

Unbuckling the “Chemical Straitjacket”: The Legal Significance of Recent Advances in the Pharmacological Treatment of Psychosis

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I. INTRODUCTION

During the past half century, courts and legal scholars have written innumerable opinions and articles that mention, discuss, praise, and criticize antipsychotic medications,¹ the class of psychoactive medications that physicians began prescribing in the 1950s² to treat psychoses.³ In

1. The earliest case in the LEXIS database of combined federal and state case law that mentions an antipsychotic medication is *Williams v. United States*, 133 F. Supp. 319 (E.D. Va. 1955). *Williams* concerns a *non compos mentis* seaman who underwent treatment at “Central State Hospital . . . the only public or private institution available to Negro mental patients in Virginia.” *Id.* at 321. The decision describes the overcrowding at this “public institution,” where, in early 1955, “there were 4578 patients on hand, or an excess of 1180 over the rated capacity. . . . To care for the 4578 patients there are two psychiatrists . . .” *Id.* at 323. After discussing the limitations of then available psychiatric therapies, “the Court . . . noted an interesting article appearing in *Time* magazine (March 7, 1955) involving the use of new drugs referred to as chlorpromazine and reserpine which have been very effective in certain types of schizophrenia cases.” *Id.* at 322.

For a review of earlier criticisms of antipsychotic medications, see generally Thomas G. Gutheil & Paul S. Appelbaum, “*Mind Control*,” “*Synthetic Sanity*,” “*Artificial Competence*,” and *Genuine Confusion: Legally Relevant Effects of Antipsychotic Medications*, 12 HOFSTRA L. REV. 77 (1983). For a recent critical discussion of these medications, see generally BRUCE J. WINICK, *THE RIGHT TO REFUSE MENTAL HEALTH TREATMENT* 61–86 (1997). A highly critical view of antipsychotic medication appears in the majority opinion in *State v. Perry*, 610 So. 2d 746, 758–60 (La. 1992) (describing involuntary psychopharmacological treatment of a condemned inmate—who would receive a lethal injection if competent for execution—as “the physical intrusion of powerful, dangerous and unpredictable drugs into his body and brain”).

2. Chlorpromazine, more commonly known by its proprietary name Thorazine®, was the first of these drugs. See discussion *infra* Part III.A. (discussing its discovery and initial use in the 1950s). Throughout this Article’s main text, medications are referred to primarily using their nonproprietary names, in accordance with the usual policies of scientific publications. Medications’ better known trade names, which often appear in legal publications, are mentioned in these footnotes.

3. In current medical usage, “psychosis” is “a mental disorder characterized by gross impairment in reality testing as evidenced by delusions, hallucinations, markedly incoherent speech, or disorganized and agitated behavior, usually without apparent awareness on the part of the patient of the incomprehensibility of his behavior.” DORLAND’S ILLUSTRATED MEDICAL DICTIONARY 1489 (29th ed. 2000) [hereinafter

the rapidly growing field of mental disability law,⁴ antipsychotic medications figure prominently in cases and legislation involving hospitalized patients' right to refuse treatment,⁵ involuntary psychiatric hospitalization,⁶ outpatient civil commitment,⁷ the Americans with Disabilities Act,⁸ malpractice litigation,⁹ Medicaid entitlements,¹⁰ rights

DORLAND's]. The various syndromes classified as psychotic disorders "emphasize different aspects of the various definitions of *psychotic*." AM. PSYCHIATRIC ASS'N, DIAGNOSTIC AND STATISTICAL MANUAL FOR MENTAL DISORDERS 827 (4th ed. text rev. 2000) [hereinafter DSM-IV-TR]. Psychotic symptoms occur in several types of mental disorders. *Id.* at 750–51. See *infra* note 136 (listing several currently recognized varieties of psychotic disorders).

4. See 1 MICHAEL L. PERLIN, MENTAL DISABILITY LAW: CIVIL AND CRIMINAL 1–6 (2d ed. 1998) (summarizing "the astonishing development" and "recent explosion of mental disability legislation and litigation").

5. See generally 2 PERLIN, *supra* note 4, at 153–385 (1999). The seminal cases in this area are *Rogers v. Okin*, 478 F. Supp. 1342 (D. Mass. 1979), *modified*, 634 F.2d 650 (1st Cir. 1980), *vacated and remanded*, 457 U.S. 291 (1982); *Rennie v. Klein*, 462 F. Supp. 1131 (D.N.J. 1978), *suppl.*, 476 F. Supp. 1294 (D.N.J. 1979), *modified*, 653 F.2d 836 (3d Cir. 1981), *vacated and remanded*, 458 U.S. 1119 (1982); and *Rivers v. Katz*, 495 N.E.2d 337, 504 (N.Y. 1986). The *Rogers* and *Rennie* decisions limited themselves to antipsychotic medications. *Rogers*, 634 F.2d at 653 n.1; *Rennie*, 653 F.2d at 839 n.2. *Rivers* also mentions the use of lithium, a mood stabilizing medication used for many psychiatric conditions, including manic depressive illness. *Rivers*, 495 N.E.2d at 340.

6. In *Vitek v. Jones*, the U.S. Supreme Court found that notwithstanding a prisoner's conviction for robbery and incarceration in state prison, he retained "a residuum of liberty that would be infringed by a transfer to a mental hospital without complying with minimum requirements of due process." 445 U.S. 480, 491 (1980). One reason for this was that at the hospital, the convict might receive "[c]ompelled treatment in the form of mandatory behavior modification programs." *Id.* at 492. The "compelled treatment" was antipsychotic medication. Brief of Appellee Larry D. Jones at 16, *Vitek v. Jones*, 445 U.S. 480 (1980) (No. 78–1155).

7. State statutes and case law concerning outpatient commitment (OPC) frequently mention compliance with medication as a criterion for allowing this procedure instead of inpatient commitment. 1 PERLIN, *supra* note 4, at 493 n.1384 (citing statutes and cases). Civil libertarian commentators have criticized OPC as a tool for forcing patients to take medication. Steven Schwartz & Cathy Costanzo, *Compelling Treatment in the Community: Distorted Doctrine and Violated Values*, 20 LOY. L.A. L. REV. 1329, 1368 (1987) (stating that OPC is "synonymous with forced medication"); Susan Stefan, *Preventive Commitment: The Concept and Its Pitfalls*, 11 MENTAL & PHYSICAL DISABILITY L. REP. 288, 294 (1987) (stating that forced medication is the "core" of OPC). Psychiatrists endorse using OPC to force medication compliance as a means of keeping patients from becoming violent. See generally Jeffrey Geller, *Rights, Wrongs, and the Dilemma of Coerced Community Treatment*, 143 AM. J. PSYCHIATRY 1259 (1986). Perlin recognized that OPC can both extend state "control over those not subject to inpatient commitment" and permit persons to remain free in the community rather than being hospitalized. 1 PERLIN, *supra* note 4, at 499. See discussion *infra* Part V.B.3 (discussing the relationship between OPC and medication).

8. Americans with Disabilities Act of 1990, Pub. L. No. 101-336, 104 Stat. 327 (codified as amended in scattered sections of 29 U.S.C., 42 U.S.C., 47 U.S.C.); see also *Olmstead v. L.C.*, 527 U.S. 581, 587 (1999) (requiring community placement of mentally disabled persons when treating professionals recommend such placement, the patients agree to placement, and the placement can be reasonably accommodated considering the state's resources and treatment needs of other patients). In his *Olmstead* concurrence, Justice Kennedy worried that release of psychiatric patients from

of incarcerated felons,¹¹ competence to stand trial,¹² the insanity defense,¹³ and administration of the death penalty.¹⁴

institutions might result in their becoming homeless, in part because of the “common phenomenon” in which “a patient . . . because of the mental illness itself, lacks the discipline or capacity to follow the regime the medication requires.” *Id.* at 610 (Kennedy, J., concurring).

9. *E.g.*, *Clites v. State*, 322 N.W.2d 917, 923 (Iowa Ct. App. 1982) (affirming the jury’s negligence award for tardive dyskinesia caused by improperly administered antipsychotic medications).

Tardive dyskinesia is a syndrome of long-standing or permanent abnormal involuntary movements that is most commonly caused by long-term use of typical antipsychotic (neuroleptic) drugs. . . . Tardive dyskinesia presents clinically as involuntary movements of the tongue, facial, and neck muscles, upper and lower extremities, truncal musculature, or occasionally muscle groups that subserve breathing and swallowing. . . . [Examples of these movements include] tongue protrusions, lip smacking, puckering of the lips, chewing movements, . . . cheek puffing[,] . . . grimacing, blinking, . . . and rapid ticlike movements of the face. . . .

STEVEN E. HYMAN ET AL., *HANDBOOK OF PSYCHIATRIC DRUG THERAPY* 35 (3d ed. 1995). For a recent discussion of malpractice aspects of tardive dyskinesia, see generally John Baker, *Tardive Dyskinesia: Reducing Medical Malpractice Exposure Through a Risk-Benefit Analysis*, 1 DEPAUL J. HEALTH CARE L. 799 (1997).

10. *Visser v. Taylor*, 756 F. Supp. 501, 507 (D. Kan. 1990) (holding that state Medicaid programs were obligated to make clozapine, a then new and expensive antipsychotic drug, available to beneficiaries when doctors felt that the drug was medically necessary); *Alexander L. v. Cuomo*, 588 N.Y.S.2d 85, 88 (Sup. Ct. 1992) (holding that state Medicaid programs were obligated to make clozapine, a then new and expensive antipsychotic drug, available to beneficiaries when doctors felt that the drug was medically necessary); *see* discussion *infra* Part III.D.1 (discussing clozapine).

11. *Washington v. Harper*, 494 U.S. 210, 236 (1990) (holding that involuntary medication is permissible to prevent harm to an inmate or others, when shown to be medically necessary, and that the prison’s procedure for overriding an inmate’s refusal met the requirements of the Due Process Clause); *Gates v. Shinn*, 98 F.3d 463, 472 (9th Cir. 1996) (concluding that not providing clozapine to inmates was not a violation of the court order); *Large v. Superior Court*, 714 P.2d 399, 409 (Ariz. 1986) (holding that state constitutional protection against arbitrary government action gives a prisoner a qualified right to refuse psychotropic drugs).

12. *E.g.*, *Riggins v. Nevada*, 504 U.S. 127, 138 (1992) (reversing the conviction because the defendant’s right to a fair trial was compromised by his involuntary treatment with antipsychotic medication); *United States v. Charters*, 863 F.2d 302, 305–13 (4th Cir. 1988) (limiting the right of an incompetent defendant to stand trial and to refuse antipsychotic medication); *United States v. Weston*, 134 F. Supp. 2d 115, 138 (D.D.C. 2001), *aff’d*, 255 F.3d 873 (D.C. Cir. 2001) (authorizing the involuntary medication of a pretrial detainee).

13. Concerning a defendant’s right to stop taking antipsychotic medication during a trial at which he raises the insanity defense so as to present himself to jurors in an unmedicated state, see generally 4 PERLIN, *supra* note 4, § 9A-4.6g, at 206–07 (2002). *Compare* *People v. Hardesty*, 362 N.W.2d 787, 797 (Mich. Ct. App. 1984) (stating that the court was “declin[ing] to adopt a per se rule that a drug-normalized accused must be allowed to discontinue medicinal treatment so that the jury may observe his demeanor in

The pharmacotherapeutic properties of antipsychotic medications—their actions, therapeutic uses, benefits, adverse effects, contraindications, and risks—are quintessentially medical topics, even when the situations and contexts in which doctors prescribe or recommend their use raise legal questions. Frequently, however, the legal database (that is, published opinions, legislation, regulation, and law review articles) is the principal or sole information source cited and consulted by lawyers, judges, and scholars who write about these drugs and make decisions concerning the persons that may have to take them.¹⁵ What often results is the perpetuation of mistaken, outdated, distorted, biased, contradictory,¹⁶

a drug-free state”), *appeal dismissed*, 477 U.S. 902 (1986), with *State v. Hayes*, 389 A.2d 1379, 1381 (N.H. 1978) (stating that a “defendant has no absolute right to be tried free from the influence of the drugs administered to him”). One would expect that it would take far longer than three days for the defendant to return to the same “unmedicated state” in which he might have been before being arrested. For most antipsychotic drugs, when an individual has received the medication for several weeks, detectable, clinically significant amounts of the medication or its active metabolites may remain in the body long after the individual has stopped taking the medication. Also, the antipsychotic effects of these drugs may persist long after patients stop taking them. HYMAN ET AL., *supra* note 9, at 14 (“[B]ehavioral effects in patients can last long after serum levels are no longer detectable.”).

14. In at least two cases, state supreme courts have held that involuntarily medicating condemned inmates to make them competent for execution would violate state constitutional provisions. *State v. Perry*, 610 So. 2d 746, 747–48 (La. 1992); *Singleton v. State*, 437 S.E.2d 53, 60–62 (S.C. 1993), *rev’d in part*, *State v. Torrence*, 406 S.E.2d 315 (S.C. 1991). See generally 4 PERLIN, *supra* note 4, § 12-4.3, at 550–53 (2002) (listing cases and scholarly articles).

15. See, e.g., *Hightower by Dehler v. Olmstead*, 959 F. Supp. 1549, 1552 (N.D. Ga. 1996) (citing cases and law review articles concerning actions and side effects of antipsychotic drugs); *In re Guardianship of Roe*, 421 N.E.2d 40, 53–54 (Mass. 1981) (utilizing a 1973 law review article as the principal source for a description of adverse effects); *Steele v. Hamilton County Cmty. Mental Health Bd.*, 736 N.E.2d 10, 15–17 (Ohio 2000) (citing only cases and law review articles); 2 PERLIN, *supra* note 4, at 161–64 (1999) (law review articles are the principal sources for the text’s description of side effects, though dozens of medical articles are listed in footnotes).

16. For example, Justice Kennedy’s views regarding mental illness and the role of pharmacotherapy in *Olmstead v. L.C.*, 527 U.S. 581 (1999), conflict with the views he expressed in *Riggins*, 504 U.S. at 138. In *Riggins*, Kennedy acknowledged the value of antipsychotic medication in treating psychosis, but would forbid involuntary pharmacological treatment of mentally ill pretrial defendants to restore their competence. He stated that the side effects of antipsychotic drugs seemed so inevitably severe and disabling that they “can compromise the right of a medicated criminal defendant to receive a fair trial” by altering his demeanor and ability to confer with counsel. *Id.* at 142–44 (Kennedy, J., concurring). Seven years later, by contrast, Kennedy noted that “medical science” had made “remarkable advances and achievements” and that mental illnesses were “treatable.” *Olmstead*, 527 U.S. at 608 (Kennedy, J., concurring). He stated “that for the person with severe mental illness who has no treatment[,] the most dreaded of confinements can be the imprisonment inflicted by his own mind, which shuts reality out and subjects him to the torment of voices and images beyond our own powers to describe.” *Id.* at 609–10. Many patients, “because of the mental illness itself, lack[] the discipline or capacity to follow the regime the medication requires.” *Id.* Medical science had indeed advanced in the seven year period between these opinions, and

or just plain foolish ideas about psychotic disorders, the actions and adverse effects of antipsychotic drugs, and physicians' goals in treating patients with psychoses.¹⁷ At the same time, the emerging scientific understanding of psychotic disorders and the role drugs play in their treatment remains misunderstood and underappreciated.¹⁸

Courts' and legal scholars' potential for misunderstanding antipsychotic treatment has recently acquired a new dimension. In the 1990s, the U.S. Food and Drug Administration approved four new antipsychotic drugs¹⁹ for the treatment of patients with psychotic disorders. These medications are not always effective and, like the older drugs, do not cure psychotic disorders. However, these new medications are at least as effective as, and possibly more effective than, previously available compounds.²⁰ Moreover, the new antipsychotic drugs are "novel" or "atypical" in that

several of these advances are discussed in subsequent sections of this Article. However, severe mental illnesses were quite treatable in 1992, and the consequences of leaving them untreated were no different seven years later. For pre-1992 discussions by psychiatrists concerned about this problem, see generally E. FULLER TORREY, *NOWHERE TO GO: THE TRAGIC ODYSSEY OF THE HOMELESS MENTALLY ILL* (1988), and H. Richard Lamb, *Will We Save the Homeless Mentally Ill?*, 147 AM. J. PSYCHIATRY 649 (1990).

17. Indeed, Drs. Gutheil and Appelbaum published their 1983 *Hofstra Law Review* article to counter just these problems. Gutheil & Appelbaum, *supra* note 1, at 79; see also *infra* Part VI.B.1.

18. See, e.g., *Perry*, 610 So. 2d at 758 (likening treatment with antipsychotic medications to government restrictions on individuals' access to pornography); Sheldon Gelman, *Mental Hospital Drugs, Professionalism, and the Constitution*, 72 GEO. L.J. 1725, 1747–48 (1984) ("The physiological causes and concomitants of mental illness remain matters for speculation. Physiologically, antipsychotic effects cannot be confidently distinguished from crude measures—such as bleeding, purging, and, in all probability, lobotomy—which render individuals too weak or preoccupied to attend to their psychotic urgings." (footnote omitted)); Bruce J. Winick, *The Right to Refuse Mental Health Treatment: A First Amendment Perspective*, 44 U. MIAMI L. REV. 1, 28–29 (1996) (endorsing the same view).

19. The medications were clozapine, risperidone, olanzapine, and quetiapine. A fifth new antipsychotic agent, ziprasidone, became available in early 2001 and a sixth agent, aripiprazole, may be released before the end of 2002. Melody Petersen & Andrew Pollack, *Problems at Bristol Are Clear; Solution Isn't*, N.Y. TIMES, Apr. 5, 2002, at C1. See *infra* Part III.D (describing these medications further).

20. Michael D. Jibson & Rajiv Tandon, *New Atypical Antipsychotic Medications*, 32 J. PSYCHIATRIC RES. 215, 220–21 (1998). The degree to which the new antipsychotics are better is a matter of ongoing debate. See, e.g., John Geddes et al., *Atypical Antipsychotics in the Treatment of Schizophrenia: Systematic Overview and Meta-Regression Analysis*, 321 BRIT. MED. J., 1371–76 (2000) (noting that meta-analysis of fifty-two randomized trials suggests that the newer drugs are only slightly more effective than the older drugs at high doses; compared to moderately dosed older drugs, newer "antipsychotics had no benefits in terms of efficacy or overall tolerability," but caused fewer side effects).

they alleviate psychotic symptoms with a much reduced risk of the side effects that were a nearly inevitable consequence of treatment with the older, “conventional” medications.²¹

This last point has special *legal*, as well as therapeutic, significance because the drawbacks of the older antipsychotic agents generated much of the concern about, and litigation related to, the use of these drugs. The side effects of antipsychotic drugs have been a specific element in the U.S. Supreme Court’s Fourteenth Amendment analysis of a pretrial detainee’s right to refuse treatment²² and of the right of prisoners not to receive involuntarily administered antipsychotic drugs absent certain procedural safeguards.²³ Side effects also have figured prominently in state court decisions concerning administration of antipsychotic drugs to civilly committed inpatients,²⁴ to incompetent individuals with guardians,²⁵ and to condemned inmates that have been found incompetent to be executed.²⁶ A few malpractice cases have made psychiatrists subject to potentially massive judgments for failing to properly use and monitor these medications.²⁷

The potential advantages of the new antipsychotic agents are now beginning to influence courts’ opinions. A July 1, 2002 search of the LEXIS database of federal and state cases after 1944 showed that at least

21. Jibson & Tandon, *supra* note 20, at 215. For more on the problems caused by older antipsychotic drugs, see *infra* Part III.C.

22. *Riggins v. Nevada*, 504 U.S. 127, 137–38 (stating that the involuntary administration of thioridazine, and resulting side effects, could infringe on fair trial rights by compromising testimony, communication with counsel, and ability to follow trial).

23. *Washington v. Harper*, 494 U.S. 210, 221 (1990) (recognizing an inmate’s “significant liberty interest in avoiding the unwanted administration of antipsychotic drugs” and stating that although an inmate’s liberty interest in avoiding unwanted medication was not insubstantial, prison regulation concerning the procedure for overriding an inmate’s refusal met the requirements of the Due Process Clause).

24. See, e.g., *Rennie v. Klein*, 720 F.2d 266, 269 (3d Cir. 1983) (“[O]ne of the factors to be considered in the exercise of professional judgment . . . is whether and to what extent the patient will suffer harmful side effects.”); *Rogers v. Comm’r of Dep’t of Mental Health*, 458 N.E.2d 308, 319 (Mass. 1983) (finding “adverse side effects” to be a factor in the judge’s decision concerning the involuntary administration of medication); *Rivers v. Katz*, 504 N.Y.S.2d 74, 81 (1986) (stating that the court is to consider, among other factors, “the adverse side effects” before ordering medication for an incompetent psychiatric inpatient).

25. *In re Guardianship of Roe*, 421 N.E.2d 40, 53–54 (Mass. 1981) (stating that the possibility of adverse effects requires that decision for administration be made by a judge, not by the guardian).

26. *State v. Perry*, 610 So. 2d 746, 760 (La. 1992) (characterizing antipsychotic medications as “powerful, dangerous and unpredictable”).

27. *Clites v. State*, 322 N.W.2d 917, 917, 922–23 (Iowa Ct. App. 1982) (affirming a \$760,000 damage award and describing side effects); *Accardo v. Cenac*, 722 So. 2d 302, 313 (La. Ct. App. 1999) (revising a tardive dyskinesia award *upward* to \$1.2 million).

171 cases had mentioned or discussed these new drugs,²⁸ these cases address a variety of issues, including informed consent,²⁹ the right to refuse treatment,³⁰ and the rights of Medicaid patients³¹ and prisoners³² to have these drugs available. A search that same date of the LEXIS law review database revealed sixty-six articles that mention these medications. Legal scholars have considered the cost issues and the antitrust implications of the method by which the first of these new drugs was introduced,³³ and the new medications have begun to receive attention from law review authors writing about malpractice,³⁴ the right to refuse treatment,³⁵ managed psychiatric care,³⁶ outpatient commitment,³⁷ research

28. The search strategy, “((new or newer or novel or atypical) w/3 ((anti-psychotic or antipsychotic) pre/1 (medication or medicine or drug))) or cloza! or risperidone or resperidone or respiridone or risperdal or olanzap! or zyprexa or quetiapine or seroquel or geodon or ziprasidone,” was designed to include cases that referred to the new antipsychotic drugs without mentioning one of them specifically by name. See *State v. Jung*, 724 N.E.2d 1262, 1263 (Ohio Ct. App. 1999) (citing Dr. Douglas Songer’s discussion of “several newer medications which have fewer side effects”), and cases in which the names of these medications were misspelled. The strategy may not have found cases with unanticipated misspellings. See, e.g., *Commonwealth v. Brown*, No. 96–11156(001–004), 1998 Mass. Super. LEXIS 664, at *2–3 (Mass. Dist. Ct. Dec. 18, 1998) (referring to “Resperidol” and “Zypreza” but containing the proper spelling of olanzapine). All cases found are listed in this Article’s Appendix.

29. See *infra* Part V.B.2.

30. See *infra* Part VI.C.

31. See *infra* Parts IV.A and V.C.1.

32. See *infra* Part V.C.1.

33. Michael A. Sanzo, *Antitrust Law and Patent Misconduct in the Proprietary Drug Industry*, 39 VILL. L. REV. 1209, 1224–25 (1994) (arguing that a court would have found that bundling clozapine to a patient monitoring system violated the *Jefferson Parish* test); Robert N. Swidler, *Medical Innovations and Ethics: A State Government Perspective*, 57 ALB. L. REV. 655, 666–72 (1994) (commenting on ethical issues surrounding the State of New York’s concerns about the cost of clozapine); Mark A. Hurwitz, Note, *Bundling Patented Drugs and Medical Services: An Antitrust Analysis*, 91 COLUM. L. REV. 1188, 1215–20 (reasoning that the tying of clozapine to lab tests does not violate Justice O’Connor’s “rule of reason” test articulated in *Jefferson Parish Hosp. Dist. No. 2 v. Hyde*, 466 U.S. 2 (1984)).

34. See generally Baker, *supra* note 9.

35. See Dennis E. Cichon, *The Right to “Just Say No”: A History and Analysis of the Right to Refuse Antipsychotic Drugs*, 53 LA. L. REV. 283, 299 & nn. 88–89 (1992) (discussing the risks of clozapine); Dora W. Klein, *Trial Rights and Psychotropic Drugs: The Case Against Administering Involuntary Medications to a Defendant During Trial*, 55 VAND. L. REV. 165 (2002) (opposing the use of medications to restore a criminal defendant’s competence to stand trial); David M. Siegel et al., *Old Law Meets New Medicine: Revisiting Involuntary Psychotropic Medication of the Criminal Defendant*, 2001 WIS. L. REV. 307 (2001) (discussing, inter alia, the implications of new treatments for restoring competence to stand trial); Daniel Abraham, Note, *Riggins Protects the Insanity Defendant*, 44 N.Y.L. SCH. L. REV. 131 (2000) (urging courts to be wary of

on persons with mental impairments,³⁸ the Americans with Disabilities Act,³⁹ professional rivalries,⁴⁰ and assessing the professional judgment of psychiatrists.⁴¹

That legal thinkers sometimes regard antipsychotic medication as a “chemical straitjacket”⁴² reflects both a flawed understanding of what

medication side effects in insanity defendants, notwithstanding the availability of new antipsychotic agents); Recent Case, *United States v. Weston*, 255 F.3d 873 (D.C. Cir. 2001), *D.C. Circuit Holds that the Government May Forcibly Treat Incompetent Criminal Defendants with Antipsychotic Medication to Render Them Competent to Stand Trial*, 115 HARV. L. REV. 737 (2001) (discussing the implications of medicating defendant to restore trial competence). In the author’s opinion, David Siegel’s article contains what is, to date, the best summary in law review articles concerning the properties of the new antipsychotics. Siegel et al., *supra* at 346–51.

36. See Mary R. Anderlik & Wendy J. Wilkinson, *The Americans with Disabilities Act and Managed Care*, 37 HOUS. L. REV. 1163, 1179 (2000) (discussing the failure of health plans to cover novel antipsychotics); Emile L. Loza, *Access to Pharmaceuticals Under Medicaid Managed Care: Federal Law Compiled and State Contracts Compared*, 55 FOOD & DRUG L.J. 449, 469–70 (2000) (describing the restrictions on clozapine in managed state Medicaid programs).

37. Ken Kress, *An Argument for Assisted Outpatient Treatment for Persons with Serious Mental Illness Illustrated with Reference to a Proposed Statute for Iowa*, 85 IOWA L. REV. 1269, 1319–1320 (2000) (discussing the relationship between the severity of side effects and the justification for outpatient commitment).

38. Laurie M. Flynn & Ronald S. Honberg, *Achieving Proper Balance in Research with Decisionally-Incapacitated Subjects: NAMI’s Perspectives on the Working Group’s Proposal*, 1 J. HEALTH CARE L. & POL’Y 174, 176 (1998) (explaining the benefits and potential risks of participating in research involving antipsychotic drugs).

39. Kathleen D. Zylan, Comment, *Legislation That Drives Us Crazy: An Overview of “Mental Disability” Under the Americans with Disabilities Act*, 31 CUMB. L. REV. 79, 119 (2000–2001) (discussing the interplay among clozapine therapy, the ADA, and *Sutton v. United Airlines*, 527 U.S. 471 (1999)).

