal Impact of Physical Impact

by Claudia O. Torrey*

Introduction

The following information is an abbreviated monograph about *Metro-North Commuter Railroad Company v. Buckley*.[1] The *Buckley* case concerns itself with the health contaminant asbestos. The format for the abbreviated monograph will entail an overview of the facts, the issues, the holding, a decision discussion and a conclusion.

Facts

Respondent Michael Buckley ("Respondent") was employed by Petitioner railroad company ("Petitioner") in 1985 as a pipe fitter. Respondent's duties required him to maintain and repair pipes within the steam tunnels of Grand Central Terminal in New York City. The pipes were covered in a white insulation material that had to be removed prior to any maintenance and/or repair work.

According to Respondent, the white insulation material scattered particles everywhere.[2] Fans used to make the stifling heat bearable would further spread the white insulation material that had already fallen to the floor. In Respondent's words, the atmosphere was "just like taking baby powder and shaking it."[3] The white insulation material would cover Respondent from head to toe. The material would even enter Respondent's nose and mouth. Respondent and his co-workers were often called the "snowmen of Grand Central."[4]

In September of 1986, Petitioner was cited for various asbestos-related violations following a fire in the Grand Central Terminal. Despite being aware since the mid-1970s that asbestos was a carcinogen, Petitioner made no attempt to either warn Respondent and his co-workers that the white insulation material covering them was asbestos, or to train them in the safe handling of asbestos.

Eleven months later, Petitioner required its pipe fitters to attend an asbestos awareness class, whereupon Respondent learned that the white insulation material covering the pipes in the steam tunnels was asbestos. Respondent became aware of many important facts regarding asbestos, including how deadly it can be, that his smoking habit coupled with asbestos exposure could increase his risk of cancer, and how to remove asbestos using the glove bag method and a half-face respirator. Neither the glove bag method nor the half-face respirator properly protected Respondent from asbestos exposure.[5]

Respondent was exposed to asbestos for three years (1985-1988). In 1989, Respondent started receiving periodic medical check-ups for cancer and asbestosis. In 1991, Respondent reduced his 15-year habit of smoking up to a pack of cigarettes per day to an average of one cigarette per day. To date, it appears that Respondent's check-ups have revealed no evidence of cancer or any other asbestos-related disease.[6]

Buckley's 1994 complaint was precipitated by the 1990 case of *Giammona v. Metro-North Commuter Railroad*.[7] *Giammona* involved an action by the plaintiff under the Federal Employers' Liability Act (FELA)[8] to recover damages for emotional harm and the costs of continuous medical treatment. The plaintiff alleged that the defendant failed to provide a safe work environment when the plaintiff was exposed, without warning and without protective clothing, to harmful levels of asbestos and other hazardous materials. According to the plaintiff, the inhalation of the asbestos fibers started a scarring process in his lungs. Such a process rendered him more susceptible to a variety of diseases.[9]

Pursuant to Federal Rules of Civil Procedure 12(b)(6), the defendant moved to dismiss the plaintiff's suit for failure to state a claim upon which relief can be granted. Senior District Judge Knapp denied the motion. Judge Knapp held that the plaintiff had alleged actual physical injury with regard to the scarring process in his lungs. Judge Knapp expressly declined to address the issue of whether a plaintiff, suing under the FELA, could recover for emotional distress absent a showing of physical harm.[10]

In 1994, Respondent filed suit in federal District Court against Petitioner under the FELA.[11] Respondent sought relief for negligent infliction of emotional distress (NIED), and the costs of future medical monitoring (MM). Respondent became the test plaintiff for all employees of Petitioner that were exposed to asbestos.

A jury trial began in February of 1995. Before the jury could deliberate on the evidence, Petitioner moved for a judgment as a matter of law pursuant to Federal Rules of Civil Procedure 50(a). The District Court judge granted the motion and dismissed the jury.[12] Respondent appealed to the Second Circuit, which promptly reversed and remanded the case.

The Second Circuit held that Respondent's contact with the asbestos in the Grand Central Terminal steam tunnels had created a "physical impact," as previously defined by the United States Supreme Court in *Consolidated Rail Corporation v. Gottshall*.[13] Thus, the Second Circuit concluded that a reasonable person could infer that Respondent feared for his life, thereby creating a valid claim for NIED. The Second Circuit also held that Respondent could recover his MM costs. The Supreme Court granted certiorari in order to review the Second Circuit's holdings under *Gottshall*.[14] The Second Circuit opinion was reversed and remanded.

In a recent telephone conversation with Respondent's attorney, this author was informed of a remand decision delivered by the United States Court of Appeals for the Second Circuit on Wednesday, March 18, 1998. The remand decision was delivered in the form of a *mandate* that vacated the Second

Circuit opinion and affirmed the judgment of the District Court in accordance with the opinion of the Supreme Court.

Issues

The issues addressed by the Supreme Court were (1) whether or not Respondent, negligently *exposed* to a hazardous substance, successfully alleged a NIED claim under the FELA; and (2) whether or not Respondent, negligently exposed to a hazardous substance but not manifesting a physical injury, could recover future MM costs under the FELA.

Holdings

The Supreme Court, with Justice Breyer writing for the majority, held that Respondent, under *Gottshall*, could not recover damages under the FELA on either the claim of NIED or the claim of future MM costs. The opinion of the Second Circuit was reversed and remanded for further proceedings consistent with the Court.

Justice Ginsburg, joined by Justice Stevens, concurred with the majority opinion concerning the denial of the NIED claim, but dissented from the majority opinion regarding the denial of future MM costs.

