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A Message from the Section Chair

I hope that you have had a fine summer and that it included some relaxation time. Our field of law can carry a great deal of stress. As a result, it is truly important to allow ourselves an opportunity for rest and renewal.

The Section continues to grow thanks to your enthusiasm. As our numbers increase and committee membership flourishes, we can look forward to increased visibility and the ability to provide more services to our members. This past year our educational programs and legislative efforts have truly placed the Section "on the map." The job bank has received great reviews and is already helping health lawyers and potential employers to find one another. Thanks again to Robert Swidler who is overseeing the bank and the Section's Web site. If you haven't seen it, I encourage you to pay a visit.

Upcoming Events!

The Health Law Section has a large number of events planned for the next few months. A Section meeting will take place at the Best Western Motel, Albany, November 13-14, 1997. In addition to meetings of all committees, a program on Corporate Compliance is scheduled for November 13, 1997, and a discussion of The Health Care Continuum in conjunction with the Elder Law Section is set for the following day. Please watch your mail for further details.

Phil Rosenberg reports that the next CLE offering, "An Introduction to Health Care Financing and Reimbursement," will take place in New York City (December 1, 1997), Uniondale (December 16, l997), Buffalo (December 5, l997) and Albany (December 3, l997). The outline is very comprehensive and the list of speakers outstanding. This promises to be a great course, be it as an introduction or a refresher.

Medical Marijuana

Now that I have your attention, please mark your calendar for the New York State Bar Association's 121st Annual Meeting. Our section's events will be held Wednesday, January 28, 1998. We are currently putting final touches on a program dealing with contemporary issues in managed care. Also, in keeping with the Section's reputation for not ignoring current controversial issues, we are planning a program about medical uses of marijuana. A member luncheon complete with guest speaker and committee meetings will also take place at the Annual Meeting. Please plan to attend.

New Editors

Dale Moore has resigned as Editor of the *Health Law Journal* due to her increasing responsibilities as Associate Dean of Student Affairs and as Professor at Albany Law School. She will, however, continue to chair the Publications

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Committee. Thanks, Dale, for getting the *Journal* off the ground so quickly and for creating a high quality periodical.

I am pleased to introduce Barbara Atwell and Audrey Rogers as our new Editors, effective as of the next issue. As professors in the health law program at Pace University School of Law, Audrey and Barbara bring knowledge, enthusiasm (and hopefully a bevy of law students) to the *Journal*. Welcome aboard!

A Final Word

This is your Section. Please participate in its committees, continuing legal education programs and the Annual Meeting. Also, communicate with your Committee Chair or Executive Committee if you have any suggestions on how the Section can do a better job. Thanks!

Barry A. Gold
Chair

From the Editor

This issue highlights several important matters. First, Claudia Torrey's column summarizes the promulgation of federal regulations allowing for waivers of consent in certain types of "emergency" research on human subjects. Whether such research is ethical, or, indeed, even necessary, is controversial. Proponents would argue that the subject populations, *e.g.*, unconscious head-trauma victims, are clearly incapable of consenting to participation in research that might benefit them but must be initiated within a very small time window of opportunity (two to four hours after the injury); accordingly, waivers of consent are essential. Opponents, on the other hand, would point out that the requirement that surrogate consent be obtained might reduce subject accrual and hence be inconvenient, but would not make it impossible to conduct the research. Another controversial human subjects question was addressed recently in New York in a case involving involuntarily committed psychiatric patients. Marie Roccapriore's article discusses that case. Howard Krooks, a regular contributor, has again supplied a valuable update on elder law. He reviews recent cases as well as the status of federal statutory provisions criminalizing certain asset transfers. Finally, Colleen Galligan provides an overview of health care reform following the failure of the ambitious Clinton plan.

I am pleased to announce that two new editors will be assuming responsibility for the *Health Law Journal*, beginning with the next issue. They are Professors Barbara L. Atwell and Audrey Rogers, both of whom teach at the Pace University School of Law. I know that they welcome the submission of articles that would be of interest to Health Law Section members. You may reach them at the following addresses and phone numbers:

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Thanks to all of you who have provided support, assistance, and encouragement during the "start-up" phase of the *Health Law Journal*. I hope that you will continue to support, assist, and encourage Barbara and Audrey in their endeavors.

Dale L. Moore
Editor

For Your Information

by Claudia O. Torrey*

On November 1, 1996, final rules and regulations developed by the United States Food and Drug Administration (FDA) regarding informed consent, the protection of human subjects, and emergency medical research became effective. These rules and regulations were published in the Federal Register on October 2, 1996 (the "Final Rule"),[1] and are entitled "Protection of Human Subjects; Informed Consent."

The Final Rule authorizes an exception to the Code of Federal Regulations' known requirement of obtaining informed consent from human subjects participating in research/clinical trials.[2] Specifically, the Final Rule applies to a discrete class of human research subjects who are in need of *emergency* medical intervention, but who *cannot* give informed consent because of their life-threatening conditions and their lack of legally authorized persons to represent them. This emergency research exception (ERE) is codified in Title 21, Part 50 of the Code of Federal Regulations.[3] It is also noted that the National Institutes of Health (NIH), under the auspices of the Department of Health and Human Services, have aligned their regulations with those of the FDA.[4] According to the background information in both the FDA and NIH materials, the ERE to informed consent is a necessary response to the growing opinion among medical experts that current regulations make high quality research in emergency situations difficult, at best, or almost impossible to carry out at a time when the need for such research is becoming increasingly recognized.

Typically, the type of institutions/entities that will primarily be affected by the ERE are national medical centers and/or laboratories. Such entities are governed by an institutional review board (IRB) at their facilities.[5] The IRB *must* make sure that the protocols involving the ERE are being performed under the umbrella of either a separate investigational new drug application (IND) or an investigational device exemption (IDE).[6]

The FDA received numerous comments, pro and con, regarding the ERE. There have been, and continue to be, ethical debates and explicit concerns as to whether or not the ERE is the beginning of a "slippery slope" trend toward easing patient consent/notification rules.

Attorneys in the health care field may be interested to know that some of the explicit concerns involved issues of preemption, and whether or not the ERE is "at odds" with the United States Supreme Court's decision in *Cruzan v. Director, Missouri Department of Health*.[7] The FDA claims it does not intend to preempt any existing state or local requirements that provide additional protections for human subjects involved in an ERE.[8] With regard to the *Cruzan* case, the Supreme Court held, among other things, that although Ms. Cruzan allegedly did not wish to remain on life-sustaining treatment, her desire was not clear enough for the Court in its attempt to balance the state's interest in the preservation of life and the patient's desire to terminate life-sustaining treatment should she face life as a "vegetable."[9] Thus, the FDA states that unlike the *Cruzan* case, the ERE focuses upon the preservation of life when an individual's wishes are unknown.[10]

The ERE is being utilized by a number of medical facilities with regard to a new blood substitute product known as HemAssist (HA).[11] The HA product, developed by Baxter International Inc. of Deerfield, Illinois ("Baxter"), is a hemoglobin therapeutic designed to increase the survival rate of patients suffering from blood loss and shock caused by severe trauma.

According to a November 21, 1996, Baxter press release, the trauma protocol will have enrolled patients by early 1997. It is designed to evaluate the outcomes of accident and trauma victims resuscitated with the current standard of care, compared to those resuscitated with HA in addition to the current standard of care. HA is an oxygen-carrying solution that is intravenously administered to patients. It is being studied for its potential to temporarily replace lost blood, restore blood pressure and increase oxygen delivery to tissues. HA is made from human hemoglobin—the iron-containing protein that enables blood to transport oxygen to tissues throughout the body. It does not require typing or cross-matching, can be administered immediately to the critically ill and injured, and can be stored for much longer periods of time than whole blood.

A May 6, 1997, Baxter press release announced that Baxter's marketing authorization application for HA was accepted for filing by the European Medicines Evaluation Agency (EMEA). Based upon data collected in a European cardiac-surgery research trial, Baxter is seeking EMEA approval to market HA as an alternative to blood in cardiac-surgery patients following cardiopulmonary bypass. If approved, Baxter will be allowed to market HA in all 15 European Union countries.

There are no easy answers for the potential questions the ERE raises. Perceived advances in emergency medicine necessarily dictate venturing into "choppy waters." Companies, like Baxter, who are in the vanguard of medical research view the ERE as a positive move forward by the federal government—this remains to be seen.

Currently, according to a policy staffer at the FDA's Office of Health Affairs, plans are being developed for a public meeting update on the ERE. The tentative meeting dates are September 29-30, 1997, in the Washington, D.C., area.

Endnotes

1. 61 Fed. Reg. 51,498-51, 531.
2. 21 C.F.R. pt. 50, § 50.20.
3. The ERE is codified at 21 C.F.R. § 50.24, and is added to subpart B. It is entitled "Exception from informed consent requirements for emergency research."
4. 61 Fed. Reg. 51, 531-51, 533; *e.g.*, 45 C.F.R. pt. 46.
5. 21 C.F.R. pt. 56.
6. 21 C.F.R. pt. 50, § 50.24(d).
7. 497 U.S. 261 (1990).
8. *E.g.*, 61 Fed. Reg. at 51,525-51,526.
9. *E.g.*, 497 U.S. at 285.
10. *E.g.*, 61 Fed. Reg. at 51,505-51,506.
11. HemAssist™ is also known as Diaspirin Cross-linked Hemoglobin or DCLHb.

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T.D. v. The New York State Office of Mental Health: New York State Regulations Violate Rights of Vulnerable Research Subjects

by Marie Carol Roccapriore*

This article discusses a recent decision by the New York State Supreme Court, Appellate Division, First Department, in *T.D. v. The New York State Office of Mental Health*.[1] In this case, the court ruled that certain Office of Mental Health (OMH) regulations governing research on human subjects were promulgated without the proper authority and permitted actions that are unconstitutional pursuant to both the federal and state constitutions.[2] Part I of this article provides an overview of ethical and legal standards and a brief history of human research. Part II defines several important terms. The focus of Part III is the decision and reasoning of the court in the *T.D.* case. Part IV offers some comment about the impact of this case for the future regulation of research.

Part I

The actions of professionals are substantially guided by ethical and legal principles.[3] In the practice of medicine, specifically the practice of medical research, there has been much debate regarding the ethical standards that researchers, many of whom are also physicians, should observe. When an ethical *should* becomes a legal *must*, however, is determined by legislatures or courts.[4]

More than two decades ago, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (the "Commission") identified three fundamental ethical principles as particularly relevant to the ethics of research involving human subjects: respect for persons, beneficence, and justice.[5] Promotion of personal autonomy and the protection of those with diminished autonomy is the essence of the respect-for-persons principle, which is implemented in part by requiring informed consent.[6] The principle of beneficence creates an obligation to shelter individuals and to promote technological advancement through research.[7] The renowned Hippocratic Ethic of "do no harm" is a general rule that falls within the scope of the beneficence principle.[8] To research with beneficence, the researcher must weigh the risks and benefits and anticipate the experiment will do good as well as not harm the subjects.[9] The principle of justice requires "a fair and equitable sharing of both burdens and benefits."[10] "[T]he class of persons that share the burden should receive an appropriate benefit, and the class primarily intended to benefit shares a fair proportion of the risks and burdens."[11] These three principles provide the fundamental ethical concepts on which most rules and regulations that govern research are based.[12]

Based on the above principles, six ethical norms for research involving human subjects may be identified:

1. good research design;
2. competent investigators;
3. a favorable balance of harm and benefit;
4. informed consent;
5. equitable selection of subjects; and
6. compensation for research-related injury.[13]

Although each norm is equally important when analyzing any research project, the following discussion will address only the favorable balance of harm and benefit and informed consent, because those two areas are directly dealt with in the rationale of the appellate division in the *T.D.* case.