40. See Peter Margulies, *The Cognitive Politics of Professional Conflict: Law Reform, Mental Health Treatment Technology, and Citizen Self-Governance*, 5 HARV. J.L. & TECH. 25, 28–29 (1992) (using clozapine to illustrate interprofessional conflicts).

41. Marc J. Posner, *The Estelle Medical Professional Judgment Standard: The Right of Those in State Custody to Receive High-Cost Medical Treatments*, 18 AM. J.L. & MED. 347, 348 (1992) (discussing clozapine treatment of detainees or committed patients); Susan Stefan, *Leaving Civil Rights to the “Experts”: From Deference to Abdication Under the Professional Judgment Standard*, 102 YALE L.J. 639, 691 (1992) (discussing cost factors as nonclinical influences on medical decisions).

42. See, e.g., Winick, *supra* note 18, at 72 (stating that patients experience these drugs as a “chemical straight-jacket”); Gelman, *supra* note 18, at 1737, 1783 (advocating use of the phrase “chemical restraint” in judicial opinions on antipsychotic drugs because of the phrase’s political connotations); Elizabeth Dickinson Furlong, Note, *Coercion in the Community: The Application of Rogers Guardianship to Outpatient Commitment*, 21 NEW ENG. J. ON CRIM. & CIV. CONFINEMENT 485 (1995) (containing several references to antipsychotic drugs as “chemical restraints”); see also *Cochran v. Dysart*, 965 F.2d 649, 650 (8th Cir. 1992) (describing psychotropic medication as an “alternative” to “straitjackets” and “frontal lobotomies”); *United States v. Watson*, 893 F.2d 970, 978 (8th Cir. 1990) (describing psychotropic medication as an “alternative” to “straitjackets” and “frontal lobotomies”), *vacated by United States v. Holmes*, 900 F.2d 1322 (8th Cir. 1990); *In re Guardianship of Roe*, 421 N.E.2d 40, 60 (Mass. 1981) (stating that when the safety of others is part of the justification for involuntary medication, “antipsychotic drugs function as chemical restraints”).

these drugs do⁴³ and the genuine limitations⁴⁴ of all the antipsychotic medications that were available in the United States until just a few years ago. The arrival of novel agents, however, has allowed patients to receive antipsychotic medication with fewer side effects, a lower risk of neurological damage,⁴⁵ and possibly better outcomes⁴⁶ than the older drugs permitted. Thus, most patients who take antipsychotic drugs need no longer endure chemical straitjacketing to get relief from their delusions, hallucinations, and disordered thinking. Judges, legal scholars, and lawyers who deal with persons who take antipsychotic drugs now should experience an analogous process, one that unbuckles the *conceptual* straitjacket that frequently has prevented recognition of the need for and value of antipsychotic medications. Courts and legal scholars must evaluate antipsychotic drugs without being misled by distorted and increasingly outdated views found in existing case law and secondary legal sources.

The goal of this Article is to encourage legal scholars and decisionmakers to reconsider the legal significance of antipsychotic medication. To do this, the Article presents the legal literature's first systematic review of the emerging legal significance of, and unresolved issues related to, the recent advances in the psychopharmacology of psychoses. The next two Parts offer summaries of psychiatry's current views on the nature of schizophrenia⁴⁷ and its pharmacotherapy.⁴⁸ Schizophrenia is just one of the psychiatric disorders for which novel antipsychotic drugs are officially indicated⁴⁹ and prescribed.⁵⁰ This Article focuses its discussion

43. See *infra* Parts III.A–B (reviewing the actions of antipsychotic drugs).

44. See *infra* Part III.C (discussing the side effects of older drugs).

45. See *infra* Parts III.C, IV.B.1 (discussing the risks associated with the newer drugs).

46. See *infra* Part III.D.2.

47. See *infra* Part II.

48. See *infra* Part III.

49. See PHYSICIANS' DESK REFERENCE 2319 (56th ed. 2002) [hereinafter PDR] (stating that clozapine "is indicated for the management of severely ill schizophrenic patients"); *id.* at 1797 (stating that risperidone "is indicated for the management of the manifestations of psychotic disorders"); *id.* at 1974 (stating that olanzapine "is indicated for the treatment of schizophrenia" and "acute manic episodes"); *id.* at 685 (stating that quetiapine "is indicated for the treatment of schizophrenia"); *id.* at 2689 (same for ziprasidone).

50. "Once a product has been approved for marketing [for any disorder], a physician may choose to prescribe it for uses or in treatment regimens or patient populations that are not included in approved labeling. . . . [A]ccepted medical practice includes drug use that is not reflected in approved drug labeling." *Id.* at foreword. Numerous articles discuss the use of novel antipsychotic drugs for conditions other than

on schizophrenia both to simplify exposition and because recent advances in understanding this disorder typify psychiatrists' current thinking about severe mental illnesses generally, as well as the role that antipsychotic drugs play in treating those illnesses.

Subsequent Parts discuss legal issues and policy problems in which the newer antipsychotic agents are already or may soon be figuring importantly. Part IV examines the relationship between the high cost of novel antipsychotics compared to older, generic antipsychotic medications and the implications this cost differential may have for policymakers and third party payment decisions. Part V reviews potential sources of physician and institutional liability that might arise from financially motivated decisions to restrict or limit use of novel antipsychotics. Part VI reviews litigation on the right to refuse treatment with antipsychotic medication, focusing on how the benefit and side effect profiles of novel agents have influenced courts' perceptions of and decisions about involuntary administration of these drugs. Part VII presents a short quantitative summary of cases that mention novel antipsychotic agents, and Part VIII summarizes this Article's major points.

II. THE CURRENT CONCEPTION OF SCHIZOPHRENIA

Recent studies estimate that about two million adults in the U.S.,

schizophrenia. Joseph R. Calabrese et al., *Clozapine for Treatment-Refractory Mania*, 153 AM. J. PSYCHIATRY 759, 762 (1996) (stating that clozapine is often effective in manic patients that have not responded to treatment with mood stabilizers); Robert M. A. Hirschfeld et al., *Practice Guideline for the Treatment of Patients with Bipolar Disorder (Revision)*, 159 AM. J. PSYCHIATRY 4, 9 (Supp. Apr. 2002) (recommending novel agents for treatment of acute mania in bipolar disorder); Susan L. McElroy et al., *An Overview of the Treatment of Schizoaffective Disorder*, 60 J. CLINICAL PSYCHIATRY 16, 20 (1999) (reviewing novel antipsychotic agents useful in treating schizoaffective disorder); Rajesh Narendran et al., *Olanzapine Therapy in Treatment-Resistant Psychotic Mood Disorders: A Long-Term Follow-Up Study*, 62 J. CLINICAL PSYCHIATRY 509, 515 (2001) (concluding that the use of olanzapine is more successful in patients with mood symptoms); S. Nassir Ghaemi, *New Treatments for Bipolar Disorder: The Role of Atypical Neuroleptic Agents*, 61 J. CLINICAL PSYCHIATRY 33, 33 (2000) (discussing the role of atypicals in treating persons with bipolar disorder); Paola Rocca et al., *Treatment of Borderline Personality Disorder with Risperidone*, 63 J. CLINICAL PSYCHIATRY 241, 241 (2002) (concluding that risperidone can help some patients with borderline personality disorder); Martha Sajatovic et al., *Quetiapine Alone and Added to a Mood Stabilizer for Serious Mood Disorders*, 62 J. CLINICAL PSYCHIATRY 62, 62 (2001) (stating that quetiapine may help persons "with serious mood disorders who are suboptimally responsive to mood stabilizers alone"); Trisha Suppes et al., *Report of the Texas Consensus Conference Panel on Medication Treatment of Bipolar Disorder 2000*, 63 J. CLINICAL PSYCHIATRY 288, 292 (2002) (stating that all atypicals have a potential role in treating bipolar disorder's manic phase and that olanzapine is an appropriate first choice); Mauricio Tohen et al., *Olanzapine Versus Placebo in the Treatment of Acute Mania*, 156 AM. J. PSYCHIATRY 702, 708 (1999) (concluding that olanzapine is effective in reducing manic symptoms).

approximately one percent of the U.S. adult population, suffer from the disorder that psychiatrists diagnose as schizophrenia.⁵¹ Psychiatrists' current goals in the pharmacological treatment of schizophrenia reflect the capabilities of the antipsychotic drugs now available, medical science's developing conceptualization of the disorder itself, and physicians' beliefs about how antipsychotic medications correct or modify the pathological processes that manifest themselves in symptoms and psychological dysfunction.⁵² Although antipsychotic drugs are still termed "major tranquilizers" in case law,⁵³ legal publications,⁵⁴ physicians' testimony,⁵⁵ and even the *Physicians' Desk Reference*,⁵⁶ this designation ignores the specific actions of these drugs and misleadingly suggests that their main role is to reduce agitation. This Part presents a summary of modern psychiatry's understanding of schizophrenia as it has emerged in

51. William E. Narrow et al., *Revised Prevalence Estimates of Mental Disorders in the United States: Using a Clinical Significance Criterion to Reconcile 2 Surveys' Estimates*, 59 ARCHIVES GEN. PSYCHIATRY 115, 121 (2002). See *infra* Part II.B. (describing the clinical criteria that psychiatrists use to diagnose schizophrenia).

52. For a recent and well-organized summary of theories concerning the etiology of schizophrenia, see generally Debra A. Pinals & Alan Breier, *Schizophrenia*, in 2 PSYCHIATRY 936 (Allan Tasman et al. ed., 1997).

53. See, e.g., *People v. Lewis*, 28 P.3d 34, 47, 49, 55 (Cal. 2001) (making three references to major tranquilizers); *People v. Kinkead*, 695 N.E.2d 1255, 1259 (Ill. 1998) (referring to Thorazine as a potential "major tranquilizer" or "an antipsychotic"); *In re Conservatorship of Foster*, 547 N.W.2d 81, 83 n.1 (Minn. 1996) (stating incorrectly that medical literature uses the terms "neuroleptic," "antipsychotic," and "major tranquilizer" interchangeably); *Irick v. State*, 973 S.W.2d 643, 648 (Tenn. Crim. App. 1998) (calling Thorazine a "major tranquilizer"). Currently, psychiatrists frequently use the terms "neuroleptic" or "conventional agent" to refer to older antipsychotic medications, and the terms "novel" or "atypical" to refer to the antipsychotic medications introduced since 1989. See *infra* in Parts III.C, D.1 (discussing these terms).

54. Baker, *supra* note 9, at 824; Sharon L. Flower, Comment, *Resolving Voluntary Mental Health Treatment Disputes in the Community Setting: Benefits of and Barriers to Effective Mediation*, 14 OHIO ST. J. ON DISP. RESOL. 881, 881 n.2 (1999) (stating that "Thorazine is a major tranquilizer"); M. Catherine Healy, Comment, *Riggins v. Nevada: Are "Synthetically Sane" Criminal Defendants Competent to Stand Trial?*, 20 NEW ENG. J. ON CRIM. & CIV. CONFINEMENT 385, 385 (1995) (stating that patients treated with "major tranquilizers" are "zombified"); Avital Stadler, Comment, *California Injects New Life Into an Old Idea: Taking a Shot at Recidivism, Chemical Castration, and the Constitution*, 46 EMORY L.J. 1285, 1306 (1997). But see Lester J. Perling, *Health Care Advance Directives: Implications for Florida Mental Health Patients*, 48 U. Miami L. Rev. 193, 201 (1993) (stating that the term "major tranquilizer" is used "incorrectly").

55. *Williamson v. Haynes* Best Western of Alexandria, 688 So. 2d 1201, 1214 (La. Ct. App. 1997) (physician uses term); *People v. Posby*, 574 N.W.2d 398, 402 (Mich. Ct. App. 1997) (physician uses term), *vacated*, 583 N.W.2d 458 (Mich. 1998).

56. PDR, *supra* note 49, at 2533 ("Haloperidol is the first of the butyrophenone series of major tranquilizers.").

the last quarter century, with the aim of helping readers appreciate how leading psychiatric researchers conceptualize the role of antipsychotic therapy.

A. Twentieth Century Developments in Understanding the Disorder

1. Bleuler's Conception

The contemporary view of schizophrenia has its roots in the work of Eugen Bleuler, a Swiss psychiatrist who coined the word “schizophrenia” early in the twentieth century.⁵⁷ Although the term “schizophrenic” is often used colloquially to describe the holding of dual, conflicting attitudes, as though the term referred to a multiple or split personality,⁵⁸ the word’s Greek roots, σχιζειν and Φρήγ actually connote a mind that is divided or torn apart.⁵⁹ According to psychiatrist Nancy Andreasen, Bleuler’s use of the term schizophrenia emphasizes that the disorder should be “defined by an underlying cognitive process” rather than by its often-variable outward appearance,⁶⁰ or, as Bleuler himself put it, as a “splitting of the psychic functions.”⁶¹ Throughout the twentieth century,

57. EUGEN BLEULER, *DEMENTIA PRAECOX OR THE GROUP OF SCHIZOPHRENIAS* (Joseph Zinkin trans., 1950).

58. Pinals & Breier, *supra* note 52, at 928.

59. 2 THE COMPACT EDITION OF THE OXFORD ENGLISH DICTIONARY 2159, 2664 (1971).

60. Nancy C. Andreasen, *A Unitary Model of Schizophrenia: Bleuler's "Fragmented Phrene" as Schizoencephaly*, 56 ARCHIVES GEN. PSYCHIATRY 781, 782 (1999). For a slightly different interpretation, see Pinals & Breier, *supra* note 52, at 928. However, the latter authors agree with Andreasen that “Bleuler used the word [schizophrenia] to capture his belief that this mental illness was one in which different aspects of the psyche were split.” *Id.*

61. BLEULER, *supra* note 57, at 9. His description continued:

In every case we are confronted with a more or less clear-cut splitting of the psychic functions. . . . The psychic complexes do not combine in a conglomeration of strivings with a unified resultant as they do in a healthy person Often ideas are only partially worked out, and fragments of ideas are connected in an illogical way to constitute a new idea. Concepts lose their completeness, seem to dispense with one or more of their essential components; indeed, in many cases they are only represented by a few truncated notions.

Thus, the process of association often works with mere fragments of ideas and concepts. This results in associations which normal individuals will regard as incorrect, bizarre, and utterly unpredictable. Often thinking stops in the middle of a thought; or in the attempt to pass to another idea, it may suddenly cease altogether, at least as far as it is a conscious process (blocking). Instead of continuing the thought, new ideas crop up which neither the patient nor the observer can bring into any connection with the previous stream of thought.

. . . In the severest cases emotional and affective expressions seem to be completely lacking.

Id. at 9–10.

the term schizophrenia, when used by psychiatrists, denoted a severe and debilitating disorder characterized by a pervasive impairment in thinking, behavior, and interpersonal relationships.⁶²

Bleuler's approach to schizophrenia assumed that this condition, like any medical disorder, should be described and understood by cataloging constellations of signs and symptoms and by paying careful attention to the disorder's clinical course and patients' ultimate outcomes.⁶³ Under this "medical model" of illness, schizophrenia was a condition equivalent to pneumonia or diabetes, that is, a specific, diagnosable, organically based disorder with well-defined manifestations, a typical course, and a characteristic prognosis. The disorder's treatment, which consisted of hospitalization, physician administered and directed therapy, as well as the supportive efforts of medical personnel (for example, nursing staff), followed logically from this medical diagnosis and was directed toward alleviating symptoms and restoring functioning, to the extent possible.⁶⁴

2. *Mid-Century Views*

By the 1960s, schizophrenia had become disputed territory. Though the Bleulerian medical paradigm retained its adherents, several other schools of thought within and without psychiatry offered alternative, competing explanatory models for the disorder.⁶⁵ Under the behaviorist or "moral model" of illness, a patient's unacceptable behavior, rather than his underlying sickness or diagnosed condition, was the nexus of clinical concern. Treatment, administered by psychologists and other behavioral experts rather than physicians, was designed to alter that behavior via a set of contingencies or reinforcements.⁶⁶ In the

62. Susan K. Schultz & Nancy C. Andreasen, *Schizophrenia*, 353 LANCET 1425, 1425 (1999).

63. For a short description of Bleuler's contributions to the modern conception of schizophrenia, and for a discussion of other disease-model-oriented twentieth century approaches to the description of schizophrenia, see Pinals & Breier, *supra* note 52, at 928–29, and J. Hoenig, *The Concept of Schizophrenia: Kraepelin-Bleuler-Schneider*, 142 BRIT. J. PSYCHIATRY 547, 549–52 (1983).

64. Miriam Siegler & Humphry Osmond, *Models of Madness*, 112 BRIT. J. PSYCHIATRY 1193, 1194–95 (1966).

65. *Id.* at 1193.

66. *See id.* at 1195–97. "[B]y and large the view of operant behavior therapists is that maladaptive behavior is no different than any other behavior The problem facing the therapist is therefore to identify maladaptive behaviors in an individual's repertoire and *remove* them through operant techniques." JOSEPH F. RYCHLAK, INTRODUCTION TO PERSONALITY AND PSYCHOTHERAPY: A THEORY-CONSTRUCTION APPROACH 335

“psychoanalytic model,” schizophrenia was part of a continuum of emotional difficulties that arose either from traumatic experiences or from failures to negotiate an earlier phase of psychological development. Psychoanalytic treatment of schizophrenia consisted in talking therapy that aimed to interpret pathological thinking, help the patient achieve insight, and thereby permit the patient to overcome the early childhood conflict from which the symptoms arose.⁶⁷ The “family interaction model” placed the locus of sickness in the family, rather than within an individual. Under this view, the schizophrenic patient reflected and acted out the disturbed functioning of his family, and treatment was focused on getting the family to interact in a healthier way.⁶⁸ The Szaszian “conspiratorial model” held that neither schizophrenia nor any other mental illness existed. What was called schizophrenia was merely deviant behavior, and calling someone crazy was a political act that served to justify interference with his civil liberties through forced therapy and hospitalization. According to Szasz and his adherents, psychiatrists were agents of social control.⁶⁹

3. *Medical Science’s Current View: A Brain-Based Disorder*

By the end of the twentieth century, scientific evidence had shown overwhelmingly that schizophrenia was a brain-based illness that could be addressed effectively, though not cured, with pharmacological agents that altered neuronal⁷⁰ functioning.⁷¹ Several other studies had shown

(1973). For a description of the in-hospital behavioral treatment of a person with schizophrenia, in which desired (rational) behaviors are rewarded and bizarre behaviors are ignored (extinguished), see *id.* at 337–38. The classic exposition of the behaviorist’s world view is *Beyond Freedom and Dignity*. B.F. SKINNER, *BEYOND FREEDOM AND DIGNITY* (1971).

67. Siegler & Osmond, *supra* note 64, at 1197–98. For a summary of psychodynamic contributions to the treatment of schizophrenia, see Pinals & Breier, *supra* note 52, at 958. There are two classic works in this area. SILVANO ARIETI, *INTERPRETATION OF SCHIZOPHRENIA* (1955); HARRY STACK SULLIVAN, *SCHIZOPHRENIA AS A HUMAN PROCESS* (1962).

68. Siegler & Osmond, *supra* note 64, at 1198–1200. There are also two classic works in this area. Gregory Bateson et al., *Toward a Theory of Schizophrenia*, 1 *BEHAVIORAL SCI.* 251 (1956) (describing the “double bind” as a causative factor); GREGORY BATESON, *STEPS TO AN ECOLOGY OF MIND* (1972).

69. THOMAS S. SZASZ, *LAW, LIBERTY, AND PSYCHIATRY: AN INQUIRY INTO THE SOCIAL USES OF MENTAL HEALTH PRACTICES* (1963); THOMAS S. SZASZ, *THE MYTH OF MENTAL ILLNESS: FOUNDATIONS OF A THEORY OF PERSONAL CONDUCT* (1974); Siegler & Osmond, *supra* note 64, at 1200.

70. The word “neuronal” means “pertaining to a neuron or neurons.” DORLAND’S, *supra* note 3, at 1212. Neurons are “the conducting cells of the nervous system.” *Id.* at 1211.

71. Innumerable studies have reported the effectiveness of antipsychotic drugs in quelling the symptoms of schizophrenia. For a summary of early research, see Jonathan O. Cole et al., *Phenothiazine Treatment in Acute Schizophrenia*, 10 *ARCHIVES GEN.*

that by continuing to take antipsychotic medication after they recover, patients can greatly reduce their risk of suffering a relapse.⁷² This was not to say that individual psychotherapy, behavioral treatments, or family therapy had no role in treating schizophrenia. Research had clearly shown that these treatments could be very useful.⁷³ However, nonpharmacological interventions were now regarded as helping patients and their families cope with the consequences of a biologically-based disorder and as addressing symptoms that medication alone could not completely correct.⁷⁴ Several independent lines of evidence support the contention that “[s]chizophrenia is a biological brain disease.”⁷⁵

a. Genetic Evidence

First, individuals vary greatly in their genetic susceptibility to schizophrenia, just as is the case with other common medical disorders. The probability that a first-degree relative of someone with schizophrenia will himself contract the disorder is ten times greater than the probability of someone who has no first-degree relatives with schizophrenia. The concordance rate of schizophrenia in monozygotic (identical) twins, who share the same genetic makeup, is higher than the concordance rate for dizygotic (fraternal) twins.⁷⁶

PSYCHIATRY 246 (1964). More recent summaries also concern older antipsychotic medications. See John M. Davis et al., *Important Issues in the Drug Treatment of Schizophrenia*, 6 SCHIZOPHRENIA BULL. 70 (1980); John M. Kane, *Treatment of Schizophrenia*, 13 SCHIZOPHRENIA BULL. 133 (1987) (noting both pooling and summarizing studies showing that antipsychotic drugs are effective for approximately seventy percent of patients in acute episodes of schizophrenia).

72. See, e.g., Patricia L. Gilbert et al., *Neuroleptic Withdrawal in Schizophrenic Patients: A Review of the Literature*, 52 ARCHIVES GEN. PSYCHIATRY 173 (1995) (presenting a meta-analysis showing that after 9.7 months, patients maintained on antipsychotic drugs experienced a sixteen percent relapse rate and fifty-three percent of patients not taking medication relapsed).

73. See, e.g., Sukhwinder S. Shergill et al., *Auditory Hallucinations: A Review of Psychological Treatments*, 32 SCHIZOPHRENIA RES. 137 (1998); Dennis G. Dyck et al., *Management of Negative Symptoms Among Patients with Schizophrenia Attending Multiple-Family Groups*, 51 PSYCHIATRIC SERVICES 513 (2000) (stating that multifamily educational groups are effective in reducing negative symptoms).

74. See Pinals & Breier, *supra* note 52, at 958–960. Substantial evidence suggests that nondrug therapies can work in concert with antipsychotic medication to improve outcomes in patients with schizophrenia. *Id.*

75. Paula C. Ashe et al., *Schizophrenia, a Neurodegenerative Disorder with Neurodevelopmental Antecedents*, 25 PROGRESS NEURO-PSYCHOPHARMACOLOGY & BIOLOGICAL PSYCHIATRY 691, 692 (2001).

76. DSM-IV-TR, *supra* note 3, at 309; see also, e.g., Preben Bo Mortensen et al.,

b. Viral Etiologies

Second, studies have revealed an association between prenatal exposure to viral infections and schizophrenia. A study of persons born after the 1957 influenza epidemic in Helsinki suggested that individuals whose mothers were exposed to the virus while pregnant, especially those whose mothers were exposed during the second trimester, a critical period for brain development, were at increased risk of developing schizophrenia.⁷⁷ Several studies have demonstrated an increased rate of winter births among persons with schizophrenia, suggesting that susceptibility to the disorder may be linked to the higher rates of viral infections during those months.⁷⁸

c. Evidence from Brain Scans and Autopsy Studies

Third, a host of computerized tomography (CT) and magnetic resonance imaging (MRI) studies have demonstrated that persons with schizophrenia have enlarged brain ventricles,⁷⁹ which implies a decrease in brain matter itself.⁸⁰ Radiological studies have demonstrated size decrements in portions of the brain that are responsible for memory, attention, emotional expression, social affiliation, and information integration.⁸¹

Effects of Family History and Place and Season of Birth on the Risk of Schizophrenia, 340 NEW ENG. J. MED. 603, 603 (1999) (finding that having a parent or sibling with schizophrenia increased the relative risk of developing schizophrenia by factor of seven to nine).

77. See generally Sarnoff A. Mednick et al., *Adult Schizophrenia Following Prenatal Exposure to an Influenza Epidemic*, 45 ARCHIVES GEN. PSYCHIATRY 189 (1988) (finding that second trimester exposure to an influenza epidemic increased the risk of psychiatric hospitalization with diagnosis of schizophrenia); E. O'Callaghan et al., *Schizophrenia After Prenatal Exposure to 1957 A2 Influenza Epidemic*, 337 LANCET 1248 (1991) (finding that a study of England and Wales births yields similar finding and provides "clinical and neuropathological evidence of aberrant fetal brain development in the pathogenesis of schizophrenia").

78. See generally Richard L. O'Reilly, *Viruses and Schizophrenia*, 28 AUSTRALIAN & N.Z. J. PSYCHIATRY 222 (1994).

79. The four brain ventricles are "the cavities within the brain which are filled with cerebrospinal fluid." DORLAND'S, *supra* note 3, at 1955. Their structure is illustrated, *id.*, and their function is described in many texts on nervous system anatomy. See, e.g., MALCOLM B. CARPENTER, *CORE TEXT OF NEUROANATOMY* 25–28 (1972).

80. Pinals & Breier, *supra* note 52, at 938–39. A recent meta-analysis of fifty-eight previously published studies concludes that "cerebral volume was lower . . . and total ventricular volume was higher . . . in patients with schizophrenia than in comparison subjects." Ian C. Wright et al., *Meta-Analysis of Regional Brain Volumes in Schizophrenia*, 157 AM. J. PSYCHIATRY 16, 22 (2000). For a highly technical but authoritative summary of brain abnormalities ascertained in "neuroimaging studies," that is, radiologic studies of brain structure, such as CT and MRI scans, see Jeffrey A. Lieberman, *Is Schizophrenia a Neurodegenerative Disorder? A Clinical and Neurobiological Perspective*, 46 BIOLOGICAL PSYCHIATRY 729, 733–34 (1999).

