Recent Developments in Health Law

Class Action Suits Allege Improper Charitable Care Practices

Ellen Moskowitz

On September 13, 2004, Yale-New Haven Hospital was named in a federal class-action lawsuit alleging improper charitable care practices.[1] This was the forty-seventh such suit filed across the country since the middle of June.[2] Two weeks later, on September 28 and 29, hospitals in the Northwest were added to the list of defendants, in a coordinated attack by Richard F. Scruggs, the Mississippi lawyer who is best known for spearheading lawsuits against the tobacco industry.[3]

Factual Background

Mirroring those filed in other jurisdictions, the Yale-New Haven complaint bases its claims on state law, the Emergency Medical Treatment and Active Labor Act (EMTALA), and the federal tax laws.[4] The Connecticut state law claims include breach of the duty of good faith and fair dealing, unjust enrichment, and violation of the Connecticut statute that prohibits charging uninsured patients more than the cost of the service provided.[5] The claim under EMTALA alleges a failure to "treat patients without regard to ability to pay," in violation of the federal law.[6] The allegation that has received the most attention from attorneys on both sides of the litigation nationwide, however, is that nonprofit hospitals entered into an express and/or implied contract with the United States requiring them to "provide mutually affordable medical care...in return for substantial federal, state and local tax exemptions."[7] In particular, the Yale suit notes tax exemptions under 26 USC § 501(c)(3) and Conn. Gen. Stat. § 12-81.[8]

Defendants allegedly breached a contract and, further, a public charitable trust, by:

> [F]ailing to provide emergency room medical care...without regard to their ability to pay for such medical care; charging Plaintiff and the Class the highest and undiscounted cost of medical care; charging Plaintiff and the Class significantly more than their insured patients for the same medical services; failing to use their net assets and revenues in the billions of dollars to provide mutually affordable medical care...; utilizing aggressive and abusive and humiliating collection practices such as lawsuits, liens, and garnishments to collect such inflated and unreasonable medical debt...; and allowing noncharitable for-profit entities to derive a profit from use of their tax-exempt hospitals.[9]

With such lurid allegations on the table, the prospect of a sympathetic jury is no doubt on the minds of both sides of the suits.

In response, defendants across the nation have attacked plaintiffs' standing – and their grasp on reality. A brief in a related Arizona case argues that Section 501(c)(3) does not require nonprofits to provide emergency services for all or medical care at subsidized rates, or to forgive debt, and "even if there were such an obligation, it would at most be enforceable by the IRS, not patients or taxpayers."[10] A similar brief in an Illinois case made a related point, stating:

> Universal health care coverage may be a valid social policy goal,

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but it is not the law and not something courts should impose. To suppose, as plaintiffs do, that the federal government actually implemented universal health coverage over one hundred years ago when it enacted a general law concerning an income tax exemption for charities – and that no one before plaintiffs noticed – is fantasy.[11]

Defense teams also argue that the suits siphon off funding and attention from deeper problems with the American health care system. The American Hospital Association (AHA), a named co-defendant in each of the suits filed nationwide, was accused by Scruggs spokesman Robert D. Siegfried of acting as a "cross-pollinator" of improper practices.[12] Alicia Mitchell, a spokeswoman for the AHA, called the lawsuits "baseless and misdirected, diverting focus away from the real issue of how we as a nation are going to extend health coverage to all Americans."[13]

In Connecticut specifically, Yale-New Haven noted that it has already taken steps in a positive direction in response to a series of lawsuits, including one filed by Connecticut Attorney General Richard Blumenthal in 1993 that is still in litigation.[14] These steps have included closing accounts over five years outstanding, removing property liens against former patients, and a sliding scale to provide discounted and free care to patients below certain incomes.[15] Spokesman Vin Pettrini said, "We feel these are issues that we've addressed comprehensively, both at Yale-New Haven and our affiliates."[16] Blumenthal did not necessarily agree with the hospital's characterization of its progress. In response to the class-action he said, "The aggressive, abusive and humiliating collection practices alleged in this lawsuit are much the same as we have set forth in our legal action. The effects are to discourage patients from seeking necessary medical care and burdening them with oppressive debt."[17]

However, some patient advocates note that Scruggs has taken on a less clear-cut crusade this time around. "Having more scrutiny of billing practices is a good thing, but the risk is we're not taking on big tobacco, we're taking on a vital service. It's an industry I want to preserve, not bring down," said Mark Rukavina of the Access Project, a national resource center working to improve health and health-care access.

Discussion

The United States Congress has entered the fray, reflecting the importance and growing prominence of the issue. On June 22, the Subcommittee on Oversight of the House Committee on Ways and Means held the first hearing in a proposed series on tax exemption.[18] Entitled "Pricing Practices of Hospitals," the hearing of hospital CEOs included a warning from Ways and Means Chairman Bill Thomas to the non-profit hospital industry, stating, "If in fact there are as many for-profits that can be shown to give a break to low-income [patients] as not-for-profits, then that's not really a difference for receiving the tax benefit."[19]

However, some patient advocates note that Scruggs has taken on a less clear-cut crusade this time around. "Having more scrutiny of billing practices is a good thing, but the risk is we're not taking on big tobacco, we're taking on a vital service. It's an industry I want to preserve, not bring down," said Mark Rukavina of the Access Project, a national resource center working to improve health and health-care access.[20] Seemingly aware of the concern, Siegfried said on the day of the Connecticut filing, "We're not looking to go after hospitals that are financially impaired where our litigation could cause the hospital to become insolvent or go out of business."[21] Indeed the complaint alleges that the non-profit Yale-New Haven hospital system is "actually quite 'profitable,'" citing 2002 net assets of $534 million.[22]

On October 20, the Judicial Panel on Multidistrict Litigation handed defense teams a victory in ruling against the consolidation of the lawsuits. Thus, each suit will need to move forward separately and hearings will be held in jurisdictions around the country.[23] The AHA said in a press release that it "welcomes the decision....[A]sking the court to consolidate the cases was simply a legal maneuver to benefit trial lawyers at the expense of hundreds of local hospitals."[24]

Conclusion

Legal experts are uncertain about where the suits will go. Samuel Issacharoff, a professor at Columbia Law School, called the "legal obligation to provide a charity care" a "moving part," and stated that determining who should have been charged how much less for treatment is a "terribly complicated issue."[25] However, on November 23 and 30, motions to dismiss for failure to state a claim were granted in cases filed in the Western District of Pennsylvania and Northern District of California, respectively.[26] In California, the court rejected the notions that Section 501(c)(3) contains an implied right of action, that plaintiffs established standing to contest a breach of contract between a hospital and the federal government, and that the defen-

dant was governed by the terms of the Fair Debt Collection Practices Act.[27] In Pennsylvania, the court additionally stated that "the Supreme Court has long denied attempts to characterize a tax exemption as a contract" and that plaintiffs failed to plead a valid EMTALA claim because they did not allege personal harm.[28] While the decisions highlight the weaknesses of the federal law claims, the issue is unlikely to disappear with the adverse rulings. One fact that both sides seem to accept is that the uninsured are being charged at higher rates than the insured, who can take advantage of the discounts negotiated by insurance companies and HMOs.[29]

Furthermore, as Attorney Eugene E. Elder of the law firm Akin Gump Strauss Hauer & Feld said in June, "More and more people have become sensitized to [the high price of hospital care] and it's easy to get outraged."[30] Without a legislative solution to both the discrepancy in rates and the increasingly unaffordable cost of health care across the board, there is fuel to fire charitable care lawsuits, albeit ones perhaps more likely to proceed on the state level.

