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Recent Developments in Health Law

Harvard Law & Health Care Society

Human Stem Cell Research: NIH Releases Draft Guidelines for Comment

In December 1998, two groups of scientists announced that they had successfully isolated and cultured human pluripotent stem cells. This news was greeted with both tremendous enthusiasm and concern. Because these cells can develop into most types of cells or tissues in the human body, they hold great promise for scientific research and medical advances. For example, stem cells can potentially be used to:

- Generate cells and tissues for transplantation and therapy for conditions such as Parkinson's disease, spinal cord injury, stroke, burns, heart disease, diabetes, and arthritis;
- Improve scientists' understanding of the complex events that occur during normal human development, as well as the ab-

normal events which cause conditions such as birth defects and cancer; and

- Substantially change the development and testing of drugs. New medications could be tested initially on stem cells, and only drugs which were safe and effective on the cells would be tested further on laboratory animals and humans.

At the same time, the advent of laboratory-ready human pluripotent stem cells provokes pressing legal and ethical concerns. The derivation of stem cells from human embryos and fetal tissue raises legal issues in light of the federal ban on human embryo research and federal regulations on fetal tissue research. There is also considerable ethical disagreement on the appro-

priate level of respect for human embryos and fetal tissue as sources of stem cells. Finally, some fear that stem cell research sits at the brink of a slippery slope that may lead to human cloning practices.

In January 1999, the General Counsel of the Department of Health and Human Services (HHS) determined that federal law does not prohibit public funding of pluripotent stem cell research. Although federal law bans HHS' funding of research in which human embryos are created for research purposes or are destroyed or subjected to greater than minimal risk (P.L. 105-277, section 511,112 STAT. 2681-386), the ban does not apply to research with stem cells obtained from human embryos. The legal opinion also specified that stem cells derived from fetal tissue can be used for re-

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search, but since these stem cells fall within the legal definition of human fetal tissue, the research must comply with federal regulations on fetal tissue research (42 U.S.C. 289g-2(a), 45 CFR § 46.210, 42 U.S.C. 289g-1).

Following HHS' legal clearance, the NIH Director, Harold Varmus, convened a 13-member working group to draw up guidelines for the proper conduct of research involving human pluripotent stem cells. The group comprises representatives from a broad range of interest groups, including scientists, ethicists, lawyers, clinicians, patients and patient advocates. The working group held a public meeting in April 1999 to discuss the guidelines and hear commentary from various parties, including the American Society of Cell Biology, National Conference of Catholic Bishops, Alliance for Aging Research, House Pro-Life Caucus, and National Bioethics Advisory Commission.

On December 2, 1999, the NIH released the working group's draft of the Human Pluripotent Stem Cell Research Guidelines. 64 Fed. Reg. 67576 (December 1999). The NIH has solicited feedback on the draft guidelines and recently extended the comment period until February 22, 2000. Thousands of comments had been submitted as of mid-January. The working group will carefully consider the comments and make revisions to the guidelines. Until the final guidelines are adopted, all publicly-funded research involving pluripotent stem cells is on hold. An NIH official has indicated that the final guidelines would probably not be ready until early summer.

The draft guidelines

The draft guidelines cover any applications or proposals for federal research funding involving human pluripotent stem cells. See generally Fact Sheet on Human Pluripotent Stem Cell Research Guidelines (Dec. 1, 1999) <<http://www.nih.gov/news/stemcell/factsheet.html>>. The guidelines do not

apply to privately funded research on human pluripotent stem cells, though the National Bioethics Advisory Commission (NBAC) strongly encourages private researchers to voluntarily comply with similar guidelines.

According to the guidelines, scientific investigators must demonstrate the following to qualify for federal funds:

- If the stem cells originate from human embryos, the embryos must have been excess embryos created for the purposes of infertility treatment, not expressly for research. The investigator must not be involved in the infertility treatment, play any role in the donor's decision to donate the embryos, or offer monetary or any other incentive to donate the embryos.
- If the human pluripotent stem cells originate from fetal tissue, the research must be in compliance with all laws and regulations governing human fetal tissue research and the fetal tissue transplantation research statute.
- Excess embryos and fetal tissue must be obtained with the donor's informed consent. Several requirements for informed consent are specified, including provisions that donors will not receive any information regarding the subsequent testing on the fetal tissue or cells, that all identifiers will be removed from the cells, and that donors will not receive any financial reward from the research on the cells.

To ensure compliance and monitor the development of research practices, the guidelines establish the Human Pluripotent Stem Cell Review Group (HPSCRG or "Review Group"). The Review Group would conduct an additional review of any research proposal involving pluripotent stem cells after the proposal has been approved by an institutional review board and NIH peer review

group. If a proposal involves a newly-derived line of stem cells, the Review Group would hold a public review meeting. The Review Group would also be responsible for assembling an annual report on the number of proposals reviewed and the titles of all awarded applications, supplements or administrative approvals for the use of existing funds and intramural projects.

Finally, the guidelines expressly forbid certain practices with federal funds, including the creation of stem cells expressly for research purposes and the addition of stem cells to human or animal eggs or embryos via somatic cell nuclear transfer. The prohibition on somatic cell nuclear transfer reflects concern that this technique could be used for human cloning purposes.

Reaction to the guidelines

Response to these draft guidelines has been mixed and vehement. The Patients' Coalition for Urgent Research hails the guidelines as a step toward "a new area of science with tremendous promise for alleviating and even curing catastrophic illness," perhaps for more than 100 million patients nationwide. Similarly, Rep. Nina Lowey (D-NY) views this research as offering Americans "the promise of better treatment and perhaps even cures for diseases like cancer, Parkinson's, Alzheimer's and diabetes."

On the other hand, many members of Congress object to federal funding of stem cell research because the cells originate from the death of a human embryo. Rep. Christopher Smith (R-NJ), a leading opponent of stem cell research, called the new guidelines "a sham . . . [t]hey attempt to give a glow of respectability to truly barbaric and grotesque experiments on human beings." The National Right to Life Committee, like many anti-abortion groups, argues that the guidelines "would result in federal sponsorship and funding of experiments in which living human embryos are dissected and killed

—a clear violation of federal law. . . .¹

The scientific community has generally praised the draft guidelines. University of California at San Francisco researcher Roger Pedersen calls the guidelines “a positive thing, a very thoughtful and thorough response” to a delicate political situation. Some scientists advocate a less cumbersome system of regulation. For example, Paul Berg, Ph.D., a Stanford University professor and Chair of the American Society of Cell Biology Public Policy Committee, feels that federally-funded investigators should not be held responsible for monitoring stem cell derivation procedures when private industry is the source of the cells.² Similarly, the Federation of American Societies for Experimental Biology (FASEB) President David Kaufman, M.D., Ph.D., believes that independent certification of derivation and consent protocols by each investigator would cause “an unnecessary duplication of effort.” Kaufman suggests instead the establishment of a certification process for stem cell lines, with publication of the cell lines that are acceptable for use. FASEB also recommends that research using stem cells derived before the publication of the draft guidelines should be eligible for federal funding, even though the currently available stem cell lines do not meet the criteria set forth in the draft guidelines.³

Recent and upcoming events

Stem cell research will soon enter the political spotlight.⁴ On January 31, 2000, Senate Appropriations/HHS Subcommittee Chair Arlen Specter (R-PA) and Ranking Minority Member Tom Harkin (D-IA) introduced Bill S2015 which would allow for federal funding of stem cell derivation as well as research. (Under NIH draft guidelines, investigators cannot use federal funds to derive the stem cells; instead, they must obtain them from private sources such as in-vitro fertilization [IVF] clinics.) The Specter/Harkin measure would also enable institutional

review boards to determine whether stem cell research proposals conform with NIH guidelines and would require the HHS Secretary to submit an annual report to Congress on stem cell research funded under the legislation. Like the NIH guidelines, the bill prohibits the federally-funded creation of human embryos or clones, and forbids the transfer or acquisition of embryos via monetary transactions. On February 22, the Subcommittee plans to hold a hearing on stem cell research which will include testimony from science and disease research advocacy groups, as well as celebrities Christopher Reeve and Michael J. Fox. On March 8, the subcommittee is scheduled to discuss the President’s FY 2001 budget for the NIH March 8. In the House, expected hearings on embryo or fetal research issues include a Commerce/Health Subcommittee hearing on Representative Tom Tancredo’s (R-CO.) H. Res. 350, a resolution to prevent the trafficking of aborted fetal tissue and body parts for profit and a Science Committee hearing on cloning research.

Another important recent development was the February 1, 2000 announcement of the University of Wisconsin’s intent to distribute its line of human pluripotent stem cells. University of Wisconsin researcher James Thomson generated one of the two current lines of stem cells with the sponsorship of the Wisconsin Alumni Research Foundation (WARF) and Geron Corporation. Starting in late spring, WiCell, a non-profit research institute established by WARF, plans to distribute the stem cells developed by Thomson. According to WiCell, scientists interested in obtaining the cells would submit a confidential summary of research plans to WiCell which would review the plans for appropriate use and adequate respect for the stem cells (e.g., cloning research would be prohibited). Academic researchers would be able to obtain two vials of the stem cells for \$500, though if researchers subsequently wished to commercialize any of their findings, they

would have to negotiate with WiCell and potentially Geron. Industry researchers, on the other hand, would have to pay significant up-front fees for the cells and provide royalties to WiCell and/or Geron for any revenue realized from the cells. WiCell’s plan has been praised by scientists as “an excellent idea to share these cells.”⁵

The next few months will be an important and interesting time for human pluripotent stem cell research. Many events, including the promulgation of the final NIH guidelines and developments in Congress, are likely to have a pivotal role in determining the course of regulation for this crucial area of scientific research.

Susan Lee

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ERISA and RICO: New Tools for HMO Litigators

Fiduciary duty under ERISA

As the shield preempting state suits under the Employee Retirement Income Security Act (ERISA) has been successfully pierced (see *California Div. Of Labor Standards Enforcement v. Dillingham Constr. N.A. Inc.*, 519 U.S. 316 (1997) and *Duke v. U.S. Healthcare, Inc.*, 57 F.3d 350 (3rd Cir. 1995)), plaintiff attorneys have begun to use the ERISA statute itself to fur-

ther litigation against managed care organizations. The court in *Shea v. Esensten*, 107 F.3d 625 (8th Cir. 1997), held in a landmark decision that an HMO's failure to disclose financial incentives that discourage a treating physician from providing essential health care referrals for conditions covered under the plan benefit structure is a breach of ERISA's fiduciary duties. The pertinent ERISA provision requires that plan fiduciaries "discharge [their] duties with respect to a plan solely in the interest of the participants and beneficiaries." See 29 U.S.C. § 1104(a)(1) (1999). In *Shea*, the primary care physician, disregarding Mr. Shea's extensive family history of heart disease and classic symptoms of a heart condition, assured the patient that it was not necessary for him to see a cardiologist. Subsequent to his death from a heart attack a few months later, Mr. Shea's wife successfully argued that had her husband known that the primary care physician would be penalized for too many specialist referrals or receive a bonus for reducing specialized care, he would have disregarded his physician's advice and obtained a cardiologist's advice at his own expense. The court therefore found it imperative to impose a duty upon the HMO to disclose financial arrangements between managed care organizations and their contracting physicians.

