

TARDIVE DYSKINESIA: TREMORS IN LAW AND MEDICINE

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TARDIVE DYSKINESIA AND ANTI-PSYCHOTIC MEDICATION

Although debate exists as to the incidence and prevalence of antipsychotic induced tardive dyskinesia (TD), it is readily accepted that antipsychotics can and often do induce this potentially irreversible movement disorder. Studies commonly report a prevalence rates of 25%-40% and incidence rates of 1-3% annually. (1,2,3). Contemporary and controversial research suggests that tardive dyskinesia may be part of the normal aging process occurring in up to 32% of persons never exposed to an antipsychotic. (1,2,3). Despite these findings, a treating physician may be sued for malpractice if a person develops TD and has ever been exposed to an antipsychotic during treatment. These cases are psychologically and fiscally expensive to treating psychiatrists.

The treating psychiatrist's risk of being sued is proportionate to the patient's likelihood of developing TD. A patient's risk factors for developing TD are thought to include age, duration of treatment and average and highest dose of drug used. In Kane's study of younger adult patients (mean age of 29 years) the incidence of TD was about 4% per year of cumulative drug exposure for at least the first 5 years (1). Approximately 20% of those patients who develop TD do so within 3 years of initiating treatment. After this high risk period, the incidence falls to about 1% per year, close to the spontaneous rate for the condition.

The scientific basis for the development of the disorder is not fully understood. The underlying etiology and pathophysiology of TD are still unknown. Although often cited, the dopamine supersensitivity hypothesis is a gross oversimplification in that the change in receptor sensitivity happens after even a single dose of drug whereas it usually takes years of exposure to develop TD.

In addition, the standards for prescribing antipsychotics continue to evolve. There was a time when it was argued that drug holidays were beneficial and acted to prevent TD by decreasing the total exposure (duration x dose). More recent studies (4,5) suggest that drug holidays more often are associated with the development of TD.

Clozapine, the first atypical antipsychotic, promised no risk of TD. Indeed, after over 10 years' clinical use, there are still no confirmed cases of TD from exposure to clozapine (6). Casey (7) reports that "there is virtually no risk of tardive dyskinesia" with clozapine. However, the 1-2% risk of agranulocytosis associated with administering clozapine has scared away many physicians and patients from prescribing or using this valuable medication. With the release of other atypical antipsychotics such as risperidone, olanzapine and quetiapine came the hope/promise of safer medications without the risk of TD.

The recent evidence for increased safety with these newer agents is impressive. The apparent incidence of TD with risperidone is between 0.03 and 2.4% (8,9,10). With olanzapine the incidence of TD is 0.5-1% compared with 4.5-7.5% for haloperidol (11,12). The quetiapine safety, tolerability and efficacy study followed patients for up to 2 years during which no cases of TD developed (13). Comparison of this clinical data with that from classic antipsychotics suggests a significantly lower risk of TD, despite episodic case reports of TD occurring with some of the atypical antipsychotics. This argues strongly for the use of risperidone, olanzapine and quetiapine as a first line treatment.

In addition, there is controversy as to whether schizophrenia, affective disorders or organic disorders are more likely to predispose a patient to TD (1,2,14,15). Nonetheless, a disappointed patient can find an expert willing to testify that another practitioner deviated from accepted medical standards and was otherwise remiss in her/his use of antipsychotic medication when a psychiatric patient develops TD and its associated pain, disfigurement and potential irreversibility after a course of traditional antipsychotic medication.

MALPRACTICE LIABILITY THEORIES

Any patient who develops TD may assert a malpractice claim against the treating psychiatrist invoking any or all of four different legal theories. First, the patient may claim malpractice liability based on the intentional tort of battery or on grounds of negligence for unwarranted administration of drugs without the patient's meaningful consent to the course of treatment, i.e., without careful explanation of the potential side-effects, including the incidence of TD. Second, the same disappointed patient may also claim that the treating psychiatrist committed negligence because the psychiatrist made an inappropriate assessment, took an improper or incomplete medical and psychiatric history, conducted a deficient physical examination, did not require or perform a complete laboratory examination or mis-diagnosed the patient's condition. Negligent malpractice liability may also be based on lack of indication or contraindication to the medication, failure to monitor and care for side effects, excessive duration of treatment and dosage or failure to consult with another physician.

Third, a patient may also sue the treating psychiatrist as a "conduit" for administering an unsafe antipsychotic medication, in addition to bringing a product liability suit against the drug manufacturer for failure to warn of an antipsychotic drug's side effects such as the incidence and risk of TD. Products liability law in many states holds every person who transmits a defectively-made drug product from manufacture to the injured patient liable without fault for administering the drug.

Finally, those patients who have been incarcerated or committed to a state hospital may also claim that their treating psychiatrist violated their Civil Rights under the Eighth and Fourteenth Amendments to the Constitution. Under the Civil Rights Act (42 USC 1983) the allegation is that the treating psychiatrist violated the patient's civil rights because the patient was under the control of the state. The Civil Rights Act requires the patient to allege that the psychiatrist acted under color of state law in supplying psychiatric assessment and treatment to the patient, and failed to obtain appropriate consent to administer antipsychotic drugs to the patient. State-created medical malpractice claims based on negligence may be joined to a Federal Civil Rights Act suit as well. A patient who develops TD after treatment with an antipsychotic in prison or in a state mental institution can also claim that the treating psychiatrist was "deliberately indifferent" to the patient's condition, a separate "Constitutional Tort" that permits recovery of damages for pain, suffering, impairment of functioning and loss of earnings.