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Organ Advertising: Desperate Patients Solicit Volunteers

Christopher Robertson

Patients waiting on long lists for organ transplants have recently begun to take matters into their own hands, launching advertising campaigns to solicit organ donations. In one case, Todd Krampitz, a thirty-two-year-old liver-cancer patient, bought newspaper ads, leased billboards, and set up a toll-free number, all in search of a liver donor.[1] It worked; a family decided to donate the liver of their deceased loved one to Krampitz. The transplantation was successful.

In another case, Bob Hickey needed a kidney transplant and paid $295 monthly to Matching Donors.com, a website that advertised for donors.[2] Hickey received over five hundred offers, and he chose a thirty-two-year-old Tennessee man, Rob Smitty, as his donor.[3] Hickey paid for Smitty's and his family's expenses to fly to Colorado, and planning for the surgery began. Given Smitty's history of drug abuse and his arrest record, the transplant surgeon, Dr. Igal Kam, became concerned that Smitty might have been motivated by an under-the-table payment, which is illegal under federal law.[4] Kam postponed the operation to allow the hospital ethics committee to make a determination. The committee approved the transplantation two days later, and both men survived the procedure. Days later, Smitty was arrested for failure to pay $8,100 in child support, but anonymous benefactors posted the necessary funds for his release.[5]

These two cases were extensively covered in the local, national, and global media. Concerns were expressed by ethics professionals,

though it appears that neither lawsuits nor formal criminal investigations were initiated. The putative success of these patients' advertisements is motivating other desperate patients to follow suit with their own advertising campaigns.[6] These cases are igniting a debate about the ethics of advertising for organs and raising questions about the fairness and efficacy of the current system of organ donation.

Factual and Legislative Background

Organ transplantation has become a fairly routine medical procedure, saving or improving the lives of about 20,000 Americans per year.[7] However, over 87,000 people continue to remain on the organ waiting list for months or years. Each year, 39,000 new donees join the list, and more than 6,000 die while waiting for a donor. The situation is getting worse, as both the numbers of those waiting, and the numbers of those dying while waiting, grow each year.[8] Indeed, "the biggest problem facing the transplant community today is the extreme shortage of organs."[9]

Meanwhile, on the supply side, most organs come from cadaveric donors, and each donor can benefit as many as fifty recipients. Yet only about 14,000 people each year die in ways that allow for transplantation, and most of their organs are buried or incinerated, for lack of permission to transplant them.[10]

Because of this shortage, desperate patients turn to living donors, asking them to undergo surgery to donate a kidney, or a liver, lung, or pancreas segment. In 2003, there were 6,811 of these live organ donations, and almost ninety percent of these were from close relatives. There are the routine risks that come with any major, invasive surgery, but organ transplantation obviously creates additional risks. In kidney transplants alone, there have been seven donor deaths over a recent three-year period, or one for every 2255 donors.[11] One commentator contrasts this risk with other routine medical procedures, stating, "the likelihood of death in living kidney donation is about 400 times higher than the risk of death from smallpox vaccination."[12]

The legal regime is fairly minimalistic. As one member of the Colorado hospital ethics committee explained, "there are very few laws" regulating the organ transplant system, which is "really built on a system of trust."[13] In the U.S., the basic legal contours of organ donation were established by federal legislation and the Uniform Anatomical Gift Act (UAGA) of 1968, which all states adopted.

The UAGA requires that if a person records a preference for or against donating organs, those preferences must be honored upon death. Section 6 of the UAGA provides that donated organs may be designated for a specific recipient. The National Conference of Commissioners on Uniform State Laws has recently opened the UAGA for revision, and the United Network for Organ Sharing (UNOS) Board has recommended changes to prohibit designations that discriminate on race, national origin, and so on.[14] Recent legislative attention has also focused on transplants between HIV infected individuals. For example, Illinois has recently changed its laws to allow such transplants, thereby stopping the waste of those infected organs that would otherwise be discarded.[15] Under a new Wisconsin law effective in 2004, living organ donors receive tax deductions for up to $10,000 in non-medical expenses (such as travel, lodging and lost wages) associated with giving an organ.[16] Ten other states have introduced similar legislation.[17]

Federal law gives broad discretion to the Secretary of Health and Human Services to design and administer the system for procuring and distributing organs, primarily requiring that it be done "equitably" according to a ranked list based on "membership criteria and medical criteria." The Secretary has contracted with the UNOS to administer the system.[18] UNOS maintains the waiting list, which weighs seniority (time on the list), critical need, and the quality of the physiological match for a particular donated organ. Federal law bans the sale of organs, though it allows reimbursement for reasonable expenses.[19]

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Ethics of Advertising for Directed Donations

The ethical questions surrounding these recent cases are multitudinous. Before these cases arose, there were concerns about the MatchingDonors.com website being an internet "scam," taking money from those who need organs, while the "chance of getting a donor [through the website] is very small."[20] Indeed, the UNOS ethics committee resolved that it "philosophically opposes" Matching Donors.com, stating that "it exploits vulnerable populations (i.e., donors, transplant candidates, etc.)...and subverts the equitable allocation of organs for transplantation."[21] But once the site worked to make a match and it was understood to operate on a nonprofit basis, a more favorable light was cast. Reginald Washington, chairman of the ethics committee at the hospital where the Hickey transplantation was performed, concluded that, "if crafted carefully, this will allow [donors] to be matched with people who need those organs. This is another tool. If

properly used, it could be a very helpful tool."[22]

Aside from whether the website works, a larger problem remains: should individuals be permitted to cut to the head of the long organ waiting list by using their wealth to buy an advertising campaign to find a donor that will designate him or her as the recipient?[23] The problem of wealth leading to differential access to organs is merely an instantiation of a general problem of differential health care access.[24]

This practice also gives rise to utilitarian (or efficacy) concerns about getting organs to those who need them most, as well as fairness concerns for those who have waited patiently in line. The status quo waiting lists serve both functions – fairness, recognizing first come, first served, and efficacy/utility, recognizing critical need and physiological match. In some cases (perhaps including Krampitz's), the advertising may increase the size of the pie by persuading someone to donate an organ who might not otherwise do so. In these cases, others in the waiting list would not be made any worse off. But in cases such as Hickey's, where Smitty claims that he had already decided to donate before learning about Hickey's situation, the advertising simply moves the patient up in the line, ahead of those who may have waited longer, may have more critical need, or may be a better physiological match.[25] In the end, if the practice of cutting in the organ line became widespread, more people could suffer.

On the other hand, advertising empowers the patient to *do something* in the slow and faceless system that has failed so many. Hickey says, "I don't have any shame about saying it's advertising. If we go on a list managed by the transplant center and the government, we don't have anything we can do. We just sit there waiting for someone to die."[26] Moreover, as long as all parties involved are competent adults acting voluntarily, there is a liberty interest and perhaps a First Amendment argument for allowing such advertisements.