81. Nancy Andreasen et al., *Structural Abnormalities in the Frontal System in*

Several postmortem studies have demonstrated localized, microscopic abnormalities in the shape and organization of neurons from brains of individuals that had schizophrenia.⁸²

d. Birth Complications

Fourth, schizophrenia is associated with birth complications. One recent study found that birth complications that were associated with lowered brain oxygen levels strikingly elevated the subsequent risk of developing schizophrenia,⁸³ a finding that supports an earlier report that oxygen deprivation doubled the risk of developing schizophrenia.⁸⁴ Certain areas of the brain are very sensitive to lowered blood oxygen levels, and these areas may be especially susceptible to hypoxia related damage around the time of birth.⁸⁵ In a recent MRI study of monozygotic twins who had a history of birth complications but who were discordant for schizophrenia,⁸⁶ the ill twins had smaller hippocampi and enlarged ventricles, findings frequently found in

Schizophrenia: A Magnetic Resonance Imaging Study, 43 ARCHIVES GEN. PSYCHIATRY 136, 136 (1986) (finding that “schizophrenics had significantly smaller frontal lobes, as well as smaller cerebrums and craniums”); Alan Breier et al., *Brain Morphology and Schizophrenia: A Magnetic Resonance Imaging Study of Limbic, Prefrontal Cortex and Caudate Structures*, 49 ARCHIVES GEN. PSYCHIATRY 921, 921 (1992); Hilleke E. Hulshoff Pol et al., *Volume Changes in Gray Matter in Patients with Schizophrenia*, 159 AM. J. PSYCHIATRY 244, 244 (2002) (concluding that “smaller brains of the patients with schizophrenia can be explained by decreases in gray matter volume,” especially prefrontal gray matter); Philip R. Szeszko et al., *Neuropsychological Correlates of Hippocampal Volumes in Patients Experiencing a First Episode of Schizophrenia*, 159 AM. J. PSYCHIATRY 217, 221–23 (2002) (noting the relationship between loss of tissue in a portion of the brain usually associated with memory functioning and executive functioning suggests defect in linkage of brain regions); Wright et al., *supra* note 80, at 23 (“Regional volume reductions . . . were particularly marked in the bilateral medial temporal lobe regions.”).

82. Pinals & Breier, *supra* note 52, at 939. See generally Thomas F. McNeil et al., *Relationship of Obstetric Complications and Differences in Size of Brain Structures in Monozygotic Twin Pairs Discordant for Schizophrenia*, 157 AM. J. PSYCHIATRY 203 (2000) (citing studies).

83. Gwen L. Zornberg et al., *Hypoxic-Ischemia-Related Fetal/Neonatal Complications and Risk of Schizophrenia and Other Nonaffective Psychoses: A 19-Year Longitudinal Study*, 157 AM. J. PSYCHIATRY 196, 196–97 (2000).

84. Stephen L. Buka et al., *Pregnancy/Delivery Complications and Psychiatric Diagnosis: A Prospective Study*, 50 ARCHIVES GEN. PSYCHIATRY 151, 156 (1993).

85. Pinals & Breier, *supra* note 52, at 938 (mentioning the hippocampus and neocortex as especially vulnerable areas).

86. That is, only one twin had the disorder.

schizophrenia,⁸⁷ and a pattern of complications implying that labor or delivery trauma was importantly associated with the development, decades later, of schizophrenia.⁸⁸ A recent study of minor physical anomalies (slight deviations in a person's physical characteristics that reflect disruptions in fetal development)⁸⁹ showed that in a group of children at risk for developing mental illness, those who had a higher number of such anomalies "developed schizophrenia spectrum disorders significantly more often than they developed a no mental illness outcome."⁹⁰

e. Characteristic Cognitive Impairment

Fifth, schizophrenia is associated with a variety of impairments in cognitive functioning that are predictive of poor outcome and long-term disability.⁹¹ The most commonly investigated impairments are deficits in information processing that, in some cases, have been localized to dysfunction in particular areas of the cortex.⁹² As psychiatrist Jeffrey

87. See *supra* Part II.A.3.c (citing studies).

88. McNeil et al., *supra* note 82, at 203.

89. See Baher Ismail et al., *Minor Physical Anomalies in Schizophrenia: Cognitive, Neurological and Other Clinical Correlates*, 34 J. PSYCHIATRIC RES. 45 (2000).

90. Jason Schiffman et al., *Minor Physical Anomalies and Schizophrenia Spectrum Disorders: A Prospective Investigation*, 159 AM. J. PSYCHIATRY 238, 238 (2002); see also John McGrath et al., *Minor Physical Anomalies and Quantitative Measures of the Head and Face in Patients with Psychosis*, 59 ARCHIVES GEN. PSYCHIATRY 458 (2002) (having head abnormalities increased odds of having a nonaffective psychotic disorder, that is, schizophrenia).

91. Philip D. Harvey & Richard S.E. Keefe, *Studies of Cognitive Change in Patients with Schizophrenia Following Novel Antipsychotic Treatment*, 158 AM. J. PSYCHIATRY 176, 176 (2001).

Cognitive functioning is a correlate of global and specific functional outcome in schizophrenia. Cognitive impairments consistently account for significant variance in measures of functional status, such as social and occupational disability, and are more strongly related to functional outcome than other aspects of the illness such as positive symptom severity.

Id.; see also Stanley R. Kay & Lisa M. Murrill, *Predicting Outcome of Schizophrenia: Significance of Symptom Profiles and Outcome Dimensions*, 31 COMPREHENSIVE PSYCHIATRY 91, 97 (1990) (finding that thought disturbance predicts poor functional outcome).

92. See, e.g., Esther F. Rabinowicz et al., *Auditory Sensory Dysfunction in Schizophrenia: Imprecision or Distractibility?*, 57 ARCHIVES GEN. PSYCHIATRY 1149, 1153 (2000) (finding that tone matching deficits appear to be caused by dysfunction at the level of the auditory sensory cortex); Daniel R. Weinberger et al., *Physiologic Dysfunction of Dorsolateral Prefrontal Cortex in Schizophrenia: I. Regional Cerebral Blood Flow Evidence*, 43 ARCHIVES GEN. PSYCHIATRY 114, 114 (1986) (finding that persons with schizophrenia fail to activate the prefrontal cortex during a Wisconsin Card Sort procedure). In recent years, most issues of the *American Journal of Psychiatry* have contained at least one illustration that depicts a connection between localized brain activity and some feature of schizophrenic psychopathology. See, e.g., Tamara A.

Lieberman explained: “The average schizophrenic patient in the first episode of psychosis performs a full standard deviation below the normal mean. This translates to a reduction in cognitive performance to the seventeenth percentile or an IQ score-equivalent of 85.”⁹³ The onset of this reduction appears to begin before persons develop full-blown symptoms of schizophrenia.⁹⁴

f. Mechanism of Antipsychotic Drug Action

Sixth, all antipsychotic medications have a consistent property; they block the dopamine-D₂ receptor.⁹⁵ Dopamine is one of many brain chemicals dubbed “neurotransmitters” because of its role in transmitting signals between nerve cells.⁹⁶ At least five major types of dopamine receptors⁹⁷ can be found in various locations in the brain,⁹⁸ and all

Russell et al., *Exploring the Social Brain in Schizophrenia: Left Prefrontal Underactivation During Mental State Attribution*, 157 AM. J. PSYCHIATRY 2040, 2041 (2000) (comparing activation of brain areas in healthy persons and patients with schizophrenia that were asked to describe the mental state reflected in photographs of persons' eyes).

93. Lieberman, *supra* note 80, at 733.

94. Rebecca Fuller et al., *Longitudinal Assessment of Premorbid Cognitive Functioning in Patients with Schizophrenia Through Examination of Standardized Scholastic Test Performance*, 159 Am. J. Psychiatry 1183, 1186 (2002) (stating that lower grade 11 Iowa Test scores support “previous findings that children who later develop schizophrenia manifest intellectual differences from peers before illness onset”). In addition, teenagers who do not yet show characteristic signs and symptoms of schizophrenia, but who later go on to develop that disorder, have more signs of impaired functioning and higher rates of psychiatric disorders. Mark Weiser et al., *Association Between Nonpsychotic Psychiatric Diagnoses in Adolescent Males and Subsequent Onset of Schizophrenia*, 58 ARCHIVES GEN. PSYCHIATRY 959, 959 (2001).

95. Philip Seeman, *Atypical Antipsychotics: Mechanism of Action*, 47 CANADIAN J. PSYCHIATRY 27, 27 (2002).

96. “Neurotransmitters, the key information molecules of the brain, mediate the actions of all known psychoactive drugs.” Solomon H. Snyder & Christopher D. Ferris, *Novel Neurotransmitters and Their Neuropsychiatric Relevance*, 157 AM. J. PSYCHIATRY 1738, 1738 (2000). Snyder and Ferris provide an excellent (though highly technical) review of how current knowledge of neurotransmitters developed in the last half of the twentieth century. Concerning the role of dopamine in the brain and the impact of D₂ blockers on dopamine transmission, see HYMAN ET AL., *supra* note 9, at 12–14.

97. A receptor is “a molecular structure within a cell or on the surface characterized by (1) selective binding of a specific substance and (2) a specific physiologic effect that accompanies the binding.” DORLAND'S, *supra* note 3, at 1539.

98. Anibal Cravchik & David Goldman, *Neurochemical Individuality: Genetic Diversity Among Human Dopamine and Serotonin Receptors and Transporters*, 57 ARCHIVES GEN. PSYCHIATRY 1105, 1105–08 (2000). Dopamine receptors transduce signals within cells by coupling with specialized proteins on nerve cell membranes. *Id.* at 1106–07.

currently available antipsychotic medications prevent or alter the way that dopamine binds to a specific type of site, the dopamine-D₂ receptor, on neurons.⁹⁹ The D₂ receptor blockade is directly correlated with the potency of conventional antipsychotic drugs.¹⁰⁰ The ability of psychoactive drugs to quell some symptoms of psychosis is another powerful argument in favor of regarding schizophrenia as a disorder of brain dysfunction.

g. Drugs Can Induce Psychoses

Seventh, drugs can induce behavior and symptoms similar to those experienced by persons with schizophrenia. Although the brain's responses to particular pharmacological agents have sometimes led to simplistic hypotheses about the nature of spontaneously occurring psychoses,¹⁰¹ recent studies have shown that, for example, specific neurocognitive deficits in schizophrenia can be replicated in healthy persons by administering medications that block specific brain receptors.¹⁰² Moreover, these medications produce abnormal brain activation patterns that resemble the brain activity abnormalities exhibited by persons with schizophrenia.¹⁰³

99. Shitij Kapur et al., *A Positron Emission Tomography Study of Quetiapine in Schizophrenia: A Preliminary Finding of an Antipsychotic Effect with Only Transiently High Dopamine D₂ Receptor Occupancy*, 57 ARCHIVES GEN. PSYCHIATRY 553, 553 (2000); Shitij Kapur et al., *Clinical and Theoretical Implications of 5-HT₂ and D₂ Receptor Occupancy of Clozapine, Risperidone, and Olanzapine in Schizophrenia*, 156 AM. J. PSYCHIATRY 286, 286 (1999).

100. Ian Creese et al., *Dopamine Receptor Binding Predicts Clinical and Pharmacological Potencies of Antischizophrenic Drugs*, 192 SCIENCE 481, 481-483 (1976); P. Seeman et al., *Antipsychotic Drug Doses and Neuroleptic/Dopamine Receptors*, 261 NATURE 717, 717-719 (1976); P. Seeman & T. Lee, *Antipsychotic Drugs: Direct Correlation Between Clinical Potency and Presynaptic Action on Dopamine Neurons*, 188 SCIENCE 1217, 1218 (1975). For a recent discussion on how assay methods may be responsible for what appear to be exceptions to this rule of proportionality, see Philip Seeman & Teresa Tallerico, *Rapid Release of Antipsychotic Drugs from Dopamine D₂ Receptors: An Explanation for Low Receptor Occupancy and Early Clinical Relapse upon Withdrawal of Clozapine or Quetiapine*, 156 AM. J. PSYCHIATRY 876, 876 (1999) (stating that the "rapid release of clozapine and quetiapine from D₂ receptors by endogenous dopamine may contribute to [apparent] low D₂ receptor occupancy" in binding studies).

101. See also *infra* Part III.B.

102. For example, the drug ketamine, see discussion *infra* Part III.B, blocks the N-methyl-D-aspartate receptor (NMDAR). Daniel Umbricht et al., *Ketamine-Induced Deficits in Auditory and Visual Context-Dependent Processing in Healthy Volunteers*, 57 ARCHIVES GEN. PSYCHIATRY 1139, 1142 (2000). Recently, Umbricht and colleagues showed that ketamine, administered to healthy volunteers, could produce deficits in tone matching ability, electroencephalographic (EEG) recordings, and attention that mimicked the deficits in persons with schizophrenia. *Id.* at 1142-44. "The similarity of ketamine-induced deficits thus suggests that NMDAR-related dysfunction may contribute to the observed deficits in schizophrenia." *Id.* at 1146.

103. Alan Breier et al., *Association of Ketamine-Induced Psychosis with Focal*

The ability to chemically induce the specific neurocognitive deficits characteristic of schizophrenia suggests that the neurons affected by those chemicals have abnormalities that produce the manifold problems exhibited by persons with the disorder.

h. Functional Brain Imaging

Finally, currently available imaging techniques allow neuroscientists to watch the brain as it functions and to observe activation patterns that are distinctive to schizophrenia. For several years, psychiatrists have used information from functional imaging studies to document decreased metabolism and blood flow in the prefrontal regions of persons with schizophrenia.¹⁰⁴ Recently, scientists have used these methods to find correlations between specific psychotic symptoms and patterns of brain activity. For example, Shergill and colleagues recently used a radiographic technique called functional magnetic resonance imaging¹⁰⁵ to look at what regions of the brain are activated during periods when persons with schizophrenia hear voices, that is, experience verbal speech in the absence of external sensory input. They found that activation in an extensive network of brain areas was “associated with auditory hallucinations.”¹⁰⁶ This activation pattern was, in some respects, “remarkably similar to that seen when healthy volunteers imagine another person talking to them,”¹⁰⁷ but differed in two important respects: (1) an area of the brain associated with self-awareness was *not* activated, and (2) an area of the

Activation of the Prefrontal Cortex in Healthy Volunteers, 154 AM. J. PSYCHIATRY 805, 805 (1997).

104. Daniel R. Weinberger & Karen Faith Berman, *Speculation on the Meaning of Cerebral Metabolic Hypofrontality in Schizophrenia*, 14 SCHIZOPHRENIA BULL. 157, 157 (1988). For a recent study and discussion, see Steven G. Potkin et al., *A PET Study of the Pathophysiology of Negative Symptoms in Schizophrenia*, 159 AM. J. PSYCHIATRY 227, 227 (2002) (finding a lower prefrontal metabolic rate in patients with predominantly negative symptoms and stating: “A consistent finding . . . is a lower level of prefrontal cortical metabolism in schizophrenic subjects . . .”).

105. A full discussion of this technique lies far beyond the scope of this Article, but it involves the use of very powerful magnets to detect changes in localized blood oxygenation, which is an index of neural activity. See generally S. Ogawa et al., *Brain Magnetic Resonance Imaging with Contrast Dependent on Blood Oxygenation*, 87 PROC. NAT’L ACAD. SCI. U.S. 9868 (1990).

106. Sukhwinder S. Shergill et al., *Mapping Auditory Hallucinations in Schizophrenia Using Functional Magnetic Resonance Imaging*, 57 ARCHIVES GEN. PSYCHIATRY 1033, 1034 (2000).

107. *Id.* at 1035.

brain associated with unexpected stimuli *was* activated.¹⁰⁸ This pattern of activation provides confirmation for the idea that auditory verbal hallucinations “arise through the disruption of normal cognitive processes, such as monitoring of self-generated verbal material,” and it also “makes it easier to appreciate why patients often describe the experiences as indistinguishable from ‘real’ auditory perceptions.”¹⁰⁹ The authors also note that their findings elucidate the biological underpinnings for what patients experience and explain why certain psychological and biological treatments may be helpful.¹¹⁰ In another recent study correlating symptoms with specialized areas of brain activity, Kircher and colleagues found that the severity of disordered thinking¹¹¹ induced when schizophrenic patients commented on Rohrschach inkblots “was inversely correlated with the level of activity in the Wernicke area, a region implicated in the production of coherent speech.”¹¹²

4. *Conceptualizing Schizophrenia*

The foregoing discussion is not intended to suggest that physicians and scientists know what the cause of schizophrenia is in the way that doctors know that a specific type of bacterium is the pathogen involved in pneumococcal pneumonia. Nor are they sure why observed disturbances in brain function or morphology lead to the problems exhibited by persons with schizophrenia. However, an emerging consensus about the disorder holds that the clinical signs and symptoms of schizophrenia, whether they be florid, “positive” symptoms,¹¹³ such as crazy beliefs (delusions¹¹⁴) and hearing voices (auditory hallucinations¹¹⁵), or “negative”

108. These areas are the supplementary motor area and the left parahippocampal region, respectively. *Id.* at 1036.

109. *Id.* at 1037.

110. *Id.*

111. The authors looked specifically at manifestations of positive formal thought disorder, or the “incoherence, use of peculiar words, and distractibility” that is “one of the core features of schizophrenia.” Tilo T. J. Kircher et al., *Neural Correlates of Formal Thought Disorder in Schizophrenia: Preliminary Findings From a Functional Magnetic Resonance Imaging Study*, 58 ARCHIVES GEN. PSYCHIATRY 769, 769 (2001).

112. *Id.*

113. Positive symptoms involve the presence of abnormal clinical findings or “distortions of normal functioning.” Samuel J. Keith, *Pharmacologic Advances in the Treatment of Schizophrenia*, 337 NEW ENG. J. MED. 851, 851 (1997).

114. A delusion is:

A false belief based on incorrect inference about external reality that is firmly sustained despite what almost everyone else believes and despite what constitutes incontrovertible and obvious proof or evidence to the contrary. The belief is not one ordinarily accepted by other members of the person’s culture or subculture (e.g., it is not an article of religious faith).

DSM-IV-TR, *supra* note 3, at 821.

symptoms,¹¹⁶ such as social withdrawal and apathy, reflect an “underlying disruption in functional neural circuitry.”¹¹⁷ Symptoms of schizophrenia occur in persons who have hereditary and congenital vulnerabilities to the disorder and who may also be exposed to environmental stressors ranging from drugs of abuse to social disappointments. While these symptoms vary enormously both among persons diagnosed with the disorder and within such persons over the course of their illness, persons with schizophrenia typically display distinctive abnormalities in visual tracking of moving objects, ability to filter out interfering stimuli, information processing and attention, and working memory.¹¹⁸

Recently, Dr. Andreasen and colleagues have suggested that these difficulties reflect disruptions in neuronal circuits that are responsible for coordinating sequences of motor activity and thought “that are the hallmark[s] of normal cognition.”¹¹⁹ Persons with schizophrenia suffer from misconnected brain circuitry, because of which they cannot make normal associations among mental ideas and cannot distinguish between their own thoughts and those of others. They cannot suppress “[t]he multiple stimuli that bombard our consciousness” and have trouble ignoring trivial matters and paying attention to what is important.¹²⁰ When they experience hallucinations, it is because they interpret “internal representations,” which are their own thoughts, as coming from outside themselves. When they experience delusions, it is because their malfunctioning circuitry has made erroneous or inappropriate connections

115. A hallucination is “[a] sensory perception that has the compelling sense of reality of a true perception but that occurs without external stimulation of the relevant sensory organ.” *Id.* at 823.

116. Negative symptoms involve the absence of normal findings or “the loss of normal functioning.” Keith, *supra* note 113, at 851.

117. Andreasen, *supra* note 60, at 782.

118. *Id.* at 783–84.

Working memory is a multicomponent cognitive system that serves to hold briefly a limited amount of information ‘online’ and to manipulate that information so that it is available for further cognitive processing or to guide response selection. . . . [T]his elementary capacity is generally thought to be necessary for a wide range of complex cognitive functions such as language comprehension, learning, reasoning, and planning.

Cenk Tek et al., *Visual Perceptual and Working Memory Impairments in Schizophrenia*, 59 ARCHIVES GEN. PSYCHIATRY 146, 146 (2002) (footnote omitted).

119. Andreasen, *supra* note 60, at 783–84.

120. *Id.* at 785.

between mental phenomena.¹²¹ Disorganized thinking and speech is a reflection of faulty “[o]n-line monitoring,” poorly coordinated and mistimed brain activity being a few examples. Similarly, social ineptitude, aggression, inactivity, and even catatonia may represent results of what happens when neurons improperly match each others’ signals, mistime messages, or send transmissions to the wrong locations.¹²²

This description of Andreasen and colleagues’ interpretation of schizophrenia is not an endorsement of all aspects of its specific content.¹²³ It is valuable to a *legal* audience because it typifies psychiatrists’ and neuroscientists’ current theories about the nature of schizophrenia. The theory is an exemplar of the explanatory paradigms used in most current theories about schizophrenia. These theories all share the view that schizophrenia is not *fundamentally* a syndrome of irrational perceptions, beliefs, or actions.¹²⁴ A person with schizophrenia does not act irrationally or behave oddly because he believes things that are bizarre, impossible, maladaptive, unusual, socially inappropriate, politically unpopular, or in some other way “sick.” Schizophrenia is manifested in disturbances of what, in ordinary language, we call thinking and behavior. Yet, the core pathological processes that are the current focus of scientific investigation are not impairments in thinking, behavior, or some other aspect of the individual’s psychology, but are instead malfunctioning brain circuitry.¹²⁵

This type of explanation differs from how, using ordinary language explanations, we describe the utterances and actions of persons. Our

121. *Id.*

122. *Id.*

123. For another, equally elegant conceptualization of neuropathology in schizophrenia, see generally Thomas H. McGlashan & Ralph E. Hoffman, *Schizophrenia as a Disorder of Developmentally Reduced Synaptic Connectivity*, 57 ARCHIVES GEN. PSYCHIATRY 637 (2000) (describing computer simulations of elimination of connections between neurons, and explaining how this process accounts for the unique symptoms, course, age of onset, neurodevelopmental deficits, limited neurodegenerative progression, and sex differences in schizophrenia).

124. “Psychotic symptoms are probably the least specific aspects of the schizophrenia syndrome, and [yet] traditionally, . . . they have been the symptoms that we emphasize. I think neuroimaging and genetics will eventually lead us to subtype patients into categories that are more biologically valid.” Donald C. Goff, *A 23-Year-Old Man With Schizophrenia*, 287 J. AM. MED. ASS’N 3249, 3256 (2002).

125. The symptoms and signs of schizophrenia are very diverse, and they encompass the entire range of human mental activity. . . . These symptoms and signs occur in patterns that may not overlap; one patient may have hallucinations and affective flattening, whereas another has disorganized speech and avolition [lack of motivation]. The diversity and nonoverlapping pattern of symptoms and signs suggest a more basic and unifying problem: abnormalities in neural circuits and fundamental cognitive mechanisms.

Nancy C. Andreasen, *Understanding the Causes of Schizophrenia*, 340 NEW ENG. J. MED. 645, 646 (1999).

ordinary language explanations of behavior are grounded in the assumption that persons are practical reasoners whose beliefs and desires account for what they do.¹²⁶ By contrast, current theories that attempt to account for the signs and symptoms of schizophrenia, as well as for many other biologically conceptualized psychiatric disorders, are materialist¹²⁷ and are structurally similar to how we explain the output of a malfunctioning computer. We do not *explain* a computer's malfunction by referring, for example, to a scramble of lines or symbols on a monitor, although these might provide *evidence* that something is wrong with the computer. Instead, we interpret a scrambled screen as an indication of malfunctioning at a more fundamental level, such as a problem with the computer's microcircuitry or with how its software was controlling that microcircuitry. Similarly, proposed explanations of schizophrenia no longer attribute patients' disorganized thinking and delusional statements to erroneous beliefs, reactions to others, or emotional conflicts. Instead, neuroscientists' explanations are efforts to describe how disruptions in the brain's computational processes may produce failures in basic cognitive functions that in turn lead to the observed craziness and irrationality of persons that suffer from the illness.¹²⁸

126. For a superb explanation of the explanatory paradigm that underlies most everyday discussions of behavior and the paradigm that the law uses to describe actions, see MICHAEL S. MOORE, *LAW AND PSYCHIATRY: RETHINKING THE RELATIONSHIP*, 67–90 (1984). The connection between this paradigm, our conception of criminal responsibility, and the insanity defense is cogently summarized in Stephen J. Morse, *Craziness and Criminal Responsibility*, 17 *BEHAV. SCI. & L.* 147 (1999).

127. To give even a short description of the philosophical issues raised by this explanation approach would be far beyond the scope of this Article. For an excellent explanation of the kind of philosophical eliminative materialism to which neuroscientists may be implicitly committed, see generally PAUL S. CHURCHLAND, *A NEUROCOMPUTATIONAL PERSPECTIVE* (1989). A recent, clever, and accessible discussion of dualist, materialist, and functionalist explanatory perspectives is found in Kenneth S. Kendler, *A Psychiatric Dialogue on the Mind-Body Problem*, 158 *AM. J. PSYCHIATRY* 989 (2001).

128. "Schizophrenia is a disease of the brain that is expressed clinically as a disease of the mind. . . . The working hypothesis shared by most investigators is that schizophrenia is a disease of neural connectivity caused by multiple factors that affect brain development." Andreasen, *supra* note 125, at 646. For a description of the neuropathological processes that might generate the disturbance of neural connectivity, see Bryan T. Woods, *Is Schizophrenia a Progressive Neurodevelopmental Disorder? Toward a Unitary Pathogenetic Mechanism*, 155 *AM. J. PSYCHIATRY* 1661, 1666 (1998) (stating that the underlying disease process begins before birth and leads to progressive loss of brain volume). For the classic exposition of how gross mental functioning is comprised of many smaller functions, see MARVIN MINSKY, *THE SOCIETY OF MIND* (1985).

B. The Diagnosis of Schizophrenia

Notwithstanding the last quarter century's neuroscientific advances, the diagnosis of schizophrenia remains a "low tech," clinical process. That is, the major activities in the diagnostic process involve interviewing the patient concerning his problems, symptoms, and history. Interview findings are often supplemented with information from medical records and from other persons, including family members, that know about the patient's situation, recent behavior, and background.¹²⁹ The most recent edition of the American Psychiatric Association's diagnostic manual¹³⁰ states that a diagnosis of schizophrenia may be rendered when the following clinically ascertained criteria are met:

- (A) For a significant portion of time during a one month period, the individual has had two or more of the characteristic symptoms of schizophrenia. These include positive symptoms such as delusions, hallucinations, disorganized speech, and grossly disorganized or catatonic behavior.¹³¹ Also factored in are the presence of abnormal clinical findings or negative symptoms, such as lack of emotional expression,¹³² speech that is a diminished amount or that conveys little information,¹³³ or an inability to initiate and sustain important activities such as work or self-care.¹³⁴
- (B) The individual has experienced marked deterioration in ability to work, interpersonal relations, or ability to take care of himself.
- (C) The disturbance has lasted at least six months, during which the (A) criteria have lasted at least one month (unless successfully treated).
- (D) The (A) criteria symptoms are not accompanied by severe mood disturbances.¹³⁵

129. Pinals & Breier, *supra* note 52, at 929–31, 945–48.

130. DSM-IV-TR, *supra* note 3, at 312.

131. *Id.* at 820–21 (listing "[m]arked motor abnormalities including . . . immobility[,] . . . certain types of excessive motor activity[,] . . . apparent motiveless resistance to instructions or attempts to be moved," and other movement and speech disturbances).

132. Psychiatrists term this "blunted affect." *Id.* at 819.

133. Psychiatrists term this diminished production of speech "alogia." *See id.* at 820.

134. The psychiatric term for this deficit is "avolition." *Id.*

135. Were severe mood symptoms present, the individual's mental disturbance might be better diagnosed as an instance of schizoaffective disorder, *see id.* at 319–23, or as an episode of mood disorder with psychotic features, *see id.* at 411–17. Psychotic symptoms may form part of major depressive episodes, manic episodes, and "mixed" episodes, in which manic and depressive symptoms appear together. *Id.* at 411–17.