Decision Discussion

Part I

A decision discussion concerning the FELA would be remiss without a brief historical overview of its enactment. The FELA was enacted by Congress in response to a high number of railroad accidents.[15] During the early 1900s, rail transportation was the primary mode of surface travel. There existed an oversupply of labor, unions were virtually nonexistent and contemporary concepts of work-related disability claims were unknown.[16] Because railroad work was (and is) dangerous, railroad employees were suffering from some of the highest accident rates in history.[17]

Discontented with the high level of risk involved in most railroad work, many railroad employees "lobbied" Congress to enact some type of legislation that would compensate and protect them and their families.[18] Railroad labor wanted a no-fault compensation system, but the railroads rejected this idea and settled for a tort-oriented statute requiring proof of fault.[19]

The first FELA was enacted in 1906.[20] However, it was subsequently found unconstitutional because it attempted to regulate *intrastate* railroad activities.[21] The FELA was reenacted in 1908 so that it only regulated *interstate* railroad activities.[22]

Among other things, the 1908 FELA included a pure comparative negligence standard,[23] a modified contributory negligence standard[24] and the ability of an employer to assert the defense of assumption of risk. In 1910, the FELA was amended to allow concurrent state and federal jurisdiction.[25] In 1939, Congress eliminated the assumption of risk defense,[26] created a three-year statute of limitations[27] and made it a crime for anyone to interfere with a person attempting to provide information on a FELA claim.[28] Thus, the overall effect of the FELA was (and is) to shift liability onto the railroad entities, and not the railroad employees whose work the entities profited therefrom.[29]

The Court has interpreted Congress' intent for the FELA, a humanitarian remedial statute, with a liberal standard of construction.[30] For over 40 years, such an interpretation has been a guiding principle because the FELA was founded on concepts of common law negligence and injury.[31]

Part II

The initial provision of the FELA states, in relevant part, that "(e)very common carrier by railroad . . . shall be liable in damages to any person suffering injury while he is employed by such carrier in such commerce, or, in case of the death of such employee, to his or her personal representative, for the benefit of the surviving widow or husband and children of such employee . . . for such injury or death resulting in whole or in part from the negligence of any of the officers, agents, or employees of such carrier."[32] It is this provision and its use of the word "injury" that laid the groundwork for the *Gottshall* Court.

The *Buckley* Court relied heavily on its earlier opinion in *Gottshall*. *Gottshall*, like *Buckley*, involved NIED claims by railroad employees under the FELA. Since the *Gottshall* case consolidated two cases, a factual review of both cases is appropriate:

Gottshall v. Consolidated Rail Corporation[33]

In the summer of 1988, James Gottshall and his friend Richard Johns were part of a nine-member work crew sent by the defendant to the Watertown Secondary near Turbotville, Pennsylvania, to replace some defective track.[34] The conditioning and age of the crew were not conducive to either the strenuous work or the hot weather.[35] The supervisor, Michael Norvick, forced the crew to work hard and did not give them any breaks.[36]

After two-and-a-half hours, Johns collapsed.[37] It is alleged that the defendant knew of Johns' weight problem, high blood pressure, cardiovascular disease and his medication needs.[38] Johns regained consciousness only to collapse five minutes later.[39] Gottshall came to Johns' aid and administered cardiopulmonary resuscitation (CPR), while Norvick went to get medical assistance.[40] Due to communication difficulties, medical help did not arrive until almost an hour later.[41] In the interim, Johns died. His body was covered and laid beside the track, where Norvick ordered his crew back to work.[42] Three hours later, after the coroner had determined the cause of death to be a heart attack, Gottshall carried Johns' body to the ambulance.[43]

Gottshall and Johns had been close friends for approximately 15 years.[44] According to other colleagues, Gottshall

was emotionally upset throughout the entire incident and continued to cry after leaving the work site.[45] The next day, after being reprimanded by the defendant for attempting to administer CPR to Johns, Gottshall was sent back to the same track as the day before.[46] Several days later, Gottshall became so preoccupied with the death of Johns that he left work sick and never returned.[47]

Afraid that he would die in the same condition as Johns, Gottshall suffered from insomnia, loss of appetite, suicidal preoccupations and nightmares.[48] Gottshall was diagnosed as suffering from depression and post-traumatic stress disorder.[49] After two more physicians confirmed the diagnosis, Gottshall subsequently filed suit in federal District Court against the defendant for emotional and physical injuries caused by the defendant's alleged negligence in creating the circumstances surrounding Johns' death.[50] The District Court granted the defendant's motion for summary judgment, stating that Gottshall had failed to satisfy any elements of a recognized action for recovery.[51] The Court of Appeals reversed and remanded for trial, stating that FELA's liberal recovery policy should guide the court in determining whether the victim's emotional injury was genuine, giving credence to a NIED claim.[52]

Carlisle v. Consolidated Rail Corporation[53]

Alan Carlisle worked for the defendant as a supervisor of all rail operations in the Philadelphia area.[54] Carlisle's responsibilities, as well as his stress, increased because of the defendant's sharp work force reduction and the risks involved in working with the defendant's aging railstock and outdated switching equipment.[55] Carlisle became increasingly anxious with the defendant's failure to alleviate these safety concerns because of a potential slow-down in the defendant's schedules.[56]

By 1988, Carlisle was a trainmaster. This required him to work long hours in hazardous conditions.[57] The defendant's cutbacks meant that Carlisle continued to work double duty as a supervisor of dispatchers.[58] After a consecutive 15-day stretch of working 12- to 15-hour days, Carlisle had a nervous breakdown.[59]

Carlisle filed suit in federal District Court under the FELA for NIED.[60] Carlisle testified that the defendant was nonresponsive to his complaints regarding the excessive hours and stresses of his job.[61] The District Court held that the defendant was negligent in failing to provide a safe workplace, due to the unreasonably stressful and dangerous conditions.[62] The Third Circuit affirmed the jury verdict in favor of Carlisle.[63] It appears that the Third Circuit expanded on its holding in the previous case by imposing liability on employers for emotional injuries caused by the foreseeable, job-related stress of their employees.[64]

Justice Thomas, writing for the *Gottshall* majority, noted that "although common-law principles are not necessarily dispositive of questions arising under FELA, unless they are expressly rejected in the text of the statute, they are entitled to great weight. . . . Because FELA is silent on the issue of NIED, common-law principles must play a significant role in our decision."[65] Justice Thomas noted that the injury considered in a NIED claim is mental or emotional, apart from the tort law concepts of pain and suffering.[66] The NIED injury is caused by the negligence of another and not directly brought about by a physical injury, but may manifest itself in physical symptoms.[67]

The fact that the common law right of NIED has been around since late in the last century,[68] and is a viable claim under the FELA,[69] was not the hard issue for the *Gottshall* Court. The salient concern for the *Gottshall* Court seemed to be in establishing a limit to or boundary of recovery for NIED claims under the FELA. Accordingly, Justice Thomas laid out the main three main common law tests that have developed for a NIED claim.