Historical Information

Fifty years ago, 23 Nazi physician-experimenters who conducted horrific nontherapeutic, nonconsensual concentration camp research on humans were tried at Nuremberg.[14] The Nuremberg Code was a product of this trial.[15] In these alleged *experiments*, "Nazi physicians [claimed they] kill[ed] for the sake of the health of the state, 'to preserve—to "heal" [their] people.'"[16] The Nuremberg Code consists of ten nonwaivable provisions that protect a research subject's individual rights. It applies internationally and remains "the most authoritative legal and ethical [human rights] document" in the realm of human experimentation.[17]

The Nuremberg Code was not satisfactory to many researchers, who claimed it did not appropriately change with the times.[18] In 1964, the World Medical Association answered researchers' calls for change by promulgating the Declaration of Helsinki to replace the Nuremberg Code with a more benevolent ethics model.[19] The Declaration of Helsinki supplied a set of ethical guidelines, which, most pointedly, separated the term "research" into two categories: therapeutic and nontherapeutic.[20] This alteration caused great confusion, which continues to date, in classifying actions and interpreting and applying regulations.

Meanwhile, in the United States, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research published "The Belmont Report."[21] The Belmont Report expanded on those three general principles of ethics that pervade every rule and regulation concerning human experimentation.[22] Subsequently, Congress enacted a statute authorizing the promulgation of regulations to deal specifically with research on human subjects.[23] These regulations are presently modified and enforced by federal agencies such as the Department of Health and Human Services (HHS) and the Food and Drug Administration

(FDA).[24] The federal regulations, however, apply only to research involving investigational drugs or devices subject to FDA jurisdiction, projects conducted or supported by the federal government, and research conducted under the auspices of an institution that has signed an "assurance" by which it promises to apply the same standards to all research, whether that research otherwise would be subject to federal jurisdiction or not.[25] Individual states are left to enact more specific legislation. In New York, such legislation may be found in article 24-A of the Public Health Law, which was enacted in 1975.[26] In a memorandum accompanying this legislation, its sponsor recounted some local reprehensible experiments performed on humans.[27] These included cancer experiments on the elderly at the Jewish Chronic Disease Hospital, as well as hepatitis vaccine experiments on retarded children at Willowbrook State Hospital, both of which occurred in the 1960s.[28] With this legislation, the state of New York regulates human research for which the investigator is not obligated to follow the federal regulations.[29]

Pursuant to section 2446 of this statute, OMH wrote a series of regulations that went into effect in November of 1990.[30] The purpose of the regulations was "to promote mental health research while providing a panoply of protections for mental patients."[31] Although these regulations may have promoted mental health research, the First Department found they did not adequately protect mental patients.

Part II

Several terms are frequently used terms when discussing human research. They include: therapeutic, experimental, minimal risk, consent, and vulnerable. The definitions of these terms provide significant meaning to the remainder of the discussion.

Research is termed "therapeutic" when there is a possibility of a direct benefit to the subject-patient that would be important to this person's health.[32] Nontherapeutic research confers no direct benefit to the subject-patient.[33] The distinction is important because if an experiment is considered therapeutic to the subject-patient, different considerations come into play.[34]

Research involves "minimal risk," according to HHS, when "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."[35] The demarcation between minimal risk and more-than-minimal risk is not clear, because it must be decided on a case-by-case basis.[36]

"Informed consent" was first recognized as a prerequisite to participation in experimentation in the Nuremberg Code and it remains a requirement today. "Modern informed consent doctrine . . . is meant to safeguard the patient's interest in both decision-making autonomy (liberty) and dignity."[37] This is true with the incompetent patient as well as the competent patient.[38] One's capacity should not change the need for proper consent or refusal.

"Vulnerable" persons have diminished capacity for self-determination and may be more complacent about participating in research.[39] People identified as being in vulnerable classes include prisoners, students, the elderly, children, those with malignant diseases, the psychotic or emotionally disturbed, those with language problems, ethnic minorities, the unborn, the indigent and the uneducated.[40] The vulnerable subjects in the *T.D.* case were psychiatric patients, both children and adults.[41]

Part III

The plaintiffs in *T.D. v. The New York State Office of Mental Health* included six people involuntarily hospitalized in OMH-supervised psychiatric facilities.[42] These individuals were "adjudicated mentally incapable of giving or withholding informed consent . . . [and were] medicated over [their] objections."[43] Although they had not yet been forced to participate in experimentation projects, they feared the possibility. If they were considered "incapable," the regulations in question would have permitted OMH to make them involuntary subjects.[44] These plaintiffs brought their lawsuit against the state Office of Mental Health, its commissioner, and the Commissioner of the New York State Department of Health.[45]

The plaintiffs claimed that the OMH regulations permitted the following experiments, to which they feared being subjected:

1. greater than minimal risk nontherapeutic experiments on incapable adults and children;
2. possibly therapeutic experiments on children, performed without the consent of the children's parents or guardians;
3. possibly therapeutic experiments, not approved by a court, performed on incapable adults;
4. possibly therapeutic experiments performed on incapable adults over their objection; and
5. experiments performed on subject-patients without their knowledge.[46]

The plaintiffs essentially made two arguments: that the regulations exceeded the authority of OMH and that they violated the constitutional rights of the subject-patients.

Statutory Issues

First, the plaintiffs questioned the authority of the OMH to promulgate regulations authorizing human experimentation. The trial court found,[47] and the appellate division affirmed,[48] that the authority to promulgate rules governing human subject research lies with the Commissioner of Health, not the Commissioner of the Office of Mental Health, pursuant to a

specific legislative mandate. Therefore, the regulations were invalid.[49]

Inquiry was also raised whether federal or state law applies to OMH experiments. New York's Public Health Law article 24-A and HHS regulations govern human experimentation. The New York statute does not apply to research that complies with federal regulations.[50] Accordingly, the New York statute would appear to apply to nonfederally funded human experiments at OMH-licensed and -operated facilities.[51] The Department of Mental Hygiene, however, had filed a Multiple Project Assurance, which is essentially a promise made to HHS that the entity under whose auspices research is being conducted will voluntarily comply with HHS regulations for the protection of human subjects, even if the research does not fall into one of the categories covered by federal regulation. By such voluntary compliance with *all* applicable federal regulations, the defendants could escape a requirement of compliance with article 24-A.[52] The federal regulations call for a researcher to report certain events to a federal agency called the Office for Protection from Research Risks (OPRR).[53] Instead of reporting to OPRR, however, OMH made the required reports to an institution called the Research Foundation for Mental Hygiene.[54] The Research Foundation and OMH have a close relationship, in that the foundation is intimately involved with OMH research projects.[55] Given that the defendants had elected, in effect, to report to themselves rather than OPRR, both the trial[56] and appellate[57] courts found that state law, thus, article 24-A, applied.

The trial court further found that the nonfederally funded experiments to which the plaintiffs feared being subjected violated article 24-A. Article 24-A sets out procedural requirements regarding informed consent for minors, incompetent persons, and mentally disabled persons, and the approval of a human research review committee and the Commissioner of Health to conduct the research must be sought before the research begins.[58] Defendants "admittedly ha[d] not obtained the consent of the Commissioner of Health to conduct the research involving minors, incompetents and mentally disabled persons."[59] This inaction was a direct contravention of the statutory requirement; therefore, the defendants were not complying with the procedural requirements of article 24-A.

The trial court found the regulations were invalid and unenforceable for these reasons. On appeal, the First Department affirmed the reasoning and decision of the lower court, but went further to address the constitutional questions raised by the plaintiffs. Although the following findings were superfluous in terms of invalidating the regulations, the court believed they were necessary to guide the institutions' future actions, with or without the regulations.[60]

Constitutional Issues

The Law

Mentally ill and involuntarily committed patients maintain their fundamental liberty interest to refuse antipsychotic medication, except when the state has a compelling interest in exercising its police or *parens patriae* power.[61] The starting point for determining involuntarily committed patients' rights to refuse *experimental* medication is the law surrounding the administration of standard medication to involuntarily committed patients.[62] Both case law and regulations are applicable.

Procedural due process requires an appeal process be available to the patient, in which decisions to administer antipsychotic medication are reviewed and an opportunity to defend his or her position is permitted.[63] Administrative review, established by regulations, must be exhausted before an institution's determination reaches judicial review.[64] At a judicial hearing regarding capacity, the court applies a de novo standard of review, for which the court need not give weight to any previous findings in making its decision, and the patient is entitled to representation.[65] Once a court decides a patient is incapable, a surrogate is appointed who has authority to consent or refuse for the potential subject-patient.[66] If these protections are not provided, then a vulnerable population of human beings is potentially subject to abuse.

The New York Court of Appeals has found constitutional authority[67] for the proposition that an involuntarily committed individual has a fundamental right to refuse antipsychotic medication.[68] "The common law right [of those with mental illness] to refuse medical treatment is 'coextensive with the patient's liberty interest protected by the due process clause of our State Constitution.'"[69] A patient's refusal of such medication may be overridden by an institution only when procedures designed to protect privacy and due process rights are followed.[70] Patients' refusal rights may also be overridden in certain emergency situations, such as when a person, whether incapacitated or not, presents an imminent danger to self or others.[71] Here, as in all other treatment contexts, competence is presumed to exist; an involuntarily committed patient should never be presumed incapable of exercising informed consent.[72] Protection of a person's autonomy mandates that standard medications not be administered, absent an emergency, against the wishes of a patient whose capacity is questioned, until a proper determination is made regarding capacity.[73]

The Foreseeable Problems

The plaintiffs identified an array of unlawful and unethical possibilities by which the regulations would allow mental institutions to transform vulnerable patients into subjects without respecting their autonomy rights. As the plaintiffs identified them, the broader problematic prospects were the lack of an appeal process when capacity was determined[74] and/or refusal was overridden, and the surrogate consent provisions of the OMH regulations, which allowed virtually anyone to consent for the incapable or minor patient.[75]

According to the plaintiffs, the regulations permitted incapable adults and children to be placed in risky, nontherapeutic experiments,[76] with parental or surrogate consent; in addition, possibly therapeutic experiments could be performed without the approval of the Commissioner of Health. Both kinds of

experiments could be administered without the patient's knowledge or consent.[77] Furthermore, incapable adults and children could be compelled to be the subjects of risky, possibly therapeutic experiments over their surrogates' objections because of the institution's power to override an objection or waive the consent requirement.[78] A surrogate's consent could be waived in the case of a child, based merely on the institution's suspicion of child abuse or neglect,[79] or otherwise if the research experiment "holds out a direct benefit that is important to the general health or well being of the patient and is available only in the context of the research."[80] This definition of "direct benefit," according to the court, does not require that the subject have a condition intended to be treated by the research.[81] These possibilities do not promote respect for persons, beneficence, or justice, the three basic ethical principles researchers are advised to advance.

The Decision

The plaintiffs challenged the power of institutions over incapable or minor patients, arguing that inadequate procedural protections existed.[82] The administrative processes offered by the regulations consisted merely of a determination of capacity by a "qualified person" and an "appropriate person," which would then be reviewed by the clinical director, who ultimately would decide the issue.[83] Three problems are evident in such a process. First, there are no guidelines or criteria for the institution to use to determine a patient's capacity; second, there is no requirement that a patient be notified that his or her capacity is being reviewed; and third, there is no provision for review of the clinical director's decision of incapacity.[84] The absence of these three characteristics from the administrative process of the regulations provides inadequate protection of the subject-patients' privacy and due process rights.[85] Furthermore, the determination of capacity has been repeatedly recognized as "'uniquely a judicial, *not* a medical function.'"[86]

Once a court finds that a patient lacks capacity, the regulations provide for a legally authorized representative to consent to the patient's being a subject of research.[87] The regulations allow consent to be given by someone who is neither a guardian nor a health care agent of the patient, without any guarantee he or she will act in the best interests of the subject-patient.[88] The regulations do not provide the subject-patient with knowledge of or recourse for these actions.[89] The only requirement for the surrogate is that he or she be competent.[90] Although the regulations' list of potential surrogates is similar to the surrogate list supplied by do-not-resuscitate (DNR) provision of the Public Health Law, the DNR rules provide for notice, administrative review, and a judicial finding of capacity, and the OMH regulations do not.[91]

Moreover, the regulations do not place limitations on a subject's exposure to risk. Parents or guardians may consent to a child's participation as a subject in research provided that the research is therapeutic and involves minimal risk.[92] However, the regulations also would permit a child, or incapable adult, to be a subject of nontherapeutic more-than-minimal-risk experimentation.[93] The court found this unacceptable.