(E) The (A) criteria symptoms are not due to a medication, drug of abuse, or a general medical condition.¹³⁶

The next step in diagnostic classification is to categorize an individual's syndrome as falling into one of the following subtypes of schizophrenia:

Paranoid Type: The individual is preoccupied with one or more delusions or frequent auditory hallucinations but does not display other prominent active phase symptoms (catatonia, disorganized behavior or speech, flat or inappropriate affect).¹³⁷

Disorganized Type: The individual displays disorganized speech, disorganized behavior, and flattened or inappropriate affect, but no catatonia.¹³⁸

Catatonic Type: The individual is immobile or displays excessive, purposeless motor activity. The individual resists all instructions; maintains a rigid or bizarre posture; and will not speak, holds himself bizarrely, makes repetitive movements, or repeats the words or movements of others.¹³⁹

Undifferentiated Type: The individual's problems do not fit the paranoid, disorganized, or catatonic subtypes.¹⁴⁰

Residual Type: Although the individual does not exhibit prominent delusions, hallucinations, disorganized speech, disorganized behavior, or catatonic behavior, either (1) negative symptoms are present, or (2) at least two of the symptoms listed above in paragraph (A) appear in attenuated form.¹⁴¹

Finally, when the illness has been present for at least a year after the onset of active phase symptoms, the diagnostician may summarize the disorder's "longitudinal course" using a variety of "specifiers." The specifiers briefly characterize the illness, stating whether the individual has

136. For a summary of the decision process for differentiating schizophrenia from other disorders that may cause psychotic symptoms, see *id.* at 750–51. For a decision tree that outlines how schizophrenia can be distinguished from the many other psychiatric conditions that present with psychotic symptoms, see *id.* A partial list of these conditions includes: psychotic disorders caused by general medical conditions, *id.* at 334–38, psychotic disorders induced by medications or intoxicants, *id.* at 338–43, schizophreniform disorder, *id.* at 317–19, schizoaffective disorder, *id.* at 319–23, mood disorders with psychotic features, *id.* at 411–17, delusional disorder, *id.* at 323–29, and brief psychotic disorder, *id.* at 329–32.

137. *Id.* at 313–14.

138. *Id.* at 314–15.

139. *Id.* at 315–16.

140. *Id.* at 316.

141. *Id.* at 316–17.

suffered one or more episodes of the (A) criteria symptoms, and whether he recovered partially or fully after or between episodes of (A) criteria symptoms.¹⁴²

Having completed a short summary of modern psychiatry's current understanding and diagnosis of schizophrenia, this Article now turns to psychiatrists' principal means for helping patients cope with the disorder—antipsychotic medication.

III. ANTIPSYCHOTIC MEDICATION

A. *The Benefits and Impact of Antipsychotic Drugs*

Antipsychotic drugs are the mainstay of modern medical treatment for schizophrenia¹⁴³ and are frequently used to treat persons that suffer from several other mental disorders¹⁴⁴ that include psychotic symptoms.¹⁴⁵ Although the symptoms of psychotic disorders have been recognized since antiquity,¹⁴⁶ effective and specific pharmacological treatments for

142. Examples of longitudinal course specifiers are “episodic with interepisode residual symptoms,” “continuous . . . with prominent negative symptoms,” and “single episode in partial remission.” *Id.* at 312–13.

143. “Antipsychotic medications are indicated for nearly all acute psychotic episodes in patients with schizophrenia . . . [P]sychiatrists should avoid withholding medications for [more than a period of several days] . . . as this may delay the patient's recovery and place the patient at risk of suicide and other dangerous behaviors . . .” Marvin I. Herz et al., *Practice Guideline for the Treatment of Patients with Schizophrenia*, 154 AM. J. PSYCHIATRY 2 (Supp. Apr. 1997). The coding of the guideline indicates that this recommendation is made “with substantial clinical confidence.” *Id.* The guideline expresses the same level of confidence concerning continuation of antipsychotic medication during the first six months after recovery from acute psychosis, and for longer periods to reduce the risk of relapse. *Id.* at 4.

144. Other psychotic disorders for which antipsychotic drugs are indicated include acute manic episodes, depression with psychotic features, delusional disorders, and some instances of delirium. HYMAN ET AL., *supra* note 9, at 14–22.

145. For several years, courts have recognized the central importance of antipsychotic medication in treating schizophrenia. *See, e.g., Rennie v. Klein*, 462 F. Supp. 1131, 1137–38 (D.N.J. 1978) (“[N]o other treatment modality has achieved equal success in the treatment of schizophrenics. . . . [P]sychotropic drugs are widely accepted in present psychiatric practice. . . . They are the treatment of choice for schizophrenics today.”), *suppl.*, 476 F. Supp. 1294 (D.N.J. 1979), *modified*, 653 F.2d 836 (3d Cir. 1981), *vacated and remanded*, 458 U.S. 1119 (1982).

146. For example, the Bible describes a successful effort to feign a severe mental disorder. After David learned that King Saul wanted him killed, he fled to the court of King Achish of Gath. The courtiers recognized him, however. I *Samuel* 21:11–22:1.

So he [David] concealed his good sense from them; he feigned madness for their benefit. He scratched marks on the doors of the gate and let his saliva run down his beard. And Achish said to his courtiers, “You see the man is raving; why bring him to me? Do I lack madmen that you have brought this fellow to rave for me? Should this fellow enter my house?”

TANAKH—THE HOLY SCRIPTURES: THE NEW JPS TRANSLATION ACCORDING TO THE TRADITIONAL HEBREW TEXT 453–54 (1985) (footnotes omitted). David's ruse worked,

these conditions only became available in the 1950s, following the discovery that chlorpromazine¹⁴⁷ could reduce or eliminate hallucinations and delusions in many individuals with schizophrenia.¹⁴⁸ The success of chlorpromazine led, within a few years, to the development of several other phenothiazine derivatives¹⁴⁹ including fluphenazine,¹⁵⁰ perphenazine,¹⁵¹ thioridazine,¹⁵² and trifluoperazine,¹⁵³ as well as other compounds that had different chemical structures but very similar abilities to quell psychotic symptoms.¹⁵⁴

Because appellate court decisions and other legal publications often emphasize the adverse effects of older antipsychotic drugs, it is worth pausing to consider what life for psychotic patients was like before the advent of chlorpromazine and other antipsychotic drugs. “Before the introduction of chlorpromazine in 1953, most individuals with

and he escaped to the cave of Adullam. *Id.* at 454. The story implies that madness (not to mention malingering) was recognized during the time of Saul, or at the latest by the time that the books of *Samuel* were set down. Current biblical scholarship places Saul’s reign in the latter half of the 11th century B.C.E., 10 THE NEW ENCYCLOPEDIA BRITANNICA 475 (15th ed. 1998), and places the writing of I *Samuel* in the 6th century B.C.E., *id.* at 381–82.

147. Chlorpromazine is the nonproprietary name for the antipsychotic compound that probably is best known by the trade name Thorazine®, under which it is marketed by GlaxoSmithKline. PDR, *supra* note 49, at 1656. At least three other pharmaceutical firms (Elkins-Sinn, Geneva Pharmaceuticals, and Roxane Laboratories) also market chlorpromazine in the United States. *Id.* at 107.

148. For a fascinating account of the success, impact, and marketing of chlorpromazine in the 1950s, see ANN BRADEN JOHNSON, OUT OF BEDLAM: THE TRUTH ABOUT DEINSTITUTIONALIZATION 40–52 (1990).

149. Phenothiazine antipsychotic drugs all share a basic three-ring structure; their primary chemical differences arise from various moiety substitutions at the nitrogen atom in the middle ring. HYMAN ET AL., *supra* note 9, at 5–7.

150. Fluphenazine is best known by the trade name Prolixin®, *id.* at 6, and currently is marketed in the U.S. as a generic drug by at least five firms, PDR, *supra* note 49, at 112.

151. Perphenazine is marketed in the U.S. under the brand names Trilafon® and Etrafon®, PDR, *supra* note 49, at 123.

152. Thioridazine is best known by the trade name Mellaril®, HYMAN ET AL., *supra* note 9, at 6, and currently is marketed in the U.S. as the generic drug by four firms, PDR, *supra* note 49, at 129.

153. Trifluoperazine is marketed as Stelazine® by GlaxoSmithKline, and generically by two other firms, PDR, *supra* note 49, at 130.

154. In the mid-1990s, commonly prescribed nonphenothiazine antipsychotic compounds included haloperidol (Haldol®), loxapine (Loxitane®), molindone (Moban®), and thiothixene (Navane®). HYMAN ET AL., *supra* note 9, at 6–8. The older antipsychotic drugs differ at least fifty-fold in their *potency*, and therefore the dosages of these drugs differ greatly. However, “each of these agents has been found to be equally effective in treating psychotic disorders.” *Id.* at 7.

schizophrenia were destined to spend their entire adult lives within large, often remote psychiatric hospitals.”¹⁵⁵ By 1955, U.S. state mental hospitals housed more than one-half million persons,¹⁵⁶ many of whom suffered from psychotic disorders; patients often spent years and decades living in horrifying, wretched conditions. Writes Ann Braden Johnson:

If you have ever spent time with a floridly psychotic person who is expressing himself in behavior that was supposed to have been extinguished in childhood, you will never forget how terrifying it is to see someone so utterly out of control. But now imagine yourself in a huge, old building that is visibly falling apart, in charge of sixty to eighty adults, all acting like one-, two-, and three-year-olds in mid-tantrum—such were the patients that the state hospitals, alone and unaided, kept in their wards for over a hundred years [from the mid-19th to the mid-20th centuries]. A doctor from that era described a women’s ward at New York’s Pilgrim State Hospital before the introduction of phenothiazines:

[They were] so wild I couldn’t keep them decent. They’d soil themselves, tear their clothes off, smash the windows, and gouge the plaster out of the walls. One of them would even rip radiators right off the wall. We’d sometimes have to surround them with mattresses in order to give them sedative injections, and these would help for a while, but then they’d get addicted to the sedative and we’d have to take them off it.

....

... [T]he new drugs made the wholesale removal of patients from hospitals imaginable and then possible, which in the end became one of the most effective selling points of the new medications.¹⁵⁷

The long-term course for persons with schizophrenia is not necessarily one of inevitable deterioration, even when those with the disorder do not

155. Goff, *supra* note 124, at 3253–54.

156. H. Richard Lamb & Linda E. Weinberger, *Persons With Severe Mental Illness in Jails and Prisons: A Review*, 49 PSYCHIATRIC SERVICES 483, 486 (1998) (stating that 559,000 patients were in state psychiatric hospitals in 1955). By contrast, in 1998, there were just 63,525 hospital beds in the nation’s state and county psychiatric hospitals. Liz Lipton, *Few Safeguards Govern Elimination of Psychiatric Beds*, PSYCHIATRIC NEWS, Aug. 3, 2001, at 9, <http://pn.psychiatryonline.org/cgi/content/full/36/15/9>. Many psychiatrists attribute the decline in state hospital beds *solely* to antipsychotic medication. See JOHNSON, *supra* note 148, at 38–39. But according to Ronald Manderscheid, Chief of the Survey and Analysis Branch, Division of State and Community Systems Development, for the federal Center for Mental Health Services:

One key reason for this decline is that, because of the federal Institution for Mental Diseases . . . exclusion [in Medicaid law], Medicaid does not pay for the hospitalization of persons between the ages of 21 and 64 in state and county facilities. Thus, these patients were sent to community and general hospitals, which could be reimbursed. . . .

. . . [Other reasons are] the development of new treatment approaches and new psychiatric medications including the introduction of the antipsychotic thiorazine in 1954, the effort by states to save money by moving patients out of state hospitals to other forms of care, and the effort to move people into the community

Lipton, *supra*, at 9 (quoting Dr. Manderscheid) (alteration in original).

157. JOHNSON, *supra* note 148, at 45–46 (alteration in original) (quoting Morton M. Hunt, *Pilgrim’s Progress*, NEW YORKER, Sept. 30, 1961, at 71).

take antipsychotic drugs or take them erratically.¹⁵⁸ Yet, the value and importance of antipsychotic medication is unmistakable. By virtue of their ability to control psychotic symptoms, chlorpromazine and subsequently developed drugs contributed importantly to the deinstitutionalization of mental illness, and a ninety percent decrease in the number of patients held in state hospitals.¹⁵⁹ To anyone familiar with the conditions under which hospitalized patients existed before effective antipsychotic medication became available, it is hard to disagree with the 1961 report of the Joint Commission on Mental Illness and Health: “Unquestionably, the drugs have delivered the greatest blow for patient freedom, in terms of nonrestraint, since Pinel struck off the chains of the lunatics in the Paris asylum 168 years ago.”¹⁶⁰

158. Wayne S. Fenton & Thomas H. McGlashan, *Sustained Remission in Drug-Free Schizophrenic Patients*, 144 AM. J. PSYCHIATRY 1306, 1306 (1987); Thomas H. McGlashan, *A Selective Review of Recent North American Long-Term Followup Studies of Schizophrenia*, 14 SCHIZOPHRENIA BULL. 515, 515 (1988). However, many psychiatrists are convinced that early pharmacological intervention in schizophrenia can improve the long-term course of the disorder, and some psychiatrists even propose treating persons who merely have prodromal symptoms of schizophrenia. For a discussion of this idea, see Thomas H. McGlashan, *Psychosis Treatment Prior to Psychosis Onset: Ethical Issues*, 51 SCHIZOPHRENIA RES. 47, 47 (2001) (“Compelling but tentative evidence suggests that early treatment may improve course and prognosis, and this has initiated a paradigm shift in thinking about the risks and benefits of early intervention.”). Also, some psychiatrists have used novel agents to reverse cognitive deficits in nonpsychotic relatives of persons with schizophrenia. See Ming T. Tsuang et al., *Treatment of Nonpsychotic Relatives of Patients with Schizophrenia: Four Case Studies*, 45 BIOLOGICAL PSYCHIATRY 1412, 1412 (1999) (finding that risperidone produced “reductions in negative symptoms, and . . . substantial improvements on some tests of attention and working memory”); see also *infra* notes 206–07 and accompanying text.

159. See Timothy A. Kelly, *Heritage Foundation Backgrounder No. 1522: A Policymaker's Guide to Mental Illness*, Heritage Foundation, at <http://www.heritage.org/Research/HealthCare/BG1522.cfm> (Mar. 7, 2002):

In the early 20th century, asylums became “mental hospitals,” and the numbers of Americans committed within their walls grew substantially, reaching a high of nearly 560,000 in 1955. . . .

In the mid-1950s, the discovery of antipsychotic medications such as chlorpromazine sparked a revolution in mental hospitals. These new medications controlled psychotic symptoms, and for the first time, people with schizophrenia and other psychotic disorders could be discharged and returned to their home communities. The census of mental hospitals began a dramatic drop in their rolls, which now stand at just over 55,000.

160. JOHNSON, *supra* note 148, at 46 (quoting JOINT COMM'N ON MENTAL ILLNESS AND HEALTH, ACTION FOR MENTAL HEALTH 39 (1961)).

B. How Antipsychotic Drugs Work: A Puzzle

Although medical scientists had no trouble recognizing and demonstrating *that* these first antipsychotic drugs were useful, it took several years before they could be sure *what* these compounds did. In 1963, Carlsson and Lindqvist¹⁶¹ offered what came to be termed the “dopamine hypothesis” of schizophrenia, which in its most simplistic form suggested that schizophrenia resulted from an excess of dopamine.¹⁶² The dopamine hypothesis drew support from observations that hallucinations and delusions could be induced by high doses of amphetamines and other drugs that increase brain levels of dopamine¹⁶³ and from the finding that the potency of *all* then available antipsychotic drugs was directly proportional to their ability to block the dopamine-D₂ receptor.¹⁶⁴

By the 1980s, many lines of evidence had made it clear that the simplistic excess dopamine hypothesis was inadequate to explain the causes and phenomena of schizophrenia and other psychotic disorders. For example, compounds such as phencyclidine (PCP) and the anesthetic ketamine can cause florid psychoses even though they have little direct effect on brain dopamine activity.¹⁶⁵ Also, it was recognized that in

161. See Arvid Carlsson & Margit Lindqvist, *Effect of Chlorpromazine and Haloperidol on Formation of 3-Methoxytyramine and Normetanephrine in Mouse Brain*, 20 ACTA PHARMACOLOGICA ET TOXICOLOGICA 140 (1963) (finding that after administration of antipsychotic drugs, extracellular dopamine was not increased, but its metabolites were, which suggested that the drugs blocked dopamine receptors and activated feedback pathways).

162. GOODMAN AND GILMAN'S THE PHARMACOLOGICAL BASIS OF THERAPEUTICS 389 (7th ed. 1985).

163. *Id.* at 168, 553–54; see Yoshimoto Sekine et al., *Methamphetamine-Related Psychiatric Symptoms and Reduced Brain Dopamine Transporters Studied With PET*, 158 AM. J. PSYCHIATRY 1206 (2001) (discussing the long-term impact of methamphetamine on dopamine transporter density, and its relationship to psychotic symptoms).

164. See *supra* Part II.A.3.f. For a recent description of still valid aspects of the dopamine hypothesis and confirmatory findings from brain imaging studies, see Anissa Abi-Dargham et al., *Increased Baseline Occupancy of D₂ Receptors by Dopamine in Schizophrenia*, 97 PROC. NAT'L ACAD. SCI. U.S. 8104, 8104, 8109 (2000) (also showing “direct *in vivo* evidence that schizophrenia is associated with excessive stimulation of D₂ receptors by dopamine [as opposed to excess dopamine *simpliciter*], and that this dysregulation is predictive of good treatment response to antipsychotic drugs”).

165. In 1979 the ability of ketamine and phencyclidine to mimic psychoses was found to be related to interaction by the drugs with a unique receptor; once bound to this receptor, phencyclidine is not displaced by dopamine or other chemically similar neurotransmitters. J.P. Vincent et al., *Interaction of Phencyclidine (“Angel Dust”) with a Specific Receptor in Rat Brain Membranes*, 76 PROC. NAT'L ACAD. SCI. U.S. 4678, 4678 (1979); S.R. Zukin & R.S. Zukin, *Specific [3H]Phencyclidine Binding in Rat Central Nervous System*, 76 PROC. NAT'L ACAD. SCI. U.S. 5372, 5372 (1979). For this reason, the psychotic symptoms induced by phencyclidine are not reversed by antipsychotic drugs. For a recent explanation of the effects of ketamine and phencyclidine, see generally Ilana Zylberman et al., *Phencyclidine Use Disorders*, in 1

many cases, the hallmark symptoms of schizophrenia that are mimicked by overdoses of dopaminergic¹⁶⁶ drugs, including hallucinations and delusional thinking, often could be alleviated without having much impact on a patient's functioning. Increasingly, psychiatrists recognized that the positive symptoms could be less devastating to a person's functioning and long-term outcome than the negative symptoms that afflict many persons with schizophrenia.¹⁶⁷ Some evidence suggested that negative symptoms such as deficits in a patient's interest in surroundings, volume of communication, and social relationships, might, in fact, be related to a dearth of dopaminergic activity in certain areas of the brain.¹⁶⁸

PSYCHIATRY 827 (Allan Tasman et al. ed., 1997).

166. That is, "activated or transmitted by dopamine . . . pertaining to tissues or organs affected by dopamine." DORLAND'S, *supra* note 3, at 540.

167. See Nancy C. Andreasen et al., *Positive and Negative Symptoms in Schizophrenia: A Critical Reappraisal*, 47 ARCHIVES GEN. PSYCHIATRY 615, 615 (1990) (affirming the validity of the negative subtype of schizophrenia, which "may be characterized by a variety of hypothesized correlates of structural brain abnormality, including . . . poor response to treatment"); Wayne S. Fenton & Thomas H. McGlashan, *Antecedents, Symptom Progression, and Long-Term Outcome of the Deficit Syndrome in Schizophrenia*, 151 AM. J. PSYCHIATRY 351, 351 (1994) ("[D]eficit syndrome was associated with a very high risk of poor outcome and long-term disability."); Wayne S. Fenton & Thomas H. McGlashan, *Natural History of Schizophrenia Subtype: II. Positive and Negative Symptoms and Long-Term Course*, 48 ARCHIVES GEN. PSYCHIATRY 978, 978 (1991) (having "many negative symptoms was associated with poor premorbid functioning, insidious onset, partial or no remissions during the first several years of illness, and in most cases a progressive course leading to permanent disability"). "Positive schizophrenia is characterized by prominent delusions, hallucinations, positive formal thought disorder, and persistently bizarre behavior; negative schizophrenia, by affective flattening, alogia, avolition, anhedonia, and attentional impairment." Nancy C. Andreasen & Scott Olsen, *Negative v. Positive Schizophrenia*, 39 ARCHIVES GEN. PSYCHIATRY 789, 789 (1982).

168. See David Pickar et al., *Neurochemical and Neural Mechanisms of Positive and Negative Symptoms in Schizophrenia*, in 24 MODERN PROBLEMS OF PHARMACOPSYCHIATRY 124-51 (Nancy C. Andreasen ed., 1990) (linking deficit symptoms to functional frontal dopamine dysfunction); Terry E. Goldberg et al., *Cognitive and Behavioral Effects of the Coadministration of Dextroamphetamine and Haloperidol in Schizophrenia*, 148 AM. J. PSYCHIATRY 78, 78 (1991) (finding that the addition of amphetamine, a dopaminergic drug, to schizophrenic patients' medication regimen improved some aspects of cognition, motivation, and affect); Jonathan D. Cohen & David Servan-Schreiber, *A Theory of Dopamine Function and Its Role in Cognitive Deficits in Schizophrenia*, 19 SCHIZOPHRENIA BULL. 85, 85 (1993) (noting that a computer model suggested that dopamine deficiency is responsible for cognitive deficits observed in persons with schizophrenia); Kenneth L. Davis et al., *Dopamine in Schizophrenia: A Review and Reconceptualization*, 148 AM. J. PSYCHIATRY 1474, 1474 (1991) (suggesting "that schizophrenia is characterized by abnormally low prefrontal dopamine activity (causing deficit symptoms) leading to excessive dopamine activity in

C. Problems Associated with Older Drugs

Although the D₂ blockers that were available before 1990 were clearly beneficial, they had serious limitations and drawbacks. They reduced many patients' psychotic symptoms but they did not help all patients that suffered from schizophrenia or other psychotic disorders. Studies reviewing the effectiveness of older antipsychotic drugs in schizophrenia typically reported that fifty to seventy-five percent of patients have "a moderate to excellent response and up to ninety percent of patients show[] some response,"¹⁶⁹ which implies that ten to fifty percent of patients show no response or only a partial one. Many patients who do respond to older antipsychotic agents experience noticeable, but only partial, reduction in their positive symptoms¹⁷⁰ and little improvement in their cognitive impairments and negative symptoms.¹⁷¹

Pre-1990s antipsychotic drugs also consistently cause a constellation of side effects known as "extrapyramidal symptoms,"¹⁷² including stiffness, diminished facial expression, tremors, and restlessness.¹⁷³ Indeed, the pronounced effects of these drugs on many aspects of the nervous system led to their being termed "neuroleptics," a combination of the Greek words νεύρου (nerve) and ληψις (to take hold).¹⁷⁴ Patients often will quit taking their medication because these side effects are esthetically unappealing and intensely unpleasant to experience.¹⁷⁵ As Dr. Samuel Keith noted, "[e]stimates of 40 percent rates of noncompliance

mesolimbic dopamine neurons (causing positive symptoms)").

169. Daniel P. Van Kammen & Stephen R. Marder, *Dopamine Receptor Antagonists*, in 2 COMPREHENSIVE TEXTBOOK OF PSYCHIATRY/VI, at 1987 (Harold I. Kaplan & Benjamin J. Sadock eds., 6th ed. 1995).

170. HYMAN ET AL., *supra* note 9, at 16.

171. Lisa B. Dixon et al., *Conventional Antipsychotic Medications for Schizophrenia*, 21 SCHIZOPHRENIA BULL. 567, 572 (1995); Herbert Y. Meltzer & Susan R. McGurk, *The Effects of Clozapine, Risperidone, and Olanzapine on Cognitive Function in Schizophrenia*, 25 SCHIZOPHRENIA BULL. 233, 235 (1999) (seeing "some evidence" that neuroleptics "cause selective impairment of some cognitive functions").

172. The term "extrapyramidal" refers to those neurons involved in controlling movements that lie outside the "pyramidal tracts." DORLAND'S, *supra* note 3, at 638. The pyramidal tract "provides for direct cortical control and initiation of skilled movements, especially those related to speech and involving the hand and fingers." *Id.* at 1861. "Extrapyramidal system" is "an imprecise term referring to a functional rather than an anatomical part of the central nervous system[;] . . . it includes . . . [brain structures that] control and coordinate especially the postural, static, supporting, and locomotor mechanisms." *Id.* at 1776.

173. Keith, *supra* note 113, at 851.

174. DORLAND'S, *supra* note 3, at 1210. The French psychiatrists Delay and Deniker coined the term "neuroleptic" in 1955. JOHNSON, *supra* note 148, at 40.

175. The classic study on this topic is Theodore Van Putten, *Why Do Schizophrenic Patients Refuse to Take Their Drugs?*, 31 ARCHIVES GEN. PSYCHIATRY 67, 70 (1974) (stating that antipsychotic noncompliance is strongly associated with extrapyramidal involvement, especially akathisia, the subjective experience of restlessness).

among patients treated with [older] antipsychotic agents were not unusual; when noncompliance was combined with the therapeutic limitations of the drugs, rates of relapse were quite high.”¹⁷⁶ In addition, many patients who take neuroleptics develop permanent and sometimes disabling neuromotor syndromes such as tardive dyskinesia (TD),¹⁷⁷ and a small fraction of patients develop a severe and sometimes fatal reaction to these drugs called “neuroleptic malignant syndrome.”¹⁷⁸

D. “Novel” Agents: A New View of Treatment

1. Clozapine

Although U.S. psychiatrists did not begin prescribing atypical antipsychotic agents extensively until the mid-1990s, the FDA’s approval of clozapine in late 1989¹⁷⁹ paved the way for this change in psychiatrists’ practices.

176. Keith, *supra* note 113, at 851; *see also* Van Putten, *supra* note 175, at 67 (commenting that forty-six percent of patients took less medication than was prescribed, probably to avoid distress related to extrapyramidal side effects); Joyce A. Cramer & Robert Rosenheck, *Compliance with Medication Regimens for Mental and Physical Disorders*, 49 PSYCHIATRIC SERVICES 196, 196 (1998) (analysis of twenty-four reports on antipsychotic drug compliance yielded an average rate of fifty-eight percent, with a range of twenty-four to ninety percent).

177. *See supra* note 9 (describing TD). TD rarely occurs in young individuals who have been exposed to neuroleptics for fewer than three months. HYMAN ET AL., *supra* note 9, at 35. Approximately one-fifth of patients undergoing long-term treatment develop TD; current estimates place the risk of developing TD at approximately five percent per year of neuroleptic exposure. Dilip V. Jeste and Michael J. Caligiuri, *Tardive Dyskinesia*, 19 SCHIZOPHRENIA BULL. 303 (1993) (“The overall mean prevalence of TD among chronically neuroleptic-treated patients is approximately 24 percent. The annual incidence in younger adults is 4 to 5 percent.”). The risk for elderly patients is much higher in their initial year of treatment. *See, e.g.*, Robert A. Sweet et al., *Duration of Neuroleptic Treatment and Prevalence of Tardive Dyskinesia in Late Life*, 52 ARCHIVES GEN. PSYCHIATRY 478, 478 (1995) (noting a twenty-nine percent risk with three to twelve months of drug exposure).