The first test that the *Gottshall* Court looked at regarding a NIED claim was the *physical impact* test.[70] The test originated over a century ago, and was utilized by most of the industrial states at the time Congress enacted the FELA in 1908.[71] The physical impact test requires a NIED plaintiff to have contemporaneously sustained a physical impact (no matter how slight), or injury due to the defendant's conduct.[72]

The second test the *Gottshall* Court reviewed was the *zone of danger* test. This test is predicated on the realization that "a near miss may be as frightening as a direct hit."[73] The zone of danger test limits recovery for emotional injury to those plaintiffs who sustain a physical impact as a result of a defendant's negligent conduct, or who are placed in immediate risk of physical harm by that conduct.[74]

The third test enunciated by the *Gottshall* Court was the *relative bystander* test. This test was first outlined in *Dillon v. Legg*.[75] The *Dillon* court rejected the zone of danger test regarding an emotional injury for a plaintiff, and suggested that a plaintiff's recovery turns on whether the defendant could have reasonably foreseen the emotional injury to the plaintiff.[76] The *Dillon* court substantiated its suggestion with three factors for consideration:

> (1) whether plaintiff was located near the scene of the accident as contrasted with one who was a distance away from it. (2) whether the shock resulted from a direct emotional impact upon plaintiff from the sensory and contemporaneous observance of the accident, as contrasted with learning of the accident from others after its occurrence. (3) whether plaintiff and the victim were closely related, as contrasted with an absence of any relationship or the presence of only a distance relationship.[77]

The *Gottshall* Court quickly dismissed the relative bystander test as being an inappropriate rule in the FELA context.[78] Besides lacking historical support, most jurisdictions that adhere to the relative bystander test limit recovery to per-

sons who witness the severe injury or death of a close family member.[79] Presumably, only railroad employees (and their estates) may bring FELA claims.[80] It would be a rare occurrence for a worker, during the course of his employment ("on-the-job"), to witness the injury or death of a close family member.[81]

"Respondent in the Buckley case was exposed to asbestos, but did not suffer from an actual injury or disease. The pivotal point seems to be that Respondent's exposure to asbestos did not place him at risk of imminent harm, as such was stated in the Gottshall *zone of danger test."*

The *Gottshall* Court adopted the zone of danger test suggested by the railroad company because in its opinion, the zone of danger test best reconciled the concerns of the common law with the principles underlying FELA jurisprudence.[82] The zone of danger test effectively narrows the class of persons allowed to assert a NIED claim under the FELA.

Writing for the *Gottshall* dissent, Justice Ginsburg thought it strange that the majority would choose the zone of danger test for NIED FELA claims, since there is no unitary common law governing claims for NIED.[83] The NIED "common law" exists not in the singular, but in the plural.[84] While the rule the Court has selected is consistent with one common law rule that some states have adopted, it is inevitably inconsistent with others.[85] According to the dissent, "[t]he 'zone' rule . . . seems . . . inappropriate for a federal statute designed to govern the discrete category of on-the-job injuries sustained by railroad workers. . . . [O]ur charge from Congress is to fashion remedies constantly 'liberal,' and appropriately 'enlarged to meet changing conditions and changing concepts of industry's duty toward its workers.'"[86]

Justice Souter concurred with the *Gottshall* Court, but wrote separately to express his view of the Court's duty in interpreting FELA.[87] That duty is to develop a federal common law of negligence under FELA, informed by reference to the evolving common law.[88] Justice Souter concluded by stating that the Court was faithful to said duty because there can be no question that adoption of the zone of danger test is well within the discretion left to the federal courts under FELA.[89]

Arguably, there are those who would purport that the *Gottshall* Court expressly narrowed the FELA's historical precedent of liberal construction.[90] However true that may be, a sound case could be made for the proposition that the facts presented by Respondent in *Buckley*, which were theoretically weaker than those in *Gottshall*, were destined to fail—a necessary consequence of the proverbial "handwriting on the wall."

Respondent in the *Buckley* case was exposed to asbestos, but did not suffer from an actual injury or disease. The pivotal point seems to be that Respondent's exposure to asbestos did not place him at risk of imminent harm, as such was stated in the *Gottshall* zone of danger test.[91] The *Buckley* Court points out that Respondent's set of facts are illustrative of the problems in separating meritorious NIED claims from trivial NIED claims.[92] Respondent presented very, very little evidence of his emotional distress, apart from his own testimony.[93] Respondent continued to work with the asbestos material, though he could have transferred elsewhere,[94] and, despite physician warnings, Respondent continued to smoke for several years after he became aware that he was working with asbestos.[95] These actions bolstered Petitioner's assertion that Respondent was never within any zone of danger and, therefore, had no viable foundation for a NIED claim under the FELA.

The *Buckley* concurrence[96] opined that Respondent's asbestos exposure had constituted a physical impact within the context of the *Gottshall* zone of danger test.[97] However, because Respondent did not present objective evidence of severe emotional distress, the concurrence agreed with the *Buckley* Court that the NIED claim should fail under the FELA.[98]

Respondent's set of facts unfortunately played right into some of the concerns expressed in *Gottshall*—that is, FELA cases require guidance from the common law, and the common law restricts recovery for NIED on several policy grounds: the potential for a flood of trivial suits, the possibility of fraudulent claims that are difficult for judges and juries to detect, and the specter of unlimited and unpredictable liability.[99] Great weight was given to unlimited liability.[100]

The current practitioner may be in her or his right to think that any confusion about employer liability for a NIED claim under the FELA has been settled in the wake of the *Gottshall* decision, especially given the outcome in *Buckley*. Clearly, it can be argued, the *Gottshall* zone of danger test for a NIED FELA claim helps potential litigants to review the validity of their claim(s) and thereby limit potentially unnecessary litigation. The zone of danger test seeks to allow NIED FELA recovery without requiring a per se physical injury, yet curtails unlimited and unpredictable liability. Therefore, "'[b]ecause the etiology of emotional disturbance is usually not as readily apparent as that of a broken bone following an automobile accident, courts have been concerned . . . that recognition of a cause of action for (emotional) injury when not related to any physical trauma may inundate judicial resources with a flood of relatively trivial claims, many of which may be imagined or falsified, and that liability may be imposed for highly remote consequences of a negligent act.'"[101]

Part III

The next issue the *Buckley* Court reviewed was Respondent's claim for future MM costs.[102] At the outset, the *Buckley* Court pointed out that their denial of Respondent's NIED claim necessitated denial of the future MM costs claim.[103] Thus, Respondent did not have a viable claim for future MM costs because the alleged costs were not connected to an emotional injury.