Aside from the line-cutting problems, such *live* organ donor transplants between strangers raise ethical questions about the medical duty to do no harm. After all, unlike most other medical interventions, the invasive surgery necessary to donate an organ does not make the donor any better off, but subjects him to the risk of complications, even death. In order to square this with the proviso to do no harm, one might turn to the definition of "harm," from one legal philosopher, Joel Feinberg: "Only setbacks to interests that are wrongs, and wrongs that are setbacks to interests, are to count as harms in the appropriate sense."[27] One might expand the notion of *interests* to include altruistic interests that the donor has in helping others, or one might focus on the notion of *wrong*, so as to say that procedures done on the basis of informed consent are *prima facie* not wrong. In any case, it is clear that such procedures require close scrutiny.

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Systemic Questions

These multiple ethical problems are overshadowed by systemic questions. After all, advertising for live organ donations is an act of desperation, one that would be unnecessary if there were a sufficient supply of cadaveric organs in the first place. Until recently, the debate over organ transplantation has turned on three alternative systems: an organ market, routine harvesting of organs (also known as "presumed consent," or "opt-out" systems), or the status quo system of altruism.[28] These create existential choices: Do we want to be the kind of society in which everything, even our bodies, is for sale? Do we want to be a society in which the government confiscates whatever it deems necessary? Or do we want to be a society that talks about altruism, but allows many people to die who could be helped?

In this moral impasse, recent attention has focused on proposals to create a "preferential" system – i.e., one that links organ procurement with organ distribution, so that those who are willing cadaveric organ donors receive preferential access to the organ pool if they someday needed one.[29] Thus people would have a reason, as a matter of prudence, to sign up as organ donors. The flip side of this coin is that under such a system, those who do not choose to be organ donors are discriminated against when it comes time to distribute organs.

Such a preferential system seems fair on its face – after all in a time of shortage, why should people be permitted to free-ride on the organ system, taking organs but refusing to give them? Indeed, as long as there are more organ takers than givers, it is not surprising that there is a shortage.

On the other hand, preferential systems give rise to questions of both efficacy and ethics. The chance of any one person needing an organ is remote, and people have lots of other things to do besides planning for such contingencies. Even if it were in their interests, many would likely still never get around to signing up, and thus the donor pool might not grow significantly.

Further, is it fair to discriminate against people who have simply never considered being an organ donor? It is one thing to discriminate against those who have consciously decided to be free-riders, but such dire consequences should not be imposed on those who have simply never considered it.

Some states, including Texas and Virginia, have experimented with mandated choice systems where all persons are required to decide whether to donate an organ when they apply for a license at the Department of Motor Vehicles (DMV).[30] Even if a preferential system were imposed under such a mandatory choice regime, it would still be ethically problematic. After all, in a preferential organ system, saying *no* is tantamount to the refusal of a life-saving treatment. In analogous situations, where a patient is considering forgoing chemotherapy for example, the patient might deliberate for weeks over the decision, searching his or her soul, vividly experiencing the tradeoffs of pain and standard of living, consulting doctors, chaplains, and family members. Such a robust process of informed refusal is a stark contrast to making a medical decision on the spot standing in line at the DMV, years in advance, anticipating a remote hypothetical situation, without counsel.

In a parallel question, it may be worthwhile to consider why we do not require all persons to decide at the DMV whether to be resuscitated in hypothetical future emergencies. Because resuscitation is in the typical person's interests, we instead have an opt-out policy of resuscitating everyone, unless there is explicit notice of a contrary decision.[31]

Several European states have implemented opt-out organ systems, with mixed success, but the ethics of such systems are questionable since, unlike resuscitation, there is no reason to presume that the typical person would consent as a matter of prudence.[32] Yet in a *preferential* organ system, being included *would* be in the typical person's interests (as it would improve his or her chances of someday getting a needed organ). Thus, could an opt-out, preferential organ system be efficacious and fair?[33] Under such an opt-out preferential system, the few who wanted to remove themselves could do so through robust informed refusal processes, without imposing on the majority who are tacitly content to both give and receive.

For *any* organ system to succeed, doctors must actually remove organs when appropriate in these tragic and sometimes chaotic emergency situations at the end of life.[34] For those individuals who did not opt-out, a hybrid system's preferential basis may help persuade surgeons and next-of-kin to proceed with organ removal, since the deceased person received preferential protection throughout his or her life, and now has a patent obligation to reciprocate. Indeed, aside from these structural changes, study ought to be done on the rhetorical framing of the organ decision as one of altruism versus one of reciprocal cooperation.[35] People may be more willing to give if it was a matter of reciprocal duty – i.e., repaying a debt, rather than one of anonymous charity.

Conclusion

Organ advertising is the tip of the ethical iceberg of organ transplantation. While giving rise to its own problems of fairness and utility, it also requires us to ask why there is such a large organ shortage, and why so many usable organs are buried or incinerated. Indeed, the giving and receiving of organs begs even larger questions about who we are and what we owe to each other.

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The Path to Cheaper and Safer Drugs: Revamping the Pharmaceutical Industry in Light of GlaxoSmithKline's Settlement

Benjamin Falit

Suicide is the eighth leading cause of death in the United States and accounts for 1.5% of all annual deaths.[1] For approximately the last decade, there has been a controversy as to whether selective serotonin reuptake inhibitor (SSRI) antidepressants can increase suicidality and suicidal ideation in vulnerable individuals.[2]

On June 2, 2004, Eliot Spitzer, the Attorney General of the State of New York, filed a complaint against GlaxoSmithKline in New York state court, alleging that the drug manufacturer concealed information about the safety and efficacy of paroxetine HCL (Paxil).[3] On August 26, 2004, the parties entered into a settlement whereby GlaxoSmithKline agreed to pay $2.5 million in damages and publicly disclose information on *all* clinical studies in the future.[4] Although this settlement marks a great victory for the public, insofar as GlaxoSmithKline's disclosure policy possesses the potential for setting a precedent that all pharmaceutical companies will follow, policy makers must ensure that firms do not prematurely terminate studies that are likely to produce negative results.

Background

The first report of a link between SSRIs and suicidality came in 1990 with a study conducted by several researchers at Harvard Medical School.[5] Their report described six patients who experienced paradoxical reactions to fluoxetine (Prozac) characterized by intense, violent, and suicidal thoughts.[6] Following Teicher's report, numerous additional reports and comments appeared in the literature.[7] While many studies bolstered Teicher and colleagues' tentative conclusions,[8] others were highly critical of their findings.[9] In 1991, Dr. Bruce Stadel, Branch Chief of the Food and Drug Administration's (FDA's) Division of Epidemiology and Surveillance, announced that the FDA's spontaneous reporting system had received almost 15,000 physician reports of adverse events from fluoxetine, of which 519 were suicide attempts.[10] Nevertheless, the FDA refused to withdraw its approval for the drug and declined to mandate a black box warning regarding the link between fluoxetine and suicidality.[11]