178. This syndrome occurs in one-tenth to one percent of persons receiving neuroleptics, and “is characterized by the development of fever, rigidity, autonomic instability, altered consciousness, . . . [elevated cardiac enzymes,] and raised WBC [white blood cell] count.” Herbert Y. Meltzer & S. Hossein Fatemi, *Treatment of Schizophrenia*, in THE AMERICAN PSYCHIATRIC PRESS TEXTBOOK OF PSYCHOPHARMACOLOGY 760–61 (Alan F. Schatzberg & Charles B. Nemeroff eds., 2d ed. 1998); *see also* HYMAN ET AL., *supra* note 9, at 34.

179. FDA Approves Clozapine for Treatment of Schizophrenia; Careful Monitoring Required, 40 HOSP. COMTY. PSYCHIATRY 1310, 1310 (1989) (requiring FDA approval); Stuart L. Nightingale, *Approval of Clozapine for Refractory Schizophrenia*, 263 J. AM. MED. ASS’N 202, 202 (1990) (requiring FDA approval); *F.D.A. Approves a Backup Therapy for Severe Schizophrenia*, N.Y. TIMES, Oct. 4, 1989, at A24 (reporting FDA approval).

Clozapine was the first truly novel antipsychotic medication to become available in thirty-five years, and was dubbed “atypical” because it could alleviate psychotic symptoms without inducing the extrapyramidal side effects that were the typical, expected accompaniments to therapy with conventional D₂ blockers.¹⁸⁰ Moreover, clozapine works better than conventional neuroleptics. Thirty to sixty percent of schizophrenic patients who do not respond to the older drugs improve when they take clozapine,¹⁸¹ and clozapine may also be better at reducing negative symptoms than the conventional antipsychotic drugs.¹⁸² Clozapine achieves these superior therapeutic results with a much lower likelihood of extrapyramidal symptoms and the damaging neuromotor syndromes that are associated with neuroleptic drugs.¹⁸³

Patients who take clozapine for extended periods incur a small risk of developing agranulocytosis,¹⁸⁴ a potentially fatal side effect in which the

180. Michael J. Owens & S. Craig Risch, *Atypical Antipsychotics*, in THE AMERICAN PSYCHIATRIC PRESS TEXTBOOK OF PSYCHOPHARMACOLOGY, *supra* note 178, at 323, 333. In 1993, psychiatrist Jeffrey Lieberman proposed what many clinicians now regard as the defining characteristics of an atypical antipsychotic drug. These include “pre-clinical” (that is, laboratory findings often worked out in animals) evidence of efficacy and nontoxicity, and the following three “clinical” criteria: (1) effectiveness in reducing psychotic symptoms, (2) little or no induction of extrapyramidal symptoms and tardive dyskinesia, and (3) no elevation of prolactin (a hormone involved in breast milk production, secretion of which is increased in men and women who take typical antipsychotics). Jeffrey A. Lieberman, *Understanding the Mechanism of Action of Atypical Antipsychotic Drugs: A Review of Compounds in Use and Development*, 163 BRIT. J. PSYCHIATRY 7, 7–18 (Supp. 22, 1993).

181. For the landmark study reporting clozapine’s efficacy in patients who had failed to benefit from neuroleptics, see John Kane et al., *Clozapine for the Treatment-Resistant Schizophrenic: A Double-Blind Comparison with Chlorpromazine*, 45 ARCHIVES GEN. PSYCHIATRY 789, 789–96 (1988) (demonstrating improvement in thirty percent of previously refractory patients over a six-week period, compared with just four percent of patients who received chlorpromazine). Subsequent studies looking at treatment refractory patients treated with clozapine for longer periods have yielded higher estimated rates of improvement. See, e.g., John M. Kane et al., *Clozapine and Haloperidol in Moderately Refractory Schizophrenia: A 6-Month Randomized and Double-Blind Comparison*, 58 ARCHIVES GEN. PSYCHIATRY 965, 965 (2001) (showing a fifty-seven percent response rate); Jeffrey A. Lieberman et al., *Clinical Effects of Clozapine in Chronic Schizophrenia: Response to Treatment and Predictors of Outcome*, 151 AM. J. PSYCHIATRY 1744, 1744 (1994) (showing a fifty percent response rate in treatment-refractory patients).

182. David Pickar et al., *Clinical and Biologic Response to Clozapine in Patients with Schizophrenia: Crossover Comparison with Fluphenazine*, 49 ARCHIVES GEN. PSYCHIATRY 345, 348 (1992).

183. Daniel E. Casey, *Effects of Clozapine Therapy in Schizophrenic Individuals at Risk for Tardive Dyskinesia*, 59 J. CLINICAL PSYCHIATRY 31, 31–37 (Supp. 3, 1998); Herz, *supra* note 143, at 17, 19.

184. “Clozapine was first tested in the 1960s but was withdrawn from general use” because of this problem. HYMAN ET AL., *supra* note 9, at 29. Initial estimates placed the risk of agranulocytosis at one percent. *Id.* A more recent estimate sets the risk at only thirty-eight hundredths of a percent. Gilbert Honigfeld, *Effects of the Clozapine National Registry System on Incidence of Deaths Related to Agranulocytosis*, 47

bone marrow stops making the white blood cells responsible for fighting bacterial infections.¹⁸⁵ Due to this risk, patients who take clozapine must be monitored with frequent blood tests. When clozapine was initially released, it was “bundled”¹⁸⁶ by its manufacturer, Sandoz Pharmaceuticals, with a mandatory “Clozaril Patient Management System” (CPMS) that required weekly blood tests to be performed by Caremark, a home health care division of Baxter International Inc.¹⁸⁷ The cost of the monitoring was built into the cost of drug and was estimated to run around \$9,000 a year.¹⁸⁸ Even after clozapine therapy was “unbundled”¹⁸⁹ to allow testing by a broader variety of agencies, psychiatrists recommended that the blood tests should be performed weekly for as long as a patient took clozapine and more frequently if tests suggested an abnormality might be developing. By the mid-1990s, it was recognized that if a patient taking clozapine was going to develop agranulocytosis at all, this complication usually would occur during the first six months of exposure to the drug. Currently, therefore, blood tests are performed each week for the first six months of therapy and every two weeks thereafter. Clozapine remains available only through monitoring protocols under which pharmacists do not dispense the medication until they have determined that a patient’s blood has been tested and that the laboratory values are satisfactory.¹⁹⁰

Factors such as inconvenience to patients, medical risks,¹⁹¹ the costs of

PSYCHIATRIC SERVICES 52, 56 (1996).

185. DORLAND’S, *supra* note 3, at 40, 984; Philip A. Pizzo, *The Compromised Host*, in 2 CECIL TEXTBOOK OF MEDICINE 1571 (Lee Goldman & J. Claude Bennet eds., 21st ed. 2000).

186. The initial bundling of clozapine raised antitrust issues. See Sanzo, *supra* note 33, at 1224–25; Swidler, *supra* note 33, at 666–72; and Hurwitz, *supra* note 33, at 1215–20.

187. HYMAN ET AL., *supra* note 9, at 29; Carl Salzman, *Mandatory Monitoring for Side Effects: The “Bundling” of Clozapine*, 323 NEW ENG. J. MED. 827, 827 (1990); Hurwitz, *supra* note 33, at 1190.

188. Hurwitz, *supra* note 33, at 1190; Daniel Goleman, *Outcry Grows Over Method of Selling New Drug*, N.Y. TIMES, Sept. 27, 1990, at B9 (annual cost of bundled treatment was \$8944).

189. Because Sandoz’s bundling made the drug very expensive in the United States, the program was assailed by physicians, patient advocacy groups, and Congress. Milt Freudenheim, *Maker of Schizophrenia Drug Bows to Pressure to Cut Cost*, N.Y. TIMES, Dec. 6, 1990, at A1.

190. PDR, *supra* note 49, at 2320.

191. Several other serious medical problems may be associated with clozapine therapy. The potential to develop seizures was well recognized when the drug was released in the U.S., as were other less serious but potentially troublesome problems (for example, sedation and drooling). The Medical Letter, Inc., *Clozapine for Schizophrenia*,

blood testing, the high price of the drug itself,¹⁹² FDA restrictions on approved indications for clozapine's use,¹⁹³ and the initial reluctance of third party payers to support such expensive therapy¹⁹⁴ led psychiatrists

32 MED. LETTER DRUGS & THERAPEUTICS 3, 3–4 (1990). Potential for weight gain and associated medical problems (for example, diabetes mellitus, and hyperlipidemia) were better appreciated after several years of the drugs' use. Michael Davidson, *Risk of Cardiovascular Disease and Sudden Death in Schizophrenia*, 63 J. CLINICAL PSYCHIATRY 5, 6–8 (Supp. 9, 2002) (summarizing the results of studies); Bruce D. Gaulin et al., *Clozapine-Associated Elevation in Serum Triglycerides*, 156 AM. J. PSYCHIATRY 1270 (1999) (reporting that men treated with clozapine have higher follow-up serum triglyceride concentrations in blood); David C. Henderson et al., *Clozapine, Diabetes Mellitus, Weight Gain, and Lipid Abnormalities: A Five-year Naturalistic Study*, 157 AM. J. PSYCHIATRY 975, 979 (2000) (reporting high rates of weight gain, diabetes, and hyperlipidemia in patients who took clozapine for extended periods); Brian C. Lund et al., *Clozapine Use in Patients with Schizophrenia and the Risk of Diabetes, Hyperlipidemia, and Hypertension: A Claims-Based Approach*, 58 ARCHIVES GEN. PSYCHIATRY 1172, 1174 (2001) (reporting that clozapine appears not to directly cause diabetes or hyperlipidemia, but may make people more susceptible to these disorders by inducing weight gain); Prakash Masand & Sanjay Gupta, *Long-Term Adverse Effects of Novel Antipsychotics*, 6 J. PSYCHIATRIC PRACTICE 299, 301–04 (2000).

192. In 1997, Keith estimated the cost of clozapine to be “about \$6,000 a year at [his] institution—and the additional cost of the weekly blood monitoring [was] about \$1,000 a year.” Keith, *supra* note 113, at 852. In a study conducted at VA facilities, per capita pharmacy costs in clozapine-treated patients were \$3199 a year. Robert Rosenheck et al., *A Comparison of Clozapine and Haloperidol in Hospitalized Patients with Refractory Schizophrenia*, 337 NEW ENG. J. MED. 809, 812 (1997).

193. Clozapine had been available in some European countries for many years, during which its potentially fatal association with agranulocytosis had become apparent. Thus, the FDA's requirements for approving clozapine were quite stringent. The FDA “required a demonstration of efficacy in patients whose disease was refractory to treatment with standard antipsychotic drugs. No other antipsychotic drug had ever been required to meet such a standard.” Keith, *supra* note 113, at 852.

The *Physicians' Desk Reference* still contains a warning, in boldfaced capital letters, to reserve clozapine therapy for “severely ill schizophrenic patients who fail to show an acceptable response to adequate courses of standard antipsychotic drug treatment.” PDR, *supra* note 49, at 2319. “However, ongoing clinical research investigations suggest the clinical utility of clozapine, alone or in combination with other psychotropics, in patients with schizoaffective disorder and refractory bipolar disorder (manic or depressed), as well as during the early stages . . . of schizophrenia.” Owens & Risch, *supra* note 180, at 333; see also Susan L. McElroy et al., *Clozapine in the Treatment of Psychotic Mood Disorders, Schizoaffective Disorder and Schizophrenia*, 52 J. CLINICAL PSYCHIATRY 411, 411 (1991). Successful, safe use of clozapine has also been reported in self-mutilating, but not psychotic, patients with borderline personality disorder. See Frances R. Frankenburg & Mary C. Zanarini, *Clozapine Treatment of Borderline Patients: A Preliminary Study*, 34 COMPREHENSIVE PSYCHIATRY 402 (1993); K. N. Roy Chengappa et al., *Clozapine Reduces Severe Self-Mutilation and Aggression in Psychotic Patients with Borderline Personality Disorder*, 60 J. CLINICAL PSYCHIATRY 477, 483 (1999).

194. The expense of this new treatment caused some state Medicaid programs to be reluctant to financially support clozapine therapy. In two of the first published cases involving clozapine, courts ruled that Medicaid programs were obligated to make clozapine available to beneficiaries when doctors felt that the drug was medically necessary. *Visser v. Taylor*, 756 F. Supp. 501, 507 (D. Kan. 1990); *Alexander L. v. Cuomo*, 588 N.Y.S.2d 85, 88 (Sup. Ct. 1991).

to prescribe clozapine only to patients who clearly could not benefit from, or who could not tolerate, other available antipsychotic drugs. In the early 1990s, these drugs included only conventional neuroleptics, so psychiatrists continued to view the older D₂ blockers as the “first-line” therapy for their psychotic patients. Nonetheless, clozapine signified both to psychiatrists and to patients that the potential benefits from antipsychotic drugs might be far greater than had been the case during the preceding decades.

2. Novel Agents for “First-Line” Use

The January 1994¹⁹⁵ entrance of risperidone¹⁹⁶ into the U.S. pharmacopeia dramatically altered treatment prospects for patients with psychotic disorders and initiated a change in the drugs that U.S. psychiatrists selected to treat psychoses. After the release of risperidone, U.S. psychiatrists could offer a novel antipsychotic agent as *initial* therapy for schizophrenia. Risperidone, and the more recently released olanzapine,¹⁹⁷ quetiapine,¹⁹⁸ and ziprasidone¹⁹⁹ are not associated with a substantial risk of agranulocytosis, and the recipients of these drugs do not require any special medical monitoring.²⁰⁰ Olanzapine, quetiapine, risperidone, and ziprasidone all appear to have several advantages over older neuroleptics: (1) The novel agents all treat positive symptoms at least as effectively as conventional neuroleptics, but they accomplish this with a much lower frequency and intensity of the noxious neuromotor side effects caused by the older D₂ blockers.²⁰¹ It appears

195. Reuters, *Johnson & Johnson Drug for Schizophrenia Is Approved*, N.Y. TIMES, Jan. 4, 1994, at D5.

196. Risperidone is the nonproprietary name for the product marketed as Risperdal® by Janssen Pharmaceutica. PDR, *supra* note 49, at 1796.

197. Olanzapine is marketed as Zyprexa® by Eli Lilly & Company. PDR, *supra* note 49, at 1973. It was approved for general use in October 1996. Associated Press, *A New Drug for Schizophrenia Wins Approval from the F.D.A.*, N.Y. TIMES, Oct. 2, 1996, at A21.

198. Quetiapine received FDA approval in 1997. *Zeneca Given FDA Go-Ahead for Seroquel*, INDEP. (London), Aug. 2, 1997, at 19. The drug is marketed as Seroquel® by AstraZeneca Pharmaceuticals LP. PDR, *supra* note 49, at 684–85.

199. Ziprasidone, marketed by Pfizer Inc. as Geodon®, is the most recent novel agent to receive FDA approval; it was introduced in the U.S. in early 2001. PDR, *supra* note 49, at 2688, 2692; Scott Hensley, *Schizophrenia Drug from Pfizer Wins FDA's Approval*, WALL STREET J., Feb. 6, 2001, at B21.

200. Herz, *supra* note 143, at 20–23.

201. See Jibson & Tandon, *supra* note 20, at 223 (graphically summarizing the advantages, in terms of neuromotor side effects). The details of studies are reported in

that the aripiprazole, a not-yet-approved novel agent, derives its atypicality from being a mixed agonist-antagonist of the dopamine-D₂ receptor.²⁰² (2) Not only is the level of extrapyramidal side effects much lower with newer agents, but the risk of developing tardive dyskinesia is

numerous articles. See Richard L. Borison et al., *ICI 204,636, an Atypical Antipsychotic: Efficacy and Safety in a Multicenter, Placebo-Controlled Trial in Patients with Schizophrenia*, 16 J. CLINICAL PSYCHOPHARMACOLOGY 158, 169 (1996) (reporting that risperidone is at least as effective as haloperidol with far lower incidence of extrapyramidal side effects); Guy Chouinard et al., *A Canadian Multicenter Placebo-Controlled Study of Fixed Doses of Risperidone and Haloperidol in the Treatment of Chronic Schizophrenic Patients*, 13 J. CLINICAL PSYCHOPHARMACOLOGY 25, 25 (1993) (reporting that risperidone is at least as effective as haloperidol with far lower incidence of extrapyramidal side effects); Donald C. Goff et al., *An Exploratory Haloperidol-Controlled Dose-Finding Study of Ziprasidone in Hospitalized Patients with Schizophrenia or Schizoaffective Disorder*, 18 J. CLINICAL PSYCHOPHARMACOLOGY 296, 296 (1998) (reporting that risperidone is at least as effective as haloperidol with far lower incidence of extrapyramidal side effects); Gary D. Tollefson et al., *Olanzapine Versus Haloperidol in the Treatment of Schizophrenia and Schizoaffective and Schizophreniform Disorders: Results of an International Collaborative Trial*, 154 AM. J. PSYCHIATRY 457, 457 (1997) (reporting that olanzapine is at least as effective as haloperidol with far lower incidence of extrapyramidal side effects).

These studies all compared the newer drugs to haloperidol well above patients' neuroleptic threshold, that is, the minimum dose needed to produce modest extrapyramidal side effects. For an important study of the neuroleptic threshold and its dosing implications, see Joseph P. McEvoy et al., *Optimal Dose of Neuroleptic in Acute Schizophrenia: A Controlled Study of the Neuroleptic Threshold and Higher Haloperidol Dose*, 48 ARCHIVES GEN. PSYCHIATRY 739, 739-45 (1991). Some writers believe the side effect evidence might have been less favorable toward the novel drugs had the studies used lower haloperidol doses. Shitij Kapur et al., *supra* note 99, at 291-92. See also discussion *infra* Part IV.B.1 (discussing the impact of neuroleptic dosing on apparent advantages of the newer drugs).

Despite this, most psychiatrists agree that the new drugs are an enormous boon to patients, their families, and clinicians. Meltzer & Fatemi, *supra* note 178, at 769. For a meta-analytic summary of the properties and advantages of the new drugs, see S. Leucht et al., *Efficacy and Extrapyramidal Side-Effects of the New Antipsychotics Olanzapine, Quetiapine, Risperidone, and Sertindole Compared to Conventional Antipsychotics and Placebo: A Meta-Analysis of Randomized Controlled Trials*, 35 SCHIZOPHRENIA RES. 51, 51 (1999) ("All new antipsychotic are associated with less frequent use of antiparkinson [side-effect moderating] medication than haloperidol, with risperidone appearing to have a slightly less favourable EPS-profile than the other new antipsychotics.").

Why novel antipsychotics *are* novel, that is, why they do not cause extrapyramidal side effects at nearly the frequency of the older drugs, is not clear. One explanation of atypical agents' properties may inhere in the "fast dissociation [of atypical agents] from the D₂ receptor [that] makes an antipsychotic more accommodating of physiological dopamine transmission, permitting an antipsychotic effect without motor side effects, prolactin elevation, or secondary negative symptoms." Shitij Kapur & Philip Seeman, *Does Fast Dissociation from the Dopamine D₂ Receptor Explain the Action of Atypical Antipsychotics?: A New Hypothesis*, 158 AM. J. PSYCHIATRY 360, 360 (2001); see also Seeman, *supra* note 95, at 27 (further describing the "fast-off-D₂" theory, in which rapid dissociation from D₂ receptors explains why novel antipsychotics cause fewer side effects).

202. See Stephen M. Stahl, *Dopamine System Stabilizers, Aripiprazole, and the Next Generation of Antipsychotics, Part I: "Goldilocks" Actions at Dopamine Receptors*, 62 J. CLINICAL PSYCHIATRY 841, 841-42 (2001).

lower as well.²⁰³ (3) Available evidence suggests that patients who need antipsychotic medication prefer the novel agents²⁰⁴ and may be better off taking them than the older D₂-blockers.²⁰⁵ (4) One reason for this preference may be that atypical agents leave patients less burdened with negative symptoms than they would be were they to take neuroleptics, possibly because the newer drugs induce less motor slowing.²⁰⁶ (5) A growing number of studies suggest that the atypical antipsychotics are better than the older drugs at ameliorating cognitive deficits that characterize schizophrenia.²⁰⁷ (6) Some psychiatrists believe that the

203. Stanley N. Caroff et al., *Movement Disorders Associated with Atypical Antipsychotic Drugs*, 63 J. CLINICAL PSYCHIATRY 12, 13–16 (Supp. 4, 2002) (summarizing findings from studies); Jibson & Tandon, *supra* note 20, at 224; Masand & Gupta, *supra* note 191, at 304–05. Because novel antipsychotics have lower rates of acute neuroleptic side effects, “it has been suggested that atypical antipsychotics are less likely to cause NMS [neuroleptic malignant syndrome] than conventional antipsychotics. This remains unproven, and cases of NMS associated with clozapine, risperidone, olanzapine, and quetiapine have been reported.” Carie D. Hatch et al., *Failed Challenge with Quetiapine After Neuroleptic Malignant Syndrome with Conventional Antipsychotics*, 21 PHARMACOTHERAPY 1003, 1003 (2001).

204. Shitij Kapur & Gary Remington, *Atypical Antipsychotics: Patients Value the Lower Incidence of Extrapyramidal Side Effects*, 321 BRIT. MED. J. 1360 (2000); Piper S. Meyer et al., *Comparison Between the Effects of Atypical and Traditional Antipsychotics on Work Status for Clients in a Psychiatric Rehabilitation Program*, 63 J. CLINICAL PSYCHIATRY 108, 114 (2002).

205. A. George Awad & Lakshmi N.P. Voruganti, *Quality of Life and New Antipsychotics in Schizophrenia: Are Patients Better Off?*, 45 INT’L J. SOC. PSYCHIATRY 268, 268 (1999).

206. Steven R. Hirsch et al., *A 28-Week Comparison of Ziprasidone and Haloperidol in Outpatients with Stable Schizophrenia*, 63 J. CLINICAL PSYCHIATRY 516, 519 (2002) (reporting that in previously *stable* patients, ziprasidone reduced negative symptoms more than did haloperidol); Beng-Choon Ho et al., *A Comparative Effectiveness Study of Risperidone and Olanzapine in the Treatment of Schizophrenia*, 60 J. CLINICAL PSYCHIATRY 658, 658 (1999) (reporting that olanzapine and risperidone reduced negative symptoms); Jibson & Tandon, *supra* note 20, at 221. Some authors have questioned whether atypicals actually ameliorate the “deficit” negative symptoms intrinsic to schizophrenia, or merely the “secondary” negative symptoms caused by neuroleptic side effects, lack of social stimulation, or intrusion of positive symptoms. William T. Carpenter et al., *Patient Response and Resource Management: Another View of Clozapine Treatment of Schizophrenia*, 152 AM. J. PSYCHIATRY 827, 827 (1995) (“Treatment of primary negative symptoms is not supported by the current experimental data.”).

207. Robert M. Bilder et al., *Neurocognitive Effects of Clozapine, Olanzapine, Risperidone, and Haloperidol in Patients with Chronic Schizophrenia or Schizoaffective Disorder*, 159 AM. J. PSYCHIATRY 1018, 1018, 1024 (2002) (finding that clozapine, risperidone, and olanzapine improved cognitive functioning in patients previously resistant to treatment with neuroleptics and that the atypicals differed in the types of improvements manifested); Robert W. Buchanan et al., *The Comparative Efficacy and Long-Term Effect of Clozapine Treatment on Neuropsychological Test Performance*, 36

newer drugs do more than the older drugs towards improving patients' long-term social functioning, and that this, rather than short-term reduction in positive symptoms, ought to become the basis upon which the benefits of antipsychotic therapy are judged.²⁰⁸

Because the novel antipsychotics appear to represent pharmacologically advantageous ways to treat psychoses, many psychiatrists believe that these drugs have created a new standard of care for antipsychotic therapy. In the mid-1990s, psychiatrists began suggesting that the atypical drugs should be psychiatrists' first choice when selecting an antipsychotic therapy,²⁰⁹ and within a few years, this view became dominant.²¹⁰ That this view represents a rapid and dramatic change in

BIOLOGICAL PSYCHIATRY 717, 717 (1994) (reporting that one year's treatment with clozapine yielded improvements on several measures of cognitive performance); Michael F. Green & David L. Braff, *Translating the Basic and Clinical Cognitive Neuroscience of Schizophrenia to Drug Development and Clinical Trials of Antipsychotic Medications*, 49 BIOLOGICAL PSYCHIATRY 374, 374 (2001) ("Neurocognitive deficits appear to be improved with newer (atypical) antipsychotic medications across a broad range of domains in schizophrenia patients."); Michael Foster Green et al., *Does Risperidone Improve Verbal Working Memory in Treatment-Resistant Schizophrenia?*, 154 AM. J. PSYCHIATRY 799, 799 (1997) (reporting improved verbal working memory); Corinne Hagger et al., *Improvement in Cognitive Functions and Psychiatric Symptoms in Treatment-Refractory Schizophrenic Patients Receiving Clozapine*, 34 BIOLOGICAL PSYCHIATRY 702, 702 (1993) (reporting improvement in retrieval from reference memory); Meltzer & McGurk, *supra* note 171, at 233 (reporting that risperidone produces "relatively consistent positive effects on working memory, executive functioning, and attention"); Scot E. Purdon et al., *Neuropsychological Change in Early Phase Schizophrenia During 12 Months of Treatment with Olanzapine, Risperidone, or Haloperidol*, 57 ARCHIVES GEN. PSYCHIATRY 249, 254 (2000) (reporting that olanzapine treatment is associated with improved immediate recall and nonverbal fluency); Dawn I. Velligan et al., *Does Cognitive Function Improve with Quetiapine in Comparison to Haloperidol?*, 53 SCHIZOPHRENIA RES. 239, 239, (2002) (stating that patients taking quetiapine improved more than patients taking haloperidol on overall measures of cognitive function, including verbal fluency, attention, and verbal memory, which are "domains of cognitive performance that have been found to predict role function and community outcomes").

208. Anthony F. Lehman, *Developing an Outcomes-Oriented Approach for the Treatment of Schizophrenia*, 60 J. CLINICAL PSYCHIATRY 30, 30 (Supp. 19, 1999); Sandra L. Tunis et al., *Changes in Perceived Health and Functioning as a Cost-Effectiveness Measure for Olanzapine Versus Haloperidol Treatment of Schizophrenia*, 60 J. CLINICAL PSYCHIATRY 38, 38 (Supp. 19, 1999).

209. Jeffrey A. Lieberman, *Atypical Antipsychotic Drugs as a First-Line Treatment of Schizophrenia: A Rationale and Hypothesis*, 57 J. CLINICAL PSYCHIATRY 68, 68 (Supp. 11, 1996) (offering "a rationale and hypothesis for the use of atypical antipsychotic drugs as a first-line treatment of schizophrenia").