In a rather convoluted, less than articulate fashion, the *Buckley* Court assumed that Respondent wanted a lump sum payment of his future MM costs.[104] This assumption was gleaned from the fact that Respondent stated he wanted an amount of money sufficient to compensate him for future MM expenses.[105] The Court recognized such a request as existing in common law as a separate, tort law cause of action permitting the recovery of medical cost damages in the form of a lump sum.[106] However, the Court did not find sufficient support in the common law for the unqualified rule of lump sum damages.[107] According to the Court, the FELA does not contain a tort liability rule of that unqualified kind.[108]

The *Buckley* dissent is not sure that the majority opinion actually reverses the Second Circuit's decision regarding Respondent's claim for future MM costs.[109] The dissent is annoyed that "the Court ruminates on the appropriate remedy without answering the anterior question" of whether Respondent has a claim for relief.[110] "We do not know from the Court's opinion what more a plaintiff must show to qualify for relief."[111]

Moreover, the dissent states that if the Court deems what ordinary tort law permits for future MM recovery as inappropriate under the FELA, then, for the sake of guidance to the lower courts, the Court should outline elements for a compensable MM claim.[112] The Court's enigmatic decision allows Respondent to replead a claim for relief of future MM costs, but such request must be in a form other than a lump sum.[113] "[T]he Court resists the straightforward statement that would enlighten courts in this and similar cases: A claim for MM is cognizable under the FELA; it is a claim entirely in step with 'evolving common law.'"[114]

To say that the current practitioner is left confused by the *Buckley* Court's decision regarding future MM costs under the FELA is to state the obvious. The *Buckley* dissent tackles the issue much more succinctly. The dissent may prove to be the foundation for clearer guidance in this area.

Conclusion

There are probably a number of practitioners who will view the *Gottshall* case as finally closing a door left half open.[115] For support, they could easily point to the *Buckley* case! It is unfortunate that Respondent in *Buckley* was not more proactive in concern for his health, regarding his workplace exposure to asbestos.

Respondent might have bolstered his NIED claim by submitting evidence of Petitioner's failure to follow standards promulgated by the federal Occupational Safety and Health Act (OSHA).[116] Although violations of OSHA standards are not necessarily negligence per se in a FELA case (no binding effect on railroads as a safety statute), OSHA standards may be admitted into evidence as a showing of some type of applicable standard of care.[117]

"The Court's enigmatic decision allows Respondent to replead a claim for relief of future MM [medical monitoring] costs, but such request must be in a form other than a lump sum."

In particular, Respondent could have utilized OSHA standards in asserting his claim for future MM costs. It should be noted that OSHA does not apply to state public employers like Petitioner.[118] But, New York State has adopted OSHA standards for its public employers.[119] Needless to say, if Petitioner had complied with New York State law, Respondent may have been spared the costs he now seeks to recover.[120]

Unlimited and unpredictable liability was of great concern to the *Gottshall* Court. This concern was one of the primary reasons the zone of danger test was chosen as the applicable standard for NIED FELA claims.

The Judicial Conference Report made several recommendations based on their findings that asbestos-related litigation had created many problems for the court system (volume delay); caused many pre-trial delays; and exhausted defendant assets, potentially creating the untenable situation of future claimants not being compensated at all.[121] According to the Leigh Report, workplace injuries and illnesses cost an estimated $171 billion each year and result in approximately 6,500 deaths from injury, and in over 60,000 deaths from disease.[122] The Leigh Report also notes that between 66,000 and 111,000 new cases of cancer are caused by occupational factors each year.[123] It will be interesting to watch the development(s) of *Gottshall* and its progeny.

Endnotes

1. __ U.S. __, 117 S. Ct. 2113, 138 L. Ed. 2d 560 (1997) ("*Buckley*").
2. *Buckley v. Metro-North Commuter Railroad*, 79 F.3d 1337, 1340 (2d Cir. 1996) ("Second Circuit").
3. *Id*.
4. *Id*.
5. *Id*. at 1341.
6. *Supra* note 1, at 2116.