> [A] parent or guardian, let alone another adult who may be a member of the child's family, may not consent to have a child submit to painful and/or potentially life-threatening research procedures that hold no prospect of benefit for the child and that may have the same result as a denial of necessary medical treatment.[94]

Children should not be used in nontherapeutic greater-than-minimal-risk research, because "treating people like rats is unethical, even if relatives think it is acceptable."[95]

This court followed a line of precedent that states that it is permissible for a parent or guardian to refuse therapeutic experimental medication for a child, so long as doing so would not be life-threatening.[96] Although parents maintain the right to refuse therapeutic medicine, that decision, according to the regulations, may be overridden.[97]

> [U]nder the general principles of the regulations, if a research project holds out any prospect for a direct benefit that may or may not relate to the specific condition presented by the incapable patients, the limiting conditions . . . may be waived and researchers may involve incapable patients in greater than minimal risk studies, which could be carried out using capable patients, but to which no capable individual would submit.[98]

The regulations presume that obtaining a parent's consent on behalf of a minor may not always be a "reasonable" requirement.[99] If child abuse or neglect is suspected, the regulations allow the institution to waive any parental consent requirement, thus effectively terminating the right of parents to make medical decisions for their children, without any means for the parents to challenge this decision.[100] The court, however, found that the appropriate mechanism for protecting the children who will participate as subjects is a proceeding in family court to determine whether interference with or termination of the parents' rights is justified.[101]

Part IV

Presently, OMH institutions are left with this case to guide them in their actions, since the applicable regulations are no longer valid. Clearly, the institutions must be cautious and err on the side of overprotecting their patients, if uncertain about how to proceed. If new regulations are written, certainly the procedural protections found lacking by the court should be integrated into them.[102] Proper procedure alone would have changed the outcome of this case.

The drafters of the new regulations, working this time under the direction of the Commissioner of Health, should keep in mind as they create the new instrument of guidance that

> progress is an optional goal, not an unconditional commitment, and that its tempo in particular, compulsive as it may become, has nothing sacred about it. Let us also remember that a slower progress in the conquest of disease would not threaten society, grievous as it is to those who have to deplore that their particular disease be not yet conquered, but that society would indeed be threatened by the erosion of those moral values whose loss, possibly caused by too ruthless a pursuit of scientific progress, would make its most dazzling triumphs not worth having.[103]

Endnotes

1. 650 N.Y.S.2d 173 (1st Dep't 1996), *appeal dismissed*, 89 N.Y.2d 1029 (1997).
2. *Id.*
3. *E.g.*, American Bar Association's Model Rules of Professional Responsibility, American Medical Association's Principles of Medical Ethics, American Psychological Association's Ethical Principles.
4. "Law represents a minimum standard of behavior; ethics represents an ideal." Jane Greenlaw, *Symposium on the Legal and Ethical Implications of Innovative Medical Technology*, 57 Alb. L. Rev. 551, 554 (1994).
5. Robert J. Levine, Ethics and Regulation of Clinical Research 15 (2d ed. 1986).
6. *Id*.
7. *Id.* at 17.
8. *Id.* at 16.
9. National Institutes of Health, *Protecting Human Subjects: Balancing Society's Mandates* (video, on file with author).
10. Darwin Cheney, Ethical Issues in Research 179 (1993).
11. *Id*.
12. *Id.* at 19.
13. Levine, *supra* note 5, at 17. Dr. Levine states that because the sixth norm is just starting to emerge in regulations, there are only five ethical norms. *Id.* However, I prefer to include it as a basic ethical norm.
14. George J. Annas, *Questing for Grails: Duplicity, Betrayal and Self-Deception in Postmodern Medical Research,* 12 J. Contemporary Health Law & Policy 297, 301 (1996).
15. *Id*.
16. *Id.* at 299 n.6 (emphasis added) (quoting Robert Jay Lifton, The Nazi Doctors: Medical Killing and the Psychology of Genocide 418 (1986)).
17. Annas, *supra* note 14, at 301 (quoting The Nazi Doctors and the Nuremberg Code: Human Rights in Human Experimentation (George J. Annas & Michael Grodin eds., 1992)).
18. Annas, *supra* note 14, at 303.
19. *Id*. The Declaration of Helsinki has been amended three times, in 1975, 1983, and 1989. The Council for International Organizations of Medical Sciences (CIOMS) and the World Health Organization (WHO) began examining the applicability of the Nuremberg Code and the Declaration of Helsinki in the 1970s and issued their Proposed International Guidelines for Biomedical Research Involving Human Subjects in 1982. Cheney, *supra* note 10, at 178.
20. Annas, *supra* note 14, at 303. Therapeutic and nontherapeutic experimentation will be discussed further in the Definitional Section of this paper.
21. Cheney, *supra* note 10, at 178. This report was published in 1978. *Id.* The Tuskegee experiments were exposed in 1972; it was revealed that the federal government "perpetrat[ed] medical malpractice in the name of syphilis research on [399] African Americans" from 1932 to 1972.
22. Cheney, *supra* note 10, at 178.
23. National Research Act, Pub. L. No. 93-348, 88 Stat. 342 (1974).
24. 45 C.F.R §§ 46.101-46.409 (1996); 21 C.F.R. §§ 50, 56 (1990).
25. 45 C.F.R. § 46.101(a) (1996).
26. Memorandum of Member of Assembly Alan G. Hevesi, sponsor of N.Y. Pub. Health Law art. 24-A, Bill Jacket L. 1975, c. 450 (enacted September 1, 1975).
27. *Id.*
28. *Id.* In the Jewish Chronic Disease Hospital "doctors injected live cancer cells into several dozen geriatric patients, none of whom were suffering from cancer or related ailments." At Willowbrook, parents were coerced into signing consent forms for their retarded or brain damaged children to be used "to find a cure for hepatitis." *Id.*
29. N.Y. Pub. Health Law § 2445 (McKinney 1996).
30. N.Y. Comp. Codes R. & Regs. tit. 14, § 527.10 (1990) (hereinafter N.Y.C.R.R.); *T.D. v. The New York State Office of Mental Health*, 165 Misc. 2d 62, 67 (Sup. Ct., N.Y. Co. 1995).
31. *T.D.*, 165 Misc. 2d at 67.
32. Brief for Respondents at 8, *T.D. v. The New York State Office of Mental Health*, 650 N.Y.S.2d 173 (1st Dep't. 1996) (No. 91-5136) (hereinafter "Brief for Respondents").
33. *Id.*
34. *Id*. The decision applies only to non-therapeutic experiments. Therapeutic experiments were not at issue on appeal. *See* Pub. Health Law § 3397 (McKinney 1996) (regulating specific therapeutic research programs).
35. 45 C.F.R. § 46.102(i) (1996). The OMH regulations' definition of minimal risk is substantially the same. 14 N.Y.C.R.R. § 527.10(c)(6) (1990).
36. By definition, minimal risk could differ from person to person, depending on a person's age, health, etc.
37. Annas, *supra* note 14, at 315.
38. *Rivers v. Katz*, 67 N.Y.2d 485 (1986).
39. Kathleen Scharer, *Researching Sensitive Issues in Child Psychiatric Nursing: Ethical Concerns*, 9 J. Child & Adolescent Psychiatric Nursing 17 (1996).
40. National Institutes of Health, *Protecting Human Subjects: Balancing Society's Mandates* (video, on file with author); Dale L. Moore, *An IRB Member's Perspective on Access to Innovative Therapy*, 57 Alb. L. Rev. 559, 568 (1994).
41. *T.D.*, 650 N.Y.S.2d at 185.
42. *Id*. at 177. The additional plaintiffs were several public interest attorneys and advocates as well as the Director of Mental Hygiene Legal Services. *Id.*
43. *Id.*
44. *Id*. at 178.
45. *Id.* at 177. Briefs were also submitted by various amici, representatives of the medical research community. *Id.*
46. *Id.* at 178.
47. *T.D. v. The New York State Office of Mental Health*, 165 Misc. 2d 62, 72 (Sup. Ct., N.Y. Co. 1995). Pub. Health Law art. 24-A states: "*[T]he commissioner* shall have the power to promulgate such rules and regulations as shall be necessary and proper to effectuate the purposes of this article." Pub. Health Law § 2446 (McKinney 1996) (emphasis added).
48. *T.D. v. The New York State Office of Mental Health*, 650 N.Y.S.2d 173, 180 (1st Dep't 1996).
49. *Id.* The defendant-respondents argued that the Mental Hygiene Law § 33.03(b)(4) gave OMH the authority to promulgate the regulations. The court rejected this argument. *Id*. at 182 n.5.
50. *Id*. at 180.
51. Pub. Health Law § 2445 (McKinney 1996).
52. 650 N.Y.S.2d at 183.
53. *Id*.; 28 C.F.R. § 46.103 (1997).

54. 650 N.Y.S.2d at 184.

55. *Id*.

56. 165 Misc. 2d at 74.

57. 650 N.Y.S.2d at 184.

58. 165 Misc. 2d at 71.

59. *Id.* at 75.

60. *T.D.*, 650 N.Y.S.2d at 185. The Court of Appeals dismissed the respondents' appeal on April 1, 1997.

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

62. 650 N.Y.S.2d at 191.

63. *Project Release v. Prevost*, 722 F.2d 960, 980 (2d Cir. 1983) ("The hearing need not be judicial in nature."). *See* Mental Hyg. Law art. 9 (McKinney 1996) (for administrative review).

64. 650 N.Y.S.2d at 186 (citing *Rivers v. Katz*, 67 N.Y.2d at 497). "Title 14 of the N.Y.C.R.R. § 27.8 and 27.9 provide for a right to object to treatment and for review of such objection." *Project Release*, 722 F.2d at 967.

65. 650 N.Y.S.2d at 186.

66. 14 N.Y.C.R.R. § 527.10(e)(2) (1990).

67 "'The due process clause of the New York State Constitution affords involuntarily committed mental patients a fundamental right to refuse antipsychotic medication.'" 650 N.Y.S.2d at 185 (quoting *Rivers v. Katz*, 67 N.Y.2d at 492). *See* N.Y. CONST. art. I § 6.

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

69. Brief for Appellants at 36, *T.D. v. The New York State Office of Mental Health*, 650 N.Y.S.2d 173 (1st Dep't 1996) (No. 91-5136) (quoting *Rivers*, 67 N.Y.2d 485) (hereinafter "Brief for Appellants").

70. *Rivers*, 67 N.Y.2d at 496.

71. *Id.* The state must have a compelling interest. *Id.* at 495.

72. *Rivers*, 67 N.Y.2d at 493.

73. 650 N.Y.S.2d at 187. Capacity is defined as "'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 in the research will involve no penalty or loss of benefits to which the patient is otherwise entitled.'" *Id.* at 188 (quoting 14 N.Y.C.R.R. § 527.10(c)(2) (1990)).

74. *Id.*

75. Brief for Appellants, *supra* note 69, at 26.

76. *Id*. at 51.

77. *Id*. at 34.

78. *Id.* at 64.

79. 650 N.Y.S.2d at 192.

80. 650 N.Y.S.2d at 187. The regulations state that "[a]n IRB may waive the conditions established in paragraph (6) of this subdivision, for a patient who lacks the capacity to consent, if the IRB determines and documents that the research holds out *a prospect of direct benefit* that is important to the health or well being of the patient and is available only in the context of the research." 14 N.Y.C.R.R. § 527.10(d)(7) (1990) (emphasis added).

81. 650 N.Y.S.2d at 187.

> Except as specified in paragraph (7) of this subdivision . . . [r]esearch which involves more than minimal risk and/or invasive procedures may only involve incapable subjects if the IRB has also determined and documented that the project is likely to produce knowledge which has overriding therapeutic importance for the understanding or treatment of the condition which is presented by the patient in question.

14 N.Y.C.R.R. § 527.10(d)(6) (1990).

82. *T.D.*, 650 N.Y.S.2d at 186.

83. *Id.* at 188. The IRB selects the person to assess capacity, usually the researcher, if it's a minimal risk experiment. *Id.* at 189.