Questioning the duty to disclose financial incentives

The court in *Weiss v. CIGNA Healthcare, Inc.*, 972 F.Supp. 748 (S.D.N.Y. 1997), declined to follow the *Shea* approach, holding that the physician's ethical breach in taking advantage of financial incentives by withholding necessary care is not attributable to the health plan. Alternatively, the court in *Ehlmann v. Kaiser Foundation Health Plan of Texas*, 198 F.3d 552 (5th Cir. 2000) did not explicitly rebut *Shea*, but instead refined it. *Ehlmann* held that without a specific inquiry by a plan beneficiary, or

some other special circumstance, a health plan has no duty to disclose material information about physician compensation arrangements. Unlike Mr. Shea's specific inquiry into seeing a cardiologist, Mr. Ehlmann sought an injunction requiring a general disclosure to all plan members regarding the bonus arrangement between the HMOs and their contracting physicians. The *Ehlmann* court declined to decide whether ERISA imposed such a fiduciary duty of material disclosure at all, but they did indicate in dicta where they might stand on the issue. Invoking the canon of statutory construction that the specific language in a statute rules the general, the court pointed out that while no reference is made to any disclosure duty for physician reimbursement plans, ERISA contains many other provisions detailing HMOs' disclosure duties. See 29 U.S.C. §§ 1021-1031. Although, as the plaintiff argued, at the time Congress drafted ERISA, the same incentives to cut back on healthcare expenses were not present, the court indicated that expanding these disclosure duties would exceed their judicial role. They explained, "Congress and the Department of Labor are surely aware of these changes and have chosen not to supplement ERISA's disclosure requirements." *Id* at 556.

The Supreme Court to decide if the existence of a financial incentive structure implies a fiduciary duty under ERISA

After the denial of a petition for rehearing by the Seventh Circuit en banc of *Herdrich v. Pegram*, 154 F.3d 362 (7th Cir. 1998) to review reversal of a dismissed ERISA claim, the Supreme Court granted certiorari, and oral arguments were scheduled for February 23, 2000. *Herdrich* held that financial incentives for physicians to limit medical treatment could reach the level of a breach of fiduciary duty under ERISA where the fiduciary trust between plan

beneficiaries and fiduciaries no longer exists. This fiduciary trust would no longer exist in a situation where "physicians delay providing necessary treatment to, or withhold administering proper care to, plan beneficiaries for the sole purpose of increasing their bonuses." *Id* at 373. In this case, although Mrs. Herdrich's appendix was noticeably inflamed, her physician put off for eight days the necessary diagnostic procedure. During the delay her appendix ruptured resulting in peritonitis. The court emphasizes that the dual loyalties tolerated under ERISA do not extend to such situations where a plan fiduciary "jettisons his responsibility to the physical well-being of beneficiaries in favor of 'loyalty' to his own financial interests." *Id* at 373.

The dissent in *Herdrich* argued that the court's role in ensuring that financial incentives offered by a health plan to physicians were implemented in compliance with the ERISA fiduciary duties did not arise until the market failed to align interests. Because employers have the bargaining power to choose a different health plan if one consistently fails to honor valid claims, paying meritorious claims is in the insurer's best interest, and no conflict of interest thus exists. The dissent would follow the rule laid down in *Shea* to enable the market to function by supplying the information employers need to evaluate their choice of health plans, including disclosure of any financial incentives to limit care. The dissent from the denial of the rehearing en banc, joined by Chief Judge Posner, expressed the view that the majority's holding put all HMOs at risk of being sued for breach of ERISA fiduciary duties "because the allegations in the complaint narrate mundane features" of HMOs such as limiting referrals to specialists, using capitated fee systems with bonus provisions, and limiting the provision of care to specific locations. See *Herdrich v. Pegram*, 170 F.3d 683, 687 (7th Cir. 1999).

RICO: The ability to bring federal claims against insurance companies tested

In *Humana, Inc. v. Forsyth*, 119 S. Ct. 710 (1999), a class of health insurance co-payors alleged a violation of the Racketeer Influenced and Corrupt Organization Act (RICO) claiming that Humana failed to disclose or pass on discounts negotiated with providers so that the Humana plan members paid significantly more than the contracted 20% co-payment. See 18 U.S.C. § 1964 (1984). To make a claim under RICO, a statute originally designed to allow prosecution of organized crime, the plaintiff must show both conduct of an "enterprise" through a pattern of racketeering activity and injury to the plaintiff, his business, or his property. *Id.* Forsyth claimed a pattern of racketeering activity consisting of mail, wire, radio, and television fraud and damages resulting from paying a de facto higher percentage of the co-payment than was bargained for. The Supreme Court unanimously ruled that RICO, which prohibits the same conduct as Nevada insurance law, but provides more extensive remedies including treble damages, does not "invalidate, impair or supersede" the state's laws and so is not precluded under the McCarran-Ferguson Act. See 15 U.S.C.A. § 1012(b) (1997). After the motion for summary judgment was denied, this class action suit settled. If the court approves the settlement, the co-payor and premium class members will receive \$11,986,200 and \$4,113,800 respectively. See SE34 ALI-ABA 505, 522.

In another test of the use of RICO against managed care plans, *Maio v. Aetna Inc.*, 1999 WL 800315 (E.D.Pa.) was filed alleging that Aetna's "advertising and marketing materials falsely represent that it is committed to maintaining and improving quality of care when in fact, Aetna failed to disclose that its internal policies and agreements with its providers are driven by fiscal and administrative considerations that

reduce the quality of healthcare services." See SE34 ALI-ABA 505, 523-524. This claim was dismissed with prejudice for lack of standing because the allegation that quality of care might suffer in the future was too hypothetical to carry the burden of showing an injury in fact. In a blow to the usefulness of RICO for future HMO litigation, the court went on in dicta to say that other fatal defects were present in the plaintiff's complaint. For example, the court speculated that advertisements asserting commitment to quality of care could not constitute a fraudulent inducement, but rather were mere puffery. They also thought that the plaintiffs failed to plead a sufficient RICO "enterprise," and, furthermore, should direct their dissatisfaction at legislatures and regulatory agencies rather than the courts.

Conclusion

At this point, ERISA is a more firmly established means of bringing suit against the managed care industry than is RICO. However, the future of suits brought under either statute is in limbo. The Supreme Court's treatment of *Pegram* this term will resolve the conflicting lower court opinions and clear up the fiduciary duties implicated by ERISA in the administration of financial incentive structures. Upcoming dispositions of several recently filed RICO complaints will more broadly illustrate the treatment to be expected in the future of RICO claims than the single decision by one federal district court judge thus far. In the meantime, the filing of claims against managed care plans under both ERISA and RICO continue. See *Conte v. Aetna-U.S. Healthcare Inc.*, E.D. Pa., No. 99-CV-4929, complaint filed 10/4/99, *Price v. Humana Inc.*, S.D. Fla., No. 99-8763, complaint filed 10/4/99, and *O'Neil v. Aetna Inc.*, S.D. Miss., No. 2:99CV284PG, complaint filed 10/7/99.

Elaine T. Moore

Legal Implications of Discrimination in Medical Practice

Recent medical studies have indicated that medical professionals discriminate in their treatment practices on the basis of race and gender. Among the many concerns stemming from this realization are questions about the possibility of legal actions and the availability of individual compensation for the denial of equal care. By meeting legal evidentiary standards,¹ the recent statistical data pointing to discriminatory trends have created the potential for legal recourse through Title VI of the Civil Rights Act² which prohibits recipients of federal funding from treating people differently on the basis of race or national origin. Nevertheless, it remains unclear whether patients who have been treated unequally will be able to use these studies as a basis for successful legal action.

Over the past year, the *New England Journal of Medicine* has published several studies showing disparities in referrals and treatment of women and minorities.³ The first, published in February 1999 and referred to here as the *Schulman* study, initiated the debate.⁴ Researchers videotaped eight actors portraying various pairs of patients: male and female, African-American and Caucasian, young and old. The study varied six experimental factors among the 144 personalities it created for the videotapes: race, sex, age, level of coronary risk, type of chest pain, and the results of a stress test. A total of 720 physicians each viewed one of these 144 videotapes and was asked to answer a number of questions about how to treat the patient. The *Schulman* study indicated that there were statistically significant differences in the rate of referral for cardiac catheterization between genders and races even after accounting for any physiological differences between men and women and between Caucasians and minorities. Despite

articles questioning Schulman's statistical conclusions,⁵ other recent studies have indicated racial discrepancies in access to renal transplantation,⁶ treatment of early-stage lung cancer,⁷ and success of treatment of left ventricular dysfunction.⁸ However, it is important to note that the latter two studies were explicit about not concluding *why* these disparities occurred. They noted various factors which could cause such differing results, even without any form of physician discrimination.⁹

An analysis of racial discrimination illustrates the legal questions involved in these cases. Patients who find they have been discriminated against may use these studies as evidence that minorities are treated differently by doctors, thereby creating a potential for legal recourse. However, a private plaintiff's recourse will likely only take the form of prospective, injunctive or declaratory relief. This means that a court would order the institution to undo the discrimination, if possible, or refrain from discriminating against the plaintiffs in the future. Title VI of the Civil Rights Acts provides that "[n]o person in the United States shall, on the ground of race, color, or national origin, be excluded from participation in, denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance."¹⁰ The Office of Civil Rights (OCR), located in the Department of Health and Human Services, is responsible for enforcing the federal civil rights laws in hospitals, clinics, social service centers and related agencies.¹¹ In the past, courts have held that Medicare and Medicaid are "federal financial assistance" under the statute, and therefore hospitals and their physicians must comply with the statute in order to keep their funding.¹² Moreover, the prohibition against discrimination applies to the hospital program as a whole, as a recipient of the funding, not to the individual patient beneficiaries of Medicare or Medicaid. Any patient—whether or not a Medicare or Medicaid beneficiary—will

have a cause of action against a medical establishment that discriminates, as long as the program¹³ in which they are involved does participate in Medicare or Medicaid.¹⁴

The Office of Civil Rights has promulgated regulations under Title VI which outlaw both intentionally discriminatory acts as well as programs and activities that have a racially disparate impact.¹⁵ A recipient of federal funds may not "utilize criteria or methods of administration which have the effect of subjecting individuals to discrimination because of their race, color or national origin, or have the effect of defeating or substantially impairing accomplishment of the objectives of the program as respect individuals of a particular race, color, or national origin."¹⁶ Moreover, "[i]n administering a program regarding which the recipient has previously discriminated against persons on the ground of race, color, or national origin, the recipient must take affirmative action to overcome the effects of prior discrimination."¹⁷

In *Guardians Association v. Civil Service Commission of New York*¹⁸ the Supreme Court held that in order to violate the Title VI statute itself a defendant must have intended to discriminate. However, a majority of justices stated that agency regulations promulgated under Title VI may incorporate a lower, disparate-impact standard. Therefore, discriminatory effect, without discriminatory intent is enough to violate the regulations. Two years later in *Alexander v. Choate*, a unanimous Supreme Court explained the *Guardians Association* holding by saying that "[i]n essence, then, we held that Title VI had delegated to the agencies in the first instance the complex determination of what sorts of disparate impacts upon minorities constituted sufficiently significant social problems, and were readily enough remediable, to warrant altering the practices of the federal grantees that had produced those impacts."¹⁹ Therefore the OCR regulations can rightfully prohibit disparate

impact discrimination.