210. John A. Chiles et al., *The Texas Medication Algorithm Project: Development and Implementation of the Schizophrenia Algorithm*, 50 PSYCHIATRIC SERVICES 69, 72 (1999); Neil S. Kaye & Thomas J. Reed, *Tardive Dyskinesia: Tremors in Law and Medicine*, 27 J. AM. ACAD. PSYCHIATRY L. 315, 316 (1999); Alexander L. Miller et al., *The Texas Medication Algorithm Project (TMAP) Schizophrenia Algorithms*, 60 J. CLINICAL PSYCHIATRY 649, 652 (1999); Rowland Pearsall et al., *A New Algorithm for Treating Schizophrenia*, 34 PSYCHOPHARMACOLOGY BULL. 349, 349 (1998) (suggesting that the "newer atypical agents may now be the treatment of choice for initiating therapy

psychiatrists' thinking about the pharmacotherapy of schizophrenia is suggested by noting that, in a 1995 psychopharmacology handbook, the discussion of risperidone occupies less than one page in a thirty-eight page chapter on antipsychotic medications,²¹¹ and the American Psychiatric Association's guideline for treating schizophrenia, published in April 1997, states that "conventional antipsychotic medications and risperidone are all reasonable first-line medications for patients in acute phases of schizophrenia"²¹² The next Part of this Article offers several reasons why psychiatrists may still choose to prescribe neuroleptics as first-line therapies, despite the apparent advantages of newer antipsychotic drugs. This Article then describes several possible sources of liability that now might arise from using conventional neuroleptics, and discusses the potential impact of recent cases on courts' thinking about whether use of the older drugs constitutes malpractice.

IV. COST ISSUES AND THE USE OF NOVEL ANTIPSYCHOTICS AS FIRST-LINE TREATMENTS²¹³

Psychiatrists in the U.S. think that the newer antipsychotics should be the drugs of first choice for patients suffering from their first episode of

in most clinical situations"); David N. Osser & Carlos A. Zarate, Jr., *Consultant for the Pharmacotherapy of Schizophrenia*, 29 PSYCHIATRIC ANNALS 252, 253 (1999); Steven P. Shon et al., *Mental Health Care from the Public Perspective: The Texas Medication Algorithm Project*, 60 J. CLINICAL PSYCHIATRY 16, 18 (Supp. 3, 1999); *The Expert Consensus Guideline Series: Treatment of Schizophrenia 1999*, 60 J. CLINICAL PSYCHIATRY 12, 12 (Joseph P. McEvoy et al. eds., Supp. 11, 1999) [hereinafter *Guideline Series*]; see also Roger S. McIntyre, *Psychotropic Drugs and Adverse Events in the Treatment of Bipolar Disorders Revisited*, 63 J. CLINICAL PSYCHIATRY 15, 15 (Supp. 3, 2002) ("The novel antipsychotics are now the antipsychotics of choice in the treatment of bipolar disorders."); David N. Osser & Robert Sigadel, *Short-Term Inpatient Pharmacotherapy of Schizophrenia*, 9 HARV. REV. PSYCHIATRY 89, 89 (2001) ("For initial oral treatment, monotherapy with one of the new 'atypical' antipsychotics is favored."); Renée E. Snow & Sumer Verma, *Late-life Psychosis: It's Efficacy Vs. Cost in the Tug-of-War over Treatment*, 1 CURRENT PSYCHIATRY 10, 10, 14 (2002) ("In general, atypical antipsychotics are considered first-line therapy [for treating psychotic disorders in elderly patients], unless there is a compelling reason not to use them in an individual patient.").

211. HYMAN ET AL., *supra* note 9, at 30.

212. Herz, *supra* note 143, at 3.

213. Portions of this and the following two Parts are adapted from two other articles. Douglas Mossman & Douglas S. Lehrer, *Conventional and Atypical Antipsychotics and the Evolving Standard of Care*, 51 PSYCHIATRIC SERVICES 1528 (2000); Douglas Mossman, *Malpractice Implications of Prescribing Antipsychotic Medications*, 19 DIRECTIONS IN PSYCHIATRY 311 (1999).

schizophrenia and also should be used to treat all patients with established diagnoses of schizophrenia unless there is a good reason—a patient’s personal preference, record of excellent response to an older drug, or need for an injectable preparation²¹⁴—to prescribe a conventional agent.²¹⁵ Indeed, given the advantages of the newer drugs summarized

214. On June 24, 2002, ziprasidone became the first novel antipsychotic available in a short-acting injectable form. *FDA Approves Pfizer’s Schizophrenia Medicine Geodon® in Injectable Form; First Atypical Antipsychotic Approved in Intramuscular Form to Rapidly Treat Acute Agitation in Patients with Schizophrenia*, PR NEWswire, June 24, 2002, LEXIS, PR Newswire File; see also Michael D. Lesem et al., *Intramuscular Ziprasidone, 2 Mg Versus 10 Mg, in the Short-Term Management of Agitated Psychotic Patients*, 62 J. CLINICAL PSYCHIATRY 12, 12 (2001) (reporting that injectable ziprasidone is effective in quelling acute psychosis). Other novel antipsychotic agents are available only for oral administration, although research is proceeding on injectable forms of these drugs. See, e.g., Alan Breier, *A Double-Blind, Placebo-Controlled Dose-Response Comparison of Intramuscular Olanzapine and Haloperidol in the Treatment of Acute Agitation in Schizophrenia*, 59 ARCHIVES GEN. PSYCHIATRY 441, 446–47 (2002) (reporting that injections of olanzapine rapidly and safely reduce agitation); Karena Meehan et al., *A Double-Blind, Randomized Comparison of the Efficacy and Safety of Intramuscular Injections of Olanzapine, Lorazepam, or Placebo in Treating Acutely Agitated Patients Diagnosed with Bipolar Mania*, 21 J. CLINICAL PSYCHOPHARMACOLOGY 389, 389 (2001); Osser & Zarate, *supra* note 210, at 255.

Several of the older antipsychotic drugs can be administered by intramuscular injection. Two conventional antipsychotic drugs, fluphenazine and haloperidol, are available as long acting preparations that can be administered in a single “depot” injection every two or four weeks. HYMAN ET AL., *supra* note 9, at 10–11. By administering one of the depot preparations, clinicians can be sure that patients are receiving their antipsychotic medication. For a discussion of the role of injectable antipsychotic therapy, see generally Peter Weiden & William Glazer, *Assessment and Treatment Selection for “Revolving Door” Inpatients with Schizophrenia*, 68 PSYCHIATRY Q. 377 (1997), and Marcia Valenstein et al., *Adherence Assessments and the Use of Depot Antipsychotics in Patients with Schizophrenia*, 62 J. CLINICAL PSYCHIATRY 545, 545–46 (2001). Concerning patients’ feelings about depot medication, see Yuval Bloch et al., *Injections of Depot Antipsychotic Medications in Patients Suffering from Schizophrenia: Do They Hurt?*, 62 J. CLINICAL PSYCHIATRY 855, 855 (2001), stating that “[d]epot injections are painful.” In July 2002, the FDA refused to approve a long acting, injectable form of risperidone. Geoff Dyer, *J&J Hit by FDA Drug Snub*, FIN. TIMES, July 2, 2002, at 30.

215. Chiles et al., *supra* note 210, at 72; Kaye & Reed, *supra* note 210, at 331; Lieberman, *supra* note 209, at 70–71 (“[T]he most opportune time for optimal treatment interventions appears to be the first episode of illness. . . . [T]he greatest benefits from the use of atypical antipsychotic drugs . . . should be seen in patients close to the onset of illness.”); *Guideline Series*, *supra* note 210, at 12–13, 35; Miller et al., *supra* note 210, at 652; Osser & Zarate, *supra* note 210, at 253 (stating that when treating a patient with schizophrenia, “[t]he first-line recommendation is to select one of the new generation of antipsychotic medications”).

For example, in the Texas Medication Algorithm Project (TMAP) schizophrenia algorithm, older neuroleptics are used only after trials of the novel agents have proven unsuccessful. Patients may also receive a depot neuroleptic after demonstrating poor compliance during their first trial of a novel drug. Miller et al., *supra* note 210, at 652; Chiles et al., *supra* note 210, at 72. The TMAP is an effort by public sector psychiatrists to establish a set of “best practices” for the pharmacological treatment of major psychiatric disorders. The TMAP receives financial support from several pharmaceutical

in the previous Part, why would anyone want to take or prescribe the older ones?

A. *The Costs of Novel Antipsychotics*

The main reason is the cost charged to pharmacies and other third parties that pay for antipsychotic medication.²¹⁶ Acquisition prices for the newer agents are far greater than the cost of equivalent doses of generic conventional agents, sometimes seventy to one hundred times higher.²¹⁷ For a patient with schizophrenia, taking a novel antipsychotic rather than a conventional agent might entail an added treatment cost of \$3000 to \$4000 per year.²¹⁸

If patients purchased medications with their own funds, decisions about whether to spend more money to purchase and take the newer drugs would be controlled by the persons who consumed the drugs and experienced their benefits and risks. Patients could weigh the relative advantages of older and newer medications and, after consultation with their doctors, decide for themselves whether having a newer medication was worth giving up some other item²¹⁹ on which they were spending their money.

However, for most patients with schizophrenia, money for medication comes from managed health insurance dollars or public funds administered through state budgets and Medicaid programs. This means

companies that market novel antipsychotic drugs. Don A. Gilbert et al., *Texas Medication Algorithm Project: Definitions, Rationale, and Methods to Develop Medication Algorithms*, 59 J. CLINICAL PSYCHIATRY 345, 345 (1998); Miller et al., *supra* note 210, at 649. For a discussion of the potential impact of pharmaceutical company sponsorship, see *infra* Part IV.B.1. Some clinicians outside the United States take an alternative position on medication choice. See Geddes et al., *supra* note 20, at 1371 (“Conventional antipsychotics should usually be used in the initial treatment of . . . schizophrenia unless the patient has previously not responded to these drugs or has unacceptable extrapyramidal side effects.”).

216. The novel antipsychotic drugs have some side effect disadvantages when compared to older drugs; the former seem more prone to cause weight gain and associated medical problems. See *infra* Part IV.B.1.

217. Mossman & Lehrer, *supra* note 213, at 1529.

218. *Id.*

219. Most patients with schizophrenia smoke cigarettes. Some recent evidence suggests that atypical antipsychotic drugs may promote smoking cessation. Tony P. George et al., *Nicotine Transdermal Patch and Atypical Antipsychotic Medications for Smoking Cessation in Schizophrenia*, 157 AM. J. PSYCHIATRY 1835, 1838–40 (2000). With cigarettes now costing three dollars to six dollars per pack, a heavy smoker might conclude that purchasing a newer antipsychotic and quitting smoking was a cost neutral decision (not to mention the many potential short- and long-term health benefits).

that administrators of managed care organizations or publicly funded treatment programs, rather than individual patients and doctors, must decide whether to allocate funds that might be spent on other therapies to the newer, more expensive drugs. To appreciate the kinds of decisions to be made, consider the potential fiscal impact of newer antipsychotic agents at the Ohio public sector hospital where the author works. For the more than 300 patients that receive antipsychotic drugs, switching to the atypicals might generate an additional pharmacy cost of about \$1,000,000 per year, which is about half of the total hospital budget for paying the psychiatrists that treat patients.²²⁰ A recent study of Georgia Medicaid patients treated for schizophrenia found that in constant dollars, antipsychotic expenditures increased by nine and one half times between 1990 and 2002, almost entirely because of the trend to use atypicals rather than older antipsychotic drugs. The authors of the study noted that “[t]his transition from traditional oral antipsychotics to atypicals . . . has a profound effect on drug expenditures for systems paying for the care of persons with schizophrenia.”²²¹

Courts have ruled that, in some circumstances, state Medicaid agencies are obligated to pay for qualified individuals’ treatment with clozapine,²²² and presumably the same obligation would apply to the other novel antipsychotics. However, private and public sector agencies also must administer psychiatric care within budgetary limits. These agencies thus potentially face the fiscal and moral dilemma of deciding for their patients whether the benefits of the atypicals are worth the added pharmacy expenses.

B. Pharmacoeconomic Studies

One way out of this dilemma is suggested by several published pharmacoeconomic studies, which assert that using novel antipsychotics does not really increase the *total* cost of treating persons with schizophrenia because the drugs allow patients to leave the hospital. If

220. Mossman & Lehrer, *supra* note 213, at 1529; *see also* Carolyn S. Dewa & Paula Goering, *Lessons Learned from Trends in Psychotropic Drug Expenditures in a Canadian Province*, 52 PSYCHIATRIC SERVICES 1245, 1246 (2001) (stating that despite Ontario’s cost control mechanisms, introduction of novel agents quadrupled expenditures for antipsychotic agents between 1992 and 1998 and in the latter year, novel agents still accounted for only one-third of antipsychotic drug prescriptions). *See infra* note 259 (comparing costs of neuroleptic and novel antipsychotic medications for Veterans Affairs patients).

221. Bradley C. Martin et al., *Antipsychotic Prescription Use and Costs for Persons with Schizophrenia in the 1990s: Current Trends and Five Year Time Series Forecasts*, 47 SCHIZOPHRENIA RES. 281, 281 (2001).

222. *Visser v. Taylor*, 756 F. Supp. 501, 507 (D. Kan. 1990); *Alexander L. v. Cuomo*, 588 N.Y.S.2d 85, 88 (Sup. Ct. 1991).

the new drugs reduce patients' need for hospitalization, as some interpreters of these studies have suggested,²²³ then using them is not really any more costly than using the older drugs. The money saved from reduced hospital use might even produce a net overall savings.

Whether novel antipsychotic agents really can reduce total treatment costs is still unclear. Health outcomes researcher Dennis Revicki recently reviewed extant pharmacoeconomic studies and summarized their results as follows:

The evidence, from a variety of studies, indicates that clozapine is a cost-effective treatment for neuroleptic refractory schizophrenia. Risperidone and olanzapine may be cost neutral, or at best slightly cost saving, compared with conventional antipsychotics, although they do improve patient clinical effectiveness and quality of life outcomes. There is too little data on pharmacoeconomic outcomes for sertindole and quetiapine to make any conclusions about their cost-effectiveness in treating schizophrenia.²²⁴

The following sections describe several reasons why psychiatrists and administrators should maintain a healthy skepticism about claims that novel agents reduce total treatment costs.

1. Possible Skewing of Results

Many decisionmakers treat pharmacoeconomic studies sponsored by drug manufacturers with skepticism "because of the potential bias of [the] study sponsors. . . ."²²⁵ With the novel agents, "a number of the

223. Christopher G. Fichtner et al., *Pharmacoeconomic Studies of Atypical Antipsychotics: Review and Perspective*, 28 *PSYCHIATRIC ANNALS* 381, 395 (1998) ("[F]or patients who continue to take the new treatment, overall medical resource utilization is likely to decrease, resulting in lower costs.").

224. Dennis A. Revicki, *The New Atypical Antipsychotics: A Review of Pharmacoeconomic Studies*, 1 *EXPERT OPINION ON PHARMACOTHERAPY* 249, 249 (2000), LEXIS, MEDLINE Database. "Neuroleptic refractory schizophrenia" refers to patients that suffer from the disorder and do not recover with the help of conventional (pre-1989) antipsychotic drugs.

Sertindole is a novel antipsychotic agent that the manufacturer, Abbott Laboratories, withdrew from consideration for FDA approval in early 1998. George Gunset, *Abbott Withdraws Drug Application*, CHI. TRIB., Feb. 21, 1998, at B1; Dolores Kong, *Doctors Criticize Placebo Testing: Mentally Ill Patients Worsened After Use*, BOSTON GLOBE, Mar. 21, 1999, at A1 ("serlect (sertindole) . . . was withdrawn from consideration after an FDA advisory committee questioned its safety"). The drug had been used previously in other countries, for example, in the United Kingdom, but the Danish manufacturer Lundbeck withdrew it from use in late 1998 because it caused potentially fatal heart problems. Geddes et al., *supra* note 20 at 1373; Lesley Roberts, *Drug Ban as Experts Probe Sudden Deaths*, DAILY MAIL (London), Jan. 4, 1999, at 4.

225. Peter J. Neumann, *Methods of Cost-Effectiveness Analysis in the Evaluation of*

comparative studies that have been published were developed and sponsored by the pharmaceutical companies whose medications were being evaluated, raising concerns about potential sources of bias in experimental design or interpretation of outcomes.²²⁶ Although no published report provides evidence that manufacturer sponsored studies of atypicals have been dishonest, three features of these studies may have accentuated the newer drugs' advantages.

First, some studies may have utilized data obtained from a large number of treatment resistant patients, that is, individuals who did not benefit from treatment with the older drugs.²²⁷ If this were the case, it would lead investigators to overestimate savings that would occur in

New Antipsychotics: Implications for Schizophrenia Treatment, 60 J. CLINICAL PSYCHIATRY 9, 12 (Supp 3, 1999); see also Peter J. Neumann, *Paying the Piper for Pharmacoeconomic Studies*, 18 MED. DECISION MAKING S23, S23 (Supp. 1998). "Clinical trials form the basis of effective research and development, but their reliability is currently imperilled by three major flaws: conflicts of interest on the part of the investigators; inappropriate involvement of research sponsors in their design and management; and publication bias in disseminating their results [the tendency to publish only results of studies showing that a drug worked]." Jonathan Quick, *Maintaining the Integrity of the Clinical Evidence Base*, 79 BULL. WORLD HEALTH ORG. 1093, 1093 (2001).

226. David A. Lewis, *Atypical Antipsychotic Medications and the Treatment of Schizophrenia*, 159 AM. J. PSYCHIATRY 177, 177 (2002). Two University of Michigan schizophrenia researchers commented:

[A]ggressive marketing by pharmaceutical companies and their pervasive involvement in continuing medical education has contributed to some confusion among clinicians about how available pharmacologic strategies compare and what they can realistically accomplish. Industry-sponsored drug trials are the major source of clinical trial information, and because Phase IV trials are conducted at least in part for marketing purposes, resulting biases can compromise their utility.

Rajiv Tandon & Michael D. Jibson, *Pharmacologic Treatment of Schizophrenia: What the Future Holds*, 6 CNS SPECTRUMS 980, 984 (2001) (citations omitted).

227. For example, several pharmacoeconomic studies utilize archival data obtained during pre-release efficacy studies that were conducted as a prelude to FDA approval. Patients in these efficacy studies typically were hospitalized when recruited. See, e.g., Charles M. Beasley, Jr. et al., *Olanzapine Versus Placebo and Haloperidol: Acute Phase Results of the North American Double-Blind Olanzapine Trial*, 14 NEUROPSYCHOPHARMACOLOGY 111, 112-13 (1996) (noting that a study required patients to have a minimum level of psychopathology and to be inpatients for two weeks); Stephen R. Marder & Richard C. Meibach, *Risperidone in the Treatment of Schizophrenia*, 151 AM. J. PSYCHIATRY 825, 826 (1994); Joyce G. Small et al., *Quetiapine in Patients with Schizophrenia: a High- and Low-Dose Double-Blind Comparison with Placebo*, 54 ARCHIVES GEN. PSYCHIATRY 549, 550 (1997). This means that the subset of patients that were doing well enough in the community not to need hospitalization were not represented in these studies, and that "tough-to-treat" patients were over-represented. This might also explain why response rates for the new drugs were somewhat lower, only forty-five to fifty percent, than the seventy percent response rate that is usually reported for conventional antipsychotic medications. See Douglas Mossman, *A Decision Analysis Approach to Neuroleptic Dosing: Insights from a Mathematical Model*, 58 J. CLINICAL PSYCHIATRY 66, 68 (1997) (summarizing studies).

typical populations of psychotic patients.²²⁸ Moreover, although one recently published study demonstrated the superior efficacy of atypicals in treating patients who had suboptimal responses to neuroleptics, “the effects were modest and their clinical significance limited.”²²⁹

Second, the pharmaceutical manufacturers’ prerelease studies on which many pharmaco-economic studies have relied have compared the performance of novel agents to effect of haloperidol dosed at ten to twenty milligrams/day. This dose choice was reasonable, since patients often receive such doses of haloperidol and equivalently high doses of other neuroleptics.²³⁰ However, it has been recognized for several years that only a fraction of patients benefit from doses above the equivalent of haloperidol five milligrams/day.²³¹ Above this dose, side effects increase much more than does drug effectiveness.²³² Recent evidence suggests that individuals that have never taken a neuroleptic may need only one to three milligrams/day.²³³ Even at low doses, the risk of developing tardive dyskinesia is lower with atypicals than with haloperidol.²³⁴ However, apparent superiority of novel drugs in reducing negative symptoms might be less striking if a comparison were undertaken with modest doses of haloperidol like two to five

228. Jan Volavka et al., *Clozapine, Olanzapine, Risperidone, and Haloperidol in the Treatment of Patients with Chronic Schizophrenia and Schizoaffective Disorder*, 159 AM. J. PSYCHIATRY 255, 260–61 (2002) (stating that in neuroleptics resistant patients, atypicals were better at reducing symptoms than haloperidol, but selecting such patients for study “would be expected to result in data that tend to show superior efficacy of atypical antipsychotics”).

229. *Id.* at 261.

230. Marcia Valenstein et al., *Delays in Adopting Evidence-Based Dosages of Conventional Antipsychotics*, 52 PSYCHIATRIC SERVICES 1242, 1244 (stating that between 1991 and 1995, “15 years after research reports and eight years after review articles supported moderate dosages, a troubling proportion of patients were treated with high dosages”); James T. Walkup et al., *Patients with Schizophrenia at Risk for Excessive Antipsychotic Dosing*, 61 J. CLINICAL PSYCHIATRY 344, 344 (2000) (reporting that minority patients are at a higher risk for receiving excessive doses).

231. McEvoy et al., *supra* note 201, at 742; Mossman, *supra* note 227, at 69–70 (stating that at least eighty percent of patients that can benefit from neuroleptic therapy respond at doses at or below the equivalent of haloperidol five milligrams/day).

232. P. Bollini et al., *Antipsychotic Drugs: Is More Worse? A Meta-analysis of the Published Randomized Control Trials*, 24 PSYCHOLOGICAL MED. 307, 307 (1994).

233. Shitij Kapur et al., *Relationship Between Dopamine D₂ Occupancy, Clinical Response, and Side Effects: A Double-Blind PET Study of First-Episode Schizophrenia*, 157 AM. J. PSYCHIATRY 514, 517 (2000).

234. Dilip V. Jeste et al., *Lower Incidence of Tardive Dyskinesia with Risperidone Compared with Haloperidol in Older Patients*, 47 J. AM. GERIATRICS SOC’Y 716, 716 (1999).

milligrams/day, rather than the ten to twenty milligrams/day doses that were used in prerelease trials.²³⁵

Third, persons who take the newer antipsychotics are especially susceptible to gaining weight and to developing related metabolic problems, such as diabetes mellitus.²³⁶ Taking the older antipsychotic agents also increases a patient's risk of developing these problems, but the frequency and severity of these problems are even more pronounced in patients that take novel agents.²³⁷ In a society that greatly values thinness, one must wonder how many patients might prefer a drug with a higher risk of tardive dyskinesia to a drug that had a good chance of making them fat. Moreover, psychiatrists do not yet know what will be the long-term consequences of atypical induced weight gain.²³⁸

235. Kapur et al., *supra* note 99, at 292.

236. “[N]ewer antipsychotic treatments such as clozapine and olanzapine, in comparison with typical agents, are associated with adverse effects on plasma glucose regulation . . .” John W. Newcomer et al., *Abnormalities in Glucose Regulation During Antipsychotic Treatment of Schizophrenia*, 59 ARCHIVES GEN. PSYCHIATRY 337, 342 (2002). See *id.* at 337–38 (summarizing the results of reports describing the increased risk of weight gain and diabetes).

237. David B. Allison et al., *Antipsychotic-Induced Weight Gain: A Comprehensive Research Synthesis*, 156 AM. J. PSYCHIATRY 1686, 1690 (1999) (reporting that more weight gain occurred with clozapine, olanzapine, and risperidone than with haloperidol or placebo, and that several neuroleptics are associated with weight gain as well, but generally less than the novel agents); Davidson, *supra* note 191, at 6–8 (summarizing studies of metabolic abnormalities associated with neuroleptics and the novel agents); Michael J. Sernyak et al., *Association of Diabetes Mellitus with Use of Atypical Neuroleptics in the Treatment of Schizophrenia*, 159 AM. J. PSYCHIATRY 561, 561 (2002) (noting that after controlling for age, patients who took novel agents were nine percent more likely to be treated for diabetes than were patients taking older antipsychotic drugs); Brian B. Sheitman et al., *Olanzapine-Induced Elevation of Plasma Triglyceride Levels*, 156 AM. J. PSYCHIATRY 1471–72 (1999); Maxwell Sobel et al., *New-Onset Diabetes Mellitus Associated with the Initiation of Quetiapine Treatment*, 60 J. CLINICAL PSYCHIATRY 556, 556–57 (1999); Donna A. Wirshing et al., *Novel Antipsychotics: Comparison of Weight Gain Liabilities*, 60 J. CLINICAL PSYCHIATRY 358, 361–62 (1999); Donna A. Wirshing et al., *Novel Antipsychotics and New Onset Diabetes*, 44 BIOLOGICAL PSYCHIATRY 778, 778 (1998) (reporting six new-onset cases of diabetes mellitus associated with clozapine and olanzapine and that four patients had substantial weight gain); Donna A. Wirshing et al., *Risperidone-Associated New-Onset Diabetes*, 50 BIOLOGICAL PSYCHIATRY 148, 148 (2001) (reporting two cases of diabetes); Donna A. Wirshing et al., *The Effects of Antipsychotics on Glucose and Lipid Levels*, 63 J. CLINICAL PSYCHIATRY 856, 863 (2002) (presenting a chart to illustrate a study showing elevated glucose levels and triglyceride levels in patients receiving novel agents, and recommending that physicians “be more aggressive in monitoring glucose and lipid levels in patients treated with these agents”).

238. Kevin R. Fontaine et al., *Estimating the Consequences of Anti-Psychotic Induced Weight Gain on Health and Mortality Rate*, 101 PSYCHIATRY RES. 277, 278 (2001) (“[T]he magnitude of weight gains induced by many antipsychotic agents is likely to have important deleterious effects on mortality and health.”).

2. Findings from Intent-to-Treat Studies

After clozapine was released, its recipients often were patients who had spent great lengths of time in hospitals because they could not benefit from the then-available antipsychotic drugs. Initial studies comparing total pre- and post-clozapine expenditures for the previously refractory patients who took the drug successfully suggested that clozapine was a net money saver because patients' reduced use of hospitalization more than offset costs of administering the drug to them.²³⁹ However, so-called intent-to-treat studies, which include studies that compare all patients who were offered clozapine with all patients offered a comparison medication, have concluded that the financial savings from clozapine are modest at best.²⁴⁰ Similarly, two intent-to-treat studies of risperidone did not demonstrate any actual financial savings²⁴¹ although studies using mathematical models had suggested that the drug would reduce the total cost of care.²⁴²

3. Nonunanimity of Findings

Some studies have shown that in real life treatment, results with novel agents are not necessarily better than results with conventional

239. Herbert Y. Meltzer et al., *Cost Effectiveness of Clozapine in Neuroleptic-Resistant Schizophrenia*, 150 AM. J. PSYCHIATRY 1630, 1636 (1993).