> If the person(s) making the initial assessment of capacity determines that there is a doubt about a patient's capacity he[/she]/they shall report this to the IRB and the IRB shall designate another appropriate person to examine the patient for the purpose of determining the patient's capacity to consent to participation in the research. Based on the report of both assessments the clinical director (or functional equivalent) shall make a determination of the patient's capacity.

14 N.Y.C.R.R. § 527.10(e)(2)(ix) (1990).

84. *T.D.*, 650 N.Y.S.2d at 189.

85. *Id.*

86. *Id*. at 186 (quoting *Rivers v. Katz*, 67 N.Y.2d at 496) (emphasis added).

87. 14 N.Y.C.R.R. § 527.10(e)(2) (1990).

88. *T.D.*, 650 N.Y.S.2d at 188.

89. *Id.*

90. 14 N.Y.C.R.R. § 527.10(e)(2)(v) (1990).

91. 650 N.Y.S.2d at 191. Furthermore, under the Mental Hyg. Law § 81.02 a judicial determination of incapacity is made only upon a showing by clear and convincing evidence. *Id*. The OMH list includes one with durable power of attorney, one designated by the patient-subject, a spouse, parent, adult child, adult sibling, guardian or committee, close friend or a court of competent jurisdiction. 14 N.Y.C.R.R. § 527.10(e)(2)(iii)-(iv) (1990).

92. 650 N.Y.S.2d at 185.

93. *Id.* at 187-88. The only limitations on a more-than-minimal risk experimentation are that "it must be approved by the patient's treatment team . . . and the Institutional Review Board (IRB)." 14 N.Y.C.R.R. § 527.10(d)(3), (4) (1990). "It is not disputed that participation in studies involving greater than minimal risk exposes the subjects to possible harmful, and even fatal, side effects." *T.D.*, 650 N.Y.S.2d at 191.

94. 650 N.Y.S.2d at 192. Some of the reported incidences and side effects attributable to the experiments in question area: death, suicide, stroke, heart attack, convulsions, hallucinations, Neuroleptic Malignant Syndrome, and seizures, among others. *Id.* at 175-76 n.1.

95. Annas, *supra* note 14, at 307.

96. *T.D.*, 650 N.Y.S.2d at 191. The state's interest, as *parens patriae*, is to protect the health and welfare of the child. *Id.*

97. *Id.* at 193.

98. *Id.* at 188.

99. 14 N.Y.C.R.R. § 527.10(e)(3)(iii) (1990). "If the IRB determines that a research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a *reasonable* requirement to protect the patients (for example, neglected or abused children), it may waive the requirement for the consent." *Id*. (emphasis added).

100. *T.D.*, 650 N.Y.S.2d at 192.

101. *Id*. Furthermore, the Soc. Serv. Law § 383-b allows the local commissioner of health to make medical decision for abused or neglected children. *Id.*

102. E.g., the procedural protections in *Rivers v. Katz*, in which the administrative review procedures were successfully challenged as unconstitutional.

103. Annas, *supra* note 14, at 298 (1996) (quoting Hans Jonas, *Philosophical Reflections on Human Experimentation*, 98 DAEDALUS 219, 245 (1969)).

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Elder Law Update

by Howard S. Krooks*

The "Elder Law Update" column is designed to provide members of the Health Law Section with information regarding recent legislative changes and case law in the field of elder law. In this edition, I discuss two New York cases regarding Medicaid's efforts to recover benefits paid on behalf of an individual. In *Cricchio v. Pennisi*,[1] the New York Court of Appeals held that the repayment of a Medicaid lien is required prior to the creation of a supplemental needs trust. In *Commissioner of the Department of Social Services of the City of New York v. Benjamin Spellman*,[2] the Supreme Court, New York County, denied a motion to dismiss an action brought by the Department of Social Services against a community spouse to recover benefits paid under the Medicaid program for the care of the community spouse's wife, who resided in a nursing home. While the New York courts have narrowly interpreted the Medicaid statutes in the aforementioned decisions, in *Skubel v. Fuoroli*,[3] the United States Court of Appeals for the Second Circuit held that the scope of home care services provided to an individual who has established eligibility for Medicaid extends to services provided in the community as well as in the recipient's home. Finally, I have included an update regarding section 217 of the Health Insurance Portability and Accountability Act of 1996,[4] which criminalized certain asset transfers for the purpose of qualifying for Medicaid benefits, in light of *Peebler and Nay v. Reno*[5] and recent legislative developments.

New York State Courts Support Medicaid's Efforts to Recover Benefits Paid

Medicaid is a joint federal and state entitlement program established under Title XIX of the Social Security Act. It is designed to provide Medical Assistance to persons unable to afford the cost of medical care. In order to qualify for Medicaid funds, an individual must meet certain financial and other eligibility criteria. For example, in New York an individual may not possess more than $3,450 in resources to qualify for Medicaid. Although a person has been determined eligible for Medicaid, the local department of social services providing benefits may have a right of recovery or the right to place a lien on available resources if it is determined that the individual possessed resources in excess of the allowable amount.

In *Cricchio v. Pennisi*,[6] the New York State Court of Appeals was asked to determine whether a Medicaid lien[7] placed on the proceeds of a personal injury settlement must be satisfied before those funds may be transferred to a supplemental needs trust (SNT).[8] In reversing the appellate division, the Court of Appeals concluded that the Department of Social Services (DSS) is entitled to first satisfy the lien from those funds, leaving only the remainder available for transfer to a supplemental needs trust. Mrs. Cricchio was allegedly injured due to the negligence of a third party. She applied for Medicaid and was determined by her local DSS to be eligible for benefits. Mrs. Cricchio assigned to DSS her right to recover from any third party responsible for her injury as a condition of her Medicaid eligibility. Pursuant to the settlement agreement into which Mrs. Cricchio entered with the third party, the parties agreed that after the payment of attorney's fees and other costs, the balance owed to Mrs. Cricchio would be transferred into a SNT.

A supplemental needs trust is a "discretionary trust established for the benefit of a person with severe and chronic or persistent disability . . . that clearly evidences the creator's intent to supplement, not supplant, impair or diminish, government benefits or assistance for which the beneficiary may otherwise be eligible or which the beneficiary may be receiving."[9]

Under federal and state Medicaid laws, funds placed into a SNT are not considered available resources for purposes of determining an individual's Medicaid eligibility, provided that the trust document complies with the Estates, Powers and Trusts Law. In addition, the trust document must contain a payback provision (i.e., provide the state with a remainder interest in the trust assets existing at the individual's death up to the amount of Medical Assistance provided).[10]

DSS objected to the proposed funding of the SNT on the ground that the trust document did not require satisfaction of the existing Medicaid lien from the tort settlement proceeds prior to the funding of the SNT. The supreme court denied DSS's request for immediate satisfaction of the lien, reasoning that the state's interest in reimbursement was protected pursuant to Social Services Law section 369(2), which provides DSS the right to recover all Medical Assistance provided to the individual from the remaining trust assets upon the individual's death. The Appellate Division affirmed based on the legislature's failure to enact proposed amendments to the Social Services Law that (1) would have rendered trust assets available resources for Medicaid eligibility purposes unless any outstanding Medicaid liens were satisfied; and (2) would have provided that no trust fund could be created for a disabled individual under age 65 so long as a Medicaid lien existed against the individual's property. In reversing the appellate division, the Court of Appeals concluded that DSS's rights are against the third party rather than the individual's assets; therefore, DSS's right to have the Medicaid lien satisfied attaches before the settlement proceeds become an available resource to be used to fund the SNT.

In *Commissioner of the Department of Social Services of the City of New York v. Benjamin Spellman*, the Supreme Court, New York County, denied defendant Benjamin Spellman's motion to dismiss, based on a finding that DSS was not precluded from suing a community spouse for recovery of benefits paid. In denying the defendant's motion, the court addressed an issue of first impression: whether, under New York State Social Services Law, the DSS may recover from the

community spouse Medical Assistance paid for the care of an institutionalized spouse or whether such recovery is barred because there is no analogous federal statutory scheme.

Benjamin Spellman's spouse, Pearl Spellman, was admitted in 1994 to a skilled nursing facility located in New York City and subsequently filed an application for Medicaid institutional benefits. Under section 366-c of the Social Services Law, Mr. Spellman was permitted a resource allowance of $74,820. Mr. Spellman, who is obligated to support his wife pursuant to Social Services Law section 101, possessed resources of $223,160, which exceeded the allowable resource level under Social Services Law section 366-c by $148,340. Accordingly, at the time of Mrs. Spellman's application for Medicaid, the New York City DSS requested that Mr. Spellman contribute to the cost of his spouse's care; however, Mr. Spellman refused to make his income and resources available for the cost of Mrs. Spellman's care (known as "spousal refusal"). Nevertheless, Mrs. Spellman's Medicaid application was approved in accordance with New York and federal law, which provide that eligibility for Medicaid benefits may not be denied based on the community spouse's execution of a spousal refusal.[11]

Because DSS determined that Mr. Spellman had sufficient resources under the Social Services Law to provide financial assistance to Mrs. Spellman, it instituted a suit against Mr. Spellman for reimbursement of Medicaid funds expended on behalf of Mrs. Spellman. Mr. Spellman moved to dismiss the action, claiming that the only provision in the federal Social Security Act[12] regarding recovery of Medicaid benefits correctly paid is found in 42 U.S.C. section 1396p(b). This section provides that no recovery may be made except from an individual's estate or upon the sale of property subject to a Medicaid lien. Mr. Spellman argued that the New York statutes on which DSS relied[13] are preempted by section 1396p of the federal Social Security Act.

DSS argued that section 1396p of the Social Security Act is irrelevant because section 1396k authorizes it to seek recovery from Mr. Spellman. Section 1396k provides that an individual is required, as a condition of eligibility for Medicaid, to assign to the state any rights of the individual to support and to payment for medical care from any third party. DSS argued that Mr. Spellman is a third party under section 1396k and that Social Services Law section 366(3)(a)[14] expressly creates an implied contract between DSS and Mr. Spellman, on which DSS may rely in seeking to recover the cost of Mrs. Spellman's medical care.

The court, in denying Mr. Spellman's motion to dismiss, was not persuaded by Mr. Spellman's argument that he, as a community spouse, was not a "third party" under section 1396k. The court relied on C.F.R. section 433.136(3), which defines a third party as "any individual, entity or program that is or may be liable to pay all or part of the expenditures for medical assistance furnished under the State plan." As a result of the *Spellman* decision, a community spouse with sufficient resources and income is not immune from a suit brought by DSS to recover benefits paid on behalf of an institutionalized spouse.

Disabled Persons Are Entitled to Receive Home Health Care Outside Their Homes

In *Skubel v. Fuoroli*,[15] the United States Court of Appeals for the Second Circuit affirmed the district court's granting of summary judgment to a class of disabled individuals who sought Medicaid funding for nursing services provided to them outside their homes. The plaintiffs are children suffering from severe medical conditions who require nearly constant supervision. Jacinta Skubel was eight years old at the time the action resulting in the appeal was initiated. She suffered from various medical ailments, including lissencephaly, a mixed seizure disorder and global developmental delay. Her doctor prescribed a minimum of 76 hours per week of nursing services for the maintenance of her breathing and administration of her medications. Travis Hardy was 12 years old and also suffered from multiple medical disorders, including spastic quadriplegia resulting from bronchopulmonary dysplasia, seizure disorder and mental retardation. His doctor prescribed 40 hours per week of nursing services.

Both children could participate safely in educational and social activities available in the community only if accompanied by a nurse. Both children requested Medicaid funding for nursing care outside their homes, but the Connecticut Department of Social Services denied funding based upon a United States Health and Human Services regulation[16] limiting Medicaid funding to home health services "provided to a recipient . . . [a]t his place of residence."

On appeal, DSS argued that the district court erred in granting summary judgment in favor of plaintiffs because (1) the district court should have dismissed the action for failure to exhaust administrative remedies; and (2) the regulation was a reasonable interpretation of the Medicaid statute. With respect to plaintiff's failure to exhaust administrative remedies, the court noted that, prior to initiating this action, a letter was written to Alfred G. Fuoroli, then regional administrator of the Health Care Financing Administration (HCFA) of the United States Department of Health and Human Services, for clarification of the home health services regulation. In his response, Fuoroli indicated that, absent a court order, home health services would continue to be limited to services provided within the physical confines of the recipient's home. Based upon Fuoroli's and other HCFA responses indicating that HCFA had no plans to extend the boundaries of the place of service limitations, the Court of Appeals held that plaintiffs were excused from exhausting their administrative remedies under an exception which forgives the failure to do so when it is clear that seeking redress in an administrative forum would be futile.