7. 750 F. Supp. 662 (S.D.N.Y. 1990).
8. 45 U.S.C. §§ 51-60 (1994) (FELA).
9. *Supra* note 7, at 663.
10. *Id*. at 664.
11. Second Circuit at 1341.
12. *Id*. at 1342.
13. 512 U.S. 532, 114 S. Ct. 2396, 129 L. Ed. 2d 427 (1994) ("*Gottshall*"). *See infra* notes 33-90 and accompanying text for a discussion of *Gottshall*.
14. *Supra* note 6.
15. Eugene W. Herde, *FELA—Should It Be Abolished?*, 17 FORUM 407, 409 (1981).
16. *Id*. at 410.
17. *Id*. at 418. *See also* Arnold B. Elkind, *Should the Federal Employers' Liability Act be Abolished?*, 17 FORUM 415 (1981).
18. *Id*. at 415.
19. *Id*.
20. Pub. L. No. 59-219, 34 Stat. 232 (1906).
21. *Howard v. Illinois Central Railroad*, 207 U.S. 463, 28 S. Ct. 141, 52 L. Ed. 297 (1908).
22. *Supra* note 8.
23. 45 U.S.C. § 52.
24. 45 U.S.C. § 53.
25. 45 U.S.C. § 56. The amendment also extended venue provisions to allow plaintiffs to file suit in any jurisdiction where the defendant resided or did business, or where the cause of action arose. 28 U.S.C. § 1445(a) (1994).
26. 45 U.S.C. § 54.
27. *Id.*
28. *Supra* note 8, 45 U.S.C. § 60.
29. *Tiller v. Atlantic Coast Line Railroad Co.*, 318 U.S. 54, 58, 63 S. Ct. 444, 87 L. Ed. 610 (1943) (Congress created the FELA as a federal remedy that would shift the human overhead of doing business from employees to their employers); *Gaston v. Flowers Transportation*, 866 F.2d 816, 818 (5th Cir. 1989) (analyzing the 1908 Senate Report to determine the purpose behind the statute).
30. *See Urie v. Thompson*, 337 U.S. 163, 69 S. Ct. 1018, 93 L. Ed. 1282 (1949); *Rogers v. Missouri Pacific Railroad Co.*, 352 U.S. 500, 77 S. Ct. 443, 1 L. Ed. 2d 493 (1957); *Kernan v. American Dredging Co.*, 355 U.S. 426, 78 S. Ct. 394, 2 L. Ed. 2d 382 (1958) ("*Kernan*").
31. *See Atchison, Topeka and Santa Fe Railway Co. v. Buell*, 480 U.S. 557, 568, 107 S. Ct. 1410, 94 L. Ed. 2d 563 (1987); *Rogers v. Consolidated Rail Corp.*, 948 F.2d 858, 862 (2d Cir. 1991); *Edsall v. Penn Central Transportation Co.*, 479 F.2d 33, 35 (6th Cir. 1973).
32. *Supra* note 8, 45 U.S.C. § 51.
33. 988 F.2d 355 (3d Cir. 1993).
34. *Id*. at 358.
35. *Id*.
36. *Id*.
37. *Id*.
38. *Id*.
39. *Id*.
40. *Id*.
41. *Id*. at 359.
42. *Id*.
43. *Id*.
44. *Id*.
45. *Id*.
46. *Id*.
47. *Id*.
48. *Id*. at 360.
49. *Id*.
50. *Gottshall v. Consolidated Rail Corp.*, 773 F. Supp. 778 (E.D. Pa. 1991).
51. *Id*.
52. *Supra* note 33.
53. 990 F.2d 90 (3d Cir. 1993).
54. *Id*. at 92.
55. *Id*.
56. *Id*.
57. *Id*.
58. *Id*.
59. *Id*.
60. *Carlisle v. Consolidated Rail Corp.*, 790 F. Supp. 521 (E.D. Pa. 1992).
61. *Id*.
62. *Id*.
63. *Supra* note 53.
64. *Id*. at 97.
65. *Supra* note 13, at 544.
66. *Id*.
67. *Id*.
68. *Id*. at 545.
69. *See Erie Railroad Co. v. Collins*, 253 U.S. 77, 40 S. Ct. 450, 64 L. Ed. 790 (1920); *Bullard v. Central Virginia Railway*, 565 F.2d 193, 197 (1st Cir. 1977).
70. *Supra* note 13, at 547.
71. *Id*.
72. *Id*.
73. *See* R.N. Pearson, *Liability to Bystanders for Negligently Inflicted Emotional Harm—A Comment on the Nature of Arbitrary Rules*, 34 U. FLA. L. REV. 477 (1982); *id*.
74. *Id*. at 548.
75. 68 Cal. 2d 728, 441 P.2d 912 (1968) ("*Dillon*").
76. *Supra* note 74.
77. *Id*. (citing *Dillon*).
78. *Id*. at 556.
79. *Id*.
80. *Id*.
81. *Id*.
82. *Id*. at 554.
83. *Supra* note 13, at 571.
84. *Id*. at 572.
85. *Id*.
86. *Id*. (citing *Kernan*).
87. *Supra* note 13, at 558.
88. *Id*.
89. *Id*. at 559.
90. *Supra* note 13, at 559-60 (Ginsburg, J., dissenting, joined by Blackmun, J., and Stevens, J.).
91. It is well known that disease symptoms from exposure to hazardous substances like asbestos often take a long time to develop. *See* Judicial

Conference, "Report of the Judicial Conference Ad Hoc Committee on Asbestos Litigation" (1991) ("Judicial Conference Report") (The Chief Justice of the United States appoints the committee). Thus, use of a test with the term *imminent* seems incredulous when dealing with a hazardous substance like asbestos.

According to *Webster's Third New International Dictionary* (1981) (unabridged), the word "imminent" refers to something: ready to take place, near at hand, impending, menacingly near, or hanging threateningly over one's head. It is noted that the underlying effect of the *Gottshall* decision, with regard to impacts that don't "show up" right away, seems to require one to wait until they are sick before bringing a NIED FELA suit. At that point, hopefully, the affected railroad worker(s) will be able to connect their alleged illness to the hazardous substance encountered (X) years ago.

92. *Supra* note 1, at 2119.
93. *Id*.
94. *Id*.
95. *Id*.
96. *Id*. at 2124-25 (Ginsburg, J., concurring, joined by Stevens, J.).
97. *Id*. at 2124.
98. *Supra* note 96. *See also supra* note 13, at 571. This author notes that even though the Second Circuit found for Respondent, the court acknowledged that the fact that Respondent complained of his fears and concerns to his supervisors, to the Metropolitan Transit Authority Inspector General, and to state authorities still created *slim* evidence for a NIED FELA claim. *Supra* note 2, at 1346.
99. *Supra* note 13, at 557.
100. *Id*. *See also* Id. at 545-46.
101. W. Prosser and W. Keeton, TORTS § 54, at 359-61 (5th ed. 1984).
102. *Supra* note 1, at 2121-24.
103. *Id*. at 2121.
104. *Id*. at 2122.
105. *Id*.
106. *Id*.
107. *Id*. at 2124.
108. *Id*.
109. *Id*. at 2126 (Ginsburg, J. dissenting, joined by Stevens, J.).
110. *Id*.
111. *Id*.
112. *Id*. at 2127, 2129.
113. *Id*. at 2130.
114. *Id*. (Souter, J., concurring, citing *Gottshall*, 512 U.S. at 558).
115. *Cf. Buell supra* note 31, at 567 ("[W]e do not decide today whether purely emotional injuries are cognizable under the FELA").
116. *See* 29 U.S.C. §§ 651 *et seq*. (1985) ("OSHA").
117. *Robertson v. Burlington Northern Railroad Co.* (9th Cir. 1994).
118. 29 U.S.C. § 652(5) (1985).
119. N.Y. Labor Law § 27-a(1)(a) (1986 and Supp. 1997).
120. *Supra* note 96, at 2128.
121. *Supra* note 91.
122. J. Paul Leigh, *Occupational Injury and Illness in the United States: Estimates of Costs, Morbidity and Mortality*, 157 ARCHIVES INTERNAL MED. 1557 (1997) ("Leigh Report").
123. *Id*.