Each of these branches of malpractice liability has its own case law and legal strategy. Unfortunately, much of the case law in this area is difficult to track; settlements are common and appeals few. Therefore, the standard reporting systems disclose only the tip of the medical malpractice iceberg that stems from patients developing TD after receiving antipsychotic medication.

INFORMED CONSENT

As a general rule, a psychiatrist who prescribes or administers medication to a patient without the patient's informed consent commits negligent malpractice. However, if the physician administers medication without any consent, the physician commits an intentional tort of battery (16) The difference between an invasion characterized as battery and negligent failure to disclose is accurately summarized by *Lackey v. Bressler*, (17) a combined negligent medical malpractice, assault and battery, breach of contract for the use of antipsychotics which resulted in the development of TD. Although the plaintiff's case was dismissed as time-barred due to the statute of limitations the court offered this explanation of the difference between negligent failure to warn and intentional battery:

Where a medical procedure is completely unauthorized, it constitutes an assault and battery, i.e., trespass to the person If, however, the procedure is authorized, but the patient claims a failure to disclose the risks involved, the cause of action is bottomed on negligence.

Plaintiff alleged that her treating physicians intentionally did not tell her of the risk associated with her antipsychotic medication when they obtained her consent to administer medication. The North Carolina statute of limitations for recovery for intentional torts was longer than that for negligent malpractice. The court decided her injuries were the result of negligent failure to inform, were brought after the statute of limitations had run out, and did not address the issue of TD directly.

The physician is responsible for any damage done to the patient by any medication administered without fully informed consent. To complicate matters, administering antipsychotic medication to a patient without providing the patient with all appropriate information may be negligence as well. For consent to be "informed" it must be voluntary. The treating physician must explain to the patient or to the patient's guardian, if the patient is incompetent, the reasons for intervention along with the possible alternatives to treatment and the likely course of the patient's condition with no treatment at all (16). In addition, the potential risks and benefits are to be clearly explained before the patient accepts a particular course of therapy. In the case of an antipsychotic, this would include discussion of both the short term and the long term risks as they are understood by the relevant scientific community at the time treatment is initiated. In addition, if new information develops it is incumbent upon the physician to apprise the patient of these changes and to allow the patient to alter the course of treatment if the patient desires. Similarly, if because of psychosis or mental illness an individual is unable to fully understand or appreciate the risks, it is at a minimum a requirement that once the patient's faculties have improved, that the attempt for informed consent be made again. Some states such as Massachusetts, New York and New Jersey, have special provisions for obtaining consent to use antipsychotics under such circumstances (19,20,21)

The cases that are important to remember in dealing with informed consent issues include *Barclay v. Campbell*,⁽²²⁾ a 1986 decision by the Texas Supreme Court. In *Barclay*, it was undisputed that in 1978, the defendant, Dr. Campbell prescribed antipsychotics to Mr. Barclay, who had been diagnosed with Schizophrenia, without warning him of the potential risks. Barclay developed TD. The Texas Supreme Court did recognize the dilemma faced by Dr. Campbell in that the patient may well have refused the treatment if Dr. Campbell fully and accurately informed him of the risks associated with the medication administered. The trial court directed a verdict for Dr. Campbell on the issue of informed consent, which was not submitted to the jury. The jury returned a take-nothing verdict on the issue of negligent treatment. The Texas Court of Appeals affirmed the trial court and plaintiff took the case to the Texas Supreme Court. The Supreme Court of Texas felt the issue of informed consent was proper for the jury and reversed the lower court's verdict sending the case back for re-trial on the issue of informed consent. The Texas courts apparently viewed the treating psychiatrist's liability as grounded only in negligent failure to inform the patient of known risks associated with treatment. (22)

In *Timmel v. Phillips*,⁽²³⁾ the patient claimed that his treating psychiatrist, Dr. Phillips, failed to obtain plaintiff's informed consent to administration of perphenazine, resulting in Timmel developing TD. Specifically, Timmel alleged that Dr. Phillips did not explain the potential side effects of the drug to him before administering it. The case was tried to a six person jury who returned a verdict for defendant. The plaintiff appealed, claiming the jury was improperly selected. The U.S. Court of Appeals for the Fifth Circuit affirmed the District Court. The case was submitted to the jury on negligent failure to explain the risk of TD to the patient.

Nolen v. Peterson (24) is the case of a patient who was involuntarily committed to the North Alabama Regional Hospital. Drs. Peterson and Wicks, his treating psychiatrists, administered fluphenazine, decanoate and thioridazine for Manic-Depressive Disorder. The trial court granted Dr. Peterson's summary judgment motion on the ground that a person involuntarily confined to a mental hospital could not refuse treatment with antipsychotic drugs. The Alabama Supreme Court overturned the judgment for defendant, holding that the plaintiff still retained a constitutionally-protected right to reject potentially harmful antipsychotic medication and noted that his rights to informed consent were not ipso facto relinquished merely because of his involuntary status (24). This case seemed to be related to an intentional invasion of the patient's body by treating physicians, rather than to negligent failure to inform the patient of the known risk of developing TD.