Although it is clear that the statute and regulations cover intentional and disparate impact cases, it is not equally clear that private plaintiffs can sue to enforce the OCR regulations. The Office of Civil Rights itself can bring enforcement actions requiring medical centers to comply with their regulations. However, in order for injured patients to sue there must be a private right of action. In *Guardians Association*, five justices endorsed without holding the existence of a private right of action for discriminatory effects regulations cases.²⁰ This suggests that injured plaintiffs may be able to bring lawsuits if their medical institutions have unintentionally or intentionally discriminated against them. An important question in the determination of whether the regulations imply this right, is whether the Title VI statute itself implies a private right of action. If it does, then a regulation within its scope will also imply a private right of action.²¹ The Supreme Court in *Guardians Association* said that Title VI itself gives rise to a right of action, at least for claims for injunctive relief.²² However, the Court has already established that regulations can be broader than the Title VI statute itself, by covering disparate impact scenarios. Therefore, the question remains whether there is an implied right of action for those parts of the regulations not within Title VI's actual ambit. Both the Third Circuit and the Eleventh Circuit have analyzed this question in depth and have held that there is an implied right of action for regulations promulgated under Title VI, even though these regulations, by reaching disparate impact, are broader than the statute itself.²³ Therefore, the courts at this point seem favorable to the possibility of injured patients suing to enforce the OCR regulations which proscribe disparate treatment in medical facilities.

Even if patients will be able to establish discrimination suits under the OCR regulations covering medical cen-

ters, it is less clear what remedies will be available to these plaintiffs. The possibility of a compensatory damages remedy for such a violation is questionable after *Guardians Association*. The *Guardians* Court made it clear that compensatory relief is not available, at least unless discriminatory intent has been proven.²⁴ One explanation for this limitation is derived from the fact that Congressional authority to create Title VI came from its Spending Clause power.²⁵ When legislating through this power, the government effectively proposes a contract with the states: if a state accepts a specific form of federal funding, it must follow certain regulations, like the prohibitions on discrimination. The Supreme Court in *Pennhurst State School v. Halderman*,²⁶ held that under Spending Clause statutes, courts cannot award relief other than that contemplated by the statute; otherwise they would be adding burdens to the states that were not there at the time the contract was made.²⁷ Supreme Court precedent has established that the legislative history shows that Congress did not intend to include a damages remedy for non-intentional violations.²⁸ In addition, private plaintiffs can not sue to have an institution's funding withdrawn for violation of the statute. Only the overseeing federal agency may act to withdraw the funding. Therefore, absent intentional violation, a plaintiff's remedies may only be prospective relief, such as an injunction requiring compliance with the statute and regulations.

In considering these issues, it is critical to distinguish between intentional discrimination and unintentional discriminatory effects: at what point does a discriminatory practice become intentional? Given these recent studies, the medical community will have a more difficult time in the future arguing that they were not aware that such violations were occurring. For example, these recent studies may not be evidence that individual doctors are intentionally treating minorities and women differently, but they can still be

used to show that medical institutions were aware of the problem. That may be sufficient to prove intentionality if nothing is done to correct the practice. A deliberate indifference standard of intentionality has been accepted in parallel Title IX²⁹ cases where the Supreme Court has held that knowledge of sexual harassment can be violative of Title IX if the harassment is not corrected.³⁰ Moreover, the OCR regulations themselves seem to prohibit deliberate indifference,³¹ suggesting that such behavior may be sufficient to support an intentional discrimination claim. This interpretation is favorable to plaintiffs since the Supreme Court has suggested that compensatory damages may be available in those circumstances.

Over the past decade, our country has focused on tackling the issues of gender and race discrimination both legally and culturally. The recent studies above have brought significant media and congressional attention to this highly relevant strand of the issue: discrimination in health care.³² Whether or not most of these occurrences are blatantly intentional, that inquiry seems irrelevant to anyone who has been injured by these practices. So long as relief is only prospective, the legal machinery will not likely cause a social reconstruction: plaintiffs will have little incentive to bring the legal action which would undoubtedly force medical institutions to face this problem head on. An injunction preventing future discrimination is little consolation to a patient was not referred for cardiac catheterization in time, or was not informed about renal transplantation options. Whether discrepancies exist because physicians tend to have different non-scientific expectations for women and minorities, or because communication between people is affected by race and gender,³³ or for some presently undiscovered reason, sub-optimal health care without physiological basis is not acceptable. Further study into the reasons for inconsistent handling of medical situations is nec-

essary to provide mechanisms for improving health care quality.³⁴ Medical professionals must scrutinize their individual behavior to determine if and when they are letting sociological biases and expectations invade hospital rooms and dictate their patients' futures.

Jessamyn S. Berniker

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7. Bach, *supra* note 3, at 1198.

8. Dries, *supra* note 3, at 609.
9. Bach, *supra* note 3, at 1204; Dries, *supra* note 3, at 616.
10. 42 U.S.C. § 2000d.
11. Barnes, *supra* note 1, at 1984.
12. *U.S. v. Baylor Univ. Med. Ctr.*, 736 F.2d 1039, 1042 (5th Cir. 1984).
13. The meaning of "program" is more limited under the regulations than under Title VI. As used in the regulations it refers only to the specific activities receiving the funding. With respect to Title VI the term has been statutorily extended and applies to the recipient of funding on an institution-wide basis. 42 U.S.C. § 2000d-4a. Therefore, under Title VI if any program within the institution receives funding, all institutional activities are subject to the statute. See *Cureton v. NCAA*, 198 F.3d 107, 115-116, 119-21 (3rd Cir. 1999).
14. *Id.* at 1047-48.
15. See 45 C.F.R. § 80.3(b).
16. 45 CFR § 80.3(b)(2).
17. 45 CFR § 80.3(b)(6)(i).
18. *Guardians Ass'n v. Civil Serv. Comm'n of N.Y.*, 463 U.S. 582, 607-08 (1983).
19. *Alexander v. Choate*, 469 U.S. 287, 293-94 (1985).
20. *Powell v. Ridge*, 189 F.3d 387, 397 (3rd Cir. 1999).
21. *Id.* at 397-98.
22. *Guardians Ass'n*, 463 U.S. at 593-95.
23. *Powell*, 189 F.3d at 399; *Burton v. City of Belle Glade*, 178 F.3d 1175, 1202 (11th Cir. 1999); *Sandoval v. Hagan*, 197 F.3d 484, 502-07 (11th Cir. 1999).
24. *Guardians Ass'n*, 463 U.S. at 607.
25. U.S. CONST. art. I, § 8, cl. 1.
26. *Pennhurst State Sch. v. Halderman*, 451 U.S. 1 (1981).
27. *Id.* at 17.
28. See *Guardians Ass'n*, 463 U.S. at 599-600.
29. 20 U.S.C. §§ 1681 *et seq.*
30. *Davis v. Monroe County Bd. of Educ.*, 526 U.S. 629 (1999).
31. 45 CFR § 80.3(b)(6)(i).
32. Legislation is currently being introduced in both houses of Congress for the purpose of studying disparities in health care in relation to both race and gender. See H.R. 2391, 106th Cong. (1999); S. 1880, 106th Cong. (1999).
33. See L. Cooper-Patrick, "Race, Gender, and Partnership in the Patient-Physician Relationship," *JAMA* 282 (1999): 583 (levels of patient participation in decision-making vary significantly with the race of the patient, and whether or not the doctor is of the same race).
34. See *id.*

Wrongful Death: Oklahoma Supreme Court Replaces Viability Standard with "Live Birth" Standard

On December 7, 1999, a divided Oklahoma Supreme Court held in *Nealis v. Baird*¹ that a claim may be brought under Oklahoma's wrongful death statute² on behalf of a nonviable fetus born alive. The decision represents a departure from the traditional notion that "viability"—the ability of a fetus to sustain life outside the womb with or without medical assistance—is the standard for wrongful death recovery. In replacing the "viability" standard with a "live birth" standard, the majority maintained that live birth is the "unsailable point at which legal rights must be said to attach to the human person."³ By holding a nonviable fetus a legal "person" for the purpose of a wrongful death claim, the court's decision emphasizes the limited application of the United States Supreme Court's holding in *Roe v. Wade*⁴ that a fetus is not a person for the purposes of the Fourteenth Amendment.

Case history

Sheila Nealis had her first and only appointment with Dr. Baird, an Oklahoma Board-certified family physician, on August 28, 1991. Later that night, she discharged fluid and blood. When Mrs. Nealis returned to the clinic in the morning, she was examined by Dr. Hartwig who diagnosed her as threatening miscarriage and ordered an ultrasound. The ultrasound showed no abnormalities. Mrs. Nealis continued to bleed and experience intermittent cramping but did not return to the clinic. One month later, Mrs. Nealis presented herself to the Perry Memorial Hospital (PMH) emergency room where she was seen by Dr. Hartwig, who again diagnosed her condition as threatening miscarriage. Another ultrasound indicated a possible placen-

tal abruption. After Mrs. Nealis missed two follow-up appointments, Drs. Hartwig and Baird sent her a certified letter discharging her from their care.

On November 25, Mrs. Nealis was treated for premature labor by Dr. Knecht, the on-call physician in the PMH emergency room. A third ultrasound confirmed a placental abruption and established the age of the fetus as 20-21 weeks. Dr. Knecht then prescribed Demerol to induce labor, despite its effect of suppressing respiration in newborns. At birth, although nurses testified to gasping noises, measurements of the baby's functions were zero and Dr. Knecht recorded a still birth.

Mr. and Mrs. Nealis pressed two claims in a medical malpractice action. First, they sought damages for personal injuries resulting from the prenatal care provided to Mrs. Nealis by Drs. Baird and Hartwig. Second, they sought recovery from Drs. Baird, Hartwig and Knecht for the wrongful death of their prematurely born child. The jury found for the defendants on both claims and the appellate court affirmed.

Nealis v. Baird

While the Oklahoma Supreme Court affirmed the jury verdict exonerating Drs. Baird and Hartwig on the first claim and Dr. Knecht on the second claim, it reversed the judgment exonerating Drs. Baird and Hartwig on the second, wrongful death claim. The court's reversal rested on an erroneous jury instruction that the fetus must have been viable at the time of birth for liability to attach.

Oklahoma's wrongful death statute applies to a "person" who could have brought actions for personal injury "had he lived." In interpreting the language of this statute, the Oklahoma Supreme Court "reject(ed) the notion that the distinction between biological existence and personhood can extend beyond live birth," holding instead that "once live birth occurs, the debate over whether the fetus is or is not a person

ends.”⁵ The court held that the phrase “had he lived” could apply to a nonviable fetus because “Contemporary scientific precepts accept as a given that human life begins at conception.”⁶

In *Nealis*, the defendant doctors argued that taken together, *Evans v. Olson*⁷ and *Guyer v. Hugo Publishing Co.*⁸ indicate no cause of action for the wrongful death of a nonviable fetus under any circumstances. In *Evans*, the Oklahoma Supreme Court held that a surviving child could bring a common law personal injury action for prenatal injury and, if the prenatal injury resulted in the death of a viable child in the mother’s womb, the child’s representatives could bring an action under the wrongful death statute. In *Guyer*, the Court of Civil Appeals held that Oklahoma did not recognize a wrongful death action for the loss of a nonviable stillborn fetus. The Oklahoma Supreme Court, however, disagreed with the doctors, maintaining that *Evans* and *Guyer* did not govern the *Nealis* case since they both involved a fetus not born alive.

At the same time, however, the court found overbroad the *Nealis*’ interpretation of its decision in *Graham v. Keuchel*,⁹ which held that a wrongful death action in Oklahoma can be predicated upon a prenatal injury that occurs prior to viability. Mr. and Mrs. *Nealis* urged that *Graham* removed viability as a consideration in wrongful death actions if the decedent is born alive at any time during gestation. The court rejected this argument because the question of the child’s viability at the time of its birth and death was not an issue in *Graham*, as the child in that case was born alive after a full-term pregnancy. In *Graham*, the court simply denied the necessity of showing viability at the time of the tortious act causing the injury. Thus, *Graham* did not answer the question of whether a wrongful death action will lie for the death of a nonviable fetus born alive.