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IRS Warns Tax-Exempt Hospitals on Alliances

by Francis J. Serbaroli

The competitive pressures on non-profit hospitals brought about by drastic changes in the economics of health care have forced these institutions to think and act more like businesses. Among the many innovations that would have been almost unthinkable in years past are the many types of joint ventures that non-profits have entered into with for-profit entities. These have been a source of much-needed capital for the non-profits, as well as a way of sharing the risks and benefits of providing new facilities and extending the range of medical services. Preserving the tax-exempt status of the non-profit hospital while structuring a workable joint venture has always been a major concern in these transactions. Just as the joint venture momentum has been picking up, the Internal Revenue Service has issued a long-awaited Revenue Ruling[1] that may derail some contemplated deals, force a radical restructuring of others and send many more back to the drawing board.

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Background

In recent years, larger for-profit healthcare providers like Columbia/HCA and Tenet have approached or been approached by non-profit hospitals both large and small to discuss possible relationships ranging from management contracts to outright sale. In some situations, a hospital board may want to sell or transfer its hospital to a new joint venture company formed by the not-for-profit and a for-profit, thereby enabling the hospital to obtain an infusion of capital while also allowing the hospital's board to retain a degree of control over how the hospital is operated going forward. It is this degree of control that is at the heart of the IRS' new ruling. Apparently prompted by VHA and other alliances of non-profit hospitals concerned over the intrusion of investor-owned companies in acquiring hospitals,[2] the new Revenue Ruling requires that in order for a non-profit hospital corporation to retain its tax-exempt status under Section 501(c)(3) of the Internal Revenue Code ("I.R.C.") after entering into the joint venture, the non-profit participant must retain more than 50 percent control over the joint venture, and must "give charitable purpose priority over maximizing profits."

Examples

The Revenue Ruling cites two hypothetical cases that result in opposite conclusions. In the first, A is a non-profit tax-exempt hospital, and B is a for-profit corporation that owns and operates a number of hospitals. B wants to invest in A, which needs additional funding, so they form C, a new limited liability company, to which A contributes all of its operating assets including its hospital, while B also contributes assets. In return, A and B receive ownership interests in C proportional to their respective contributions. C's governing board consists of three individuals chosen by A and two by B. A's appointees are community leaders not on the hospital's staff and not otherwise engaged in business transactions with the hospital. C's governing documents may only be amended with the approval of both owners, and a majority of at least three board members must approve major decisions relating to C's operations, including:

- C's annual capital and operating budget
- distribution of C's earnings
- selection of key executives
- acquisition or disposition of health care facilities
- contracts in excess of a certain dollar amount
- changes to the types of services offered by the hospital
- renewal or termination of management contracts

C's governing documents also require:

- that the hospital be operated "in a manner that furthers charitable purposes by promoting health for a broad cross section of its community";
- that the members of C's governing body have a duty to operate C in a manner that furthers charitable purposes by promoting health in a broad cross section of the community, and that this duty overrides any duty to operate C for the financial benefit of its owners; and
- that all returns of capital and distributions of earnings made to C's owners be proportional to their ownership interests.

The terms of C's governing documents must be legal, binding and enforceable under applicable state laws. C will be treated as a partnership for federal income tax purposes, and A intends to use any distributions it receives from C to fund grants to support activities that promote the health of A's community and to help the indigent obtain health care. Lastly, none of the officers, directors, or key employees of A who were involved in making the decision to form C were promised

employment or any other inducement by C or B and their related entities.

The Revenue Ruling analyzes the language of I.R.C. § 501(c)(3) and a number of cases interpreting the statute, and concludes that A can retain its 501(c)(3) status under the facts as stated. The IRS cites several reasons for its conclusion:

- A's activities will consist of the health care services it now provides through C as well as making grants using income derived from C to support education and research and to help provide healthcare to the indigent;
- A's interest in and income from C will be proportional to the value of the assets it invested in C;
- C's charitable purposes will have priority over maximizing profits for its owners; and
- A's voting control of C's board and on major decisions will ensure that the assets it owns and the activities it conducts through C are used primarily to further exempt purposes.

Management

The Revenue Ruling further hypothesizes that C enters into a management contract with a company that is unrelated to A or B to provide day-to-day management of the hospital. The management agreement is for a five-year period, renewable for additional five-year periods by mutual consent; the management company is paid a fee based upon C's gross revenues; the contract terms and conditions, including the fee structure and term, are reasonable and comparable to what other firms receive for similar services at similarly situated hospitals; and C may terminate the agreement for cause. Since the terms and conditions of the management contract are reasonable, including the terms for renewal and termination, it will not affect A's 501(c)(3) tax-exempt status.

The second hypothetical offered in the Revenue Ruling posits D as a 501(c)(3) tax-exempt non-profit corporation that owns and operates an acute care hospital. E is a for-profit corporation that owns and operates a number of hospitals and provides management services to hospitals that it doesn't own. D and E form a limited liability company, F, to which D contributes all its operating assets including its hospital, and to which E also contributes assets. In return, D and E receive ownership interests proportional and equal in value to their respective contributions. F's governing board consists of three individuals chosen by D and three by E. D will appoint three community leaders experienced in hospital matters but not on the hospital staff and not otherwise engaged in business transactions with the hospital. F's governing documents may only be amended with the approval of both owners, and a majority of board members must approve certain major decisions including:

- F's annual capital and operating budgets
- distributions of F's earnings over a required minimum
- usually large contracts
- selection of key executives

F's corporate purpose is to construct, develop, own, manage and operate the health care facilities it owns, and to engage in other health care-related activities. F is treated as a partnership for federal income tax purposes, and all capital returns and earnings distributions are made to F's owners proportional to their ownership interest.