Since the release of fluoxetine in 1987, numerous other SSRIs have hit the market, including paroxe-

tine HCL.[12] David Healy, a researcher at the North Wales Department of Psychological Medicine in England, performed a meta-analysis on the medical literature to determine if SSRI antidepressants can trigger suicidality and/or suicidal ideation in vulnerable individuals.[13] Healy's study revealed the following: (1) The vast majority (if not all) of prior studies suggesting no causal relationship between SSRI use and suicidal impulse rest on shaky methodological ground;[14] (2) Numerous independent studies have observed a causal link between SSRI use and suicidality;[15] (3) Evidence suggests that SSRIs reduce suicidality in some patients, and thus the net increase in SSRI-related suicidal acts observed in prior studies indicates that SSRIs have the potential to increase suicidality in some patients by a much larger degree than previously thought.[16]

Although hundreds of suits have been brought against SSRI manufacturers,[17] only three cases have been decided by a jury verdict,[18] and only one resulted in a judgment for the plaintiff.[19] On June 2, 2004, Spitzer filed a complaint against GlaxoSmithKline in New York state court, alleging that the drug manufacturer concealed and misrepresented information about the safety and efficacy of paroxetine HCL (Paxil).[20]

The Complaint

The State of New York filed suit under N.Y. Executive Law § 63(12), which authorizes the Attorney General to seek a judgment that "enjoins repeated or persistent fraudulent or illegal business acts or practices, including any misrepresentation, concealment or suppression of a material fact."[21] In the complaint, the State of New York alleged that GlaxoSmithKline permitted public disclosure of information that supported pediatric use of paroxetine (Paxil), but concealed and distorted information that questioned the safety and efficacy of the drug in children and adolescents.[22] Although the FDA had not approved paroxetine for use in children, the State of New York permits physicians to prescribe FDA-approved drugs for "off-label" uses when they feel that the potential benefits outweigh the costs.[23] Spitzer contended that GlaxoSmithKline's policy of disclosing only favorable data supplied physicians with false and misleading information regarding paroxetine's off-label pediatric uses.[24]

Prior to the initiation of the lawsuit, GlaxoSmithKline conducted randomized, placebo-controlled, double-blind studies (referred to by the company as studies 329, 377 and 701) to assess the safety and efficacy of treating childhood and adolescent depression with paroxetine.[25] The company also conducted "extension studies" of studies 329 and 701, which specifically focused on safety rather than efficacy.[26] According to the State of New York, studies 377 and 701 failed to show that paroxetine was more effective than a placebo, while study 329 presented a mixed picture of paroxetine's efficacy.[27] Additionally, the three original studies suggested that potentially suicidal behavior was two times more likely in the paroxetine group than in the placebo group, and the extension studies supported these findings.[28]

The complaint alleged that GlaxoSmithKline attempted to suppress and misrepresent the studies' findings on several levels.[29] First off, the company permitted the study with ambiguous results, study 701, to be published, but did not release the results of studies 377 and 701 or the extension studies.[30] Secondly, the complaint asserted that GlaxoSmithKline misrepresented the safety and efficacy outcomes to its drug representatives, tacitly encouraging the reps to distribute the information to physicians.[31] The complaint cites an internal memo to all sales representatives selling Paxil, which stated: "Paxil demonstrates REMARKABLE Efficacy and Safety in the treatment of adolescent depression."[32] The word "remarkable" appeared in capital letters and the entire sentence was printed in bold-faced type.[33] Thirdly, the State of New York alleged that GlaxoSmithKline misrepresented the data in the "medical information letters" that it provided to doctors upon their unsolicited requests for information.[34] Finally, the Attorney General contended that the company *knew* that its conduct misrepresented the data, since its behavior conflicted with various admissions to drug-related administrative agencies (including the FDA).[35] According to the complaint, on numerous occasions GlaxoSmithKline admitted that paroxetine should not be used to treat pediatric depression because of its lack of efficacy and potential for generating suicidal behavior.[36]

The Settlement

On August 26, 2004, after the defendant removed the case to federal court, GlaxoSmithKline and the State of New York entered into a settlement whereby the pharmaceutical company agreed to pay $2.5 million in damages and publicly disclose information on *all* clinical studies in the future.[37] The settlement agreement specifically stated that GlaxoSmithKline does not admit or deny any of the acts alleged in the complaint by agreeing to the entry of the consent order and judgment.[38]

Under the binding settlement, GlaxoSmithKline has committed to establish and maintain a Clinical Trial Register (CTR) that will provide public on-line access to summaries of all company-sponsored clinical studies from December 27, 2000 forward, and any earlier studies likely to affect a physician's medical judgment.[39] The CTR must be maintained from February 1, 2005 until February 1, 2015, and a link to the register must be conspicuously displayed on the company's website during this time.[40] Additionally, GlaxoSmithKline must "use reasonable efforts" to exclude provisions limiting the publication of clinical

study summaries in the future, and "make reasonable efforts" to secure the right to publish summaries of trials conducted prior to the settlement.[41]

The settlement additionally stipulated that, for ten years following the entry of the consent order and judgment, GlaxoSmithKline must provide the Attorney General with copies of any communications (including medical information letters) sent to a New York physician concerning the use of paroxetine to treat pediatric depression.[42] Finally, GlaxoSmithKline was obligated to arrange and pay for the publication of an "advertisement" to run in the print and electronic editions of major medical journals such as *The Journal of the American Medical Association* and *The New England Journal of Medicine*.[43] The uniform advertisements explained the CTR and discussed the company's commitment to maintaining it.[44]

Discussion and Recommendations

At first glance it appears as if the GlaxoSmithKline settlement represents an incontrovertible victory for the public, insofar as GlaxoSmithKline's disclosure policy possesses the potential for setting a precedent that all pharmaceutical companies will follow. A closer analysis, however, reveals that the universal establishment of clinical trial registers by all pharmaceutical companies carries the potential to make drugs even more dangerous. Aware that summaries of all *completed* trials will inevitably be released to the public, pharmaceutical companies will rationally choose to prematurely terminate projects that are likely to produce negative results.[45] The premature abortion of such studies may lower the number of negative studies that become available to physicians, thereby increasing the chance that a patient will receive inefficacious treatment or suffer an adverse reaction. In order to prevent the pharmaceutical industry from falling subject to such perverse incentives, the government could require all drug companies to publicly disclose the termination of clinical trials, along with the rationale for each decision. This mandate, in conjunction with a commitment by all companies to publicly release summaries of completed trials, could go a long way in making sure that doctors are fully informed about the products they are prescribing.[46]

In its complaint, the State of New York alleged that GlaxoSmithKline both concealed and misrepresented the nature of clinical trials.[47] Although the adoption of the aforementioned proposal could help to address the problem of concealment, it may not have any effect on firms' ability to distort the truth. In fact, if pharmaceutical companies are required to disclose negative findings, firms whose products are faced with the potential of losing market share due to adverse data will have an incentive to "twist the truth" in order to meet investors' expectations. Therefore, in order to prevent the occurrence of such misrepresentation, it may be necessary for the government to intervene a bit further.