In most jurisdictions, if a child is stillborn but survived an injury in utero to reach the point of viability, a wrong-

ful death action may be maintained. However, where the child is born alive prior to attaining viability, decisions conflict about whether a wrongful death action is similarly permissible. The reasons courts have put forth against permitting the action include lack of precedent, difficulty of proof, fear of fictitious claims, the necessity of legislative action authorizing such actions, and the traditional notion that the fetus is not a person prior to viability. These reasons were rejected by the Oklahoma Supreme Court in *Nealis*. While the court conceded that “precedent is sketchy,”¹⁰ it discerned no greater problem regarding matters of proof or fictitious claims than exist in any other tort case. Furthermore, the court argued that the state legislature, by tying the state’s wrongful death statute to the common-law action for damages for personal injury, left the reach of the wrongful death statute to the growth of the common law.

Implications for abortions

The Oklahoma Supreme Court paid special attention to the potential objection to their decision in *Nealis* based on *Roe v. Wade*.¹¹ After noting that nothing in *Roe* prohibits the states from affording legal protection to fetuses born alive, the court argued that *Roe*’s conclusion that a fetus is not a person for purposes of the Fourteenth Amendment to the United States Constitution does not require that it be considered so for every other purpose: *Roe v. Wade* and its progeny “proscribe(s) the state’s protection of the interests of the fetus only when (they) conflict with the privacy-anchored constitutional right . . . to an abortion.”¹² However, “Where both the state and the mother have identical interests in preserving the child’s life and in vindicating harm resulting in its death, *Roe* poses no legal obstacle.”¹³

Oklahoma statutes enacted to operate in the context of abortion¹⁴ presume the viability of an unborn child over 24 weeks old and mandate the

rendering of reasonable medical care during the abortion of a viable child. In *Nealis*, the Oklahoma Supreme Court upheld the appellate court’s decision that the statute does not apply to a spontaneous miscarriage or natural, premature birth. Judge Opala wrote, “The intent of the legislature in enacting this statute was to criminalize certain abortions and not to shift the burden of producing evidence on the issues of viability and the appropriate standard of care in a wrongful action arising out of spontaneous delivery.”¹⁵

Instead of viewing the statutes as setting up an equation between the rights of an aborted infant and a naturally born infant, as Mr. and Mrs. *Nealis* urged, the court perceived the statutes as setting forth a comparison in which the right to medical care of a naturally born infant is used as the baseline for the medical care afforded to an aborted infant of similar status. The court was not persuaded by the argument that a rejection of their position gives an aborted child greater access to medical care than to the *Nealis* child because, according to the ultrasound, he was less than 24 weeks old, removing any requirement of medical care under the abortion statute.

Dissent

Judges Hodges, Struhbar and Johnson dissented from the majority’s decision to depart from the “viability” standard. Writing for the dissent, Judge Hodges argued that, despite a few contrary decisions, there is general consensus that a wrongful death action cannot be maintained for the loss of a nonviable fetus. He argued that the “live birth” standard is based on an arbitrary distinction: whether a nonviable fetus dies shortly before or shortly after a miscarriage. The “viability” standard, on the other hand, merely recognizes that a non-viable fetus cannot survive. Although it is possible for a nonviable infant to show signs of life, such as heartbeat, breathing and brain-wave,

the nonviable infant "lacks sufficient lung tissue to permit survival."¹⁶

Furthermore, the dissent claimed that maintaining the "viability" standard in wrongful death actions would be consistent with the Oklahoma Court of Criminal Appeals' adoption of "viability" as the standard to determine which fetuses will be afforded protection under Oklahoma's homicide statute. "The determination of whether a defendant wrongfully caused the death of a fetus should be guided by the threshold question of 'viability' whether the cause is civil or criminal,"¹⁷ wrote Judge Hodges.

Conclusion

Since the United States Supreme Court decision of *Roe v. Wade*, the line of viability for human fetuses has been consistently pushed back to earlier and earlier gestational ages. Granting "person" status to a *nonviable* fetus, even if only for purposes of the wrongful death statute, as the Oklahoma Supreme Court did in *Nealis v. Baird*, represents an important expansion of fetal rights. Although the court explicitly limited its decision to nonviable fetuses born alive, Judge Opala conceded that much of his opinion could apply equally to stillborn fetuses. The court's decision in *Nealis* raises important questions about the limits of a nonviable fetus's rights under the law and, consequently, the limits of tort liability, particularly for physicians.

Fatma Marouf

References

1. 1999 WL 1116790 (Okla.)
2. 12 Okla. Stat. 1991§ 1053. An action for wrongful death permits the decedent's personal representative (in this case, his parents) to bring a lawsuit only if the decedent had a right of recovery for injuries at the time of his death.
3. *Supra* note 1, at 17.
4. 410 U.S. 113, 93 S.Ct. 705, 35 L.Ed. 2d, 147 (1973).
5. *Supra* note 1, at 9.
6. *Id.*
7. 1976 OK 64, 550 P. 2d 924, over-

ruling *Howell v. Rushing*, 1953 OK 232, 261 P. 2d 217 and *Padillow v. Elrod*, 1967 OK 18, P. 2d 16.

8. 1991 OK CIV APP 121, 830 P. 2d 1393.

9. 1993 OK 6, 847 P.2d 342

10. *Supra* note 1, at 10.

11. *Supra* note 4.

12. *Supra* note 1, at 10

13. *Id.*

14. 63 O.S. 1991 § 1-732; 59 O.S. 1991 §§ 524.

15. *Supra* note 1, at 15.

16. Bodkin, Delivery Room Decisions for Tiny Infants; An Ethical Analysis, 1 J. Clinical Ethics, 306, 307 (Winter 1990), as quoted in *Nealis v. Baird*, *supra* note 1, at 18.

17. *Nealis v. Baird*, *supra* note 1, at 18.

EMTALA: OIG/HCFAs Special Advisory Bulletin Clarifies EMTALA, American College of Emergency Physicians Criticizes It

In December 1998, the Office of Inspector General (OIG) and the Health Care Financing Administration (HCFA) solicited comments from health care providers regarding the federal anti-patient dumping statute, the Emergency Medical Treatment and Active Labor Act (EMTALA) (42 USCA §1395dd). EMTALA is a federal health care law of unprecedented breadth—the first universal benefit guaranteed by the federal government. It requires Medicare-participating hospitals with public emergency rooms, emergency physicians, and ancillary surgical and medical specialists to render adequate stabilizing treatment to whoever requests it. The 1998 Special Advisory Bulletin (63 FR 67486-01) sought input on four principal dimensions of EMTALA: (1) the statutory obligation to furnish adequate medical screening to anyone who visits an emergency room; (2) the responsibilities of health care providers towards enrollees of managed care organizations (MCOs); (3) the prior authorization and pay-

ment rules for Medicare and Medicaid; and (4) what practices would promote hospital compliance with EMTALA.

Last November, OIG/HCFAs published another Advisory Bulletin (64 FR 61353-01) which enumerated the salient issues raised by respondents to the December 1998 Bulletin and clarified how EMTALA is to be interpreted in light of these concerns. The practical effect of the latter Bulletin is to clarify for hospitals how to comply with EMTALA and thereby avoid the legal remedies OIG/HCFAs is empowered to seek. These remedies include statutorily created penalties such as termination of Medicare provider agreements, and civil money damages against both hospitals and individual physicians.

Also in November 1999, the American College of Emergency Physicians (ACEP) released a timely task force report, *Defending America's Safety Net* (available at: <<http://www.acep.org/pdf/safetynet.pdf>>). The report argues that EMTALA has compromised emergency care across the nation by mandating that health care providers render emergency treatment to whoever requests it, regardless of his or her ability to pay. ACEP contends that the federal unfunded mandate disproportionately affects rural and inner-city hospitals because they serve a higher proportion of non-paying patients and tend to have less robust operating budgets. Moreover, ACEP claims that the demands of uncompensated care drive physicians to restrict their availability and, hence, attenuate the already limited resources of many emergency rooms.

EMTALA Advisory Bulletin

Over 150 health care providers contributed to the OIG/HCFAs request for commentary on EMTALA. The subsequent November 1999 Advisory Bulletin addressed the respondents' most prominent concerns: (1) voluntary withdrawal; (2) inquiries from prospective patients about their ability to

pay for emergency care; (3) dual staffing; (4) prior authorization; and (5) use of financial responsibility forms. In addition to delineating these concerns, the Bulletin set forth guidelines to help health care providers understand EMTALA requirements.

Voluntary Withdrawal

According to the Bulletin, hospitals are not permitted to keep patients waiting so long that they elect to withdraw voluntarily and forgo treatment. In the event of a withdrawal, the hospital ought to take the following steps: (1) re-offer the treatment; (2) inform the patient of the risks of leaving; or (3) secure the patient's written informed consent to refuse the treatment. Significantly, the burden rests with the hospital to demonstrate that it has taken appropriate measures to discourage patients from withdrawing.

Inquiries from Patients

And what if patients inquire about financial liability prior to treatment? The Bulletin advises hospitals to defer further discussions until after an appropriate medical screening. Several commentators to the December 1998 Bulletin suggested that this practice may deter unscreened patients from remaining at the hospital because they will be uncertain about what costs they may incur. Nevertheless, the Bulletin maintains that hospitals ought to rebuff such inquiries, placing greater weight on the goals of screening and stabilization. Disclosure of relevant financial information, however, is appropriate as long as it does not interfere with expeditious treatment.

Dual Staffing

An EMTALA-compliant practice has arisen in which hospitals maintain a secondary emergency room staff to treat indigent, uninsured and underinsured patients. Though there is concern that this practice results in dispar-

ate standards of care, the Bulletin contends that there are insufficient data to support this conclusion. As such, dual staffing is not an EMTALA violation *per se* but may be conducive to practices or occurrences that do violate the statute such as substandard medical screening or unreasonably long waits.

Prior Authorization

A dilemma exists for hospitals: they are required by law to accept contracts with MCOs but may violate EMTALA if they comply with the MCOs's prior authorization rules. Generally speaking, these rules require MCOs to authorize all but the most routine procedures and absolve them of financial responsibility if this authorization is not secured. In worst case scenarios, patients and hospitals may bear the financial burdens of unauthorized but nevertheless medically justified emergency care. Though EMTALA does not confer the authority on OIG/HCFR necessary to resolve this conflict perfectly, the Bulletin emphasizes that a physician may contact an MCO for authorization once he or she has rendered initial stabilizing treatment.

Financial Responsibility Forms

Hospitals often present patients with Advance Beneficiary Notices or similar documents, which explain that patients is liable for the costs of any uninsured treatment. The Bulletin endorses a "best practice" of deferring presenting documents until after stabilizing treatment, lest prospective patients be discouraged from staying. Alternatively, it is permissible under EMTALA to incorporate financial matters into a reasonable registration process so long as initial treatment is not unduly delayed.

ACEP's Survey: Defending America's Safety Net

Coinciding with the EMTALA Bulle-

tin, ACEP published an expansive survey of the financial health of the nation's emergency care system, *Defending America's Safety Net*. The report focuses on the frontline providers of last resort who comprise the most vital strands of what ACEP calls the "safety net", and how that net has begun to fray under the weight of copious EMTALA requirements. Given the number of uninsured Americans (estimated to be 43 million), compliance with EMTALA often imposes non-trivial financial burdens on hospitals and, ACEP argues, interferes with the quality of emergency care for those whom it is meant to serve. In dramatic language, ACEP characterizes EMTALA requirements as "a clear and present danger to the integrity of the nation's delivery system for emergency medical care."