Gatling v. Perna (25) involves a patient's allegation that her treating psychiatrist, Dr. Mauk, did not obtain her informed consent in 1980 to a five year course of antipsychotic medications specifically because the doctor did not explain the potential side effects of the treatment. She also alleged that Dr. Mauk was negligent in not referring the patient to a neurologist after she developed TD and fraudulently concealed his malpractice by lulling her into believing that her TD was not a byproduct of the medications. The trial court granted summary judgment for the defendant on the ground that the statute of limitations had run on her claim for relief, but the Texas Court of Appeals reversed and remanded the case. In its decision, the court was especially critical of the notion that Dr. Mauk may have attempted to reassure the patient by telling her that her neuromuscular disorder was "nothing to worry about." The court considered that Dr. Mauk fraudulently concealed the patient's true condition by this "reassurance." This case was remanded to the trial court on negligent failure to explain to the patient the risk of developing TD. Dr. Mauk's "reassurance" kept the statute of limitations from expiring on the claim of negligent failure to inform. (25)

In *Clites v. State of Iowa*, (64) a mentally retarded man confined to Glenwood Hospital-School was awarded \$760,165 for TD on the grounds that the hospital violated accepted medical standards by using antipsychotics in his care and failure to obtain informed consent from the patient or his parents before using the medication. The Iowa Court of Appeals upheld the jury verdict and award. Interestingly, regarding the size of the award, Justice Snell remarked: "Although the evidence may have justified a higher award, such is not controlling. The determinative question posed is whether on the record, giving the jury its right to accept or reject whatever portions of the conflicting evidence it chose, the verdict effects substantial justice between the parties." (26)

In *Gertrude Adkins, Billy Bob Adkins and David Adkins v. Robert Tafel, M.D., and*

Richard Boardman, Registered Pharmacist (27) Plaintiff Gertrude Adkins and her husband Billy Bob Adkins sued Dr. Robert Tafel, M.D., Dr. Stephen R. Neece, M.D. and Richard Boardman, Registered Pharmacist for medical malpractice following a course of treatment for a severe organic brain injury suffered in an automobile accident. Dr. Neece, the primary treating physician, prescribed haloperidol for her symptoms from 1981 to 1989. Plaintiffs alleged that Dr. Tafel, who was her personal treating physician, continued the haloperidol prescription and failed to recognize that Mrs. Adkins' tremors were evidence of developing TD. Plaintiffs also alleged that Dr. Tafel failed use a less hazardous medication, failed to disclose to Mrs. Adkins or her family the risks and hazards of continued use of the medication and failed to properly monitor the patient and to recognize the side effects of the medication. These facts were not disputed by defendants' motion for summary judgement. The trial court granted the defense summary judgment motion because the statute of limitations had run. Had the case been submitted to a jury, Dr. Tafel may very well have been found liable for failure to explain to Mrs. Adkins and her family the side-effects of haloperidol, in addition to liability based on failure to identify and monitor Mrs. Adkins' TD.

In summary, a treating psychiatrist has a legal duty to fully inform each patient of the potential side-effects of any antipsychotic medication, particularly those which have a known relationship to TD. Failure to do so may be both negligent malpractice and an unwarranted extension of consent to treat.

MISDIAGNOSIS

Misdiagnosis is a special area of malpractice law. Tort law theory underlies malpractice claims. There are four legal elements to a cause of action for negligent malpractice. A defendant physician must be found to have been Derelict (negligence) in his Duties (doctor-patient relationship) which Directly (causation) gives rise to Damages. Absent all four D's, malpractice should not be found.

The legal standard for due care in diagnosis and treatment of a patient includes taking the appropriate history and ordering and interpreting the appropriate laboratory tests. In addition, a physician is expected to apply sound reasoning to the conclusions reached from the data obtained. Although the law does not require a physician to always be "correct" in the decision making process, the standard of care for making a decision is relevant. As stated in the preceding section, a physician can be held liable for improper documentation (including informed consent). It is therefore highly important that the rationale behind reaching a diagnosis and embarking on a treatment course should be clear from the records.

It is not always possible to be certain of the diagnosis in a psychotic individual. Organic psychoses (including substance induced psychoses), Bipolar Disorder, Schizophrenia, Schizophreniform Disorder, Schizoaffective Disorder, Delusional Disorder and Brief Psychotic Disorder all can mimic one another. If uncertain of the diagnosis, either from history or from clinical presentation or both, it is wisest to use a working diagnosis and to refer to a differential diagnosis list. In addition, it is then necessary to refer to this and to attempt to reach a more definitive diagnosis over time.

The following cases focus on treating psychiatrists who were sued for misdiagnosis by patients who developed TD from a treatment regimen. In *Outman v. United States*, (28) Outman was initially treated for Schizophrenia with antipsychotics at a Veterans Administration Hospital. Over time, his diagnosis was changed to Bipolar Disorder. Outman initially filed an administrative claim for service-connected disability in 1976 after he developed TD. After his VA disability claim was dismissed, Outman filed a pro se federal civil suit alleging medical malpractice against his VA treating psychiatrists and the VA. Dr. Dudley, the plaintiff's expert argued that because of the misdiagnosis, Mr. Outman was erroneously treated with antipsychotics and hence developed TD. At issue was the date that Outman should have noticed he had TD. The United States argued for 1976 and Outman claimed that he learned of his true condition only in 1982 when he first saw Dr. Dudley. The trial court dismissed his case on grounds of missing the statute of limitations under the Federal Torts Claims Act, accepting the United States' argument for the earlier date. The Ninth Circuit affirmed, relying on its earlier definition of malpractice:

"a misdiagnosis injury arises when a condition which could otherwise be treated is misdiagnosed and the result is the worsening of some prior condition. When a claim of medical malpractice is based on the failure to diagnose or treat a pre-existing condition, the injury is not the mere undetected existence of the medical problem at the time the physician failed to diagnose or treat the patient or the mere continuance of that same or undiagnosed problem in substantially the same state. Rather, the injury is the development of the problem into a more serious condition which poses greater danger to the patient or which requires more extensive treatment. In this type of case, it is only when the patient becomes aware or through the exercise of reasonable diligence should have become aware of the development of a pre-existing problem into a more serious condition that his cause of action can be said to have accrued for purposes of section 240(b)" (29).