The Court of Appeals next turned to the substantive question of the validity of the at-home limitation to home health services under 42 C.F.R. section 440.70. The Medicaid statute provides that states may include "home health care services" in their Medicaid programs[17] but does not specifically authorize or prohibit reimbursement for home health care services outside the recipient's residence. Because the statute was ambiguous, the court inquired whether DSS's interpretation of the

statute was reasonable. In finding no reasonable justification for the at-home limitation, the court noted that community access is desirable for disabled individuals and affirmed the judgment of the district court. Further, in light of the appellant's failure to articulate a logical basis for its statutory interpretation, the significant benefits to recipients and the negligible costs to the Medicaid program, the regulation was deemed unreasonable and invalid, and appellants were permanently enjoined from denying funding to Medicaid home health care recipients for medically necessary home health nursing services outside their residences.

Update on Section 217 of the Health Insurance Portability and Accountability Act of 1996

As I reported in the Spring 1997 issue of the *Health Law Journal*,[18] the Health Insurance Portability and Accountability Act of 1996 (also known as the Kennedy-Kassebaum bill) was signed into law by President Clinton on August 21, 1996. Under section 217 of this new law, which became effective January 1, 1997, it is a criminal offense punishable by up to one year in prison and a fine of $10,000 for an individual to

> knowingly and willfully [dispose] of assets (including by any transfer in trust) in order for an individual to become eligible for medical assistance under a State plan under Title XIX, if disposing of the assets results in the imposition of a period of ineligibility for such assistance under section 1917(c).[19]

Serious interpretation and application problems with the new legislation have been noted by elder law practitioners in New York State and across the nation.[20] First, it is unclear whether there is any penalty at all under section 217, which imposes criminal liability only upon a "statement, representation, concealment, failure or conversion." Unless a disposition of assets can be interpreted as any one of the foregoing, there appears to be a technical flaw in the statute since no penalty attaches to a "disposition." Second, the mens rea aspect of section 217 raises the issue of whether an individual "knowingly and willfully" disposed of assets. Suppose that an individual transfers assets for a reason other than to qualify for Medicaid (i.e., estate planning purposes) or that securing Medicaid eligibility was only one of several reasons for the asset transfer. Would such an individual be deemed to have violated the statute if he or she subsequently applies for Medicaid? Furthermore, aiding and abetting issues arise for attorneys who may be held to have violated the statute for counseling another in the commission of a federal offense.

When the statute was enacted, section 217 was replete with vague provisions, the application of which was likely to become known only over the course of time. Due to the confusion existing about the statute's application, the new legislation was certain to have a chilling effect on Medicaid planning. Nevertheless, the language of section 217 is such that planning options involving exempt transfers of assets clearly remain available to individuals, and such exempt transfers are unaffected by this statute. For example, in New York, the law imposing a penalty period on asset transfers is applicable only in the nursing home context; no penalty period currently is imposed for individuals applying for Medicaid home care benefits. Furthermore, certain transfers of assets are exempt from the penalty period transfer rules (i.e., homestead transfers to a caretaker child or to a sibling with an equity interest in the property, spousal transfers, transfers to a disabled child, etc.). Such transfers will undoubtedly continue to be permissible under section 217 and should be considered by individuals in the context of Medicaid planning.

The confusion surrounding section 217 primarily involved asset transfers resulting in a penalty period. Upon the enactment of section 217, three possible scenarios evolved: (1) a Medicaid application is filed after the 36-month lookback period (the period of time during which the local department of social services looks to determine if a transfer of assets was made) (a majority of practitioners took the position that no penalty period is imposed in such a case and, therefore, section 217 does not apply); (2) a Medicaid application is filed within the lookback period but after the penalty period has expired (this was the most ambiguous of the three scenarios because it was unclear whether a penalty period was "imposed." While some practitioners took the position that section 217 applied in this case, the consensus was that there could be no "imposition of a period of ineligibility" since the penalty period had expired and, accordingly, section 217 should not apply); and (3) a Medicaid application is filed within the penalty period (in this case, section 217 clearly would apply since there is the "imposition of a penalty period").

One of the scenarios where it was unclear how section 217 would be interpreted involved the case where an individual transferred assets and applied for Medicaid during the 36-month lookback period but after the expiration of the penalty period. In this case, it was unclear whether a penalty period would be "imposed" by the local department of social services, thereby triggering section 217 liability. In *Peebler and Nay v. Janet Reno*,[21] the Attorney General of the United States took the position that section 217 is not violated if an individual applies for Medicaid after the penalty period has expired even if the transfers occurred within the 36-month lookback period. In *Peebler*, Margaret Peebler, an 87-year-old widow with no living children or siblings, and her attorney, Tim Nay, sought declaratory relief that section 217 is unconstitutionally vague in violation of the due process clause of the Fifth Amendment. As of February 1997 (the lawsuit was filed on February 14, 1997), Mrs. Peebler's total assets were about $15,000 and her only income was a $393 social security check. Mr. Nay advised Mrs. Peebler to transfer a portion of her assets so that she could meet the requirements for Medicaid eligibility. In accordance with Mr. Nay's advice, Mrs. Peebler transferred $7,785 on February 12, 1997, to her great-nephew. In Oregon, the $7,785 transfer resulted in a penalty period of three months. The Attorney General of the United States moved to dismiss the action for lack of subject matter jurisdiction, asserting that enforcement of section 217 against Mrs. Peebler and Mr. Nay was neither "actual" nor "imminent" enough to

satisfy the standing requirements of article III of the Constitution and that the plaintiffs therefore lacked standing to challenge the constitutionality of section 217 in federal court. In granting the government's motion to dismiss, the court stated that "the government has represented in its motion to dismiss that, if Mrs. Peebler waits until [the expiration of the penalty period] to apply for Medicaid benefits, 'no period of ineligibility for such benefits will be imposed.'. . . If no period of ineligibility is imposed, neither of the Plaintiffs can be prosecuted under § 217." Accordingly, the only criminal act under section 217 would be a transfer of assets followed by the submission of a Medicaid application prior to the expiration of the applicable penalty period.[22]

Recent legislative activity regarding the repeal of section 217 is as follows: On January 8, 1997, Rep. Steven LaTourette (R-Ohio) of the U.S. House of Representatives introduced a bill (H.R. 216) to repeal section 217. On February 11, 1997, Senator James Jeffords (R-VT) of the U.S. Senate introduced a bill (S. 369) to repeal section 217. As of April 1997, more than 35 national organizations, 46 members of the U.S. House of Representatives and 11 U.S. Senators, and millions of Americans support the repeal of section 217.[23]

In June 1997, the House Commerce Committee introduced a bill which would replace the risk of criminal liability for senior citizens (the individual who transfers assets and subsequently applies for Medicaid) with that risk to be borne by attorneys and other professionals who counsel clients in this area. Under the proposed House bill,

> [a] person commits a crime who . . . for a fee knowingly and willfully counsels or assists an individual to dispose of assets (including by any transfer in trust) in order for the individual to become eligible for medical assistance under a State plan under Title XIX, if disposing of the assets results in the imposition of a period of ineligibility for such assistance under section 1917(c).

The Senate has proposed a bill containing similar language. If enacted, the above provision would significantly impede a senior citizen's ability to obtain accurate information from attorneys and other advisors regarding Medicaid. Furthermore, this provision raises First Amendment issues regarding free speech since attorneys and other professionals would be left with no choice but to not counsel clients. While efforts to repeal section 217 are ongoing and should be monitored, the Peebler decision discussed above clarifies the federal government's position regarding the interpretation and likely enforcement of section 217. As a result of *Peebler*, it is now clear that Medicaid planning by individuals continues to be a viable planning vehicle even under section 217.[24]

Endnotes

1. N.Y.L.J., Mar. 26, 1997, p. 26, col. 1.
2. N.Y.L.J., Feb. 10, 1997, p. 1, col. 6.
3. N.Y.L.J., May 28, 1997, p. 25, col. 4.
4. 42 U.S.C. § 1320a-7b(a)(6).
5. Civ. Action No. 97-256-HA (D. Or. Apr. 25, 1997).
6. N.Y.L.J., Mar. 26, 1997, p. 26, col. 1.
7. Pursuant to Soc. Serv. Law § 104-b.
8. The case of *Link v. Town of Smithtown*, 1997 N.Y. LEXIS 310, also was decided by the Court of Appeals in the same decision as *Cricchio*. However, only the *Cricchio* case is discussed for simplicity purposes.
9. Est. Powers & Trusts Law 7-1.12(a)(5).
10. *See* 42 U.S.C. § 1396p(d)(4); Soc. Serv. Law § 366(2)(b)(2)(iii).
11. 42 U.S.C. § 1396r-5(C)(3); Soc. Serv. Law §§ 366(3)(a), 366-c(5)(b).
12. Title XIX of the Social Security Act, codified at 42 U.S.C. § 1396, *et seq*.
13. Soc. Serv. Law §§ 366(3)(a), 366(3)(c).
14. Soc. Serv. Law § 366(3)(a) provides that

    > medical assistance shall be furnished to applicants in cases where, although such applicant has a responsible relative with sufficient income and resources to provide medical assistance as determined by the regulations of the department, the income and resources of the responsible relative are not available to such applicant because of the absence of such relative to provide the necessary care and assistance. In such cases, however, the furnishing of such assistance shall create an implied contract with such relative, and the cost thereof may be recovered from such relative in accordance with title six of article three and other applicable provisions of law.

15. N.Y.L.J., May 28, 1997, p. 25, col. 4.
16. 42 C.F.R. § 440.70(a)(1).
17. 42 U.S.C. § 1396d(a)(7).
18. *See also* David Goldfarb, *The Criminalization of Asset Transfer in Medicaid Planning*, HEALTH LAW J., Spring 1997, vol. 2, no. 1.
19. 42 U.S.C. § 1320a-7b(a)(6).
20. See Harry S. Margolis, *Congress Criminalizes Asset Transfers*, THE ELDER LAW REP., vol. VIII, no. 2, Sept. 1996, for a more in-depth analysis of the criminalization statute and the issues presented thereby. *See also* Daniel G. Fish, *Criminal Penalties for Medicaid Motivated Transfers*, N.Y.L.J., Sept. 28, 1996, p. 1, col. 1.
21. Civ. Action No. 97-256-HA (D. Or. Apr. 25, 1997).
22. Great care should be taken by the practitioner regarding the calculation of the Medicaid penalty period. Even a small error in the mathematics of this calculation could result in the premature submission of a Medicaid application and consequent criminal liability under section 217.
23. National Academy of Elder Law Attorneys, Public Policy Committee, Legislative Update, April 10, 1997, page 1.
24. *See* Daniel G. Fish, Peebler v. Reno*: Granny Does Not Go to Jail*, N.Y.L.J., June 13, 1997, p. 1, col. 1.