Under the current regime, the FDA is responsible for approving the release of new drugs, but refrains from evaluating the products any further.[48] In other words, once the FDA decides that a given product meets the threshold level of efficacy and safety necessary to receive approval, it avoids any further assessment of the drug. This leaves pharmaceutical companies responsible for informing physicians about the efficacy and safety of their drugs beyond that of the initial market approval. Pharmaceutical representatives are the primary vehicles by which the companies provide doctors with information about their products.[49] Typically, pharmaceutical sales representatives are college graduates who spend approximately six to eight weeks in training before entering the field.[50] Despite their ability to effectively promote drugs by delivering samples[51] and providing physicians with perks (pens, free meals, etc.),[52] evidence suggests that the majority of drug reps have limited information to offer prescribing physicians after their product has been on the market for six months to a year.[53] Furthermore, notwithstanding the fact that the majority of doctors fail to recognize errors, research suggests that a significant percentage of pharmaceutical representatives provide physicians with inaccurate information.[54]

The pharmaceutical industry currently spends approximately $54 billion on marketing, which is almost double what it spends on research and development.

Pharmaceutical companies are for-profit enterprises, and drug representatives are paid to promote their products in the same way that a car salesman is paid to sell cars.[55] We therefore should expect the information that they provide to physicians to be biased, a fact that is not a cause for concern since physicians can pool the data that they receive from competing companies in order to arrive at the "truth."[56] There is a fine line, however, between partiality and misrepresentation. Policy makers should devise a scheme that (1) makes it difficult for sales representatives to distort the truth, (2) makes it easier for physicians to identify inaccurate information, and (3) reprimands companies (and possibly reps) who disseminate misleading information. These three goals could be served by instituting a program whereby the FDA, in addition to approving or denying drugs, rates new products on three dimensions:

(1) cost-effectiveness (whether the drug makes financial sense to patients – an issue that is addressed by weighing the benefits of the treatment against its pecuniary and non-pecuniary costs), (2) efficacy, and (3) safety.[57] These ratings could be included on the package insert of each drug, as well as in the Physician's Desk Reference (PDR), and could be accompanied by brief explanations of the rationales behind the ratings. Physicians could be required to report any perceived distortion to the FDA, a process that would be furthered by establishing a web-site where doctors can easily submit complaints.

An FDA rating system could make it more difficult for pharmaceutical representatives (and pharmaceutical companies in general) to distort the truth, and easier for physicians to identify misrepresentations, since representatives who sell products with sub par ratings would be forced to explain their products' poor performance. The establishment of such a rating system may also help to control the high costs of pharmaceuticals. The pharmaceutical industry currently spends approximately $54 billion on marketing, which is almost double what it spends on research and development.[58] Industry experts believe that a mutual scale-back in the number of sales representatives would benefit the entire industry.[59] It appears that no company is willing to make the change, however, because doing so would hurt market share if the firm's competitors failed to adopt a similar policy.[60] The establishment of an FDA rating system would likely catalyze an efficiency-generating scale-back of pharmaceutical representatives that resulted in lower drug prices (assuming that drug companies do not pocket the savings). Drugs whose FDA ratings dwarfed the competition's would essentially sell themselves, and thus the marginal return on the employment of additional sales reps would decline.[61] Moreover, it is reasonable to believe that the quantification of a drug's value would lower physicians' susceptibility to the fringe benefits doled out by pharmaceutical representatives. Each drug's three-pronged score would serve as a constant reminder to doctors that they must carefully weigh the pros and cons of competitors' products before writing a prescription.

The FDA rating system may also serve to decrease the conflict of interest inherent in post-approval surveillance. Under the current all-or-nothing approval process, the FDA does not explicitly distinguish between drugs that barely reach the efficacy and safety thresholds, and those that clear the hurdles by a mile. Therefore, to the American public, all FDA-approved drugs are essentially equal. This distorted public schema interjects bias into the FDA's post-launch monitoring efforts by exacerbating the backlash associated with withdrawing a drug from the market whose efficacy and safety were marginally sufficient upon approval. In other words, the FDA is hesitant to remove a drug's approval status because the public is prone to overestimating the magnitude of the administration's change in judgment. The FDA rating process may make the FDA more willing to withdraw dangerous or inefficacious products from the market, since the public will be fully cognizant of the fact that the drugs were barely approvable in the first place.

The establishment of an FDA rating system will likely involve significant upfront costs (including the retraining of pharmaceutical sales representatives who lose their jobs), as well as the downstream costs associated with paying experts to make these important judgments. Funding for the project could come from the pharmaceutical companies in the form of higher fees (for the use of the FDA approval process). The ability to downscale sales forces will likely more than offset the increased user fees, and thus the American public could still reap the benefits of lower drug prices (assuming again that the firms pass the savings on to the consumer).[62]

Conclusion/Summary

The State of New York's ability to secure a settlement from GlaxoSmithKline in which they agreed to publish summaries of completed trials is a step in the right direction. It is likely that other pharmaceutical companies will follow suit and establish Clinical Trial Registers for their own drugs. In order to make such a transition positive, however, the government could consider further remedies, including mandating that pharmaceutical companies publicly disclose all premature terminations of clinical trials. If such a policy is not adopted, firms may have an incentive to withdraw funding for projects that are likely to produce negative results. In order to reduce pharmaceutical companies' ability to misrepresent the results of clinical trials, the FDA could begin rating drugs on the basis of their cost-effectiveness, efficacy and safety. Such a policy would have the effect of both improving patient outcomes and reducing the cost of pharmaceuticals.

References

1. A. E. Falsetti, "Fluoxetine-Induced Suicidal Ideation: An Examination of the Medical Literature, Case Law, and the Legal Liability of Drug Manufacturers," *Food and Drug Law Journal* 57 (2002) 273-292, at 273.
2. D. Healy, "Lines of Evidence on the Risks of Suicide with Selective Serotonin Reuptake Inhibitors," *Psychotherapy and Psychosomatics* 72 (2003) 71-79, at 71.
3. *The People of the State of New York v. GlaxoSmithKline*, Verified Complaint at 1.
4. *The People of the State of New York v. GlaxoSmithKline*, Verified Consent Order & Judgment at 5-6.
5. A. E. Falsetti, *supra* note 1 at 275 (citing M. H. Teicher et al., "Emergence of Intense Suicidal Preoccupation During Fluoxetine Treatment," *American Journal of Psychiatry* 147 (1990) at 207-10).
6. *Id.* at 275 (citing M. H. Teicher et al., "Emergence of Intense Suicidal Preoccupation During Fluoxetine Treatment," *American Journal of Psychiatry* 147 (1990) 207-10, at 207.).
7. Id. at 276 (citing, *inter alia*, T. D. Brewerton, "Fluoxetine-Induced Suicidality, Serotonin, and Seasonality," *Biological*

Psychiatry 30 (1991) at 190-96; G. Chouinard, "Fluoxetine and Preoccupation with Suicide," *American Journal of Psychiatry* 148 (1991) at 1258-59; K. Dasgupta, "Additional Cases of Suicidal Ideation Associated with Fluoxetine," *American Journal of Psychiatry* 147 (1990) at 1570; J. Downs et al., "Preoccupation with Suicide in Patients Treated with Fluoxetine," *American Journal of Psychiatry* 148 (1991) at 1090-91.