Had Outman brought suit within two years after initially discovering he had TD and Dr. Dudley had supported his claim of mis-diagnosis, this suit could very well have resulted in a large judgment against both the United States and Outman's treating psychiatrist.

Frasier v. Department of Health and Human Resources (30) is similar to the claim asserted by Outman. *Frasier* involves a plaintiff charging that negligent misdiagnosis of her condition as Schizophrenia rather than Manic-Depressive caused an increase in exposure to antipsychotics resulting in her developing TD. In addition, she claimed that she was never given informed consent for the administration of the medication. Plaintiff lost her malpractice claim because the expert witnesses at trial testified that "Manic Depression and Schizophrenia are continuously overlapping and that it is a common error to confuse the diagnosis between the two." (30) The trial court found for the defendant. The Louisiana Court of Appeal affirmed, holding that treating mental health physicians did not have to be able to differentiate between Manic Depressive Disorder and Schizophrenia before the publication of DSM-III.

In this relatively early case, the court thoroughly reviewed the medical record. This included a review of: the medical standard during the time of her treatment, consideration of the defendant's degree of knowledge and skill, defendant's exercise of reasonable care and diligence in diagnosis and treatment, and defendant's duty in obtaining informed consent. The court noted that the withdrawal of antipsychotic drugs was a suggested practice at that time, but was by no means the only accepted practice at that time. The court found that there was informed consent.

These "mis-diagnosis" cases show that treating psychiatrists may be held liable for negligent malpractice when a patient develops TD. A forensic non-treating expert may relate an opinion that another diagnosis was more accurate than that of the treating psychiatrist, a diagnosis that would not call for administration of antipsychotic medication. Therefore, administering older antipsychotics with a higher risk of TD would have been negligent treatment due to mis-diagnosis.

MONITORING

As a part of the standard of care doctrine, all physicians are required to monitor the treatment of their patients. Although medical malpractice law is in conflict on the applicability of nationwide rather than local standards of care, the American Psychiatric Association has set a standard for the profession regarding the monitoring of persons on antipsychotics who are at risk for developing TD (1). It now requires that anyone starting on an antipsychotic should have a screening test for movement disorders and that this should be repeated on a regular basis. Documentation of the test, its results and the treating psychiatrist's discussion with the patient as to the significance of the test and results is required.

A few "failure to monitor" cases illustrate this point. In *Bolen v. United States*, (31) another Federal Torts Claims Act suit against the Veterans Administration, the plaintiff argued that the Veterans Administration failed to monitor him appropriately for side effects and as a result he developed TD from the chronic ingestion of trifluoperazine. Interestingly, Bolen received the drug for paranoid ideation and anxiety associated with a traumatic brain injury. He was started on the drug in 1963 before any research studies disclosed the potential for TD to develop. The case was tried before the Judge sitting without a jury. The US District Court for the District of Idaho dismissed Bolen's suit on two grounds. First, it noted that the statute of limitations had been passed for filing suit. The court also held that Bolen's doctors at the Veterans Administration had no duty at the time they were treating him between 1963 and 1980 to monitor him for TD. The defense experts testified that there was no clear understanding of the potential for TD in those years. Further, Bolen did not show any evidence of TD and at that time the knowledge of the potential effect of antipsychotics to cause TD was not the community standard.(31)

The Michigan case of *Coen v. Oakland County and Sinai Hospital of Detroit* (32) raised similar issues relating to monitoring. Coen, a young woman with schizophrenia who was on haloperidol and thioridazine, developed TD. She argued that the drugs should have been stopped when the TD appeared. She accused the state-operated mental health clinics and her treating psychiatrist of failure to monitor her condition. The trial court and the Michigan Court of Appeals never reached the merits of her case because they held that the county and mental hygiene clinic enjoyed governmental immunity from suit. Both courts also found that the doctor's actions were discretionary rather than ministerial and entitled him to qualified tort immunity.

Although *Leal v. Simon* (33) involves contractures and not TD as a side effect of exposure to antipsychotic medication, it is otherwise similar to these TD cases. It has been included as contractures could be considered a movement disorder related to medication. Mr. Leal suffered from mental retardation and was cared for through the auspices of the United Cerebral Palsy Association. He had responded very well to low doses of haloperidol. In anticipation of an upcoming State review Dr. Simon, his treating physician, stopped the haloperidol which had been effective for controlling self-abusive behaviors. The patient's self-abusive behavior returned and he was treated with high doses of haloperidol to the point of catatonia. He developed contractures as a result.