240. Katherine J. Aitchison & Robert W. Kerwin, *Cost-Effectiveness of Clozapine: A UK Clinic-Based Study*, 171 BRIT. J. PSYCHIATRY 125, 127–28 (1997); Daniel J. Luchins et al., *Initiating Clozapine Treatment in the Outpatient Clinic: Service Utilization and Cost Trends*, 49 PSYCHIATRIC SERVICES 1034, 1036 (1998) (noting that the higher cost of clozapine treatment was only partially offset by decreased rate of hospitalization); Rosenheck et al., *supra* note 192, at 812.

241. Mark J. Schiller et al., *Treatment Costs and Patient Outcomes with Use of Risperidone in a Public Mental Health Setting*, 50 PSYCHIATRIC SERVICES 228, 231–32 (1999) (noting a trend toward higher costs with risperidone treatment); Gary Viale et al., *Impact of Risperidone on the Use of Mental Health Care Resources*, 48 PSYCHIATRIC SERVICES 1153, 1157–58 (1997) (noting a statistically insignificant increase in total costs).

242. Brian S. Nightengale et al., *Economic Outcomes of Antipsychotic Agents in a Medicaid Population: Traditional Agents Vs. Risperidone*, 34 PSYCHOPHARMACOLOGY BULL. 373, 380–81 (1998); Dennis A. Revicki, *Pharmacoeconomic Studies of Atypical Antipsychotic Drugs for the Treatment of Schizophrenia*, 35 SCHIZOPHRENIA RES. S101, S107 (Supp. 1999) (noting that clozapine is cost saving for treatment refractory patients and as standard therapy, atypical agents appear cost neutral); *see also* Brian C. Lund & Paul J. Perry, *Olanzapine: An Atypical Antipsychotic for Schizophrenia*, 1 EXPERT OPINION ON PHARMACOTHERAPY 305, 305 (2000) (“[P]armacoeconomic studies are needed to justify the large acquisition cost of olanzapine compared to typical agents.”).

antipsychotics. In a study involving matched schizophrenic patients that received either risperidone or conventional agents, Schiller and colleagues found that costs and effectiveness did not differ.²⁴³ A report by Binder and colleagues states that seventy-one percent of patients whose doctors had prescribed risperidone for them had stopped taking the medication two years later because of noncompliance, poor response, or side effects.²⁴⁴ Another study evaluating the impact of risperidone found not only that the drug did not reduce patient readmission rates but also that average annual treatment costs for risperidone treated patients were nearly double the costs for patients receiving conventional agents.²⁴⁵

4. How U.S. Healthcare Budgets Work

Authors in France²⁴⁶ and Australia²⁴⁷ have suggested that if their countries switched patients from conventional to atypical agents it would generate a net savings in healthcare expenses. Unlike the U.S., these countries offer all their citizens government funded medical care, so looking at potential system-wide savings is a sensible perspective from which to judge healthcare costs. In the multiple payer U.S. system, however, cost savings from novel antipsychotics, if indeed savings do occur, might not go to the agencies or organizations that pay for those drugs.²⁴⁸ Also, the financial benefits of atypicals might not occur within the time horizon of healthcare organizations' annual budgets because, for many patients, the benefits of new medications and their associated cost savings take many months to accrue.²⁴⁹

243. Schiller et al., *supra* note 241, at 231–32.

244. Renée L. Binder et al., *A Naturalistic Study of Clinical Use of Risperidone*, 49 PSYCHIATRIC SERVICES 524, 525 (1998).

245. Kim C. Coley et al., *Effectiveness of Antipsychotic Therapy in a Naturalistic Setting: A Comparison Between Risperidone, Perphenazine, and Haloperidol*, 60 J. CLINICAL PSYCHIATRY 850, 854 (1999).

246. Claude Le Pen et al., *Comparaison Économique de l'olanzapine Versus Halopéridol dans le Traitement de la Schizophrénie en France* [Economic Comparison of Olanzapine Versus Haloperidol in Treatment of Schizophrenia in France], 25 ENCEPHALE 281 (1999).

247. Alison Davies et al., *Risperidone Versus Haloperidol: II. Cost-Effectiveness*, 20 CLINICAL THERAPEUTICS 196, 207 (1998). This study was supported by Janssen-Cilag, a firm that markets risperidone; Alison Davies worked for Janssen-Cilag when the article was published. *Id.* at 211.

248. For a graphical depiction of the complex funding patterns involved in paying for antipsychotic medications and psychiatric care in general, see William Glazer & Ruth Dickson, *Pharmacoeconomics and Resource Allocation: Lessons from North America*, in SCHIZOPHRENIA AND MOOD DISORDERS: THE NEW DRUG THERAPIES IN PRACTICE 330, 331 (Peter F. Buckley & John L. Waddington eds., 2000).

249. Meltzer et al., *supra* note 239, at 1636 (cost offset occurred over two years); Robert Rosenheck et al., *Cost-Effectiveness of Clozapine in Patients with High and Low Levels of Hospital Use*, 56 ARCHIVES GEN. PSYCHIATRY 565, 569 (1999) (noting cost

5. *Are Calculated Savings Real Savings?*

Although several studies of atypicals have reported cost savings from patients' reduced need for hospitalization, those savings have merely been *calculated*. Actual cash savings do not occur unless hospitals close wards and lay off clinicians, administrators, and support staff members. Over the last fifteen years, lengths of stay in psychiatric hospitals have dropped markedly as a result of managed care and other policy decisions,²⁵⁰ and treatment agencies may not be able to fully offset increased pharmacy expenses through further reductions in hospital use.²⁵¹

6. *Would "Stepped Care" Generate More Cash Savings?*

Pharmacoeconomic studies have evaluated treatment schemes in which patients receive either a conventional neuroleptic or a novel drug from the outset. However, two studies suggest that novel antipsychotics lower treatment costs mainly for patients who had not benefited from neuroleptics or had been unusually high users of hospital services.²⁵² This suggests that the best money saving strategy may be "stepped care."²⁵³ Stepped care is a system in which schizophrenic patients first receive "older, less expensive antipsychotic[s] in judicious doses, undergo conscientious monitoring for adverse effects and clinical response, and receive novel agents only if they do not have a good

savings after one year, but only in previously high users of hospital services).

250. See, e.g., Susan H. Garritson, *Availability and Performance of Psychiatric Acute Care Facilities in California from 1992 to 1996*, 50 PSYCHIATRIC SERVICES 1453, 1455 (1999) (describing a twenty-six percent reduction in the length of stay in California psychiatric hospitals).

251. Herbert Y. Meltzer, *Outcome in Schizophrenia: Beyond Symptom Reduction*, 60 J. CLINICAL PSYCHIATRY 3, 4 (Supp. 3, 1999).

252. Rosenheck, *supra* note 249, at 565; Patrick R. Finley et al., *Risperidone: Clinical Outcome Predictors and Cost-Effectiveness in a Naturalistic Setting*, 34 PSYCHOPHARMACOLOGY BULL. 75, 78 (1998).

253. Other writers have called such strategies "fail-first" policies, derived from the notion that patients must first fail to benefit from a cheaper drug before being offered a more expensive drug. See, e.g., Omnibus Mental Illness Recovery Act § 7, <http://www.nami.org/update/omirasec7.html> (last visited Aug. 4, 2002) (discussing managed care drug formularies); Bazelon Center for Mental Health Law, *Medicaid Formulary Policies: Access to High-Cost Mental Health Medications*, at <http://www.bazelon.org/formulary.html> (Nov. 1999) (Medicaid drug formularies); National Mental Health Association, *The VA Is Restricting Access to Needed Anti-Psychotic Medication to Veterans Across the Country!*, at <http://www.nmha.org/newsroom/system/lal.vw.cfm?do=vw&rid=330> (Aug. 21, 2001) (VA antipsychotic policy).

response to, or . . . develop problems from, a . . . neuroleptic.”²⁵⁴ In some settings, first choice use of effective but inexpensive neuroleptics may be justified by the need for prudent use of limited financial resources.²⁵⁵

C. Ethical Issues in Stepped Care

Of course, a stepped care policy would result in more patients being exposed to neuroleptic side effects than would occur if atypicals were used as first-line drugs for treating schizophrenia, and this could raise a series of practical moral questions for a treatment agency that adopted such a policy. A mere listing of the questions is sufficient to suggest how complicated and troublesome they might become: (1) Would the agency be obligated to tell patients about the policy and its restrictions on use of the newer, less risky, more expensive drugs? (2) Would patients’ family members be entitled to any information?²⁵⁶ (3) How explicit should the agency be in describing the financial rationale for stepped care? (4) How should the agency disclose such information? Would it suffice to distribute written material to patients, or should

254. Mossman & Lehrer, *supra* note 213, at 1530. Note that this stepped care approach assumes that the novel agents are available for patients who need them and that treatment agencies will therefore be willing to pay for them for a portion of the individuals they serve. Some healthcare plans restrict patients to only the neuroleptics. See Christine Lehmann, *Cost Limits Drug Options for Public-Sector Patients*, PSYCHIATRIC NEWS, May 18, 2001, at 1, 1 (reporting a patient who desired risperidone although her health plan’s restricted drug formulary only covered haloperidol and chlorpromazine), <http://pn.psychiatryonline.org/cgi/content/full/36/10/1>. See William M. Glazer, *Accessibility of the New Generation Antipsychotic Medications in the United States 9–12* (2001) (unpublished manuscript, on file with author) (reporting the results of a survey concerning limited access to novel antipsychotic agents in public and private settings and describing various restrictions, including fail-neuroleptics-first policies, preferred medications, co-payment schedules, and prior authorization requirements).

255. Michael L. Zoler, *Clozapine’s Cost-Benefit Balance Questioned*, CLINICAL PSYCHIATRY NEWS, Mar. 1999, at 29, 29 (citing views of VA psychiatrist Robert Rosenheck that, for economic reasons, “[t]he best public health approach may not be using atypical antipsychotics as first-line drugs for all patients with schizophrenia”), <http://www.medscape.com/IMNG/ClinPsychNews/1999/v27.n03/cpn2703.29.03.html>; see also Geddes et al., *supra* note 20, at 1375.

256. The issue of disclosure to family members is important because of schizophrenic patients’ known limitations with regard to treatment decisionmaking. Thomas Grisso & Paul S. Appelbaum, *The MacArthur Treatment Competence Study. III: Abilities of Patients to Consent to Psychiatric and Medical Treatments*, 19 L. & HUM. BEHAV. 149, 149 (1995) (finding that compared to depressed patients and patients with heart disease, schizophrenic patients had the poorest understanding of treatment disclosure, poorest reasoning in decisionmaking regarding treatment, and greatest likelihood of not appreciating their illness or potential benefits of treatment); see also William T. Carpenter, Jr. et al., *Decisional Capacity for Informed Consent in Schizophrenia Research*, 57 ARCHIVES GEN. PSYCHIATRY 533, 533 (2000). The study by Carpenter and his colleagues describes educational interventions that can compensate for schizophrenic patients’ impairments. *Id.* at 535–38.

patients have to sign forms acknowledging receipt of information about the policy? (5) What disclosure obligations would physicians and other clinicians employed by the agency, as distinct from the agency itself, have toward patients? (6) Could agencies place the responsibility for disclosure on physicians? If so, what ought physicians who disagreed with stepped care do when discussing the policy with patients? (7) Whichever party discloses information about a money saving policy, how might such a disclosure change the doctor-patient relationship and treatment outcomes? (8) If a patient requested a newer, expensive antipsychotic drug before having tried a less expensive neuroleptic, how should the agency and treating psychiatrist respond? (9) How would agencies establish criteria for deciding what symptoms or problems a neuroleptic treated patient would need to experience before being changed to a more expensive atypical agent?

These questions, one must recognize, would not be new ones for psychiatry. Accrediting agencies require state financed facilities to meet minimum standards, but these facilities typically do not provide the fanciest care available. State hospitals typically offer psychiatric care in buildings that cost less to operate than private sector facilities. Private sector facilities that, unlike state hospitals, must compete for patients, are better staffed and more pleasant than public sector facilities. In the author's experience, it is extremely unusual for psychiatrists who work in government funded facilities to talk with patients about how public sector institutions differ from private ones.

Nor would these questions be unique to psychiatry. In an effort to control costs, managed care organizations routinely designate "preferred provider" panels of physicians for their covered patients, and specify "formularies," lists of medications that cost patients less out-of-pocket.²⁵⁷ Physicians, and sometimes patients, rail against these practices,²⁵⁸ but they are widespread and are not fundamentally different than a stepped care plan for new, but expensive, antipsychotic agents.

257. For an overview of these practices as they apply to psychiatric care, see generally Jesse A. Goldner, *Managed Care and Mental Health: Clinical Perspectives and Legal Realities*, 35 HOUS. L. REV. 1437 (1999).

258. The most prominent psychiatrist to do so is William M. Glazer, M.D., an associate clinical professor of psychiatry at Yale University School of Medicine. See, e.g., William Glazer, *What Can Clinicians Do About Restrictive Treatment Policies?*, at <http://medaccess.glazmedsol.com/articles/glazereditorial.html> (urging psychiatrists to protest managed care formulary restrictions). His website on access to atypical antipsychotics is available at <http://www.medaccess.glazmedsol.com> (last visited Aug. 4, 2002).

An adequate exploration of these ethical questions would take us far beyond the scope of this Article. Parts V and VI of this Article focus on some of the closely related legal issues that the new drugs may generate. Before turning to these matters, however, the next Section reviews some actual developments related to limitations of access to atypical antipsychotics.

D. Access to Atypicals

In July 2001, the Department of Veterans' Affairs (VA) promulgated a guideline for atypical antipsychotic use that contains two significant financially based goals. It suggests that physicians:

- (1) Prioritize the use of atypical antipsychotic medication for new antipsychotic medication starts and for patients not responding to or having problematic side effects on typical antipsychotic medication.
- (2) . . . begin therapy with an effective less expensive agent. At the present time, this would lead to the preference of quetiapine and risperidone over olanzapine.²⁵⁹

The VA's policy quickly generated protests from consumer groups, who thought the policy would jeopardize veterans' care.²⁶⁰ However, an April 2002 report by the General Accounting Office concluded that the "guideline . . . is sound and consistent with published clinical practice guidelines Almost all of the public and private sector psychiatric experts we interviewed agree that VA's use of cost as a factor to prioritize atypical antipsychotic drugs is reasonable, appropriate, and consistent with providing quality and cost-effective medical care."²⁶¹ Although most VA psychiatrists who were interviewed for the report felt that guideline allowed them to prescribe the best medication for their

259. REPORT TO THE CHAIRMAN, COMMITTEE ON VETERANS' AFFAIRS, HOUSE OF REPRESENTATIVES, VA HEALTH CARE: IMPLEMENTATION OF PRESCRIBING GUIDELINE FOR ATYPICAL ANTIPSYCHOTIC DRUGS GENERALLY SOUND U.S. GAO, PUB. NO. GAO-02-579, at 27 (2002) [hereinafter PRESCRIBING GUIDELINE]. For fiscal year 2001, the average per patient daily costs to the VA for antipsychotic medications was as follows:

clozapine	\$8.07
risperidone	3.15
olanzapine	6.28
quetiapine	2.94
ziprasidone	5.01
neuroleptics	0.26

Id. at 6.

260. See, e.g., Don Harper, *Program Robs Veterans of Help*, N. COUNTY TIMES (San Diego), June 25, 2001, <http://www.nctimes.com/news/2001/20010625/71401.html>; Letter from Rex Cowdry, Medical Director, National Alliance for the Mentally Ill & Andrew Sperling, Policy Director, National Alliance for the Mentally Ill, to Anthony J. Principi, Secretary, U.S. Department of Veterans' Affairs (July 23, 2001), <http://www.nami.org/update/20010723.html>; National Mental Health Association, *supra* note 253, at <http://www.nmha.org/newsroom/system/lal.vw.cfm?do=vw&rid=330>.

261. PRESCRIBING GUIDELINE, *supra* note 259, at 2-3.

patients, nine percent did not feel free to prescribe the medication of their choice.²⁶²

The VA's medication guideline explicitly recommends two novel agents as first-line therapy for psychoses. Neuroleptics are to be used only if several atypicals have failed.²⁶³ By the year 2000, policies that *explicitly* require first-use of neuroleptics had become rare to nonexistent. However, subtle financial incentives may affect psychiatrists' medication choices. A study by the Bazelon Center²⁶⁴ found that Medicaid patients had better access to atypicals than to comparison medications used to treat physical illnesses, but some restrictions on novel agents still operated. The authors noted that "Medicaid oversight of managed care was found to be very limited," and that in the future, "Medicaid programs will have powerful incentives to restrict access to atypical antipsychotics, given the likelihood of a continued increase in drug prices, the two- to three-times higher cost of atypical antipsychotics, and the 85 new medicines now under development to treat mental disorders."²⁶⁵

A study of Medicaid managed care plans in Florida provides an example of possible ways that access to atypicals may be limited. When provider organizations were themselves at risk for pharmacy costs, novel agents were prescribed at about half the rate demonstrated by programs that were not at risk for pharmacy costs.²⁶⁶ Recently, a Florida federal district court dismissed a suit by a pharmaceutical manufacturers association opposing development of Medicaid formularies that might limit reimbursement to specific drugs. The court held that Florida statutes and federal Medicaid law permit "the establishment of a 'preferred drug list' and a 'prior authorization program.'"²⁶⁷ However, the Florida Medicaid formulary currently includes all approved atypical antipsychotic drugs.²⁶⁸

262. *Id.* at 18.

263. *Id.* at 27.

264. "The Judge David L. Bazelon Center for Mental Health Law is a nonprofit legal advocacy organization based in Washington D.C." Bazelon Center for Mental Health Law, *Who We Are*, at <http://www.bazelon.org/who.html> (last visited Aug. 4, 2002).

265. Bazelon Center for Mental Health Law, *supra* note 253, at <http://www.bazelon.org/formulary.html>.

266. LOUIS DE LA PARTE FLORIDA MENTAL HEALTH INSTITUTE, PATTERNS OF CARE: WHAT EFFECT DO FINANCIAL INCENTIVES HAVE ON PRESCRIPTION RATES IN MEDICAID PLANS? (2000), <http://www.fmhi.usf.edu/institute/pubs/newsletters/policybriefs/issue002.pdf>. The study covered the period 1997-98, *id.*, and may not reflect more recent practices.

267. *Pharm. Research & Mfrs. of Am. v. Medows*, 184 F. Supp. 2d 1186, 1188 (N.D. Fla. 2001).

268. Agency for Health Care Administration, *Florida Medicaid Preferred Drug*

Having examined some recent developments concerning availability of antipsychotic agents, let us next consider the potential outcomes of malpractice suits and other types of civil actions alleging damages from having received an older drug rather than an atypical antipsychotic.

V. LIABILITY STEMMING FROM THE USE OF NEUROLEPTICS

A. *The Perceived Threat of Malpractice Litigation*

The view that novel antipsychotics should be the first choice treatment for most patients with schizophrenia²⁶⁹ has generated speculation that administering conventional neuroleptics could now constitute grounds for lawsuits, even if clinicians that prescribed and managed administration of the drugs followed treatment practices that would have seemed impeccable in the mid-1990s. For example, at a January 2001 workshop on liability issues sponsored by the American Health Lawyers Association, attorney Steven B. Tannenbaum commented: "In today's climate, I would not like to be a defendant psychiatrist on the witness stand being cross-examined by a plaintiff's lawyer, having prescribed a typical drug as opposed to an atypical drug. And I do not know under today's circumstances of many psychiatrists who would use a typical drug as opposed to an atypical with the risk factors involved."²⁷⁰ At the same meeting, psychiatrist William M. Glazer agreed that prescribing cheaper but more side effect prone neuroleptics increasingly exposes psychiatrists to malpractice liability.²⁷¹

These concerns must be considered in light of past experience, which suggests that psychiatrists have been overly afraid that neurologic damage from neuroleptics will lead to successful malpractice litigation,²⁷² as well as the actual practice patterns of psychiatrists that form the basis for judging whether alleged malpractice has occurred. Yet, a few well-publicized cases have resulted in large judgments against clinicians that

List, at http://www.fdhc.state.fl.us/Medicaid/Prescribed_Drug/pharm_thera/fmpdl.shtml (last visited May 1, 2002).

269. See Chiles et al., *supra* note 210, at 72; *Guideline Series*, *supra* note 210, at 12–13; Miller et al., *supra* note 210, at 652; *supra* Part IV.

270. American Health Lawyers Association, *Minimizing Physician Liability in Psychiatric Medicine*, at http://www.healthlawyers.org/publicinterest/pi_NYCsummary.cfm (last visited Sept. 23, 2002). The workshop was funded by Eli Lilly and Company, which markets olanzapine. *Id.*

271. Carl Sherman, *Antipsychotic Prescribing Limits Increase Liability*, CLINICAL PSYCHIATRY NEWS, March 2001, at 12, available at <http://www2.eclinicalpsychiatrynews.com/scripts/om.dll/serve?action=searchDB&searchDBfor=art&artType=full&id=aqc010290312>.

272. 3 PERLIN, *supra* note 4, at 380 (2000). Despite predictions of increased tardive dyskinesia litigation, "the expected 'flood' [of such cases] has not yet materialized." *Id.* (footnotes omitted).

improperly administered or monitored conventional neuroleptics,²⁷³ and these instances have probably fueled a common tendency among physicians to develop pervasive, inflated fears about their vulnerability to successful malpractice litigation.²⁷⁴

Given this background, it is not surprising that the arrival of new medications with fewer neurological side effects, coupled with published proclamations that these drugs comprise a “new standard of care,” has generated concerns about the potential for costly lawsuits stemming from continued use of the older, more risk-prone antipsychotic drugs. In January 1998, Dr. Steven E. Hyman, Director of the National Institute of Mental Health, sent what has become a widely circulated letter to Sally K. Richardson, Director of Medicaid Operations at the Health Care Financing Administration. This letter warned that state Medicaid agencies should not balk at paying for more expensive novel medications because “the potential cost of lawsuits” from tardive dyskinesia “would . . . make up the difference between the cost of generic standard antipsychotics and the atypical antipsychotic medications currently available.”²⁷⁵ Similarly, psychiatrists Kaye and Reed have warned their colleagues that allowing state-run facilities to skimp on paying for the new drugs would ultimately be foolish, because “expensive civil rights litigation arising from patients developing TD [tardive dyskinesia] from older medication is as important an economic consideration as the initial cost of medication.”²⁷⁶

This Part examines potential sources of liability related to continued use of typical antipsychotic medications. First is an explanation of why physicians’ concern about successful malpractice lawsuits brought simply because patients developed injuries during *proper* administration

273. *Clites v. State*, 322 N.W.2d 917, 923 (Iowa Ct. App. 1982) (affirming the jury negligence verdict of more than \$750,000); *Accardo v. Cenac*, 722 So. 2d 302, 313 (La. Ct. App. 1998) (ordering an increased damage award).

274. “[M]ost physicians live in constant apprehension of being named a defendant in a medical malpractice lawsuit.” MARSHALL B. KAPP, *OUR HANDS ARE TIED: LEGAL TENSIONS AND MEDICAL ETHICS* 8 (1998).

275. Letter from Steven E. Hyman, Director, National Institute of Mental Health, to Sally K. Richardson, Director, Center for Medicaid and State Operations, Health Care Financing Administration (Jan. 16, 1998), *reprinted in* National Alliance for the Mentally Ill, *HCFA Provides State Medicaid Office with Guidance on Access to Atypical Antipsychotic Medication*, at <http://www.nami.org/cgi-bin/printfyl.cgi?/update/980225.html> (last visited Aug. 4, 2002).

276. Kaye & Reed, *supra* note 210, at 331.

of older antipsychotics is, at this point, premature.²⁷⁷ This Article then reviews other types of malpractice lawsuits, including claims for injuries related to informed consent violations and wrongful death claims stemming from failure to take available precautions, which seem more likely to receive sound support from current clinical knowledge.²⁷⁸ Finally, this Part of the Article explains why litigation construing use of older drugs as violations of civil rights and of the Americans with Disabilities Act²⁷⁹ may be on the horizon.²⁸⁰

B. Malpractice Lawsuits: Four Potential Strategies

If a patient filed a suit for damages resulting from a conventional antipsychotic, defending such a prescription decision might well be an expensive and emotionally troubling experience for the accused clinician. From a legal perspective, however, the important question is whether such a lawsuit might succeed. The following Sections examine four legal theories under which such a lawsuit might be filed and consider the factors that might determine whether each type of lawsuit might lead to a successful outcome for the plaintiff.

1. Prescribing Neuroleptics as Per Se Malpractice

The previously cited comments of Mr. Tannenbaum and Dr. Glazer envision what one might call a “prescribing neuroleptics as per se malpractice” claim. Such a claim might be brought by a patient²⁸¹ who received a conventional neuroleptic well after less risky medications had become available and who, as often happens, suffered permanent neurological damage. Central to a per se malpractice claim is the belief that even if the prescribing physician followed prescribing practices that were acceptable only a few years ago, the advent of novel agents has made it possible to drastically reduce the risk of neurological damage, so that injuries from older neuroleptics ought to be compensable in a malpractice action. Unless a doctor has a compelling reason to prescribe a neuroleptic, this claim might state, failure to prescribe the more benign atypicals constitutes a deviation from the current national²⁸² standard of care.

277. See *infra* Part V.B.1.

278. See *infra* Parts V.B.2–V.B.4.

279. Americans with Disabilities Act of 1990, Pub. L. No. 101-336, 104 Stat. 327 (codified as amended in scattered sections of 29 U.S.C., 42 U.S.C., 97 U.S.C.).

280. See *infra* Part V.C.

281. To simplify exposition, this section refers to plaintiffs as though they were single patient litigants. Of course, lawsuits seeking recompense for medication induced injuries could also be brought by groups of plaintiffs or by a plaintiff’s family members.

282. For an endorsement of a national (rather than a local) standard of care, see

How might a patient-plaintiff support this contention? If his doctor prescribed a neuroleptic as the first choice antipsychotic therapy after 1999, the patient could point to the guidelines and algorithms cited earlier in this Article, arguing that these publications represent the consensus of experts about optimal care. Many prominent U.S. psychiatrists believe that the novel antipsychotics have raised expectations about therapeutic efficacy and functional outcomes for patients with schizophrenia and that these drugs have changed expectations about how to assess the effectiveness of pharmacological treatment. For example, in contrasting the treatment of a patient with schizophrenia in 1985 with current treatment, Dr. Ronald Pies suggests that formerly a substantial reduction in positive symptoms with only mild side effects represented the sought after treatment result in academic medical centers. Now, however, academic psychiatrists examine a patient's post-treatment cognitive function, affective state, relationships with family, and vocational functioning.²⁸³

Declaring novel antipsychotics the new standard of care may be an effective and legitimate rhetorical device to encourage physicians to update their practices and to goad public and private third party payers into making the new drugs readily available. In medical malpractice litigation, however, the phrase "prevailing standard of care" refers to "the average degree of skill, care and diligence exercised by members of the same medical specialty community in similar situations,"²⁸⁴ as established from the testimony of expert witnesses. Among the defenses permitted to a physician-defendant is the assertion that the chosen course of treatment had received the endorsement of "a respectable minority" of physicians and that he followed "acceptable procedures of administering the treatment as espoused by the minority."²⁸⁵

Systematic, up-to-the-minute data on the selection of antipsychotic agents are hard to come by. However, a multistate study of prescribing practices in the late 1990s found that conventional agents accounted for fifty-one percent of antipsychotic prescriptions.²⁸⁶ A 1999 publication

Morrison v. MacNamara, 407 A.2d 555, 564–65 (D.C. Cir. 1979).