8. *Id.* at 276. See, specifically, A. J. Rothschild and C. A. Locke, "Reexposure to Fluoxetine After Serious Suicide Attempts by Three Patients: The Role of Akathisia," *Journal of Clinical Psychiatry* 52 (1991), 491-93.
9. *Id.* at 277 (citing, *inter alia*, R. B. Berkley, "Discussion of Fluoxetine and Suicidal Tendencies," *American Journal of Psychiatry* 147 (1990), 1572).
10. *Id.* at 279 (citing S. R. Ahmad, "USA: Fluoxetine 'Not Linked to Suicide,'" *Lancet* 338 (1991), at 875).
11. *Id.* at 279 (citing S. R. Ahmad, "USA: Fluoxetine 'Not Linked to Suicide,'" *Lancet* 338 (1991), at 876).
12. *Id.* at 274.
13. D. Healy, *supra* note 2.
14. *Id.* at 74.
15. *Id.* at 74 and 77.
16. *Id.* at 74.
17. A. Thompson, "Paxil Maker Held Liable in Murder/Suicide," Lawyers Weekly USA, July 9, 2001, *at* <http://www.baumhedlundlaw.com/media/ssri/Paxil_murder.htm> (last visited January 25, 2005).
18. *Id.*
19. *Id.*
20. *The People of the State of New York v. GlaxoSmithKline*, Verified Complaint at 1.
21. *Id.* at 3.
22. *Id.* at 2.
23. *Id.* at 4.
24. *Id.* at 4-5.
25. *Id.* at 5.
26. *Id.* at 5.
27. *Id.* at 6. Prior to study 329, GlaxoSmithKline identified seven measures of efficacy which it purported to test. Two of these were identified as "primary" endpoints, while the other five were considered "secondary" endpoints. According to the State of New York's interpretation of study 329, paroxetine was superior to the placebo with regard to three of the five secondary endpoints but neither of the primary endpoints.
28. *Id.* at 6-7.
29. *Id.* at 8.
30. *Id.* at 8.
31. *Id.* at 9.
32. *Id.* at 9. The memorandum also stated that the information was for pharmaceutical consultants' information only and should not be distributed to physicians. The Attorney General, however, asserted that this was clearly the company's purpose for they would have no other reason to release such a memo.
33. *Id.* at 9.
34. *Id.* at 10.
35. *Id.* at 11-14.
36. *Id.* at 11-14.
37. *The People of the State of New York v. GlaxoSmithKline*, Verified Notice of Removal; *The People of the State of New York v. GlaxoSmithKline*, Verified Consent Order & Judgment at 5-6.
38. *Id.* at 1
39. *Id.* at 5.
40. *Id.* at 7.
41. *Id.* at 6.
42. *Id.* at 8.
43. In the Matter of GlaxoSmithKline, Verified Assurance of Discontinuance Pursuant to Executive Law Section 63, Subdivision 15 at 5.
44. *Id.* at Appendix C.
45. See M. E. Nagle, "State 'Fraud' Suits Over Clinical Trial Results Tread on Free Speech Rights," Mealey's Litigation Report: Antidepressant Drugs, September 24, 2004; J. Abramson, *Overdosed America* (New York: HarperCollins, 2004): at 104-105 (Discussing the Controlled Onset Verapamil Investigation of Cardiovascular End Points (CONVINCE) study, a five-year study sponsored by Pharmacia that was stopped two years early because the results up to that point demonstrated that Pharmacia's more expensive blood pressure medication Covera was slightly less effective at preventing the complications of high blood pressure than less expensive drugs; *see* B. M. Psaty and D. Rennie, "Stopping Medical Research to Save Money: A Broken Pact with Researchers and Patients," *JAMA* 289, no. 16 (2003) 2128-2131). Critics might argue that in virtually all trials, the investigators, sponsors and patients are all blinded to the treatment each participant receives, and thus it is impossible for pharmaceutical companies to know in advance whether or not a study is likely to produce negative results. In such double-blind studies, Data and Safety Monitoring Boards (DSMBs) are responsible for monitoring interim results in order to protect patients' welfare. Although employees of the trial's sponsor are not permitted to serve as members of DSMBs, they are allowed to assist the DSMB in its evaluation of clinical data. Moreover, voting members of DSMBs are permitted to have limited financial ties to the sponsor, and non-voting members are allowed even greater financial connections to the company funding the trial. See Principles on Conduct of Clinical Trials and Communication of Clinical Trial Results, *at* <http://www.phrma.org/publications/publications//2004-06-30.1035.pdf>. With such poor boundaries between DSMBs and sponsors, it seems likely that decisions to prematurely terminate clinical trials are often based at least in part on a study's potential for generating adverse data. Requiring pharmaceutical companies to submit data from all unfinished (as well as completed) trials in order to achieve FDA approval would not adequately deter the premature termination of projects that are likely to produce negative results. Under the current regime, FDA approval is granted on an all-or-nothing basis and thus public disclosure of a study with negative results could hurt market share, even though the results are not sufficiently damning to foreclose FDA approval. Under a system in which the FDA rates drugs in addition to approving them (see *infra*), however, such a mandate may sufficiently deter the premature termination of studies conducted prior to the product's launch. In order to prevent the inappropriate abortion of post-launch studies, the government would have to either (a) require all companies to publicly disclose the termination of trials, along with the rationale for each decision (see *infra*), or (b) regularly adjust the "ratings" of previously launched products according to all available data (both completed and unfinished trials).
46. The pharmaceutical industry, represented by the European Federation of Pharmaceutical Industries and Associations (EFPIA), the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), the Japanese Pharmaceutical Manufacturers Association (JPMA) and the Pharmaceutical Research and Manufacturers of America (PhRMA), has recently committed to disclosing information pertaining to all "non-exploratory," industry-sponsored clinical trials. See "Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases," *at* <http://www.efpia.org/4_pos/sci_regu/Clinicaltrials2005.pdf> (last visited January 26, 2005); "PhRMA Clinical Trial Registry Proposal" *at* <http://www.phrma.org/publications/policy/06.01.2005.1111.cfm> (last visited January 26, 2005). Although this policy has the potential to reduce pharmaceutical companies' incentive to prematurely terminate studies that are likely to produce negative data, the extent to which this occurs will depend on several factors such as (a) the number and types of studies that companies classify as "exploratory" and are thus exempted from the disclosure requirements, (2) whether the industry's commitment to disclosing "trial phase" and "trial status" includes an obligation to disclose trial terminations, (3) if pharmaceuti-

cal companies have indeed committed to announcing trial terminations, the (a) language used to convey this point, (b) the amount of time that is allowed to lapse between a trial termination and disclosure of this fact, (c) whether companies will be able to circumvent their obligations by slowing the progress of a trial to a virtual standstill instead of aborting the project entirely.