When he was finally weaned from the drug he was much better but not at his previous baseline. The New York Supreme Court, Special Term held that Dr. Simon was negligent in his monitoring of the drug, for not familiarizing himself with old records which were available and in his reasoning for changing the dose in anticipation of an outside review by the State Office of Mental Retardation. The New York Supreme Court, Appellate Division affirmed the trial court's judgment but reduced the jury verdict of \$2,500,000 to \$1,100,000.(33)

Another important lesson to be learned from this case is that errors in judgment and treatment can occur when physicians, in an effort to try to comply with audits and reviews, make decisions that fail to put patient care first.

Hedin v. United States (34), an unreported 1985 Federal Torts Claims Act case, involved a Veteran treated with thioridazine and then chlorpromazine for alcohol abuse in a Veterans Administration Hospital. He was left on the drug for four years when his doctor noticed the development of the movement disorder. Defendant admitted his negligence in prescribing excessive amounts of medication without proper supervision. The jury returned a verdict of \$2,200,000 which was not appealed.

Monitoring a patient requires the treating psychiatrist to keep proper medical records documentation showing visits and prescriptions. In *Lou Accardo, Oscar Accardo, Tammy Accardo and Rodney Accardo v. Dr. Louis Cenac, E.R. Squibb and Son, Inc., Olin Corporation, Princeton Pharmaceutical Company, Legion Insurance Company, The Louisiana Patients Compensation Fund, ABC Insurance Company and XYZ Insurance Company* (35) poor medical records forced the defendant doctor to stipulate to liability and causation of the plaintiff's tardive dyskinesia. There were billing records for monthly injections of antipsychotic medication without corresponding clinical progress notes. This served to undermine Dr. Cenac's contention that the patient was not compliant with treatment. The judgment awarded a plaintiff a total of \$227,000. The only issue before the appellate court was the amount of damages awarded by the jury. The amended award increased the general damage award to \$500,000 and increased the loss of consortium awards to \$175,000.

Ronald Bloom v. Will Creed, M.D. (36) is a disturbing case that should frighten any physician. Mr. Creed contended that the defendant failed to warn him of side effects or to monitor his condition while using antipsychotic medication. In this case, Dr. Bloom allegedly called in a prescription for antipsychotic medication while covering for a colleague. Both Mr. Creed and Dr. Bloom stated in depositions that Dr. Bloom had never met nor treated Mr. Creed. Mr. Creed also stated that he did not know Dr. Bloom. The connection between Mr. Creed and Dr. Bloom was a tax information summary at a local pharmacy suggesting that Dr. Bloom had called in a refill. The Supreme Court Mississippi ruled 7-2 in favor of Dr. Bloom. Many physicians provide coverage for one another, frequently across practices and, without access to full medical records. This case is the first to these authors knowledge suggesting a duty to provide informed consent when re-filling a prescription for a patient treated by a colleague.

All of these cases represent occasions when failure to monitor a patient resulted in expensive litigation that left the treating psychiatrist or physician without evidence of proper diagnosis and treatment at a critical period in the patient's course of treatment.

Collins v. Cushner Montgomery County Maryland (37) combines the elements of negligence, failure to warn of side effects and failure to monitor. In the case, a 56 year old woman was treated with trifluoperazine by her family physician for spastic colon and later developed TD. Her chief complaint had been anxiety. She was prescribed the drug for 6 years including a 29 month period during which she was never seen but the prescription was renewed. The case was settled for \$125,000. Many patients will call to "reschedule" but ask for a refill, often via a secretary. In an effort to accommodate the patient, many physicians will authorize the renewal. The balance between good "customer service" and malpractice risk must be made carefully and at a minimum, on an individual basis.

Spivey v. U.S. and Department of the Navy (38) is a unique case in that the \$870,191.11 awarded to Mrs. Spivey and the \$339,000 awarded to her husband is at least partially predicated on the testimony that she is likely to develop TD if she is placed back on antipsychotic medication. Mrs. Spivey had prior psychiatric problems before she developed PTSD as a result of being run off the road by a car driven by a Navy recruiter. She rolled down an embankment in a successful attempt to avoid the Navy recruiter's car. She was initially treated with an antipsychotic for her PTSD and developed TD. This resolved when the drug was stopped. However, at trial, her experts testified that it was likely she would have to resume the medication and that there is a 66% chance that any future TD will be permanent. The US Court of Appeals, Fourth Circuit reduced the award based on legal and administrative grounds to \$530,124.00 for Mrs. Spivey and to \$64,000.00 for Mr. Spivey. Spivey represents the probability that post-litigation monitoring of the patient may be factored into the amount of damages a TD patient can recover from a tort-feasor.

PRODUCT LIABILITY

Product liability refers to the liability of manufacturers and sellers to compensate consumers or users of the product for damages or injuries arising out of defects in the goods purchased. The manufacturer may be held liable for negligent design, manufacture, use or misuse of the product at any stage in the system from development of the product through its final use or disposal. In most states, the manufacturer and all the "conduits" by which the defective product reaches the victim may be held liable on contract theory for breach of implied warranty of fitness for intended use.(39) The manufacturer and all "conduits" can also be held liable without fault in most jurisdictions for damage caused by a defectively made, designed or tested product, or for failure to make appropriate warnings about potential hazards to the user. (40) As applied to treating psychiatrists, if the psychiatrist is a "conduit" for transmitting a defective medicine to a patient through injection or oral "handouts," the psychiatrist becomes liable for damages done by the product caused by defective design, manufacture and failure to warn of hazards.