Unlike other federal health care initiatives, EMTALA is an unfunded mandate. As such, it is responsible for a preponderance of the uncompensated care provided by physicians and hospitals. In its report, ACEP estimates that the direct and indirect costs of compliance are at least \$10 billion, and may be as high as \$27 billion. Since emergency rooms are the main portal of entry to the health care system for a majority of persons without insurance, a disproportion of these costs fall upon rural and inner-city providers, where most of these patients are found. As the number of uninsured grows, the requirements of EMTALA may further jeopardize the financial viability of these providers.

At the heart of the problem is emergency department (ED) saturation in many parts of the country. By this ACEP means that many EDs are inundated regularly not only with more patients than they can handle but also with many patients who cannot pay. These EDs try to cope by assigning their physicians to back-up call panels that can support the on-duty shift. EDs then confront a difficult choice: either make uncompensated coverage on these panels a condition of physician employ-

ment or subsidize care from other budgetary sources.

ACEP recommends initiatives across several frontiers. First, at the local level, it urges hospitals to affiliate themselves into cohesive networks to share more evenly the costs of EMTALA compliance. At the state level, legislatures ought to provide at least some of the resources needed to defray the costs of uncompensated care. Finally, given what it terms the "health care stalemate in Washington", ACEP is somewhat pessimistic about what the federal government can do to alleviate EMTALA pressures. As such, ACEP advocates a long-term view that emphasizes a gradual evolution towards a regime in which emergency care is accessible and appropriately compensated. To achieve these goals, ACEP encourages HCFA to experiment with creative alternatives to the current EMTALA-oriented system. For example, HCFA could oppose the criminalization as fraud and corruption the practice of using Medicare, Medicaid and similar public funds to cross-subsidize uncompensated care. Another possibility is for HCFA to require MCOs to compensate physicians who justifiably treat MCO patients, even if proper prior authorization was not secured. Only through these sorts of structural changes, ACEP believes, will stability and universal accessibility be achieved.

Conclusion

Though the Special Advisory Bulletin clarifies how health care providers are to comply with EMTALA, it leaves the largest question unanswered: What are the long-term financial implications of an onerous and unfunded mandate? The ACEP report contends that the central aim of EMTALA—a minimal universal health care benefit—is unattainable so long as providers teeter precipitously on bankruptcy. As in other areas of health care, the crux of the EMTALA debate is how to reconcile the statute's expansive goals with the

meager resources available for their realization.

Jeffrey Rowes

Disability & ADA: Disparate Insurance Coverage for Physical and Psychological Disabilities Does Not Violate ADA

In *Kimber v. Thiokol Corp.*, 196 F.3d 1092 (10th Cir. 1999), the U.S. Court of Appeals for the Tenth Circuit upheld a U.S. District Court's grant of summary judgment against an employee's claim that an employer-operated disability insurance plan, which offered different levels of compensation for disabilities due to mental and physical conditions, violated Title I of the Americans with Disabilities Act (ADA).¹ The Court of Appeals found that (1) the Thiokol plan administrator's interpretations of the plan were not arbitrary and capricious, and that (2) the plan's different treatment of disabilities caused by physical and mental conditions did not violate the ADA.

The Americans with Disabilities Act (ADA) is a general remedial statute designed to combat discrimination against persons with disabilities.² Both private plaintiffs and the Equal Employment Opportunity Commission (EEOC) may enforce the act.³ Title I of the ADA prohibits discrimination against employees "because of their disability" in the terms, conditions, and privileges of their employment.⁴

Defendant Thiokol administered a disability benefits plan for its employees. The plan compensated employees for disabilities, with no cap on the duration of benefits for a disability caused by a physical condition. Compensation for mental disabilities was limited to 24 months.

Plaintiff Ivan Kimber worked for Defendant Thiokol as a heavy equipment operator from the 1970s until the secondary effect of insulin dependent

diabetes caused him to be reassigned as a clerk, and then to leave work. The Thiokol disability insurance plan found that he was totally disabled by visual, circulatory, and other sequelae of his diabetes. Kimber's continued disability was reviewed regularly by Thiokol's benefits plan and John Hancock Co., Thiokol's external claim reviewer. In 1995, Kimber's continued disability was questioned by John Hancock. His benefits were terminated for failure to provide documentation of a continuing disability. Kimber submitted a request for continued benefits supported by evidence that he continued to be disabled by depression and possible psychosis associated with his physical condition. Thiokol reinstated Kimber's disability payments, but classified his claim as based on a mental disability, and imposed the 24 month benefits cap.

Kimber brought suit to require the continuation of benefits in the U.S. District Court for the District of Utah. He claimed that the decision to terminate was contrary to the terms of the Thiokol disability plan, and that the plan's difference in coverage for physical and mental disabilities violated the ADA. The District Court granted defendant Thiokol's motion for summary judgment. The 10th Circuit Court of Appeals reviewed *de novo*. Writing for the 10th Circuit's unanimous three-judge panel, Judge Paul Kelly evaluated and rejected Kimber's claims under the ADA and ERISA, the Employee Retirement Income Security Act ("ERISA").⁵

ERISA regulates the operation of employee benefits plans to ensure the compliance of the plan manager with its own rules, and to ensure that employees receive the benefits to which they are entitled. Kimber argued that the process and decisions by which the plan administrator reclassified and then terminated his benefits violated the law. The court rejected this claim. Benefits plan administrators' determinations of fact and interpretations of plan terms are evaluated under a highly deferential standard—they will not be dis-

turbed by a reviewing court unless arbitrary and capricious.⁶ Kimber argued that Thiokol's operation of its own self-funded plan created a conflict of interest, and that the court should therefore review the administrator's actions with reduced deference. The court rejected this contention, arguing that there was no appreciable conflict of interest because the plan was administered by a salaried employee, and that disability benefits paid under the plan only totaled 0.3% of Thiokol's annual operating expenses.⁷ The court found (1) that the administrator's reclassification of Kimber's disability was an appropriate exercise of the plan's continuing review provisions,⁸ (2) that documents supporting Kimber's claims were properly reviewed by a managed care plan contractor rather than the plan administrator herself,⁹ and (3) that the facts before the administrator could support the conclusion that the disability was due in significant part to a mental illness.¹⁰ The administrator's determination rested on her interpretation of language in the plan distinguishing between disabilities "due to" physical and mental illness.¹¹ She read the term as meaning "due, in at least significant part, to". Reviewing the administrator's interpretation of the plan, the court found that the phrase "due to" was ambiguous, and that the interpretation was a reasonable, and therefore valid, interpretation of ambiguous language.¹²

The court then considered the position of Kimber and, as *amicus curiae*, the EEOC, that providing disparate benefits for physical and mental disabilities violates the ADA. Kimber focused on the different benefits given by the plan to workers with different disabilities. Relying on decisions in similar cases from the Third¹³, Fourth¹⁴, Sixth¹⁵, Seventh¹⁶, and Eighth¹⁷ Circuits, the court dismissed Kimber's argument. Rather than adopting Kimber's stance that a court's focus should be on the disparate ex-post treatment of disabilities, the court focused on the neutral ex-ante opportu-

nity for plan participation offered to employees. In other words, the court held that instead of considering the differences between compensation paid to plan beneficiaries with different disabilities, the proper question is whether any beneficiaries with protected disabilities were discriminated against because of their disability by being denied the same benefits other plan members would receive for the same disability.

Judge Kelley noted that "[w]hile [Thiokol's disability plan differentiated between types of disabilities, this is a far cry from a specified employee facing differential treatment due to her disability. . . .]"¹⁸ The court held that "[s]o long as every employee is offered the same plan regardless of that employee's contemporary or future disability status, then no discrimination has occurred. . . ."¹⁹ Quoting the 7th circuit's decision in *EEOC v. CNA Insurance*, the court added that ". . . the ADA does not mandate equality between individuals with different disabilities."²⁰

The court also noted the potential financial implications of requiring insurance companies and employee-operated plans to provide benefits to persons with mental disabilities at the same level they do for those with physical disabilities. It echoed the Third Circuit's finding in *Ford v. Schering-Plough* that if the ADA was held to require such treatment, it "...would destabilize the insurance industry in a manner definitely not intended by Congress when passing the ADA."²¹

Finally, the court relied upon the D.C. Circuit's ruling in *Moddero v. King*²² that distinctions in benefits based on physical and mental disabilities had been valid under the ADA's predecessor, the Rehabilitation Act. Because of the similar purposes and structures of the two laws, Rehabilitation Act case law is often used as a model for interpreting the ADA.²³

The Tenth Circuit's opinion was handed down in the context of increased political activity surrounding

mental health and the mentally ill. Activists in the area have focused both on increasing the resources available to mentally ill persons and their families, and upon changing the public perception of mental illness. In the first Surgeon General's Report on Mental Illness, Dr. David Sacher notes that "[Mental disorders] continue too frequently to be spoken of in whispers and shame. Fortunately, leaders in the mental health field—fiercely dedicated advocates, scientists, government officials, and consumers—have been insistent that mental health 'flow in the mainstream of health.'"²⁴ HHS Secretary Donna Shalala has praised Tipper Gore's work as Mental Health Advisor to the President in arguing that "mental illnesses are just as real as other illnesses. . . ."²⁵

Had it adopted the position taken by Kimber and the EEOC in this matter—that the ADA requires similar treatment of physical and mental disabilities—the court would have provided a powerful tool to equalize treatment for mental illness. It would also have made a clear statement of public policy that mental illness is no less important than physical illness. The rejection of this view by the *Kimber* court and subsequently by the Ninth Circuit in *Weyer v. Twentieth Century Fox*,²⁶ has forced advocates for equal treatment to return to the legislative and administrative arenas in their search for relief.

Nicklas A. Akers

1. 42 U.S.C. §12101-12213 (Supp.II 1997)

2. 42 U.S.C. §12101(b) (Supp.II 1997) ("It is the purpose of this chapter: (1) to provide a clear and comprehensive national mandate for the elimination of discrimination against individuals with disabilities. . . .")

3. 42 U.S.C. §12117 (Supp.II 1997)

4. 42 U.S.C. § 12112(a) (Supp.II 1997)

5. 29 U.S.C. § 1001-1461 (Supp.II 1997)

6. *Charter Canyon Treatment Ctr. v. Pool Co.*, 153 F.3d 1132, 1135(10th Cir.1998); *Kimber*, 196 F.3d at 1100.