47. *The People of the State of New York v. GlaxoSmithKline,* Verified Complaint at 2.
48. See M. Meadows, "The FDA's Drug Review Process: Ensuring Drugs are Safe and Effective," FDA Consumer, July 2002, *at* <http://www.fda.gov/fdac/features/2002/402_drug.html> (last visited January 25, 2005).
49. J. A. Waltz, "CMS Report Analyzes Factors Affecting the Marketing of Prescription Drugs," Medscape from WebMD, April 22, 2003, *at* <http://www.medscape.com/viewarticle/452211_1> (last visited January 25, 2005).
50. R. E. Herzlinger, W. Lagor, C. Perry, S. St. Germain, "I've Got Rhythm: Selling Cardiac Rhythm Management Devices" Harvard Business School Case Number 9-304-012, August 20, 2004, at 6.
51. See J. A. Waltz, *supra* note 50. Although such a discussion is beyond the scope of this paper, it is highly questionable whether the distribution of samples effectuates laudable societal goals. Anecdotal evidence suggests that a high percentage of samples go to individuals who have adequate insurance coverage or can afford the medicine by themselves. Thus, the dissemination of samples does not address any distributional concerns (and may even exacerbate problems of wealth disparity), insofar as all drug users pay for the cost of samples in the form of higher insurance premiums or higher drug costs.
52. See J. Dana and G. Loewenstein, "A Social Science Perspective on Gifts to Physicians from Industry," *JAMA* 290, no. 2 (2003) 252-255 (Concluding that, notwithstanding physicians' belief to the contrary, doctors are heavily influenced by the fringe benefits provided by pharmaceutical companies); A. Wazana, "Physicians and the Pharmaceutical Industry: Is a Gift Ever Just a Gift?" *JAMA* 283, no. 3 (2000) 373-380; P. Jhon, "Drug Company Dependent?," Medscape from WebMD, 2003, *at* <http://www.medscape.com/viewarticle/414513> (last visited January 25, 2005).
53. R. E. Herzlinger, note 51 *supra,* at 5 (stating: "Physicians felt they had enough information within the first six months to year of launch...Some physicians felt they could learn more about new drugs themselves than from their sales reps. Frequently, drug reps did little more than drop off samples to the nurses or the supply cabinets.")
54. P. Jhon, *supra* note 53.
55. Pharmaceutical sales representatives are clearly subject to much higher regulation (both internally and by the FDA) than car salesmen. The point, however, is merely that both parties are expected to carefully select language (and potentially data) that portrays their products in the most favorable light.
56. See T. A. M. Kramer, "A Plea for Biased Information," Medscape from WebMD, February 10, 2004, *at* <http://www.medscape.com/viewarticle/468112_1> (last visited January 25, 2005).
57. Ratings could be made on a 1 to 100 scale or any other scale that allows for sufficient differentiation. The FDA currently assesses the efficacy and safety of drugs in an attempt to determine if they reach the threshold required for approval. This suggests that the FDA would be the best equipped (compared to other governmental bodies) to engage in the additional evaluation necessary to provide products with relative rankings. Of course, in order to accurately assess cost-effectiveness, personnel with different backgrounds (e.g. economists) would have to be hired. Although a detailed discussion of this point is beyond the scope of this paper, the FDA could establish a standardized process through which it regularly reevaluates pharmaceuticals after their launch. The FDA could be required to reassess all drugs every few years on the basis of post-launch clinical trials, and pharmaceutical companies could be permitted to petition the government for reevaluation when sufficient data becomes available.
58. M. Angell, *The Truth about the Drug Companies* (New York: Random House, 2004): at 40 and 122. The exact amounts of money that pharmaceutical companies spend on marketing and R&D are hotly debated. The pharmaceutical industry, speaking through the Pharmaceutical Research and Manufacturers of America (PhRMA), contends that R&D expenditures "far exceed" spending on marketing and promotion (see Pharmaceutical Marketing and Promotion, *at* <http://www.phrma.org/publications/policy//2004-11-10.1095.pdf>) (last visited January 25, 2005). Resolution of this issue is far beyond the scope of this paper, but it is important to realize, that regardless of which figures are used, pharmaceutical companies' marketing expenditures are large enough that a relatively modest reduction in the percent of revenue spent on promotional activities could have a substantial impact on drug prices.
59. R. E. Herzlinger, note 51 *supra,* at 5.
60. *Id.* at 5.
61. Of course, idiosyncrasies amongst the patient population may make it preferable for some patients to forego higher rated pharmaceuticals for lower rated drugs that are better suited to the patients' needs. Pharmaceutical representatives can provide physicians with valuable information by alerting them to such instances. When certain classes of people (as a whole) respond more favorably to a drug than others, the FDA may wish to provide a separate set of ratings for each group. Such disparate ratings may be warranted for SSRIs, since an antidepressant's effect on suicidality appears to depend on the personality of the user (see *supra* note 2). Therefore, it may be appropriate for the FDA to issue different safety ratings that correlate with users of different personalities. The funding necessary to create the FDA rating system from scratch and retrain pharmaceutical sales representatives will likely raise costs for pharmaceutical companies in the beginning. However, once the rating system is in place and reps have been retrained, it is likely that firms will experience significant savings.

State Court Rejects Mental Health Parity Claim

Elaine Ewing

On July 1, 2004, the Court of Appeals for the State of New York held that an anti-discrimination provision of New York state insurance law does not require that insurers or employers offer the same or equivalent benefits for physical and mental disabilities.[1] In *Polan v. State of New York Insurance Department,* the court held that while insurers cannot limit the coverage they offer an individual because of disability, the statute does not require insurers to provide comparable coverage for all types of conditions.[2]

In recent years, advocates for mental health have sought equal

treatment for insurance coverage of mental and physical illnesses. Such attempts for parity have been successful in many jurisdictions. In 1996, Congress passed the Mental Health Parity Act, which provides limited parity of coverage for mental and physical illnesses.[3] The law prevents insurers from having different annual or lifetime limits on dollar spending for mental and physical illness, but allows insurers to offer different co-pays and deductibles.[4] Additionally, more than thirty states have passed laws mandating equivalent coverage of mental and physical illness.[5] New York has not adopted such legislation, though it has been pursued at the state level.[6] For those pursuing this legislation, the holding in *Polan* was a setback.

Factual Background

Charlene Polan ("Polan") suffers from chronic depression and, as a result, has been unable to work since March 24, 1994.[7] At that time, Polan had short- and long-term disability coverage through her employer.[8] The insurance plan covered employees with physical disabilities until they reached the age of sixty-five or were no longer disabled.[9] In contrast, insurance coverage for disability caused by mental illness lasted for twenty-four months, unless the employee was hospitalized or institutionalized when the twenty-four month period ended.[10] In that case, the employee was eligible for disability benefits until he or she was released.[11] After she was no longer able to work, Polan sought disability benefits from her insurer, which were granted in February 1995, retroactive to September 16, 1994.[12] Though Polan continued to be disabled by her mental illness, her disability benefits expired twenty-four months later on September 8, 1996 in accordance with the terms of her policy.[13]

Procedural History

Initially, Polan filed suit against her employer and insurer in New York State Supreme Court.[14] The complaint alleged that the defendants had violated New York State Insurance Law §4224(b)(2). The law provides that:

> [N]o insurer may refuse to insure, refuse to continue to insure or limit the amount, extent or kind of coverage available to an individual, or charge a different rate for the same coverage solely because of the physical or mental disability, impairment or disease, or prior history thereof, of the insured or potential insured, except where the refusal, limitation or rate differential is permitted by law or regulation and is based on sound actuarial principles or is related to actual or reasonably anticipated experience.[15]

The court dismissed the complaint for want of jurisdiction, ruling that it must be filed with the Superintendent of Insurance of the State of New York.[16] Polan subsequently filed a complaint with the New York State Insurance Department ("Insurance Department").[17] The complaint again alleged that by denying her benefits beyond the twenty-four-month cap, her insurer had violated §4224(b)(2).[18] In an administrative hearing, the Insurance Department denied her claim on the grounds that the New York statute did not mandate that employers or insurers provide equal benefits for mental and physical disability. Polan then sought an order from the New York State Supreme Court directing the Insurance Department to consider whether there was actuarial or experiential data to support the differential treatment of mental and physical disabilities.[19] That court, finding that her insurer had not violated §4224(b)(2) by providing greater coverage for physical disabilities, denied the request and dismissed Polan's complaint.[20]