Lindley v. Hamilton & SK&F Co., Inc., (41) contains both the elements of product liability and medical malpractice. Ms. Lindley was treated with trifluoperazine for a diagnosis of depression from 1969 to 1973. In 1973 Dr. Hamilton diagnosed TD and changed her medication to oxazepam. Her symptoms improved but she claims that it was not until 1983 that another physician informed her that she had TD and that it was likely the result of the trifluoperazine. The action against Smith Kline & French, alleging development and marketing of a defective product with known side effects, was time barred and hence dismissed. However, the trial court awarded a jury verdict of \$400,000 against Dr. Hamilton on product liability and negligent malpractice claims. The judge entered judgement notwithstanding the verdict in favor of Dr. Hamilton on the grounds that the jury had erred on both the statute of limitations and negligence issues. The Fifth Circuit U.S. Court of Appeals affirmed this action. The court found that Dr. Hamilton did not breach the standard of care in his treatment of Ms. Lindley. Although this was ostensibly a product liability case, plaintiff raised other issues during the trial including whether drug holidays should have been used to reduce her overall exposure to the medication, as well as the appropriateness of using an antipsychotic to treat her condition, implying that misdiagnosis was also an issue.

Barnhart v. United States (42), another Federal Torts Claims Act case brought by a veteran against the Veterans Administration Hospital for TD which resulted from the use of antipsychotics prescribed to treat his Schizophrenia. He was treated beginning in the late 1960's. Although TD was suspected by his physicians in 1980 this was not discussed with the patient or family. In 1983, a private neurologist made the diagnosis and informed the patient and family. Barnhart sued one of the manufacturers in 1985 in a case that was settled for an undisclosed amount. He did not bring an action against the VA until 1987. It is unclear whether the VA action was based on medical malpractice alone or on medical malpractice and products liability. Only one case, *Griffin v. United States* (43), has held that the United States may be liable to an injured patient under the Federal torts Claims Act for administering a defectively-manufactured or tested medication. The Federal Torts Claims Act has a two-stage statute of limitations. First, the plaintiff must file a Federal Administrative Claim with the appropriate Federal agency that allegedly caused his injuries within two years after the claim accrues. Second, no civil action against the United States based on that administrative claim may be commenced more than six years after the right of action first accrues. The U. S. Seventh Circuit Court of Appeals upheld the trial court's dismissal of Barnhart's action as time barred, taking into account his mental condition from 1985 through 1987, when he filed his Federal Administrative Claim two years after the deadline set by 28 U.S.Code §2401(b). There was no need for the court to deal with the merits of Barnhart's case. However, the Seventh Circuit's opinion contained the following:

"As the district court has already noted, this case presents a most unfortunate situation which, regrettably, we cannot remedy at this late juncture. The plaintiff in this case, Stephen Barnhart, suffers from tardive dyskinesia, an irreversible neurological condition brought on by the use of certain tranquilizers for an unduly long period of time... By the time Barnhart's condition was discovered, he had suffered debilitating and irreversible damage. Unfortunately, Barnhart delayed in bringing any action or claim against the VA because he was afraid that the VA, upon which he felt completely dependent, might retaliate against him." (42)

Because of this delay, the VA denied Barnhart's claim as untimely and the District Court dismissed Barnhart's action. (42)

Barnhart shows that a patient may have more than one avenue or theory of liability to pursue and may do so separately and at a different time. It shows that the plaintiff may not always pursue only the deepest pocket but may pursue all potential sources of revenue. Barnhart first sued the drug manufacturer, then turned around and filed an administrative claim against the U.S. Department of Veterans Affairs and his treating psychiatrists. Finally, the language used by Circuit Judge Cudahy in *Barnhart* reflects sympathy for the plaintiff, which in a different case, could easily result in a high verdict.

Sandoz, Inc. v. Employer's Liability Assurance Corp., (44) represents the manufacturer's attempt to recoup losses it paid to a plaintiff who developed TD. The manufacturer carried insurance for its products and also claimed that the plaintiff's own health insurers should provide coverage. Daniels developed TD after taking thioridazine for about a ten year period. In 1980, Daniels sued Sandoz on products liability theory and a jury awarded him a verdict of \$75,000 of which Sandoz paid \$60,000 and Hartford Life Insurance Company paid \$15,000. Sandoz later sued to be reimbursed from the other liability insurance carriers who were supposed to protect Sandoz for the period of time that Daniels was receiving thioridazine made by Sandoz. The U.S. District Court for the District of New Jersey overruled defense motions to dismiss the insurance contract action.

American Cyanamid Co. v. Frankson, (45) involves a veterinarian who was injured when he fell from a horse. After the fall, his behavior became erratic and his treating psychiatrist and neurosurgeon prescribed antipsychotics including chlorpromazine, haloperidol and thioridazine and finally loxapine. Dr. Frankson developed TD allegedly due to taking loxapine. A jury gave him a verdict of \$2,695,000 actual damages against the drug company and the physicians involved in the case in a product liability suit for faulty design and marketing of the drug. The Texas Court of Appeals affirmed the trial court's findings.

Hyde v. University of Michigan Board of Regents, (46) is a condensation of three separate cases addressing the issue of whether employees of a public hospital are acting as a governmental agency and hence immune from tort liability. One of the three plaintiffs (Faigenbaum (47)) allegedly developed TD from antipsychotics prescribed by a mental health clinic and was awarded \$1,044,500 by the jury. He had previously settled with four doctors, two hospitals and three drug companies for \$378,000. In a split decision, the Supreme Court of Michigan held that defendants were immune from tort liability .