F then enters into a management contract with a wholly owned subsidiary of E to manage F. The contract is for five years, renewable for five-year periods at the discretion of E's subsidiary. F may terminate the agreement only for cause. E's subsidiary will be paid a management fee based on F's gross revenues. The remaining terms of the contract including the fee structure are reasonable and comparable to what other firms receive for similar services at similarly situated hospitals. D also agrees to approve the selection of two individuals to serve as F's chief executive officer and chief financial officer, both of whom previously worked for E in hospital management and have business expertise, and both of whom will work with E's subsidiary to oversee F's day-to-day management. Both will be compensated at rates comparable to executives at similarly situated hospitals.

D intends to use any distributions it receives from F to fund grants to support activities that promote the health of D's community and to help the indigent obtain health care. Substantially all of D's grants will be funded by its earnings from F. In addition, D's projected grant making and its participation as an owner of F will constitute D's only activities.

Unlike the situation involving A, the IRS concludes that D will be in violation of 501(c)(3) requirements when it forms F and contributes all its operating assets to F because D has failed to establish that it will be operated exclusively for exempt purposes. The IRS reasons that, even though D will still be engaged in providing health care services through F and conducting grant-making activities with income generated through F, D (unlike A) will not be engaging primarily in activities that further an exempt purpose. The IRS cites the absence of a binding obligation in F's governing documents for F to serve charitable purposes or otherwise provide its services to the community as a whole as evidence that F will be able to deny care to segments of the community such as the indigent. In addition, since D and E share control of F, the IRS concludes that D will not be able to initiate programs within F to serve new health care needs within the community without the agreement of at least one of the E-appointed governing board members. The IRS further reasons that, as a business, F will not necessarily give priority to the community's health care needs rather than to profits. Other negatives cited by the IRS in this scenario are:

- that the primary source of information to the D-appointed board members will be the E-subsidiary management company, and F's officers who were formerly associated with E.

- that the E-subsidiary management company will have broad discretion over F's activities and assets, and may also unilaterally renew the management agreement.

The IRS concludes, therefore, that any benefit to a for-profit participant in such a joint venture must be merely "incidental" to the furtherance of an exempt purpose, and if it cannot be established that the joint venture will be operated exclusively for exempt purposes, the 501(c)(3) status of the non-profit participant will be placed in jeopardy.

The Revenue Ruling comes as no surprise given the IRS' frequently-expressed concern over whether tax-exempt health care providers are or are not fulfilling their tax-exempt purposes. The clear purpose behind this "warning shot" is to remind tax-exempt providers that their status is a privilege conferred largely on the basis of the benefit they provide to their communities, and that it must not be used as a vehicle for sheltering profit-making activities, no matter how well-intended. Also telling is the fact that the Revenue Ruling was issued on March 4, took effect March 23, and even though it has the weight of regulation, the IRS did not afford any comment period. Furthermore, it appears that the ruling will apply retroactively, so that existing joint ventures that do not meet the strict criteria set forth in the Revenue Ruling will have to be restructured if the tax-exempt status of one or more of the joint venture participants is to be protected.

This important ruling will undoubtedly have at least a temporary chilling effect upon new joint ventures. Existing or contemplated joint ventures between tax-exempt health care providers and for-profit entities will have to hew closely to the IRS' standards, which may cause many to be abandoned, particularly since for-profit participants generally want at least a 50 percent ownership interest and control. It is also important to note that this ruling applies to joint ventures between tax-exempt hospitals and physicians. In many of those ventures, the physicians seek at least 50 percent control, and unless properly structured, such ventures may affect a hospital's 501(c)(3) status.

While the IRS' Revenue Ruling clarifies some aspects, there are many variations among these joint ventures and the IRS will probably find itself receiving more requests for revenue rulings in situations that don't fit the facts of the two hypotheticals presented. Given the potential menace that lies in the subtleties of these transactions, tax-exempt hospitals contemplating or already involved in joint ventures with for-profits should take appropriate steps to assure that they do not run afoul of the guidelines set forth in this Revenue Ruling and previous rulings addressing other proposed ventures.

Endnotes

1. IRS Revenue Ruling 98-15, published March 23, 1998.
2. "IRS Rule Might Slow Joint Ventures," *Modern Healthcare*, March 9, 1998. *See, also* letter dated December 10, 1996 from VHA to Marcus Owens, Director, IRS Exempt Organizations Division, published in *Highlights & Documents*, February 5, 1997.

'NET WORTH

by Margaret Moreland Murray*

The words "current awareness" make me uneasy. I am always sure that there is *something* going on I should know more about. I hear snippets of information—at meetings, on the radio or TV—and I would like to find out more, but. . . . Now there is a solution that won't require lots of research time or expense. There are many good Internet sites that not only include current legal materials in full text, but also organize them so they are easily accessible.

COURT DECISIONS

N.Y. Court of Appeals **http://www.law.cornell.edu/ny/ctap/overview.html** Just recently, while driving in my car, I heard on the radio that the New York Court of Appeals had decided a case involving frozen human embryos. If the name of the case was mentioned, I didn't hear it. I'm not involved in anything that would justify the expense of using Westlaw or Lexis, but I would like to know more about this case. The Cornell Law School Legal Information Institute's Internet site is the answer. It has Court of Appeals opinions from January 1992 to the present, organized in easily accessible ways, and in full-text format. Tables list the opinions by decision date and then by name and topic; key word searching is also supported. On May 8 it only took me minutes to find the opinion in *Kass v. Kass*, which had been handed down on May 7! Pending cases of the current term are also listed with brief descriptions, together with the names and telephone numbers of counsel. In addition, this site includes information on the background, jurisdiction and judges of the Court of Appeals. There is also a hyperlink to "Rules of the New York Court of Appeals," in full-text format, put up by the *New York Law Journal*. For those who would like to be apprised on an on-going basis of significant Court of Appeals decisions, there is even a form to fill out for a free subscription to *liibulletin-ny*, which will be transmitted via e-mail.