7. *Kimber*, 196 F.3d at 1098
8. *Id.*
9. *Id.* at 1099
10. *Id.*
11. *Id.* at 1100.
12. *Id.*
13. *Ford v. Schering-Plough Corp.*, 145 F.3d 601 (3rd Cir.1998), *cert. den'd.* 119 S.Ct. 608 (1999) (Title I does not require equal treatment of mental and physical disability in employee operated plan, Title III, relating to public accommodations, does not apply to such plans.)
14. *Lewis v. Kmart Corp.*, 180 F.3d 166 (4th Cir.1999) (Title I does not prohibit employer or its insurance company from offering different physical and mental disability coverage)
15. *Parker v. Metropolitan Life Ins. Co.*, 121 F.3d 1006 (6th Cir. 1997) (*en banc*) *cert. denied* 522 U.S. 1084 (1998) (Title I does not prohibit employer or its insurance company to offer equal benefits for physical and mental disability; Title III does not apply to employer.)
16. *EEOC v. CNA Ins. Co.*, 96 F.3d 1039 (7th Cir.1996) (Insurance company offering plan to its own employees not prohibited by Title I from offering different benefits for physical and mental disability); "Few, if any mental health advocates have thought that the result they would like to see had been there all along in the ADA." *Id.* at 1044.
17. *Krauel v. Iowa Methodist Med. Ctr.*, 95 Fed.3d 674 (8th Cir.1996) (Employer health benefit plan may exclude funding for infertility treatment under ADA Title I and Title VII.)
18. *Kimber*, 196 F.3d at 1101, quoting *Ford*, 145 F.3d at 608.
19. *Id.*
20. *Kimber*, 196 F.3d at 1101, quoting *EEOC v. CNA Ins. Co.*, 96 F.3d 1039, 1044 (7th Cir.1996)
21. *Kimber*, 196 F.3d at 1102, quoting *Ford*, 145 F.3d at 608
22. *Kimber*, 196 F.3d at 1102, quoting *Moddero v. King*, 82 F.3d 1059, 1061 (D.C.Cir.1996) (Rehab. Act does not prohibit US Foreign Service Benefit Fund from offering different health insurance benefit for physical and mental illness.)
23. *Bragdon v. Abbot*, 524 U.S. 624, 631 (1998)
24. Dr. David Sacher, *Preface*, in *MENTAL HEALTH: A REPORT OF THE SURGEON GENERAL* (1999), (Visited Feb. 21, 2000) <<http://www.surgeongeneral.gov/library/mentalhealth/home.html>>
25. Donna Shalala, *Message from Donna E. Shalala, Secretary of Health and Human Services*, in, *MENTAL HEALTH: A REPORT OF THE SURGEON GENERAL* (1999),

(Visited Feb. 21 2000) <<http://www.surgeongeneral.gov/library/mentalhealth/home.html>>

26. *Weyer v. Twentieth Century Fox Film Corp.*, 198 F.3d 1104 (9th Cir.2000) (citing *Kimber* at 1116) (Neither employer or insurance company prohibited by Title I from offering different physical and mental disability benefits, Title III does not apply to insurance company.)

AIDS: Mississippi Supreme Court Adopts New Standard for Fear of Exposure to AIDS

On November 4, 1999, in *South Central Regional Medical Center v. Pickering*, 1999 WL 1000703 (1999), the Mississippi Supreme Court created a new legal standard that allows patients to recover damages for fear of exposure to AIDS even though they cannot prove actual exposure. By adopting this standard, the Mississippi Supreme Court joined the minority of jurisdictions seeking to encourage providers to use reasonable care when handling instruments capable of transmitting disease.

Factual background

Plaintiff Jimmie Pickering is a female diabetic, who was receiving treatment at South Central Regional Medical Center (South Central) between September 30 and October 5, 1987 to regulate her blood sugar levels. Pickering used the hospital's Autoclax machine, which required that Pickering use lancets to prick her finger to draw blood.

According to Pickering, the nurse responsible for her treatment informed her that the lancets with which she had been pricking her fingers were previously used lancets. In one alleged incident, the nurse grabbed Pickering's hand, effectively preventing her from using a lancet. The nurse informed Pickering that the group of lancets from which she had chosen was a group of previously used lancets and immedi-

ately disposed of the lancets in a proper receptacle. When Pickering asked the nurse why she had not disposed of the lancets before then, the nurse allegedly responded that the receptacle was implemented only two weeks earlier and that she was not yet accustomed to using it.

Pickering further claimed that every time she had previously tested her blood for sugar levels, she had been employing used lancets. However, Pickering was unable to offer any evidence that the lancets she used were contaminated with HIV or any other communicable diseases; the lancets were disposed of by the hospital before they could be tested.

It is undisputed, however, that South Central ordered Pickering to be tested for HIV. She was tested five times between September, 1987 and September, 1988. Each time, the result of the test was negative. After learning that she was exposed to previously used lancets, Pickering allegedly became extremely anxious and afraid that she had contracted HIV. Pickering and her husband brought suit for emotional distress.

Previous court rulings

The "actual exposure" requirement was recently articulated in Mississippi in *Leaf River Forest Products, Inc. v. Ferguson*, 662 So.2d (Miss. 1995). In this 1995 decision, the Mississippi Supreme Court held that for a patient to recover for emotional distress predicated on potential future illness, "there must be substantial proof of exposure and medical evidence that would indicate a possible future illness." *Id.* at 658. In that case, the Fergusons brought suit based on a fear of developing cancer from dioxins released by a mill situated 100 miles away from their house. The Ferguson's claim was rejected on the grounds that they never tested the water from their wells and property; tests of dioxin levels in neighboring areas that they presented was deemed insufficient. The court held that "emo-

tional stress based on the fear of a future illness must await a manifestation of that illness or be supported by substantial exposure to the danger." *Id.* at 650.

A majority of jurisdictions side with the *Ferguson* requirement of actual exposure when considering emotional distress claims based on a fear of contracting AIDS. For example, in *Pendergeist v. Pendergrass*, 961 S.W.2d 919 (1998), a patient sued a hospital for allegedly giving him a human blood factor instead of a synthetic blood factor which was known to be safer. The Missouri court rejected the patient's claim, because "he failed to offer any evidence that the [human] blood product was contaminated with HIV or hepatitis B." *Id.* at 926.

A minority of jurisdictions maintains that actual exposure is not a prerequisite to recovering damages. The damage amount in these cases, however, is less than the amount in the actual exposure cases. Here, courts limit the patients' recovery for emotional distress to a "window of anxiety," defined as the period of time between when a patient learns of possible exposure to HIV and when the patient receives definitive HIV-negative results. *Faya v. Almara*, 620 A.2d 327 (1993).

***South Central Regional Medical Center v. Pickering*: A new standard is adopted.**

In Pickering's case, the Mississippi Supreme Court declined to use the actual exposure requirement to dismiss her claim. Notably, the court explained that it did not abandon the actual exposure requirement. The court held that in actual exposure cases a patient needs only to establish: (1) that the hospital owed a duty to the patient to protect her from exposure to diseases; (2) that the hospital breached that duty by "negligently allowing or causing a medically recognized instrument or channel of transmission to come into physical contact" with the patient; (3) that the resulting

emotional injury was a "foreseeable result of that breach"; and (4) that there was, in fact, an emotional injury. In such cases, where the hospital "allowed or caused the best evidence to be destroyed," thereby denying the patient an opportunity to test it, a rebuttable presumption arises in favor of the patient in court. Thus, the hospital, not the patient, carries the burden of proving that the instrument which came into contact with the patient as a result of the hospital's negligence did not carry a disease.

According to the court, the rebuttable presumption prevents the unjust result of punishing the patient in court for not being able to offer substantial proof of exposure where the source of that substantial proof has been destroyed by its source. This injustice would not occur, the court noted, if the hospital did not know or have reason to know that the evidence which it discarded was in question and where it was disposed of in the normal course of a medical practice. In such cases, then, the court held that the presumption does not arise.

Finally, the court decided that in the absence of illness resulting from the alleged exposure, as in this case, recovery is limited to compensation for emotional distress during the "window of anxiety." For Pickering, the window was the time period between when she learned of her possible exposure and when she received conclusive HIV-negative results.

Conclusion: Some policy concerns

The issue of whether a patient is required to prove actual exposure in recovery for fear of contracting AIDS is a difficult one. Indeed, courts' attempts to resolve the issue have triggered tumultuous public policy debates. The majority of jurisdictions have continued to emphasize the importance of requiring actual exposure in order to ensure that a claim is bona fide, while the minority has responded by arguing that the actual exposure rule does

not provide plaintiffs with compensation for legitimate grievances. 22 Am. J. Trial Advoc. 495 (1998). With its ruling, the Mississippi Supreme Court supplied an additional justification through its encouragement of hospitals to use reasonable care in handling instruments capable of transmitting disease and to conduct tests to determine whether such instruments are contaminated in the event that they came into contact with an individual. According to the courts, the burden should fall on the providers because they are, in the end, the greater cost-avoider: "South Central was in the best position to determine the capability of the lancet to transmit the disease causing agents. A simple and relatively expeditious test of the lancet would most likely have prevented the Pickerings from developing any substantial or reasonable fears of contracting any communicable diseases."

Iris Lan

Organ Transplantation: New Regulations to Alter Distribution of Organs

On December 17, 1999, President Clinton signed the Ticket to Work and Work Incentives Improvement Act of 1999,¹ which instituted a 90-day comment period for the amended Organ Procurement and Transplantation Network ("OPTN") Final Rule ("Final Rule"), a comprehensive set of guidelines that would affect how organs are allocated throughout the country.² Barring further legislative action, the Final Rule, which has been over five years in the making, will be effective on March 16, 2000.³

The Final Rule, issued by the Department of Health and Human Services ("DHHS") pursuant to the National Organ Transplant Act,⁴ was originally published April 2, 1998.⁵ It provided a number of substantive changes to the process through which organs are allocated by the United Network for Organ Sharing (UNOS), a private,

non-profit organization charged with administering the national organ transplantation network.⁶ Following a one-year moratorium to allow comments and review, DHHS published an amended version of the rule on October 20, 1999. This version incorporated suggestions made after an extensive review undertaken at Congress' request by the National Academy of Science's Institute of Medicine. The rule was to go into effect on November 19, 1999, but was again stayed to allow further examination as well as scientific and medical input.

The cautious approach to the Final Rule is understandable, as it seeks to adjust a delicate national system of organ allocation initiated in the 1970s. While organ transplantation has become "an established medical procedure," with over 20,000 transplants performed annually in 278 transplantation centers,⁷ the way in which organs should be allocated remains controversial. The debate over the Final Rule reflects the ideological and practical divide between DHHS and UNOS concerning the procedure and criteria for allocating organs, as well as the procedure for reviewing the organ allocation system.⁸ The root of their disagreement appears to be how to deal with scarcity. With only approximately 10,000 organ donors each year for over 60,000 patients in need, policy decisions determining who receives the limited number of organs carry crucial consequences.⁹

Under the current system, UNOS implemented guidelines where "patients are given priority for organs based first on their geographic location instead of their medical need."¹⁰ Once an organ becomes available, the system looks within the local geographical confine, allocating the organ to the patient who has the greatest medical need. This organ will normally be sent to other regions only if no one in the original locale can accept it. This system reflects the current medical reality: organs remain viable only for a limited amount of time prior to the trans-

plantation. Thus, it is not generally considered feasible to transport an organ great distances.¹¹ With the improvement of medical technology, these "cold ischemic times" (i.e., when the organ is en route) have been extended; still, neither DHHS nor UNOS maintain that organs currently remain viable for enough time to establish a true "national" list. However, despite the impracticality of a national list, some do criticize the system for adhering to the "local first" allocation policy, reasoning that the "geographic areas" could be broadened. If the size of the region is increased, they argue, those patients in greater need could receive organs without necessarily jeopardizing the organ's viability.¹²

Another criticism of the current system is the alleged lack of uniform criteria for "deciding when to list patients for transplantation and for identifying patients' medical urgency status."¹³ Insofar as "waiting time" is used as a criterion, and to the extent that an arbitrarily-defined "medical need" allows one patient to pass another on the list, DHHS argues that the system needs a common set of classifications for doctors in diverse geographic areas. Otherwise, certain patients described by their doctors "as more medically urgent than they really are"¹⁴ will be placed above others in equal or even greater need.¹⁵

A third complaint is that the final system lacks a strong, governing body to ensure non-arbitrary decisions and compliance with the rules. DHHS claims that increased accountability and review could better meet the public interest in providing for the fair, equitable, and effective distribution of organs to those patients most in need.¹⁶

While there are other alleged systemic deficiencies, the perceived problems above were the primary focal points of public scrutiny, and the main areas where the Final Rule came under attack. Relying in part on the Institute of Medicine's study, DHHS amended the original rule to address these shortcomings. The Final Rule

requires UNOS "to develop standardized criteria for listing patients and defining their medical urgency status," attempting to eliminate perceived differences in treatment based on geographic disparities.¹⁷ This enables UNOS, relying on the extensive and diverse backgrounds and experiences of its members, to determine the medical and ethical guidelines for minimizing the role of geography.¹⁸ The Final Rule also mandates that organs be provided first to those patients with the greatest need, given the ischemic restraints as well as other medical considerations such as favoring healthier patients over those who may be too ill to benefit from the transplantation.¹⁹ Finally, *inter alia*, the Final Rule establishes "an independent scientific review board" to aid the DHHS Secretary in evaluating, overseeing, and enforcing the organ allocation policies under the rule and as formulated by UNOS.