CIVIL RIGHTS ACT CLAIMS AND CONSTITUTIONAL TORTS

When a physician treats a patient and is acting on behalf of some state or federal governmental agency, such as the Department of Veterans Affairs or a State Mental Hospital or State Detention Center, the physician may be responsible for violating the patient's civil rights if the patient is under some type of legal restraint at the time of treatment such as confinement to prison, a pretrial detention center, to a mental institution or a psychiatric ward in any hospital. There are three theories of recovery based on violation of a patient's civil rights.

In the first theory of recovery, the patient seeks medical malpractice type damages based on the Federal Civil Rights Act. These actions are brought under 42 U.S.C. §1983, the Civil Rights Act of 1875. The patient alleges that a physician, acting under color of law, administered antipsychotic medication against the patient's will and further committed some form of state-based medical malpractice, which would merit a substantial damage award if true. The entire case is tried in Federal Court as a Civil Rights Act case. *Coleman v. Morall* (48) represents this kind of case. Coleman was detained in a pre-trial detention center in Colorado and was "uncooperative" and "abnormal." Dr. Morall, The detention center's physician put Coleman on haloperidol. Coleman developed tardive dyskinesia. He sued the detention center and Dr. Morall for violating his civil rights by prescribing antipsychotic medication against his will, and in prescribing too high a dose, causing him to develop TD as a side-effect of medication. The 10th Circuit reversed dismissal of Coleman's claim, sending it back to the trial court for a hearing on the merits of the civil rights violation and pendent damage claim (48).

In the second theory of recovery, the patient claims damages for pain and suffering arising from being forced to take antipsychotic medicine, on a "constitutional tort" theory of recovery. The underlying theory is similar to that in ordinary medical malpractice cases involving extension of a medical procedure beyond informed consent: the victim claims the physician committed battery by administering medication against the patient's will and as a result of violating the patient's constitutional rights. These cases started with *Bee v. Greaves* (49) in 1984. Bee was incarcerated awaiting trial and became hallucinatory. He threatened to kill himself unless he received chlorpromazine, and he was taken to the Utah State Hospital for an evaluation of mental competency. His psychiatrist prescribed chlorpromazine and found him competent to stand trial. Bee later tried to discontinue his medication, and the detention center psychiatrist Dr. Greer, ordered forcible medication. Bee brought suit under the Civil Rights Act and demanded money damages from his psychiatrist for pain and suffering caused by forcible medication. The trial court granted summary judgment to defendants but the 10th Circuit reversed, holding that Bee had a federally-mandated liberty interest in refusing medication that could not be invaded except for compelling reasons to protect Bee and others from serious bodily harm. The court held that the decision to administer antipsychotic drugs forcibly was one to be made by professional medical authorities applying accepted medical standards after considering less restrictive courses of action. The District Court presumably would have to determine on the facts whether a sufficient emergency existed to warrant such an invasion of Bee's liberty interests. Since the 10th Circuit refused to dismiss the damage issues against the jail psychiatrist, the issue of liability for administering the antipsychotic drug in a non-emergency situation would still be one left to the jury to decide as a matter of fact.

Similar liability issues also arise in civil commitment situations. For example, in *Jurasek v. Utah State Hospital* (50), a paranoid schizophrenic patient filed a Civil Rights action demanding an injunction against further treatment and money damages for invasion of privacy and pain and suffering against the Utah State Hospital and his treating psychiatrist. The U.S. District court granted defendants' motions for summary judgment which the 10th Circuit, following the law as it was laid down in *Bee*, affirmed. The 10th Circuit held that although Jurasek had a recognizable liberty interest, the hospital followed fair procedures in determining that involuntary medication was in the best interest of Jurasek's safety and the safety of its staff. Specifically, Jurasek was incapable of making the determination that he could refuse medication because he had been found incompetent in a court of law at his commitment hearing. He was also "gravely disabled" by his mental condition and a danger to himself and others, according to his treating psychiatrist and the Hospital oversight committee.

Had Jurasek been the victim of questionable treatment and the court thought that Hospital oversight committee merely rubber-stamped the recommendation of the treating psychiatrist, the psychiatrist may very well have been liable for money damages for invading Jurasek's liberty interests.

The first recovery theory is a state-law claim for malpractice. The law of liability of the state in which the alleged mal-practice occurred is simply grafted to a federal claim for violation of civil rights. The second theory rests on the patient's refusal to take antipsychotic medication voluntarily, and is based on forcible invasion of the incarcerated patient's privacy. In the third and last theory of recovery under Civil Rights law, the treating physician is liable under

wholly-federal "constitutional tort" standards independent of state-created malpractice law. The specific tort standard is "deliberate indifference" to the patient's needs, a violation of Eighth Amendment rights for which damages are recoverable.