U.S. Second Circuit **http://www.law.pace.edu/lawlib/legal/us-legal/judiciary/second-circuit.html** Pace University School of Law began publishing Second Circuit decisions on the Internet, in full-text format, in September 1995. The decisions are organized by month and then listed alphabetically. The entire database of decisions may also be searched by title, citation, docket number, decision date, plaintiff name, defendant name or judge, or with Boolean operators against the full text (the traditional method of searching Westlaw and Lexis). Also, Boolean and proximity searching may be performed to locate summary orders. A nice feature of this page is a notice of when the Web site was last updated (on May 7 it was current up through May 6). The site also includes hyperlinks to other circuit opinions and the opinions of the U.S. Supreme Court, as well as a link to the Internet site of Touro Law Center, another source for Second Circuit opinions.

U.S. Supreme Court **http://www.supct.law.cornell.edu/supct/** Once again, the Cornell Law School Legal Information Institute has assembled legal information in an outstanding manner. The full text of decisions from May 1990 to the present are included, as well as the current court calendar, schedule of oral arguments and background on current cases. Decisions from the current term are arranged by decision date. Topical tables have been created for this past term's major decisions and for all decisions from 1990 to the present. There are also tables of first and second party names for each year from 1990 through 1997. A collection of "historic" (before 1990!) decisions has also been assembled. Five hundred and eighty decisions are included, searchable by party name, topic or opinion author. Additionally, hyperlinks are provided to similar historic collections. Other Supreme Court information included here: galleries of current and former justices, the full text of Supreme Court rules, descriptions of the organization, authority and jurisdiction of the Court and a glossary of legal terms.

LEGISLATION

N.Y. Assembly Legislative Information System **http://www.assembly.state.ny.us/ALIS/** At a recent Pace Law colloquium, "Children at Risk: Legal and Policy Barriers to Access to Health Care and a Healthy Environment for the Nation's Children," a speaker mentioned new New York requirements relating to the availability of chiropractic referrals. Since, once again, I had never read or heard anything about this requirement, I started my research on the Internet. Our state assembly and senate both have Web sites, but the better one is the assembly's. Under bill information, one can search 1997/1998 assembly and senate bills by number or keyword. However, keep in mind that keyword searches are performed against bill summaries, not against the full text of the bills. The information retrieved includes the bill summary, sponsor(s), actions on the bill, votes, the memo (which includes the purpose and a summary of provisions) if available, and the full text. I was able to locate the 1997 senate bill S.05594, which was intended to amend the Insurance Law and the Public Health Law in order to provide "access to and equivalent coverage for the diagnosis and treatment of conditions, complaints, ailments, disorders and injuries by a licensed doctor of chiropractic." It was signed into law in August 1997 as Chapter 426. Under "New York State Laws" the researcher can find the full text of the N.Y. Constitution, the consolidated and unconsolidated laws (on May 7 it was current through March 23) and the 1998 Chapter Laws. The assembly's current public hearing schedule

and committee agenda are also included. There are also a number of legislative reports and Ways & Means reports that can be viewed and downloaded in full text.

THOMAS Legislative Information on the Internet **http://thomas.loc.gov/** To my mind, there is no better U.S. legislative source on the Internet than this Web site authored by the Library of Congress. Its organization is clear, its content complete and it is as current as possible. To start, the researcher can do a "quick search" with bill number or word/phrase against the full text of bills introduced in the 105th Congress. Bill summary and status, as well as enacted Public Laws by number, are available back to 1973. The full text of bills back to 1989, House roll call votes back to 1990 and Senate roll call votes back to 1989 have also been included. Major legislation from the 105th and 106th Congresses is also organized by topic, popular/short title, bill number/type and enactment date. On this Web site you can also find the *Congressional Record*, its predecessors and index, committee information including home pages, reports from the 105th and 104th Congresses, and schedules, oversight plans and selected hearing transcripts from House committees. Selected historical documents and two monographs on the legislative process are also included in full-text format. Finally, there are hyperlinks to legislative, executive, judicial, state and local Web sites.

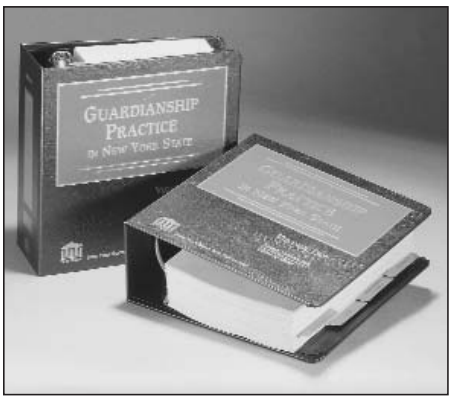
PERIODICALS

New York Law Journal **http://www.nylj.com/site.html** Unless you become a paid subscriber to the on-line version, this site is not a substitute for the print version. However, you can access current top stories, the full text of selected court decisions, summaries of the most important New York and federal opinions and other selected data from the newspaper. I think the best feature is its "Court Rules Update," which in May included the full text of the comprehensive amendments to the attorney admission rules, new Bankruptcy Court electronic case filing rules, amendments to the medical records rules issued by the Chief Administrative Judge, an amendment to Rule 50.3 of the Eastern District's Guidelines for the Division of Business, the complete rules of the Court of Appeals and many, many other current changes.

Law Journal Extra! **http://www/ljx,com/** This Web site is published by American Lawyer Media, Inc. and has a more national focus on current legal news.

***Lawyer/Librarian for Research Services, Pace University School of Law.**

Guardianship Practice in New York State



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This comprehensive guide to article 81 of the Mental Hygiene Law was written and edited by leading practitioners from throughout New York State, many of whom have participated in seminal guardianship cases. In this collaborative effort, the book's contributors discuss their experiences and provide readers with their insights and work products. The diverse group of judges, attorneys, physicians and health care professionals approaches key guardianship issues with a unique perspective, to provide readers with creative and innovative practice options.

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