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The Compartmentalization of Health Care Reform

by Colleen D. Galligan*

I. Introduction

In 1917 William Pearce sat on his front porch crippled with rheumatism. With his son off fighting the Great War, Pearce knew he would not be able to rely on his son's help around the farm. Pearce, however, had renewed hope that health care would be developed as part of social insurance. Four generations later, his hopes have not been realized. For the last hundred years we have wrestled, as a nation, with the issue of national health care reform.[1] Although the issue of a national plan has been debated in the United States since the early part of this century, changing social structures have made resolution of this conflict more urgent than ever. "The number of U.S. citizens who lack health-care coverage remains an international embarrassment."[2]

This article attempts to explore one aspect of the health care crisis, the lack of access for the uninsured. Part II will look at the historical debate over a national health care plan.[3] It will discuss some of the frustrations as well as successes of four distinct periods in our history when the debate over health care was at the forefront of American politics. Part III will explore the problem of the uninsured in light of current economic and business trends.[4] Part IV will address the economic effects of the insurance gap.[5] Part V will address the human cost of uninsurance, focusing specifically on children.[6] Part VI will discuss how the abandonment of a universalist approach to health care reform, in favor of numerous individual measures, has been ineffective in addressing the plight of the uninsured.[7]

II. Historical Background

"In a democracy, major policy changes occur either through a long period of consensus building or through a perception of crisis. In connection with health care system reform, we have some of each."[8] While the need for national health care reform has over time become an integral part of our national socio-political conscience, recent business and economic climates have created a crisis.[9]

Health care reform is not a new idea in America. Other reform efforts occurred earlier in this century[10]—in "the Progressive era, during the New Deal, under President Truman, and during the early 1970s."[11] In each of these periods, advocates fought aggressively for the adoption of a national health care plan but were disappointed.[12] Although the goal of universal health care for all Americans is yet to be realized, these historic attempts to establish such a system have resulted in increased coverage for more Americans.[13]

In the Progressive Era, prior to World War I, the idea of a national system of health care was promoted by the "elite conscience."[14] Reformers promoted a national system of health insurance, which would have been administered through social insurance.[15] Supporters believed reform would result in "improved health, health care, and economic security."[16] Although reformers had the support of the American Medical Association (AMA) during World War I, the AMA later withdrew its support.[17] Also, although reformers had strong support among the intellectual elite, most Americans were not concerned with establishing national health care. Without support from the populace or the AMA, reformers failed to effect any change.[18]

The second great opportunity to establish universal health insurance came during the New Deal Era.[19] In 1935 President Roosevelt established a special cabinet-level committee, the Committee of Economic Security (CES) to "review the circumstances of welfare, unemployment, child health, and old age poverty, and arrive at a package of programmatic suggestions."[20] Because President Roosevelt believed the most pressing issues were unemployment and welfare, and because it was thought that the AMA's presumptive opposition to national health insurance might frustrate achievement of these objectives, national health insurance was not even addressed by the committee.[21]

National health insurance resurfaced a decade later during President Truman's administration.[22] Critics "linked national health insurance with socialism, communism, and the recently demonized Soviet Union."[23] Opposition from southern conservative Democratic congressmen remained strong throughout the president's term.[24] Frustrated by the political climate, President Truman eventually scaled down his plan to include health insurance for social security recipients only.[25] President Truman's plan was eventually adopted in 1965 as the Medicare program.[26]

In the period following World War II many advances were made in the American health care system. "For example, we faced a shortage of health care personnel, a deficiency of acute care general hospital beds, and a relatively low level of total health expenditures. All of these problems were corrected (indeed over corrected)."[27] These advances were made working under the "deficit model."[28] Unfortunately, this model did not anticipate the increase in expenditures experienced in the mid-1960s.[29]

The 1970s brought renewed interest in national health insurance and more proposed legislation.[30] This era was characterized by competition among "different forms of universal health insurance: the catastrophic proposal advocated by Senators Long and Ribicoff, the Kennedy-Corman bill that so closely followed Canada's national operational program of 1971, and the Nixon administration's plan for mandated health insurance for employed Americans (known as the

Comprehensive Health Insurance Plan, or CHIP)."[31] Although there was overwhelming support for reform, the Congress was unable to render sufficient support for any individual plan.[32] More modest plans "such as the Long-Ribicoff bill—seemed too modest to those who wanted to translate the negative consensus into universal, broad coverage."[33] To those who favored a national insurance plan administered by the government, "[t]he proposal for employer-mandated insurance . . . seemed indirect, incomplete, and incapable of cost control."[34]

Although the debate over a national health care system never completely left the American political conscience, it did fade somewhat in prominence and urgency under the Reagan and Bush administrations of the 1980s. With the election of Democrat William Jefferson Clinton to the White House in 1992, national health care reform, perhaps more than ever before, was thrust to the forefront of the political agenda.[35] President Clinton established a committee, chaired by the First Lady, to investigate the state of health care in America and advance a plan for reform. The new plan called for all Americans to be issued a national health insurance card that would entitle them to health services, including emergency and preventative care.[36] Benefits of most Americans would continue to be paid for by their employers, but the government would provide coverage for others.[37] Although President Clinton intended to establish himself as the president who successfully reformed the health care system and established national health insurance, by the end of his first term the issue was all but dead.[38]

In 1996 the Kennedy-Kassebaum Bill was touted as "a health insurance bill of rights."[39] The legislation, however, does almost nothing to address the currently uninsured population.[40] Co-sponsor Senator Edward Kennedy noted this problem when commenting on a 1996 study predicting that the number of uninsured Americans will continue to rise.[41] "Far too many Americans still fall through the cracks of our health insurance system. This study gives urgency to the need for Congress to do more to make insurance accessible and affordable to all citizens."[42]

III. The Current Status of the Uninsured

The number of uninsured Americans has increased steadily since the rejection of the Clinton health plan[43] and is expected to continue to increase steadily through the year 2000.[44] "[A] study by the Lewin Group, a Washington-based health care consulting firm, estimates that the number of uninsured Americans will increase to 45.6 million by 2002."[45] The number of uninsured Americans has increased by more than five million since 1994.[46] Recent studies indicate that as many as one-quarter of all Americans experienced a lapse in insurance over the last two years.[47]

The number of children not covered by health insurance has risen in recent years,[48] and all indications are that it will continue to rise.[49] "Some 10 million American children under 18 were uninsured in 1994. . . . That was 14.2 percent of all kids, up from 12.4 percent in 1992."[50]

In the 1960s and 1970s the United States made strides in ensuring access to medical services for children.[51] The improvements gained in the 1960s and 1970s have been largely eroded in the 1980s and 1990s.[52] "Between 1977 and 1987, the percentage of U.S. children without public or private health insurance increased from 12.7 percent to 17.8 percent."[53] The number of uninsured children remained between 8.3 and 8.5 million during the period between 1988 and 1992.[54]

"[I]t is notable that the uninsured child population is comprised primarily of children whose parents have substantial alignment with the work force."[55] In 1992, 8 percent of children living in two-parent families, in which both parents worked were uninsured.[56] In the past, when employer-based coverage failed, children were shifted to public-sector programs such as Medicaid.[57] "However, more recently the number of uninsured children not shifted to Medicaid has been increasing."[58]

Several factors have contributed to the recent rise in the number of uninsured Americans.[59] Among the most influential are the changing character of the national labor force[60] and changes in the way America does business, which has had a profound effect on the health benefits of the labor force.[61]

As employers adapted their work forces to reduce operating expenses, employees have seen a reduction in benefits, most notably health insurance.[62] In 1990 77.7 percent of American workers received health insurance through employer-based plans; by 1995 the number had dropped to 73.9 percent.[63]

One change in the character of the work force is a shift in the types of jobs in which Americans are engaged. For more than a decade the United States has seen a shift in the job market to the service industry.[64] Frequently, employees in the service industry do not receive health insurance coverage as an employee benefit.[65] Another change is in the status of many workers. In order to cut costs many employers have replaced full-time employees with part-time workers.[66] By hiring employees on a part-time basis, employers can avoid providing benefits such as health insurance.[67] Although a worker working two part-time jobs may be able to earn as much money as if he or she had one full-time job, it is much less likely that he or she will receive employer-provided health insurance.

Another 1990s cost-cutting measure for employers is outsourcing.[68] When companies outsource, they contract work to smaller companies or individuals. Outsourcing certain functions allows an employer to eliminate jobs inside the company for which the employer would have provided benefits, including health insurance, and simply pay independent contractors for those services.[69]

Those American workers still receiving employer-based health benefits are being asked to contribute an ever larger por-

tion of their insurance premiums.[70] Even though companies have cut costs by using managed care, the portion of premiums passed on to employees has increased.[71] "Twenty or 30 years ago, taking care of the health care of workers was part of the corporate culture, but we've seen that start to change, especially in terms of shifting cost to workers in the past few years."[72] The percentage of American workers whose health insurance premiums were fully funded by their employers dropped from 74 percent in 1980 to 21 percent in 1993.[73]

Finally, not only are more Americans uninsured, but they are also going without insurance for longer periods,[74] increasing from a median time of 4.2 months in the late 1980s to a median of 7.1 months in 1993.[75]

One might be surprised to know just who is at risk of being uninsured. While race, education, employment status, and marital status can all be indicators, they are not determinative.[76] Although the majority of the uninsured are the working poor, a significant number are members of the middle class.[77] And because most private insurance is employment based, one important factor in determining risk is the relationship to the work force.[78] Most uninsured people live in families headed by a full-time worker who works year round.[79] "[A] study by the United States' largest medical specialists group . . . reported that a third of the uninsured live in households with an annual incomes of more than $30,300—twice the federal poverty level for a family of four."[80]

IV. Economic Effects of Uninsurance

The economic impact of millions of uninsured Americans is felt throughout the economy. Some estimates suggest that American companies contribute as much as $17.2 billion to the care of the uninsured.[81] Ed Adams of IBM addressed the economic impact of the uninsured recently when he stated that "[t]his issue has a direct impact on our business bottom line and on the overall economy."[82] Workers without insurance miss more work to stay home and care for sick children than workers with health coverage for their families.[83]

The economic impact of the uninsured is also felt by hospitals. The greater the number of uninsured Americans, the greater the burden on hospitals to provide charity care.[84] Hospitals are the "only health providers obligated by law to provide emergency care regardless of ability to pay."[85] A decrease in employer-provided health coverage has placed an increased burden on hospitals.[86] "In the next few years, a . . . financial squeeze is likely to be felt by almost any place or program that gives health care to the poor."[87] The impact is likely to be most significant for health care providers in poor neighborhoods.[88] Recent events have caused some providers of health services to the poor to question the extent of their generosity.[89]

Even schools are affected by the growing number of uninsured. Uninsured children miss more days of school, due to illness, than children with health coverage. Because school aid is tied to attendance, schools lose money every time an uninsured child is out sick.[90]

V. The Human Cost

The harms resulting from a lack of universal health care are more than economic. Americans who lack health care coverage have difficulty gaining access to, and paying for, medical care. As a result, they are sicker, require more acute care, and have a higher rate of morbidity. They "see doctors less often than others, are sicker when they do, and receive fewer cardiac procedures, fewer hospital days for their newborns and less aggressive treatment for pneumonia."[91]

The uninsured face physical and psychological, as well as financial, barriers to health care.[92] As a recent study indicated, the "vast majority of uninsured adults in poor health had difficulty getting care."[93] Many think they cannot go back to a doctor if they have an unpaid bill.[94]

More American children are without health insurance, and some say that the rate at which this group grows will increase in the future.[95] "Some 10 million American children under 18 were uninsured in 1994."[96] Financial concerns may lead parents to "delay or forgo needed pediatric medical services."[97] Children without insurance are 73 percent as likely to receive medical services as insured children.[98]

Children of families that experience periodic lapses in medical coverage are less likely to receive medical care even during periods when they are covered.[99] "[C]hildren without a regular source of care are less likely to be completely immunized, have lower rates of visits for well-child care and higher rates of visits for illness care, and have more frequent emergency department visits."[100] In contrast, children without such lapses are more likely to received needed treatment.[101]

A good illustration of the impact of uninsurance on children is to consider the case of a childhood illness: asthma. Asthma is the most common childhood illness,[102] affecting approximately 2.7 million American children.[103] If properly treated its symptoms can usually be controlled and the afflicted child can lead a normal, active life.[104] If left untreated, however, the symptoms can become so severe as to be life threatening.[105]

As the number of children without insurance grows, "evidence indicates that incidents of hospitalization and mortality due to childhood asthma are increasing."[106] Uninsured children are less likely to receive treatment for asthma.[107] Failure to receive regular treatment makes it much more likely that the child will be seen an emergency department for treatment and be hospitalized.[108]

VI. Health Care Reform Since the Failure of the Clinton Plan

Since the failure of President Clinton's comprehensive health care plan in 1993, the focus of health care reform in

America has shifted to the passage of smaller, more specialized, legislation.[109] The focus is much more on special-interest groups and on providing stop-gap measures for specific situations rather than addressing health care reform comprehensively.