While there is the expected consensus that the system should be fair and effective, disagreement appears when deciding *how* to make the system fair and effective. UNOS and many transplant practitioners fear the proposed rule, while well-intentioned, will be ineffective, and furthermore, may even cause harm. One concern is that increasing the geographic areas over which organs are distributed would unduly favor large transplant centers; if so, this trend could eventually force smaller and medium-sized centers to close. UNOS worries that if transplant centers close, people, lacking the visible reminder of the local transplant center, will be less likely to donate organs, which will further exacerbate the existing organ shortage.²⁰ On a similar note, UNOS has argued that a broader geographic list will lead to longer waits for those patients previously in a smaller geographic area; if organs are distributed nationally, and one criteria for distribution is the length of the wait, those centers with more people (and thus most likely longer waits) may command organs before the smaller center patients get their turn.²¹

Critics of the plan also fear that its provisions will lead to the sickest patients getting the organs, even if these organs would be better or more efficiently used in healthier persons with greater chances of survival.²² Finally, some worry that the regulation delegates too much power to DHHS, dubiously stripping the UNOS doctors and experts of the decision-making power only doctors and experts should have.²³

However, despite the earnest hesitation, many of these fears appear unfounded. The Final Rule grants broad latitude to UNOS in developing the medical standards to implement the rule's more general goals. Where a strict interpretation of the rule would violate the clear intent of saving lives with optimal efficiency, it can plausibly be assumed that the DHHS would hear UNOS concerns and approve them where appropriate. The Final Rule in no way suggests that sound medical practices should be abandoned for the sake of any "bright line" test erroneously read into the rule. Also, extending the geographic regions is merely an attempt to get organs to those most in need, instead of those closest to the donor (when and where medically appropriate and feasible, as determined by UNOS). As well as providing a more equitable distribution, this should allow smaller centers with fewer donors to benefit, receiving organs from other regions for critical cases that would otherwise be used by less urgent patients in the locale where the organ was donated. On a similar note, if organs are allocated beyond the region where they are procured, a local region need not produce as many donors to ensure its patients are served. This may benefit those regions where health and safety regulations lead to fewer deaths in which organ donation is possible.

Given the dissonance, it appears that the rift will continue until many of these notions are tested and evaluated using real empirical data. However, compromise is possible: the original Final Rule was amended, and, in

recent months, UNOS has adopted "larger" geographic areas for allocating livers, as well as endorsed more uniform national standards for evaluating one's need for an organ and concomitant place on the wait list. In all, despite the remaining disagreements, it appears that the Final Rule takes a necessary and flexible²⁴ step toward a more reasonable and equitable system of organ allocation.

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1. H.R. 1180, 106th Cong. § 413 (1999).

2. See 64 Fed. Reg. 71,626 (1999).

3. See *id.*; Health Resources and Services Administration, *Fact Sheet on Improving the Nation's Organ Transplantation System* (visited Feb. 10, 2000) <<http://www.hrsa.gov/osp/dot/Fact%20Sheet.pdf>>.

4. 42 U.S.C. §§ 216, 273-274d; 42 U.S.C. §§ 1302, 1306, 1320b-8, 1395hh.

5. See 64 Fed. Reg. 71,626 (1999).

6. See United Network for Organ Sharing, *Comments Sought on UNOS Liver Allocation Plan* (visited Feb. 22, 2000) <http://www.unos.org/frame_Default.asp?Category=Newsroom>. UNOS combines "medical, scientific, and educational" sources to determine how organs should be allocated from both medical and ethical viewpoints. United Network for Organ Sharing, *Public Comment: Policy and By-Law Proposals* (visited Feb. 22, 2000) <http://www.unos.org/frame_Default.asp?Category=Pcomment> ("On January 1, 1997, "UNOS received a federal contract to continue operation of the national OPTN and develop an equitable, scientific, and medically-sound organ allocation system.").

7. Health Resources and Services Administration, *Fact Sheet on Improving the Nation's Organ Transplantation System* (visited Feb. 10, 2000) <<http://www.hrsa.gov/osp/dot/Fact%20Sheet.pdf>>.

8. See generally *infra* notes 12-23 and accompanying text (describing the relative merits of the proposed Final Rule).

9. See Health Resources and Services Administration, *Fact Sheet on Improving the Nation's Organ Transplantation System* (visited Feb. 10, 2000) <<http://www.hrsa.gov/osp/dot/Fact%20Sheet.pdf>> (noting that "[a]most 5000 patients die each year, some 13 each day, while awaiting an organ for transplantation").

10. *Id.*

11. See United Network for Organ Sharing, *Justification for Equitable Organ Allocation* (visited Feb. 22, 2000) <http://www.unos.org/frame_Default.asp?Category=Newsroom>.

12. See, for example, Health Resources and Services Administration, *Secretary Shalala Statement* (visited Feb. 10, 2000) <<http://www.hrsa.gov/osp/dot/Sec%20Statement.pdf>> (stating that, "[o]rgan sharing must take place over broad enough areas to ensure that organs can reach the patients who need them most, and for whom transplantation is most medically appropriate"); see also Health Resources and Services Administration, *Fact Sheet on Improving the Nation's Organ Transplantation System* (visited Feb. 10, 2000) <<http://www.hrsa.gov/osp/dot/Fact%20Sheet.pdf>>.

13. Health Resources and Services Administration, *Fact Sheet on Improving the Nation's Organ Transplantation System* (visited Feb. 10, 2000) <<http://www.hrsa.gov/osp/dot/Fact%20Sheet.pdf>>; see also United Network for Organ Sharing, *Justification for Equitable Organ Allocation* (visited Feb. 22, 2000) <http://www.unos.org/frame_Default.asp?Category=Newsroom> ("At present, there are no rules governing what the patient's condition must be in order to be added to the list.").

14. Health Resources and Services Administration, *Fact Sheet on Improving the Nation's Organ Transplantation System* (visited Feb. 10, 2000) <<http://www.hrsa.gov/osp/dot/Fact%20Sheet.pdf>>.

15. See *id.* It should be noted that this does not necessarily imply doctors abuse the system. It only suggests that, without a uniform standard, doctors in some regions may classify patients differently than doctors in other regions. This may produce unequal results to the extent that such classifications are then used to allocate organs.

16. See *id.*

17. *Id.* See also Health Resources and Services Administration, *HHS Rule Calls for Organ Allocation Based on Medical Criteria, Not Geography* (visited Feb. 22, 2000) <<http://www.hrsa.dhhs.gov/News-PA/organreg.htm>> (stating that "allocation of scarce organs [should] be based on common medical criteria, not accidents of geography").

18. It should be mentioned that, while the criteria for allocating organs differ with each organ (e.g., certain organs require extensive prescreening to find a positive match with the patient; certain organs remain viable prior to transplant for different periods of time), these differences are

immaterial to the Final Rule. The regulation requires UNOS to implement the standards for organ allocation, and in no way requires the same set of criteria for each organ; the differences will be adjusted by UNOS *under the rule*.

19. See Health Resources and Services Administration, *Fact Sheet on Improving the Nation's Organ Transplantation System* (visited Feb. 10, 2000) <<http://www.hrsa.gov/osp/dot/Fact%20Sheet.pdf>> ("allocating organs to most medically urgent patients does not require transporting organs so far that organ viability would be threatened, but instead recognizes that medical factors limit the transportability of organs; the final rule does not require a single "national list" for allocation, but rather calls on the OPTN to develop adequately broad allocation areas to ensure best use of organs to save lives....").

20. See United Network for Organ Sharing, *IOM Report Released* (visited Feb. 22, 2000) <http://www.unos.org/frame_Default.asp?Category=Newsroom>. However, it is not clear why sending organs to a different geographic location for those most in need would deter potential donors. Furthermore, if the fear is that local transplant centers will close, thus reducing donor visibility, public information campaigns could easily reverse this decline.

21. See United Network for Organ Sharing, *Transcript of Dr. Hunsicker's Testimony* (visited Feb. 22, 2000) <http://www.unos.org/frame_Default.asp?Category=Newsroom>. This argument questionably presupposes that the length of the patient's wait will be a relevant factor; it also ignores that at some point the smaller center patients will have waited the same amount of time as the larger centers (especially if they are continually passed over in favor of said larger centers).

22. See Health Resources and Services Administration, *Fact Sheet on Improving the Nation's Organ Transplantation System* (visited Feb. 10, 2000) <<http://www.hrsa.gov/osp/dot/Fact%20Sheet.pdf>> (noting the views of the Final Rule's critics).

23. See United Network for Organ Sharing, *Transcript of Dr. Hunsicker's Testimony* (visited Feb. 22, 2000) <http://www.unos.org/frame_Default.asp?Category=Newsroom>; United Network for Organ Sharing, *IOM Report Released* (visited Feb. 22, 2000) <http://www.unos.org/frame_Default.asp?Category=Newsroom> (explaining that "Congress made clear when it passed the National Organ Trans-

plant Act 15 years ago that crucial medical decisions about transplantation should be made by the medical community.").

24. In addition to the broad latitude afforded UNOS in implementing the specifics of the Final Rule's provisions, the step can always be retraced if experience proves the rule-makers wrong.

Internet Pharmacies: Regulation of a Growing Industry

Industry analysts estimate that Internet pharmacies will generate \$1.4 billion¹ in prescription drug sales by 2001 and over \$15 billion by 2004.² The recent rush by traditional brick and mortar pharmacies either to partner with existing Internet pharmacies or to create their own web counterparts illustrates the increasing importance of business on the Internet. Last summer, retail pharmacy giant CVS acquired the Internet pharmacy soma.com and changed its name to reflect the new ownership.³ Early this year, in another key industry move, Walgreen's launched an upgraded, full-service Internet pharmacy in order to compete more successfully in the pharmacy industry.⁴ It is estimated that there are currently over 400 businesses operating on the Internet that dispense prescription drugs.

As the number of Internet pharmacies has increased, so has the concern regarding the safety of prescription drugs dispensed over the Internet. Many of these web sites prescribe prescription drugs without a valid prescription, dispense drugs of questionable quality and fail to inform patients of possible side effects and interactions. Additionally, customers have difficulty knowing whether an Internet pharmacy is a legitimate operation.