This situation applies to all patients who are receiving antipsychotic medication who are custodians of the state: prisoners, persons confined to mental health institutions, and persons in other types of state-sponsored programs such as half-way houses. Under this theory of liability, a patient who develops tardive dyskinesia while under governmental custody can sue the psychiatrist responsible for identifying, diagnosing and treating the patient under 42 U.S.C. §1983 and seek money damages for pain and suffering. The patient alleges that his or her treating physician was "deliberately indifferent" to the patient's mental and physical condition, a theory similar to the usual medical malpractice liability for failure to diagnose and treat a medical or psychiatric condition. However, the incarcerated patient must allege and prove the treating psychiatrist wantonly violated the patient's Eighth Amendment right to be free of cruel and unusual punishments and the patient's Fourteenth Amendment right to accept or refuse medication with an adequate explanation of the consequences of taking the drug. These cases are supported by the U.S. Supreme Court's decision in *Farmer v. Brennan* (51), in which the Court held that a prison inmate could maintain a Civil Rights Act suit against his warden and prison physicians for placing him in a general prison population when they knew he was a transsexual male, leading to his being beaten and raped. The Supreme Court held such gross conduct on the prison administration's part was "deliberate indifference" that would inflict a cruel and unusual punishment on inmate so treated, a violation of the plaintiff's Eighth Amendment rights. The doctrine of "deliberate indifference" was also raised in *White v. Napoleon* (52), in which White and three other prisoners in the custody of the New Jersey Department of Corrections sued Dr. Napoleon, a prison physician, for failing to treat them for a variety of conditions ranging from carbuncles to a chronic ear infection. The prisoners based their suit on 42 U.S.C. §1983 and alleged that Dr. Napoleon's deliberate indifference to their ills resulted in deprivation of their civil rights and a claim for damages for pain and suffering. The Third Circuit Court of Appeals reversed the District Court's dismissal of this action on the ground that the prisoners' claims stated a claim for relief for "unnecessary and wanton infliction of pain." Similarly, prescribing antipsychotic medication to a confined patient while knowing the likelihood of a patient developing tardive dyskinesia from such medication could be characterized as "deliberate indifference" to a patient's condition that could prove to be "unnecessary and wanton infliction of pain" on the patient within the parameters of *White*.

As of March, 1999, no court case has dealt with a psychiatrist's liability under the Civil Rights Act for "deliberate indifference" to a patient's serious medical needs for administration of an antipsychotic medication that led to tardive dyskinesia. However, there is potential exposure to "constitutional tort" claims when a psychiatrist employed by the state administers an antipsychotic drug to an unwilling person in state custody without an adequate explanation of potential side-effects of the drug.

COMMENTARY

Patients who develop TD after a course of medication may bring malpractice claims under any or all of the recovery theories discussed above. They may claim their treating psychiatrist did not obtain their consent to such medication, or that consent was negligently flawed by the psychiatrist's failure to explain the risk of developing TD. They may complain that their condition was mis-diagnosed and was not one that should have been treated by medication with such known side-effects as TD. They may assert that the treating psychiatrist failed to monitor administration of medication with a relatively high risk of TD. The disappointed patient can also sue the drug manufacturer and the treating psychiatrist on product liability grounds associated with defective design, testing or warning information relating to the antipsychotic medication that may have led to TD.

TD is a very complex entity. It is made all the more complex by the ability of medications to mask the disorder itself, a higher spontaneous occurrence rate in the very patients who are most likely to be exposed to the treatment, withdrawal emergent dyskinesia and the potential for the same or similar medications to treat this condition.

The foregoing case law discussion also showed that treating psychiatrists can practice malpractice prevention and avoid liability and damages for administering medication related or associated with incidence of TD. Where physicians have documented that medication was administered to a patient after explaining the hazards of developing TD, that a thorough medical and psychiatric history had been obtained before prescribing an antipsychotic medication and a justifiable diagnosis obtained after a thorough mental and physical examination supported by appropriate laboratory testing, the treating physician can probably defeat a malpractice claim before trial based on a defense motion for summary judgment. The threat of litigation should not stop a physician from doing what is clinically correct and indicated. The importance of documentation can not be overstated. A second opinion consult, in writing, is always a smart and may contribute to a successful defense should a suit arise. It is also clear that in many of the cases, the defendant doctor prevailed on technicalities such as failure to file within the statute of limitations or was not pursued because the plaintiff felt that there were deeper pockets elsewhere. Some of these cases revealed that the doctor had already settled, an untraceable area of significant importance.

For psychiatrists and physicians whose practice involves the care and management of incarcerated or institutionalized patients, the risk of a patient's Civil Rights Act claims can be minimized. Atypical antipsychotic medication may indeed be justified in such cases economically as well as from an anti-malpractice standpoint. Although it has been argued that absent the transfer of a patient to a less expensive care setting (e.g.: hospital to clinic) that the ongoing use of these newer medications can not be justified in a system chronically strained for fiscal resources, the avoidance of expensive Civil Rights litigation arising from patients developing TD from older medication is as important an economic consideration as initial cost of medication.

Since the 1970's the courts have tried to hold physicians to a higher standard in terms of duty to patients. The courts insist that the physician, like a trustee or guardian, put the best interest of the patient ahead of other interests such as convenience and case management. The advent of new medication for treatment of delusions and hallucinations supported by new data and the expectation of further proof of greater safety with the use of the newer agents supports a shift in the standard of care regarding the use of antipsychotics. Indeed, the AAPL Committee on Psychopharmacology and the Law has discussed this issue and members have consistently supported this position. At this time, one must ask: Does the standard of care for prescribing antipsychotics mandate that the physician start with the use of an atypical antipsychotic? Is it malpractice to start with an older medication or to not offer newer medications, even if it won't allow an individual to be moved to a less restrictive alternative or result in a cost savings for a state institution? Should all patients be offered the chance to try a newer atypical medication? It appears that both law and medicine are rapidly moving toward affirmative answers to these questions.

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