Much enthusiasm surrounded the passage of health care legislation during the last year. Legislation dealing with health-insurance portability,[110] allowing for the creation of medical savings accounts,[111] and imposing mandatory 48-hour hospital stays following childbirth[112] were all touted as improvements in health care. Recent health care reform legislation can be divided into two basic categories: legislation that addresses specific situations and legislation that deals with specific medical procedures.

One piece of legislation affecting only individuals in a particular situation is the Health Insurance Portability and Accountability Act of 1996 (HIPAA).[113] HIPAA will provide increased continuity in coverage for workers who are currently insured by allowing employees to continue under their current policies when they change jobs, barring insurance companies from refusing to cover preexisting conditions, and establishing a three-year trial period for medical savings accounts.[114]

Although HIPAA makes some significant improvements in continuity of medical coverage, it does nothing to address the problem of the uninsured. It requires insurance companies to allow employees to extend their coverage beyond the period of employment, but they must able to pay the entire premium.[115] Even if insurance companies are required to offer continued coverage to employees who lose or change jobs, many people in this position will not be able to afford the cost.[116] Those who are not currently insured will not be affected by this legislation.[117]

Individuals who wish to participate in the medical savings account program must purchase an insurance policy with a deductible of at least $1,500 per individual or $3,000 per family and must have money available to put into the savings account.[118] Once money is in the account, the individual will be penalized if it is withdrawn for a nonmedical reason.[119] In order to participate in this program families must have the ability to set money aside for medical treatment; accordingly, most currently uninsured families will be unable to afford to participate.[120]

Perhaps even more prevalent than situation-specific legislation is the appearance of procedure-specific legislation. Last year, for example, President Clinton signed legislation requiring insurance companies to provide a minimum hospital stay of 48 hours following childbirth and providing medical coverage for children of Vietnam veterans born with spina bifida.[121] Each piece of legislation was designed to address a discrete need.

This trend toward procedure-specific legislation is likely to continue. One procedure receiving a considerable amount of press is the "drive through mastectomy."[122] With critics aghast at the practice of some insurance companies of requiring that mastectomies be performed on a near outpatient basis, and several bills addressing this issue already in Congress, a federal statute regulating a minimum hospital stay is likely to be enacted this year.[123]

VII. Conclusion

The legislation we have seen introduced and adopted over the last several years takes an ad hoc approach to health care reform. As a nation we appear to have abandoned the goal of universal coverage for smaller, more discrete legislative efforts addressing specific harms. While each individual bill may address, and even correct, an individual problem, many important issues, such as the growing number of uninsured, are being ignored. This ad hoc approach to health care reform means that special interest groups dictate the national health policy and the group that screams the loudest gets the best care. The compartmentalization of health care regulation leaves health care providers, such as HMOs, with the potential for understanding that if an issue has not been specifically addressed, then the resolution is up to them. Instead of providing broadly applicable standards and guidelines, the current trend takes a piecemeal approach, leaving consumers in the unaddressed pieces with very little protection.

Endnotes

1. *See infra* notes 8-43 and accompanying text.
2. *With 40 Million Uninsured, We Still Have a Health Crisis, Cost Containment is Only a Partial Victory*, Buffalo News, Dec. 3, 1995, at F8. Lack of national health insurance "marks this country as an exception among industrialized nations, most of which guarantee health coverage for all of their citizens." *Id*.
3. *See infra* notes 8-43 and accompanying text.
4. *See infra* notes 44-80 and accompanying text.
5. *See infra* notes 81-90 and accompanying text.
6. *See infra* notes 91-108 and accompanying text.
7. *See infra* notes 111-123 and accompanying text.
8. Julius B. Richmond Rashi Fein, *The Health Care Mess: A Bit of History (Caring for the Uninsured and Underinsured)*, 273 J. Am. Med. Ass'n 69, 72 (1995).
9. *See id*.
10. Mark Goldberg, *American Health Care Reform: Separating Sense from Nonsense*, *in* Understanding Health Care Reform 1, 6 (Theodore R. Marmor 1994). *See also* Keith J. Mueller, Health Care Policy in the United States (1993) 1-11 (discussing the political history of health care reform).
11. Goldberg, *supra* note 10. *See* David F. Drake, Reforming the Health Care Market: An Interpretation of Economic History, 2 (1994). *See also* Mueller, *supra* note 10, at 3 (noting that the 20th century has been divided "into four policy periods: quality during 1900-1960, access during 1961-72, cost containment during 1973-80, and decrementalism since 1980").
12. *See* Goldberg, *supra* note 10 at 6; *see also* Drake, *supra* note 11 at 2-3.
13. Mueller, *supra* note 10, at 1.
14. Goldberg, *supra* note 10 at 6. *See also* Drake, *supra* note 10 at 2; Mueller, *supra* note 10, at 3-4 (discussing the movement to increase access to care during the early part of the twentieth century).

15. 15 Goldberg, *supra* note 10, at 6.
16. *See id*.
17. *See id.*
18. *See id*.
19. *See id*.
20. *Id*.
21. *See id*.
22. *See id*.
23. *Id*.
24. *See id*.
25. *See id*.
26. *See id*.
27. Fein, *supra* note 8, at 69.
28. *See id*. (defining the deficit model).

> While we would not argue that our earlier health policy agenda and efforts were always coherent and consistent, we do believe that the various legislative and regulatory interventions did have an overall thrust and theme. It is our thesis that we had been dealing with real and very visible shortages. In other words, we were operating on the basis of a deficit model: if we made up for deficits in the system, it would function well. As a pluralistic society we developed public and private policies to deal with deficits in human and capital resources. We expanded the knowledge base and our ability to apply it. We increased access with the enactment of implementation of Medicaid and Medicare.

Id.

29. *See id*. (explaining the deficit model's failure to control expenditures).

> Regrettably, we failed to plan for and control expenditure increases—after all, the mid 1960's were characterized by an exuberance of optimism and confidence in our ability to do almost everything: conquer space, tame the business cycle, meet all our ever-expanding population needs and wants. We were on the threshold of emerging new problems—problems bred by our very successes. Policymakers, healthcare professionals, hospital administrators, and the public had no experience with an adequacy of resources. We behaved as though we still had deficits. The United States was growing; incomes were expanding. It was easy and natural to assume further growth and to plan within an ethos of expansion that had come to be considered as synonymous with progress. There was little awareness of the need to concentrate on the equilibration of the system: to provide appropriate services for the poor and to redress the imbalance between the distribution of services—urban and rural, poor and affluent, specialist and generalists. Instead of fine-tuning the total system and redistributing resources, we continued to expand total inputs.

Id.

30. *See* DRAKE, *supra* note 11, at 2-3.
31. Goldberg, *supra* note 10, at 8.
32. *See id*. at 8-9.
33. *Id*. at 8.
34. *Id*. at 8.
35. *See* The White House Domestic Policy Council, *Health Security: The President's Report to the American People* (1993) (letter from President Clinton) (hereinafter *Health Security*).
36. *See id.*
37. *See id*. at 17.
38. *See* Richard Kirsch, *Health Care Booby-Trap for Uninsured*, NEWSDAY, Sept. 3, 1996, A31.
39. John Merline, *Health-Care Reform, The Sequel, GOP Plan May Hike Rates, Number of Uninsured*, INVESTOR'S BUS. DAILY, Mar. 25, 1996, A1 (quoting Sen. Ted Kennedy).
40. *See* Merline, *supra* note 39, at A1 (discussing the impact on the uninsured of the Kennedy-Kassebaum Health Care Reform legislation). *See also* Dave Skidmore, *Understanding the Kassebaum-Kennedy Health Coverage Bill; Measure is Valuable to Insured People Who Change or Lose Jobs, but Does Little for Uninsured*, WASH. POST, Aug. 19, 1996, at A13; *Clinton Signs Health Bill, But Insurance Gaps Persist; Insurance Bill Does Nothing For Uninsured*, SALT LAKE TRIB., Aug. 22, 1996, at A1; and Deborah L. Jacobs, *Health-care Law May Not Help Those Uninsured*, FRESNO BEE, Sept. 16, 1996 (discussing the Kennedy-Kassebaum Bill).

    "The bill focuses almost exclusively on making it easier for people who switch jobs to keep their coverage, and for people who lose their jobs to hold onto policies, even if they're sick." Merline, *supra* note 39, at A1. The Kennedy-Kassebaum bill extends health-care coverage for the sick in three ways: it places restrictions on preexisting conditions; when workers switch jobs they are guaranteed coverage at their second job; and individuals who lose their jobs can continue their coverage through an individual plan. *See id.*

    "[The] main problem is economic. With the cost of family coverage averaging $5,000 to $6,000 a year, most people can't afford insurance without an employer also contributing. Kassebaum-The Kennedy bill does not provide any government subsidies." *Clinton Signs Bipartisan Bill Revamping Health Insurance; Reforms Are Not Expected to do Much for Uninsured*, BALTIMORE SUN, Aug. 22, 1996, at 3A.
41. *See Access/Quality/Cost Health Insurance: AHA Study Predicts Increase in Uninsured* AM. POL. NETWORK, Sept. 11, 1996, at 10 (hereinafter *Access/Quality/Cost*).
42. *Access/Quality/Cost*, *supra* note 41, at 10.
43. *See* Kirsch, *supra* note 38, at A31.
44. *See Access/Quality/Cost*, *supra* note 41, at 10. *See also* Paul W. Newacheck, *et al.*, *Children and Health Insurance: An Overview of Recent Trends*, HEALTH AFF., Spring 1995, at 1 (citing *Sources of Health Insurance and Characteristics of Uninsured; Analysis of the March 1993 Current Population Survey*, EMPLOYEE BENEFIT RES. INST., EBRI 145 (Jan. 1994)). In 1992, an estimated 38.5 million persons under 65 had no health insurance, public or private, up from 33.6 million in 1988. *See id*.
45. Stuart Auerbach, *Number of Uninsured Growing: Employers Cutting Full-Time Jobs, Health Coverage*, WASH. POST, Sept. 11, 1996, at F3. *See* Laurie Abraham, *Tough Times Ahead (Health Care for the Poor and Uninsured)*, BUS. & HEALTH, Jan. 1, 1996, at 59 (discussing a report from Brandeis University which estimated "that 67 million people will be uninsured in 2002").
46. *See* Abraham, *supra* note 45.
47. *See id*.
48. *See* Rachel Jones, *Big Increases for Uninsured Kids*, STAR LEDGER, Aug. 17, 1996, at 3.
49. *See Access/Quality/Cost*, *supra* note 41, at 10.
50. Jones, *supra* note 48, at 3.
51. *See* Jeffrey J. Stoddard, *Health Insurance and Ambulatory Care for Children*, 330 NEW ENG. J. MED. 1421 (1994).
52. *See id*.
53. *Id*.
54. Newacheck, *supra* note 44, at 7.
55. *Id*. "In 1992, fully three-fourths of all uninsured children were members of families with at least one working parent. Moreover, 70 percent of the uninsured children belong to families in which the principal breadwinner was a full-time worker." *Id*.
56. *See id*. at 8.

57. Stephen Berman, *Uninsured Children: An Unintended Consequence of Health Care System Reform Efforts*, J. Am. Med. Ass'n 1472 (1995) (citation omitted).

58. *See* Berman, *supra* note 57, at 1472.

59. *See Access/Quality/Cost*, *supra* note 41, at 10.

60. *See id*.

61. *See 42 Million in U.S. Lack Health Coverage, Third of Uninsured Are in Households with Incomes Over $30,000*, St. Louis Post Dispatch, Apr. 28, 1996, at 13A (hereinafter *42 Million in U.S.*). "12.5 million people, or nearly 9 percent of the nonelderly population, lost employer-sponsored coverage between 1988 and 1993, the most recent years for which comparable data are available." *Id*.

62. *See id*. (reporting that "[i]n 1988 about 40% of all full-time workers with coverage provided through a job reported that their employer paid their entire health insurance premium; by 1994, only 31% of full-time workers reported that they paid no premiums").

63. *See* Auerbach, *supra* note 45, at F3. *See also 42 Million in U.S.*, *supra* note 61 at 13A (discussing a recent report by the American College of Physicians describing one of the reasons for the recent increase in the number of uninsured Americans as "the increase on the continuing decline in employer-provided coverage").