How pharmacies operate on the Internet

Despite the large number of Internet pharmacies, they fall primarily into four categories⁵: online pharmacies

that are partners with traditional brick and mortar pharmacies (such as drugstore.com and Rite Aid); online pharmacies that are themselves brick and mortar pharmacies (such as cvs.com); online pharmacies that operate solely on the Internet (such as planetrx.com); and web sites, usually based outside of the United States, where consumers can order prescription drugs without a prescription (such as viagra-global.com).

Each of these types of pharmacies operates differently with regard to how a patient seeks to have a prescription filled. All require the patient to set up a personal account by choosing a user name and password. This account contains basic personal information such as name, address and phone number, primarily for the purpose of billing and shipping. Only a few of the Internet pharmacies require patients to complete any type of health questionnaire detailing such relevant specifics as allergies, diagnosed illnesses and medical history.

Internet pharmacies offer the consumer several different options in filling their prescriptions. Initially, consumers can mail their prescription to an address given on the web site. This works the same way as mail order pharmacies that have existed for many years. Some pharmacies require consumers to mail in their prescription, as is the case with prescriptions for Schedule II narcotics filled on cvs.com. Second, patients can have their physician phone, fax or mail the prescription to the Internet pharmacy, just as they would with their traditional neighborhood pharmacy. Third, patients can enter their prescription information directly into the web site themselves. Depending on the particular Internet pharmacy, the web site may contact the physician to verify the prescription in every case or only on an as-determined basis. Fourth, patients can transfer existing prescriptions to Internet pharmacies by directing their current pharmacy to do so or by providing the relevant information to the web site,

which will then contact the pharmacy. Fifth, each Internet pharmacy allows consumers to obtain refills of prescriptions they have had previously filled on the web. This requires the consumer to log in to their personal account and complete a simple form. Finally, in the case of most internationally-based web sites, the consumer simply completes an order form and selects the desired drug and quantity.⁶

After the consumer transmits his or her prescription to the Internet pharmacy using one of these methods, the web site then ships the prescription directly to the patient. Consumers who use an Internet pharmacy with a brick and mortar counterpart, such as drugstore.com or cvs.com, can opt to pick up their prescription at their neighborhood pharmacy instead of having it shipped. It usually takes one to five business days to receive a prescription, depending on the shipping option selected by the consumer. In the case of internationally-based Internet pharmacies, it can take up to three weeks for delivery.

Obviously the quality and effectiveness of the pharmacy varies quite substantially from web site to web site. Serious concern exists about the quality of the drugs dispensed over the Internet. Consumers face possible adverse side effects, potentially dangerous interactions, as well as harm from contaminated, counterfeit or expired drugs. This has resulted in the call from consumer groups, the government and others for regulation of the burgeoning industry.

Regulation of Internet pharmacies

The states have traditionally regulated pharmacies and the dispensing of prescription drugs. State boards of pharmacy license both pharmacies and pharmacists to practice in their state. The Food and Drug Administration (FDA) has traditionally regulated only the drugs themselves, approving them for use to treat various illnesses or conditions and ensuring their safety. In-

creasing growth of the Internet pharmacy industry as well as growing concern about the safety of drugs dispensed over the Internet has prompted the pharmacy industry, the federal government and several states to take action.

Industry self-regulation

The primary industry response to Internet pharmacy growth has come from two sources, the National Association of Boards of Pharmacy (NABP) and a newly formed broad-based coalition. The NABP was established in 1904 to "assist state licensing boards in developing, implementing, and enforcing uniform standards to protect the Public Health."⁷ In the spring of 1999, the NABP established the Verified Internet Pharmacy Practice Sites (VIPPS) program in response to increasing public concern about the safety of Internet pharmacies.

The VIPPS program establishes a "Good Housekeeping" type seal of approval that Internet pharmacies can display on their home pages. The seal provides a direct link to the NABP. In order to receive the seal "a pharmacy must comply with the licensing and inspection requirements of their state and each state to which they dispense pharmaceuticals. In addition, pharmacies displaying the VIPPS seal have demonstrated to NABP compliance with VIPPS criteria including patient rights to privacy, authentication and security of prescription orders, adherence to a recognized quality assurance policy, and provision of meaningful consultation between patients and pharmacists."⁸

To date, the NABP has certified four Internet pharmacies: cvs.com, drugstore.com, merck-medco.com and planetrx.com. As many as thirty additional Internet pharmacies have applied for VIPPS certification. It remains to be seen what effect this will have on the overall safety of drugs prescribed over the Internet.

A new pharmacy industry coalition formed in 1999 in response to the

chaos created by the rapid growth of pharmacies on the Internet. The coalition resulted from an Internet pharmacy summit held in Washington, D.C. on November 9, 1999. The National Association of Boards of Pharmacy organized the summit after Bill Razzouk, CEO of planetrx.com, made a request for one during his testimony before the House Commerce Subcommittee on Oversight and Investigations on July 30, 1999.⁹ Members of the coalition come from federal and state governments, consumer organizations, medical groups and Internet pharmacies.¹⁰

The coalition has formulated four primary goals: first, to form a task force on technology to develop legislative and enforcement initiatives; second, to develop an aggressive consumer education plan; third, to create Operation Safe Net in order to organize the industry and serve as an agency to receive consumer complaints; and fourth, to establish the proper relationships for patients and pharmacists at Internet pharmacies.¹¹ It is currently unclear how the coalition's goals will interact with recent actions taken by state and federal governments.

Federal government regulation

The first action by the federal government came in July, 1999, when the FDA added information to its web site (fda.gov) in order to assist consumers in safely purchasing drugs over the Internet. The web site answers consumer questions such as: "Is it safe to buy prescription or over-the-counter drugs online? How can you tell if a Website that sells medical products is legitimate? What should you do before you buy medical products online?"¹² According to FDA Commissioner Jane Henney, "[t]he development of the Internet has opened up many new options for consumers to purchase products more conveniently" but has also "provided unscrupulous individuals with immense new opportunities to promote and sell prescription drugs

unlawfully to unsuspecting patients.”¹³

In order to deal with the growth of internationally-based Internet pharmacies illegally selling prescription drugs, the FDA has begun to issue “cyber” warning letters transmitted electronically to web sites the FDA has identified as selling prescriptions that may be illegal. The letters inform the web site owners that they may be in violation of U.S. laws that govern the sales of prescription drugs and further warn that United States Customs officials may detain and refuse entry to future shipments from the web site. So far one such web site has voluntarily agreed to cease its illegal activities.¹⁴

On December 28, 1999, President Clinton escalated the response of the federal government and announced a program to protect patients who purchase prescription drugs over the Internet. The plan, accompanied by \$10 million in new funds, would give the FDA authority to investigate, identify and prosecute web sites selling unapproved new drugs, counterfeit drugs, or prescription drugs without a valid prescription or those which fraudulently market drugs.¹⁵ The plan would also certify all Internet pharmacies that meet state and federal requirements, much as the NABP’s VIPPS program already does. It also creates new civil monetary penalties and gives the FDA subpoena authority to build cases against offenders, a power it now lacks.¹⁶ This proposal met with generally favorable but mixed reaction.

While some Internet pharmacies, including drugstore.com, familymeds.com and healthcentral.com, welcome the proposal as a way to deal with “rogue” web sites, the National Association of Chain Drug Stores favors a more voluntary approach to regulation.¹⁷ Some question also exists regarding the appropriateness of the FDA as the regulator of Internet pharmacies. Pharmacy regulation has traditionally been the prerogative of state boards of pharmacy and the FDA has no previous experience regulating in this area.

Additionally, Congressman Thomas Bliley, Jr. (R-VA), Chairman of the House Commerce Committee, criticized the President’s plan to expand FDA authority.¹⁸ His committee would have to approve any legislation expanding the authority of the FDA to include Internet pharmacies. Bliley is reluctant to have the federal government regulate an area traditionally controlled by the states. He is also hesitant to regulate the Internet when politicians in Washington, D.C. do not fully understand its potential.¹⁹

The United States Customs Service also plays a role in the regulation of Internet pharmacies. An increasingly high number of illegal drugs enter the United States via shipments from internationally-based online drugstores. The U. S. Customs Service seized 4.5 times as many packages of prescription drugs in 1999 as it did the year before.²⁰ While some of the seized drugs had not received approval for use in the United States, most did not comply with FDA labeling requirements or fell below federal quality standards.²¹

Consumers are purchasing increasing amounts of prescription drugs from these international Internet pharmacies because they offer much lower prices than pharmacies in the United States. For instance, drugquest.com advertises that it offers customers prescription drugs without a prescription at prices of up to 60% less than the prices charged in the United States. The reality of this claim varies greatly depending on the cost to the consumer in the United States as well as the availability and price offered by the foreign pharmacies through drugquest.com.²² The high cost of prescription drugs in the United States has prompted many individuals, especially those with chronic illnesses who take multiple medications on a daily basis, to seek alternate sources for their medication.

State government regulation

States have also begun to regulate Internet pharmacies. Several state attor-

neys general, including those in Missouri, Michigan, Kansas and Illinois, have taken legal action to prevent Internet pharmacies from filling prescriptions for citizens of their states.²³ Generally, the states allege that Internet pharmacies have failed to register with the appropriate authorities in order to lawfully conduct business in their state and fill prescriptions authored by physicians not licensed to practice medicine in their state. Some web sites have voluntarily agreed not to sell prescription drugs to residents of certain states after receiving warning letters.²⁴ Additionally, some state boards of pharmacy have issued reprimands to unlicensed Internet pharmacies.²⁵

The Attorney General of Missouri, Jeremiah “Jay” Nixon, successfully obtained a permanent injunction against pillbox.com, a Texas-based Internet pharmacy, preventing the company from selling prescription drugs to Missouri residents. Pillbox.com sold prescription drugs to Missouri customers without a state license. The injunction requires the defendants to pay a fine of \$15,000 to the state and reimburse all Missouri residents who purchased drugs on the site. Additionally, pillbox.com must clearly display a notice on their web site indicating that they cannot sell drugs to residents of Missouri. Similar lawsuits have been filed in Illinois by Attorney General Jim Ryan against expressrx.net, expresstoday.com, mdhealthline.com, rxclinic.com and maleclinic.com.²⁶ These Internet pharmacies face up to a \$50,000 penalty for each violation of the state’s consumer fraud act.

In Michigan, Attorney General Jennifer Granholm’s office conducted an investigation in which law enforcement officials posed as customers and purchased prescriptions drugs, including controlled substances, online without a prescription. In some cases, the officials posed as minors and people with illnesses who would suffer dangerous side effects from the medication they obtained. As a result of the investigation, the State of Michigan

initiated legal action against ten online pharmacies. All of them agreed to stop selling prescription drugs to Michigan residents.²⁷

Future of Internet pharmacy regulation

With the large number of Internet pharmacies in operation and an increasingly high number that illegally dispense prescription drugs, further action to regulate the industry seems certain. The jurisdictional lines, however, are far from clear. While the states have traditionally regulated pharmacies and the dispensing of prescription drugs, the federal government and the FDA have justified concerns due to the global nature of the Internet and the threats to public health and safety. The pharmacy industry also has concerns about how Internet pharmacies operate. Although the industry has adopted voluntary standards that may work for legitimate businesses, self-regulation will likely prove inadequate to control illegal practices. Because Internet pharmacies are not confined to one particular jurisdiction, cooperation between the states and federal government will be required to effectively regulate the industry and protect consumers. While this cooperation may lead to the successful regulation of Internet pharmacies that operate from within the United States, effective regulation of foreign-based pharmacies seems both difficult and unlikely.

Amy J. Oliver

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