Polan appealed this decision to the Appellate Division of New York State Supreme Court.[21] In a 3-2 decision, the Appellate Division upheld the administrative ruling and subsequent dismissal by the lower court, finding that Polan's insurer did not discriminate against her because of her mental disability and thus did not violate §4224(b)(2).[22] The dissenting judges argued that the anti-discrimination purpose of §4224(b)(2) should be construed liberally and its wording should be taken to mean that "an insurer that treats a particular disability differently from other disabilities must support such different treatment with actuarial or experiential data."[23] The dissenters argued that since Polan's insurer limited her coverage because of her disability without such basis, it violated §4224(b)(2).[24]

Court of Appeals Decision

Polan appealed the Appellate Division's decision to the New York State Court of Appeals ("Court of Appeals").[25] In its unanimous decision, the Court of Appeals upheld the ruling of the Appellate Division. In doing so, the Court of Appeals held that the requirement that insurers not refuse or limit coverage "solely because of [a] physical or mental disability" did not mean that insurers were required to offer equivalent coverage for all illnesses or disabilities unless "statistically or empirically justified."[26] The court held that insurers are allowed to limit the conditions they cover and the extent to which they cover these conditions.[27] It held that §4224(b)(2) only prohibits limiting coverage available to an individual solely because of a specific disability or disease.[28] Polan's insurer did not impose the twenty-four-month cap on her coverage because she suffered from a mental illness. Moreover, the limit was not directed at Polan individually, but applied to everyone who was insured under the plan. Accordingly, the Court found that the cap did not violate the statute.[29]

In support of its ruling, the court cited cases from Maine and Texas, which held that insurance statutes

similar to New York's did not require insurers to provide equivalent coverage for mental and physical disability.[30] The court also looked to the interpretation of the federal Americans with Disabilities Act.[31] Here, too, a number of courts have ruled that the law, which contains language similar to the New York statute, does not require equal provisions for individuals with physical and mental disabilities.[32]

While the court held that the plain language of the statute was the primary basis for its decision, it also examined the legislative intent behind the passage of the law and offered its analysis of the history in support of its ruling.[33] The court drew a comparison between §4224(b)(2) and another provision of the insurance law, §3221, which contains specific requirements for insurers and employers.[34] The court held that the plaintiff's argument that the legislature intended §4224(b)(2) to mandate equivalent coverage for mental and physical disabilities was weakened by the existence of another statute that specifically enumerates coverage requirements, but does not mandate equivalent coverage for mental and physical disabilities.[35]

The court offered additional evidence of legislative intent by providing the relevant historical context of the passage of §4224(b)(2), explaining that the anti-discrimination purpose of the statute was to prevent insurers from denying coverage to an individual because of her disability, not to ensure that all illnesses or disabilities were treated identically.[36] It explained that the law was enacted in 1994 as an extension of a 1993 law designed to prevent insurers from discriminating against providing coverage to individuals with breast cancer and was designed to extend this protection to people suffering from any illness ability or illness.[37] Citing testimony from the bill's sponsors and the Drafting Note to the National Association of Insurance Commissioners Model Regulation on Unfair Discrimination in Life and Health Insurance on the Basis of Physical or Mental Impairment, which contains language very similar to the New York statute, the court concluded that the legislative intent behind both laws was not to mandate equal coverage of all illnesses but to mandate that insurance plans give the same benefit eligibility to individual subscribers regardless of their disability status.[38]

In contrast, insurance coverage for disability caused by mental illness lasted for twenty-four months, unless the employee was hospitalized or institutionalized when the twenty-four month period ended.

Discussion

Laws requiring the provision of equal coverage for mental and physical illness and disability continue to be hotly debated. Mental health care and insurance coverage is an issue of great importance to a significant portion of the population. Forty-four million Americans suffer from mental health disorders, but only one in three sufferers have sought treatment for their illness.[39] A study by the American Psychological Association found that cost and/or lack of insurance coverage were the most common reasons that people did not seek mental health care.[40] Further, mental health parity legislation is widely supported by the American public. One poll reports that seventy-nine percent of Americans support its enactment.[41]

On the other side of the debate are those who maintain that mandating benefits of any kind raises insurance premiums, which in turn limits the number of employers and employees who can afford to provide or purchase insurance coverage.

Mental health parity legislation has been pursued on a national level. In 1996, Congress passed the Mental Health Parity Act, which requires annual and lifetime spending caps to be set at the same levels for mental and physical insurance coverage.[42] This law has been renewed several times, most recently in September 2004, and is now set to expire on December 31, 2005.[43] However, it has been largely circumvented, as eighty-seven percent of insurers that have complied with the legislation have imposed caps on length of hospital stays or numbers of outpatient doctors' visits that effectively reduce the extent of the protection provided by the law.[44]

Additional parity legislation has been championed by several prominent political figures who have experienced mental illness personally or in their immediate families, including Representative Patrick Kennedy (D-RI), Senator Pete Domenici (R-NM) and former First Lady Tipper Gore.[45] The Paul Wellstone Mental Health Equitable Treatment Act of 2003 would have closed the loopholes of its predecessor by mandating equal treatment for co-insurance, deductibles and limits on number of in-patient days and out-patient visits.[46] This bill was not passed prior to the close of the summer 2004 Congressional session. The future of this bill or similar legislation is not entirely clear, but passage in the immediate future seems unlikely.

The fate of mental health parity legislation in New York State is equally uncertain. A bill known as Timothy's Law, named for a twelve year-old boy who committed suicide in 2001, was passed several times in the New York State Assembly, most recently on March 3, 2004.[47] Its passage has been blocked in the New York State

Senate, where it has yet to make it out of committee.[48]

The various efforts at reform are made more complicated by the complicated web of laws governing insurance regulation. The effect of many new or proposed laws would be narrower than is readily apparent. For instance, Timothy's Law, if it were passed, would not govern large companies that self-insure their employees.[49] On a national level, the proposed federal legislation does not mandate that plans cover mental health care at all, only that if they do cover mental health care, they must provide benefits that are equivalent to the benefits that they provide for physical health care.[50] Notably, many of the legislative measures that have been debated and passed apply only to health plans and not to disability insurance. Thus, a New York state mental health parity law might not have been helpful to Charlene Polan. The reverse is not necessarily true, as §4224(b)(2) governs both health and disability insurance.[51] If the Court of Appeals or New York State Insurance Department had ruled that the law required equal treatment for mental and physical illness, it would have had the effect desired by those seeking mental health parity legislation.

The actual impact of the *Polan* decision is fairly limited. The ruling preserved the status quo, and so its primary effect was a setback for advocates of mental health parity who had hoped the courts might provide a mechanism for accomplishing a goal that has been difficult to obtain through the legislative branch. Despite this setback, the quest for equivalent coverage is still being pursued. Whether the next challenges come through the courts or the legislatures, the issue of mental health parity is one that is unlikely to disappear.

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