64. *See Access/Quality/Cost Health*, *supra* note 41, at 10. *See also* Abraham, *supra* note 45, at 59.

65. *See* Abraham, *supra* note 45, at 59.

66. *See* Auerbach, *supra* note 45 at 53.

67. *See Access/Quality/Cost*, *supra* note 41, at 10.

68. *See id.*

69. *See id*.

70. *See* Auerbach, *supra* note 45, at F3.

71. *See id.*

72. Lee Bowman, *Number of Uninsured Growing; Fewer Americans with Health Coverage Putting Extra Burden on Hospitals to Provide Charity Care*, Rocky Mt. News, Sept. 11, 1996, at 36A.

73. Rachel Jones, *More Children May be Uninsured as Health Care, Welfare Are Reshaped*, Fort Worth Star-Telegram, Aug. 17, 1996, at 10.

74. *See Americans Going Uninsured for Longer Periods*, Best's Rev., Aug. 1, 1995, at 59 (discussing a U.S. Census Bureau study "spanning data from February 1991 to September 1993").

75. Abraham, *supra* note 45, at 59.

76. *See id*.

77. Larry Lipman, *1 in 4 Went Uninsured, Survey Finds, Census Report Comes Amid Health Care Debate*, Atlanta J. & Const., June 24, 1996, at 1, 6 (quoting Arnold Bennett, spokesman for Families USA, a non-profit organization advocating insurance reform). *See* Kogan *et al.*, *The Effect of Gaps in Health Insurance on Continuity of a Regular Source of Care Among Pre-school Aged Children in the United States*, 274 J. Am. Med. Ass'n 1429-35 (1995) (discussing the demographics of the uninsured and noting that "[t]he families at greatest risk [are] the working poor with incomes of $10,000 to $20,000 per year"). "Ordinary, middle-class Americans are at serious risk. . . . You lose your insurance for two, three or six months and you pray that you don't have a serious health problem." *Id*.

78. *See* Lipman, *supra* note, 77 at 6.

79. *See* Gene Koretz, *The Health-Care Gap Widens: More Americans Go Uninsured*, Bus. Week, Mar. 27, 1995, at 28 (discussing uninsured Americans' connection to the work force.) "Some 85% of uninsured people live in families that were headed by workers, most of whom worked year-round. Since 1989, the percentage of workers, most of the nonelderly enjoying employer coverage has fallen from 65.9% to 60.8%." *Id*.

80. *Number of Uninsured Americans is a Record*, Los Angeles Times, Apr. 27, 1996, 8A.

81. *See* Mike McNamee, *et al.*, *Health Care: Just Address the Bills to Corporate America: Big Employers that Now Pay Much of the Uninsured Freight Expect Reform to Mean Relief. It May Not*, Bus. Week, Mar. 29, 1993, at 66. Big businesses were counting on the Clinton health care plan to "relieve them of an estimated $17.2 billion in 'cost-shifting'—what private employers pay as a hidden subsidy to take care of the uninsured and underinsured." *Id*.

82. *Business, State Want Uninsured Kids to Have Health Benefits*, Dallas Morning News, Aug. 21, 1996, at 8A (hereinafter *Business, State*) (quoting Ed Adams of IBM). Mr. Adams went on the explain, "We are already paying for the uninsured children through higher premiums, through taxes and through lost worker productivity. In addition, when workers must continually worry about the health of their children, they aren't productive and they aren't effective." *Id*.

83. *See Businesses, State*, *supra* note 82 at 8A. (stating that "[i]t also makes economic sense to avoid costly emergency room visits, keep children in school and keep parents from losing work time to stay home with sick children").

84. *See* Bowman, *supra* note 72 at 36A.

85. *Id*.

86. *Id*. (quoting Dick Davidson, President of the American Hospital Association, as saying "[h]ospitals are providing $16 billion a year in care that no one pays for. . . . Our ability to do this diminishes as the number of uninsured grow").

87. Abraham, *supra* note 45, at 59.

> Public hospitals and a clutch of urban non-profits that have made it their mission to care for the poor are the health care courts of last resort for the uninsured, destitute and otherwise medically dispossessed. But this year some of the most venerable public institutions began curtailing major services, and experts say the next decade likely will bring more downsizing, with some hospitals closing altogether.

Id. at 59.

88. *See id.*

89. *See* Michelle Nicolosi, *UCI Medical Center, Clinics Can't Afford the Poor*, Orange County Register, Sept. 10, 1996, at B1 (quoting Robert Dicker, senior vice president for health care affairs for the Association of American Medical Colleges as saying:

> A number of our members are saying, "We have a responsibility to the poor, but that is not an unending responsibility." Education costs money. Research costs money. You have to use scarce resources to support those missions. In many cases the decision is we'll continue our community-service obligations, but we'll limit it.)

90. *See Businesses, State*, *supra* note 82, at 8A (explaining that "[s]chools lose attendance-based funding when children are absent, and uninsured children are absent more often than those who have health coverage").

91. *See* Abraham, *supra* note 45 at 59.

92. *See Uninsured Report Problems Getting and Paying for Care*, Health Legis. & Reg., Nov. 7, 1996 (hereinafter *Uninsured Report Problems*).

93. *Uninsured Report Problems*, *supra* note 92.

94. *See Uninsured Report Problems*, *supra* note 92.

95. Rachel L. Jones, *Health Reform Advocates Warn of Increase in Uninsured Children*, Star-Ledger (Newark, NJ), Aug. 17, 3 (noting that "14.2 percent of all kids, up from 12.4 percent in 1992" were uninsured in 1993).

96. *Id.* at 10.

97. Berman, *supra* note 57, at 1472 (citing Kogan et al, *The Effects of Gaps in Health Insurance on Continuity of a Regular Source of Care Among Preschool-aged Children in the United States*, 274 J. Am. Med. Ass'n 1429 (1995)).

98. *42 Million in U.S.*, *supra* note 61, at 13A.

99. *See* Berman, *supra* note 57, at 1472.

> Gaps in coverage also affect the likelihood of a child having a continuous regular source of primary care during periods of time with insurance coverage as well as periods of time without coverage.
>
> . . .
>
> Gaps in insurance coverage create a more chaotic environment in which families are more hesitant to seek out and maintain a regular source of primary care; concurrently, physicians are more reluctant to accept primary care responsibility for children and families who lose their insurance or frequently change health plans.

Id.

100. Berman, *supra* note 57, at 1472.

101. Stoddard, *supra* note 52, at 1421.

102. *See* Neal Halfon and Paul W. Newacheck, *Childhood Chronic Illness: Prevalence, Severity, and Impact*, AM. J. PUB. HEALTH, Mar. 1992, at 363, 366.

103. *See id.*

104. *See* Stoddard, *supra* note 51.

105. *See id.* at 1423.

106. *Id.*

107. *Id.* at 1421.

108. *Id.* at 1423.

109. *See, e.g.*, Health Insurance Portability and Accountability Act of 1996 (hereinafter HIPAA), Pub. L. No. 104-191, 110 Stat. 1936 (to be codified at 42 U.S.C. § 210); Act of Nov. 12, 1996, Pub. L. No. 104-333 (to be codified at 42 U.S.C. § 300gg-4) (hereinafter "Minimum Hospital Stay for Childbirth Act").

110. HIPAA, *supra* note 109, §§ 101-195 (providing for continued medical coverage for employees who change employers and eliminating an insurance company's ability to refuse to cover preexisting conditions).

111. *Id.* at §§ 300-323 (providing for the creation of medical savings accounts).

112. Minimum Hospital Stay Following Childbirth Act, *supra* note 109 (requiring insurance companies to provide minimum coverage for hospital stays of 48 hours following vaginal childbirth and 72 hours following cesarean sections).

113. *Supra* note 109.

114. *See* Skidmore, *supra* note 40, at A11 (explaining the implications of the Health Insurance Portability and Accountability Act of 1996). "The bill, known as Kassebaum-Kennedy . . . is most valuable to already insured people who change or lose their jobs." *Id.*

115. *See* Carol Jouzaitis, *Congress Weighs Helping Uninsured, Health Bills Address Portability*, CHICAGO TRIB., Mar. 24, 1996, 13 (noting that many of those whom the legislation is intended to help will be unable to pay for the extended coverage).

116. *See id.* (warning that "'[i]t would be a cruel hoax' to tell consumers coverage was made available to them and then price it out of their reach").

117. *See Clinton Signs Bill to Shore up Health Coverage the New Law Protects Americans Who Already Have Health Care Benefits, But it Won't do Much for the Uninsured*, ORLANDO SENTINEL, Aug. 22, 1996. A1; Jacobs, *supra* note 40, at D2; *Clinton Signs Bipartisan Bill Revamping Health Insurance*, *supra* note 40 at 3A (explaining that the bill only provides extended coverage to the currently insured).

118. *See* Skidmore, *supra* note 40, at A13 (discussing the three-year experiment with medical savings accounts). "From 1997 through 2000, insurance companies can sell 750,000 high-deductible policies for big medical expenses. Deductibles must be between $1,500 and $2,250 for a person and $3,000 and $4,500 for families." *Id.*

119. *See id.* (noting that individuals over 65 years of age can withdraw capital from a medical savings account without penalty).

120. *See Clinton Signs Bill to Shore Up Health Coverage*, *supra* note 117, at A1 (explaining that most Americans will not be able to afford to take advantage of the new program). *See also* Skidmore, *supra* note 40, at A13 (explaining that many families are not able to put sufficient funds aside to make the medical savings program work).

121. Minimum Hospital Stays Following Childbirth Act, *supra* note 109. *See Clinton Signs Bill for Birth Hospital Stay; Insurers Dislike Cost of Two-Day Guarantee*, BALTIMORE SUN, Sept. 27, 1996, 10A (explaining two provisions of the bill which would put "an end to 'drive-through deliveries' . . . [and] ensure that children of Vietnam veterans born with spina bifida can get medical care and rehabilitative training through the Veterans Administration").

The legislation requiring insurers to provide a minimum 48 hours of hospital care after childbirth was drafted in response to reports that an increasing number of companies were refusing to pay for care and mothers and babies had died as a result of being sent home too soon. *See Bill Extends Stay in Hospital for Birth*, ORLANDO SENTINEL, Sept. 20, 1996, A1; Dave Skidmore, *Bill Would Allow 48-Hour Hospital Stays After Birth*, PORTLAND OREGONIAN, Sept. 20, 1996, A12; Robert Pear, *Senate Panel Approves Bill on Postnatal Care; Measure Would Require Health Plans to Cover 2 Days in Hospital After Birth*, AUSTIN AM.-STATESMAN, Apr. 18, 1996, A8 (explaining the reason for the legislation was insurers' increasing demand that mothers and newborns be discharged as quickly as possible and reports that this practice had led to deaths).

Studies indicating that exposure to Agent Orange put the children of Vietnam veterans at an increased risk for spina bifida established a need for treatment through the Veterans Administration. *See Clinton Signs Bill for Birth Hospital Stay*, *supra* at 10A (explaining the link between exposure to Agent Orange and the birth defect).

122. *See Bill Would Upgrade Coverage for Mastectomies, Sen. Olympia Snowe is Among those Proposing Coverage for Longer Hospital Stays and Reconstructive Surgery*, PORTLAND PRESS HERALD, Jan. 30, 1997, 6A (discussing a report from a bipartisan group of congresspersons calling for support of legislation setting minimum standards for hospital stays following mastectomies).

123. *See* Lauran Neergaard, *HMOs O.K. Hospital Stay for Mastectomies, Overturn Out-patient Classification to Defuse Threat of Legislation*, BUFFALO NEWS, Nov. 15, 1996 (discussing the introduction of legislation in response to an industry trend toward out-patient mastectomies). *See also* Christ Parsons and Rick Pearson, *Mastectomy Bill Approved in House; 4-day Hospital Stay Would be Required After Surgery*, CHICAGO TRIB., Dec. 6, 1996 (discussing opposition to the proposed legislation by insurance companies and HMOs).

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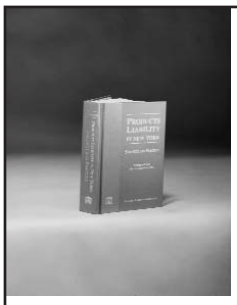

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