283. Ronald Pies, *The Shifting Paradigm of Antipsychotic Outcome Assessment*, PSYCHIATRIC TIMES, Nov. 2000, at 54, 54.

284. *Bruni v. Tatsumi*, 346 N.E.2d 673, 676 (Ohio 1976).

285. *Hood v. Phillips*, 537 S.W.2d 291, 294 (Tex. Civ. App. 1976), *aff'd*, 554 S.W.2d 160 (Tex. 1977).

286. TAMI L. MARK ET AL., ACCESS TO NEW MEDICATIONS TO TREAT SCHIZOPHRENIA (n.d.), at http://www.medstat.com/products/posters/mark_2k.pdf (last visited Sept. 24, 2002).

also reported that conventional neuroleptics still accounted for a substantial fraction of U.S. antipsychotic prescriptions.²⁸⁷ A survey of 1998 Medicare and Medicaid funded antipsychotic prescription practices in nine states, published in January 2000, showed that just over half of the prescriptions for antipsychotics were for novel agents.²⁸⁸ A study of 1998 antipsychotic prescribing patterns in Texas prisons found that eighty-seven percent of inmates received only conventional neuroleptics.²⁸⁹ In December 2000, Kapur and Remington stated that in North America, novel agents accounted for three-fourths of new antipsychotic prescriptions,²⁹⁰ implying that conventional agents still accounted for the other quarter. Finally, from the time of her arrest in June 2001 through her internationally publicized criminal trial in March 2002, Andrea Pia Yates received the conventional antipsychotic drug haloperidol, which successfully treated her psychosis.²⁹¹ A few psychiatrists in the U.S.²⁹² and Great Britain²⁹³ have voiced their support in print for trying older antipsychotic medications before employing the newer, more expensive agents.²⁹⁴ Although he was among the earliest of psychiatrists to support first-line use of novel antipsychotics,²⁹⁵ Dr. Jeffrey Lieberman nonetheless believed in late 2000 that “a clinical and public policy decision to replace conventional with atypical antipsychotic agents, although appealing, requires more empirical evidence.”²⁹⁶ Clearly, at least a

287. Meltzer, *supra* note 251, at 7.

288. CATHERINE HARRINGTON ET AL., THE LEWIN GROUP, ACCESS AND UTILIZATION OF NEW ANTIDEPRESSANT AND ANTIPSYCHOTIC MEDICATIONS (2002), at <http://aspe.hhs.gov/health/reports/psychmedaccess/index.htm>.

289. Jacques Baillargeon & Salvador A. Contreras, *Antipsychotic Prescribing Patterns in the Texas Prison System*, 29 J. AM. ACAD. PSYCHIATRY L. 48, 51 (2001).

290. Kapur & Remington, *supra* note 204, at 1360.

291. Carol Christian, *Yates on Video: 'Psychosis Seems to Have Left Me'*, HOUS. CHRON., Mar. 7, 2002, at 1A. Ms. Yates was convicted of killing her five children. Jim Yardley, *Texas Jury Convicts Mother Who Drowned Her Children*, N.Y. TIMES, Mar. 13, 2002, at A23.

292. Robert A. Rosenheck, *Taking Issue: Pharmacological Progress: Seeking Balance*, 51 PSYCHIATRIC SERVICES 1213, 1213 (2000). (“The clinical benefit of atypical antipsychotics is small to modest, with little evidence of widespread dramatic gains in quality of life. The clearest advantage is reduction of extrapyramidal side effects, but adverse effects such as weight gain, diabetes, and hyperlipidemia threaten to take their place.”).

293. Geddes et al., *supra* note 20, at 1374.

294. Worldwide, atypical agents account for only one-tenth of prescriptions for antipsychotic drugs. Herbert Y. Meltzer, *Side Effects of Antipsychotic Medications: Physicians Choice of Medication and Patient Compliance*, 61 J. CLINICAL PSYCHIATRY 3, 3 (Supp. 8, 2000). Whether prescribing practices outside the U.S. would be relevant evidence concerning behavior within “the same medical community” would, of course, be a question for courts to settle.

295. Lieberman, *supra* note 209, at 71.

296. Jeffrey A. Lieberman et al., *Commentary & Analysis: Atypical Antipsychotics and SSRIs: Second Generation Drugs of the Psychopharmacological Revolution in*

respectable minority of psychiatrists still considers that first choice use of conventional antipsychotics would constitute acceptable psychiatric care, though experts increasingly prefer and recommend other patterns of medication selection. Prescribing neuroleptics is not yet malpractice, even if the older medications come with a higher risk that patients will suffer permanent neurological damage.

2. Failure to Inform

Though there is little reason to believe that a prescribing neuroleptics as per se malpractice claim would succeed, the opposite may be true for a malpractice lawsuit alleging that damages stemming from *failing to tell* a patient about the availability and possible advantages of the novel antipsychotics. Among the first psychiatrists to recognize this were Dr. Debra Pinals and Dr. Peter Buckley,²⁹⁷ who raised the specter of a malpractice claim similar to that brought in *Osheroff v. Chestnut Lodge, Inc.*²⁹⁸

In the late 1970s, Raphael Osheroff, a physician, underwent hospitalization at Chestnut Lodge, a psychiatric hospital in Maryland that had a national reputation for treating psychiatric disorders with psychoanalytically oriented treatment. The hospital's clinicians conceptualized Dr. Osheroff's emotional problems as manifestations of personality flaws, and his treatment consisted of psychotherapy alone. After spending seven months at Chestnut Lodge without improving, Dr. Osheroff went to Silver Hill Foundation Hospital in Connecticut, where clinicians diagnosed him with severe depression and treated him with antipsychotic and antidepressant medication. In three weeks, Dr. Osheroff had improved. In three months he had recovered enough to leave the hospital and soon thereafter he returned to medical practice. In 1982, Dr. Osheroff sued Chestnut Lodge, contending that the hospital negligently failed to tell him about and offer him pharmacological treatment. He also contended that pharmacological treatment was backed by scientific studies showing that it would likely be effective for treating his condition, whereas no study supported use of psychotherapy.²⁹⁹

Clinical Psychiatry, 51 PSYCHIATRIC SERVICES 1254, 1256 (2000).

297. Debra A. Pinals & Peter F. Buckley, *Novel Antipsychotic Agents and Their Implications for Forensic Psychiatry*, 27 J. AM. ACAD. PSYCHIATRY L. 7, 16 (1999).

298. 490 A.2d 720 (Md. Ct. Spec. App. 1985).

299. Gerald L. Klerman, *The Psychiatric Patient's Right to Effective Treatment: Implications of Osheroff v. Chestnut Lodge*, 147 AM. J. PSYCHIATRY 409, 410 (1990).

Osheroff has received little discussion in formal legal circles³⁰⁰ and ultimately produced no official legal precedent or standard concerning the obligation to provide information about treatment because it was settled before trial.³⁰¹ Yet the case has been the subject of intense debate within psychiatry, where it has symbolized the specialty's ongoing and contentious disagreements about the comparative merits of pharmacological and psychotherapeutic treatments, and physicians' obligations in selecting those treatments.³⁰²

For the present discussion, the importance of *Osheroff* stems from the effect of an institution wide approach to managing psychiatric patients on the plaintiff's treatment. Psychiatrists whose drug selections reflect institutional policies, particularly money saving policies that reflect managed care incentives or limitations in public sector funding, find themselves in therapeutic contexts that are analogous to those litigated in *Osheroff*. When a treating clinician prescribes one form of therapy but knows, or at least should know, about alternative therapies that other doctors might recommend under the circumstances, what is the doctor's obligation to his patient?

300. As published, *Osheroff* does not discuss the plaintiff's substantive malpractice claims. Subsequent cases have cited *Osheroff* in connection with judicial review of malpractice arbitration claims but not regarding standards of care themselves. See, e.g., *State Cent. Collection Unit v. Gettes*, 584 A.2d 689, 693 n.3 (Md. 1991). Two law review articles briefly discuss aspects of Dr. Osheroff's complaints about his treatment at Chestnut Lodge and his lawsuit's potential implications for mental health professionals. See Ron Nichwolodoff, *Expert Psychological Opinion Evidence in the Courts*, 6 HEALTH L. J. 279, 289 (1998); Note, Deborah Pergament, *Internet Psychotherapy: Current Status and Future Regulation*, 8 HEALTH MATRIX 233, 254 (1998).

301. Alan A. Stone, *Law, Science, and Psychiatric Malpractice: A Response to Klerman's Indictment of Psychoanalytic Psychiatry*, 147 AM. J. PSYCHIATRY 419, 420 (1990).

302. The centerpieces of the debate are the two just cited articles by Klerman and Stone. Letters responding to these articles filled eight pages in subsequent issues of the American Psychiatric Association's (APA) principal scientific publication. See *Comments on the Klerman-Stone Debate on Osheroff v. Chestnut Lodge*, 148 AM. J. PSYCHIATRY 139 (1991); see also Gerald L. Klerman, *The Osheroff Debate: Finale*, 148 AM. J. PSYCHIATRY 387 (1991). For a recent discussion, see DAVID HEALY, *THE ANTIDEPRESSANT ERA* 217-55 (1997).

Dr. Klerman died in 1992. Summarizing his views in the case, psychologist Myrna Weissman wrote:

[M]y late husband, Gerald L. Klerman, M.D. (a developer of psychotherapy and an expert in treatment evaluation), argued that a patient had the right to receive treatments that had been demonstrated to be effective for his or her condition. Osheroff's serious psychotic depression had resulted in his hospitalization and damage to his personal life and had not responded to psychotherapy alone. The empirical evidence, Klerman argued, pointed to treatment with antidepressants, with or without psychotherapy, rather than long-term psychoanalytic psychotherapy alone, which had not been demonstrated to be effective for psychotic depression and had not been effective in this case.

Myrna M. Weissman, Book Review, 338 NEW ENG. J. MED. 1475, 1475 (1998) (reviewing DAVID HEALY, *THE ANTIDEPRESSANT ERA* (1997)).

O'Keefe v. Orea,³⁰³ the only published appellate level psychiatric malpractice case that concerns the issue of choosing a typical versus a novel antipsychotic drug,³⁰⁴ addresses this specific issue. Ruth O'Keefe sued the psychiatrist who treated her son Christopher as an inpatient at Florida's Baptist Medical Center in 1993. After leaving the hospital, Christopher attacked his mother and father, killing the latter.³⁰⁵ During the hospitalization, a consultant psychiatrist had evaluated Christopher and had suggested consideration of a clozapine trial.³⁰⁶ The lawsuit alleged that the treating physician had failed to discuss this suggestion with Christopher's parents and that this failure, along with many other alleged errors, constituted negligence.³⁰⁷ Although the trial court dismissed Mrs. O'Keefe's suit, an appellate court reversed.³⁰⁸ Among the appellate court's holdings was the conclusion that the psychiatrist's fiduciary obligations included "a duty to inform Christopher's parents concerning . . . the diagnosis of other physicians who had observed Christopher, together with his personal treatment recommendations and the treatment recommendations of other physicians."³⁰⁹

U.S. legal requirements regarding a physician's duty to disclose information fall into one of two major categories. Most jurisdictions assess the duty using a "customary" or "professional standard,"³¹⁰

303. 731 So. 2d 680 (Fla. Dist. Ct. App. 1998).

304. At least three other published malpractice cases have concerned alleged misuse of clozapine. *See Baker v. Lane County*, 33 F. Supp. 2d 1291, 1295–97 (D. Or. 1999) (permitting a new trial over a clozapine related death because the previous verdict had been against the great weight of evidence, and the trial court had improperly admitted prejudicial evidence about the decedent); *Presto v. Charter Peachford Behavioral Health Sys., Inc.*, 494 S.E.2d 377, 379 (Ga. Ct. App. 1997) (upholding the trial court's grant of Charter Peachford's motion for summary judgment); *Presto v. Sandoz Pharm. Corp.*, 487 S.E.2d 70, 75 (Ga. Ct. App. 1997) (upholding the trial court's dismissal of the plaintiffs' claims against Sandoz Pharmaceuticals Corporation and affirming the trial court's grant of summary judgment in favor of Caremark, Inc.). A fourth case does not mention clozapine, but concerns a patient who gained weight and died of respiratory failure while taking the drug. *Patten v. Commonwealth*, 553 S.E.2d 517, 520 (Va. 2001) (affirming the trial court's decision to dismiss because the defendants were protected by sovereign immunity); *see also Patten v. Nichols*, 274 F.3d 829, 831 (4th Cir. 2001) (describing weight gain from clozapine).

305. *O'Keefe*, 731 So. 2d at 682.

306. *Id.* at 683.

307. *Id.*

308. *Id.* at 681.

309. *Id.* at 686.

310. "[I]n most jurisdictions, . . . the duty is measured by a professional medical standard: either the customary disclosure practices of physicians or what a reasonable physician would disclose under the same or similar circumstances." Laurent B. Frantz,

according to which physicians must disclose the information that other similarly qualified and situated physicians would disclose in the same situation.³¹¹ In contrast, a minority of jurisdictions apply a “materiality of the information” approach,³¹² which requires physicians to disclose to patients all information that would be considered “material” to a reasonable patient making a decision about a physician’s proposed course of treatment.³¹³ Rules in some states, including Louisiana,³¹⁴ Iowa,³¹⁵ Oregon,³¹⁶ and Tennessee,³¹⁷ represent variations on these two major approaches.³¹⁸

Annotation, *Modern Status of Views as to General Measure of Physician’s Duty to Inform Patient of Risks of Proposed Treatment*, 88 A.L.R. 3d 1008 § 2(a) (1978) (footnote omitted).

311. For example, in Nebraska, “Informed consent . . . mean[s] consent to a procedure based on information which would ordinarily be provided to the patient under like circumstances by health care providers engaged in similar practice in the locality or in similar localities.” *Giese v. Stice*, 567 N.W.2d 156, 162 (Neb. 1997).

312. “A number of jurisdictions, however, have recently embraced the view that a physician’s duty to inform his patient of the risks of a proposed treatment is measured, not by a professional medical standard, but by the patient’s need for information material to his decision whether to accept or reject the proposed treatment.” Frantz, *supra* note 310, § 2(a).

313. The most influential decision espousing the “materiality” standard, *Canterbury v. Spence*, 464 F.2d 772 (D.C. Cir. 1972), explicitly rejected the “professional” disclosure standard, *id.* at 783–84, and held that doctors must tell patients about “the inherent and potential hazards of the proposed treatment, the alternatives to that treatment, if any, and the results likely if the patient remains untreated,” *id.*, at 787–88. For a listing of cases following this later rule, see Frantz, *supra* note 310, § 6.

314. Louisiana statutory law requires disclosure of known risks of death, brain damage, paralysis, loss of limb, loss of function of organs, and disfiguring scars. LA. REV. STAT. ANN. § 1299.40 (West 2001 & Supp. 2002). If the consent forms do not meet the statutory requirement, the materiality standard applies. *LaCaze v. Collier*, 437 So. 2d 869, 870 (La. 1983) (Dennis, J., concurring).

315. The Iowa Supreme Court has interpreted Iowa statutes as codifying the materiality standard. *Pauscher v. Iowa Methodist Med. Ctr.*, 408 N.W.2d 355, 361 (Iowa 1987) (interpreting IOWA CODE § 147.137 (1981)).

316. In Oregon, physicians must disclose only in general terms the nature of the procedure and that there may be alternatives and risks. OR. REV. STAT. § 677.097(1) (2001). The physician must then ask the patient if a more thorough explanation is desired, and if so, all material risks and viable alternatives are to be disclosed. *Id.* § 677.097(2).

317. In Tennessee, “[i]f informed consent is not effectively obtained, the Defendants’ departure from the standard of care is not negligence, but battery, because the doctrine of battery is applicable to cases involving treatment performed without informed or knowledgeable consent.” *Roddy v. Volunteer Med. Clinic, Inc.*, 926 S.W.2d 572, 576 (Tenn. Ct. App. 1996); *see also* *Ray v. Scheibert*, 484 S.W.2d 63, 70 (Tenn. Ct. App. 1972) (discussing the distinction between cases based on lack of informed consent and cases alleging injury that resulted from negligent treatment).

318. Some jurisdictions have applied the materiality standard as an additional requirement beyond what physicians customarily tell patients in similar circumstances. *Cobbs v. Grant*, 502 P.2d 1, 11 (Cal. 1972); *Cornfeldt v. Tongen*, 262 N.W.2d 684, 702 (Minn. 1977), *modified*, 295 N.W.2d 638 (Minn. 1980).

O'Keefe articulates a disclosure requirement that appears consistent with the latter approach, that is, a requirement that the psychiatrist disclose not just the information about the particular proposed therapy, which some decisions endorsing the materiality standard have emphasized,³¹⁹ but also of the existence of other therapies and the benefits and risks of those therapies.³²⁰ In *O'Keefe* this requirement stemmed from the recommendation of another psychiatrist who had personally evaluated Christopher. It would not be surprising, however, for courts in jurisdictions that follow the materiality standard to view as potentially liable for damages a psychiatrist who prescribed neuroleptics but did not tell his patient about the novel antipsychotic drugs.³²¹ This

319. See, e.g., *Blincoe v. Luessenhop*, 669 F. Supp. 513 (D.D.C. 1987). A prima facie case in an informed consent action is established when the plaintiff shows:

1. the doctor failed to inform plaintiff of certain risks of the medical procedure;
2. the undisclosed risks were "material," i.e. the reasonable person, in what the physician knows or should know to be the plaintiff's position, would be likely to attach significance to the allegedly undisclosed risks in deciding to accept or to forego the proposed treatment;
3. the prudent person, in the plaintiff's position, would have decided to decline treatment if suitably informed of all perils bearing significance;
4. the undisclosed risk actually manifested itself and caused the damage for which plaintiff seeks recovery.

Id. at 616 (citations omitted). Ohio follows the same standard. *Nickell v. Gonzalez*, 477 N.E.2d 1145, 1148-49 (Ohio 1985).

320. Compare *Blincoe*, 669 F. Supp. 513, with *Bigay v. Garvey*, 575 N.W.2d 107 (Minn. 1998), and *Farina v. Kraus*, 754 A.2d 1215 (N.J. Super. Ct. App. Div. 1999). In *Bigay*, the Minnesota Supreme Court held that:

To establish a claim of negligent nondisclosure, a plaintiff must show five elements: (1) a duty on the part of a physician to know of a risk or alternative treatment plan; (2) a duty to disclose the risk or alternative program; (3) a breach of that duty; (4) causation, i.e., the undisclosed risk must materialize in harm; and (5) damages.

Bigay, 575 N.W.2d at 111 n.3. In *Farina*, the court stated that:

[T]he informed-consent basis of malpractice, as opposed to deviation from the applicable standard of care, rests not upon the physician having erred in diagnosis or administration of treatment but rather in the failure to have provided the patient with adequate information regarding the risks of a given treatment or with adequate information regarding the availability of alternative treatments and the comparative risks and benefits of each.

Farina, 754 A.2d at 1222-23.

321. John H. Derrick, Annotation, *Medical Malpractice: Liability for Failure of Physician to Inform Patient of Alternative Modes of Diagnosis or Treatment*, 38 A.L.R. 4th 900, 903 (1985):

[T]here is a duty imposed on the physician to disclose to the patient the existence of any methods of . . . treatment that would serve as feasible alternatives to the method initially selected by the physician The failure

may apply even if the psychiatrist had disclosed the risks of neuroleptics and monitored his patient carefully, and notwithstanding agency or institutional policies that endorsed a stepped care approach³²² to drug selection.

Available empirical data suggest that in actual practice, psychiatrists often do not inform patients of serious material risks associated with neuroleptic therapy.³²³ Also, studies suggest that psychiatrists typically do not document discussions about informed consent with patients that take antipsychotic drugs³²⁴ nor have they documented telling most patients that take neuroleptics either about the availability of atypicals or about their lower incidence of side effects.³²⁵

3. *Injuries from Mandated Depot Neuroleptics*

Malpractice litigation also might arise from medication selection in circumstances where informed consent to treatment is attenuated, such as outpatient civil commitment (OPC).³²⁶ OPC is just one method used by agencies, institutions, or individuals to induce, or coerce, nonhospitalized mentally ill persons to get psychiatric treatment, including medication. Examples of other means include conditioning receipt of welfare benefits on obtaining treatment, tying favorable disposition of a criminal case to the defendant's receiving treatment mandated by a mental health court, and advance directives.³²⁷ It is easily conceivable that the liability issues discussed here concerning OPC might apply, *mutatis mutandis*, to these other forms of leveraged treatment. American psychiatrists have endorsed OPC under certain circumstances³²⁸ as a treatment for severely

of a physician to disclose feasible alternatives has been held to permit a finding that the physician thereby failed to obtain the patient's informed consent to the method employed by the physician . . . and that the physician was thereby liable for malpractice.

322. See *supra* Part IV.B.6 (discussing the stepped care approach).

323. Irwin Kleinman & Debbie Schachter, *Obtaining Informed Consent of Patients at Risk of Neuroleptic Malignant Syndrome*, 51 PSYCHIATRIC SERVICES 1182, 1183 (2000).

324. Debbie Schachter & Irwin Kleinman, *Psychiatrists' Documentation of Informed Consent*, 43 CANADIAN J. PSYCHIATRY 1012, 1015 (1998).

325. Prakash S. Masand et al., *Prescribing Conventional Antipsychotics at Two Veterans Administration Hospitals: Are There Geographical Differences?*, 6 CNS SPECTRUMS 894, 895 (2001).

326. A recent discussion of the history of OPC and empirical research was prepared under the auspices of the APA's Council on Psychiatry and Law as an information source for persons preparing legislation. See Joan B. Gerbasi et al., *Resource Document on Mandatory Outpatient Treatment*, 28 J. AM. ACAD. PSYCHIATRY & L. 127, 127 (2000).

327. John Monahan et al., *Mandated Community Treatment: Beyond Outpatient Commitment*, 52 PSYCHIATRIC SERVICES 1198, 1199–1201 (2001).

328. See generally DAVID STARRETT ET AL., INVOLUNTARY COMMITMENT TO

mentally ill persons that suffer frequent psychotic relapses because they stop taking medication.³²⁹ Such patients also appear to be at a heightened risk for becoming violent shortly after they leave the hospital.³³⁰ Long-acting, “depot” injections of medication are often recommended for patients who will not or cannot comply with oral antipsychotic therapy, but the only depot preparations currently available in the United States contain neuroleptics.³³¹

A person subject to an OPC order could develop tardive dyskinesia because he was required to receive depot injections of neuroleptics.³³² Thus far, litigation about OPC related medication has focused on whether courts could require individuals to take drugs as part of the OPC order³³³ and what legal consequences might ensue if a patient did not

OUTPATIENT TREATMENT: REPORT OF THE TASK FORCE ON INVOLUNTARY OUTPATIENT COMMITMENT 16 (1987) (stating the APA’s position favoring the judicious use of OPC).

329. Thomas W. Haywood et al., *Predicting the “Revolving Door” Phenomenon Among Patients with Schizophrenic, Schizoaffective, and Affective Disorders*, 152 AM. J. PSYCHIATRY 856, 856 (1995); see also S. Davies, *Involuntary Out-patient Commitment and Supervised Discharge*, 177 BRIT. J. PSYCHIATRY 183, 183 (2000) (reporting recidivism that was reduced in British outpatients); Marvin S. Swartz et al., *Can Involuntary Outpatient Commitment Reduce Hospital Recidivism?: Findings from a Randomized Trial with Severely Mentally Ill Individuals*, 156 AM. J. PSYCHIATRY 1968, 1973 (1999) (reporting long-term OPC reduced recidivism in North Carolina patients). But see Henry J. Steadman et al., *Assessing the New York City Involuntary Outpatient Commitment Pilot Program*, 52 PSYCHIATRIC SERVICES 330, 332–33 (2001) (reporting that OPC did not affect rates of rehospitalization).

330. Marvin S. Swartz et al., *Violence and Severe Mental Illness: The Effects of Substance Abuse and Nonadherence to Medication*, 155 AM. J. PSYCHIATRY 226, 230 (1998) (finding an increased risk of violence among discharged patients who use drugs but do not take prescribed psychotropic medication); see also Jeffrey W. Swanson et al., *Involuntary Out-Patient Commitment and Reduction of Violent Behaviour in Persons with Severe Mental Illness*, 176 BRIT. J. PSYCHIATRY 324, 329 (2000) (reporting OPC successful in reducing violence).

331. The neuroleptics are haloperidol and fluphenazine. For a chemical description of long-acting injectable haloperidol, see PDR, *supra* note 49, at 2535–56.

332. Several statutes include medication compliance as a criterion for invoking OPC. See, e.g., TENN. CODE ANN. § 33–6–602(2) (1997) (stating that an OPC patient may be “obligat[ed] to participate in any medically appropriate outpatient treatment, including . . . medication”); WIS. STAT. § 51.20(13)(dm) (1999–2000) (stating that OPC is permissible if a patient’s dangerousness “is likely to be controlled with appropriate medication administered on an outpatient basis”). Although North Carolina’s statute does not authorize forcible administration of medication, most patients believe that OPC mandates compliance with medication. Randy Borum et al., *Consumer Perceptions of Involuntary Outpatient Commitment*, 50 PSYCHIATRIC SERVICES 1489, 1489–90 (1999).

333. See, e.g., *In re K.B.*, 562 N.W.2d 208, 211–12 (Mich. Ct. App. 1997) (reasoning that returning an outpatient to a hospital involuntarily after refusing to take antipsychotic medication is not a violation of due process).

take medication.³³⁴ The arrival and increased U.S. usage of novel antipsychotics suggests another type of litigation addressed not to the requirement of medication itself, but to the *type* of antipsychotic medication that was required. A patient might bring a malpractice lawsuit alleging negligence because his doctor insisted that he needed a compliance-guaranteeing depot neuroleptic preparation and did not try one of the orally administered novel antipsychotics. Even the strong proponents of the novel agents believe that outpatient noncompliance is an unambiguous indication for a depot neuroleptic.³³⁵ Therefore, a key issue in a malpractice case would be the evidence the psychiatrist could muster to show that the patient would not have taken oral medication, would have been likely to experience quick relapse and dire consequences, and therefore needed a long-acting injectable antipsychotic drug. Although successful suits for tardive dyskinesia have been uncommon to date,³³⁶ evidence on patients' compliance with and acceptance of new medications³³⁷ may increase the likelihood that injuries from neuroleptics could lead to successful litigation over the next few years.

4. Neuroleptics and Harm to Self or Others

Persons with schizophrenia appear to be at unusually high risk for

334. *In re Matter of Tarpley*, 581 N.E.2d 1251, 1252 (Ind. 1991) (finding that the trial court lacked authority to either require the patient to take medication or hold him in contempt for noncompliance); *In re Matter of Utley*, 565 N.E.2d 1152, 1156–67 (Ind. Ct. App. 1991) (stating that the trial court committed error in finding the patient guilty of criminal contempt for failing to take medication without a determination that the patient's noncompliance was willful and not caused by illness).

335. *Guideline Series*, *supra* note 210, at 12; Miller et al., *supra* note 210, at 652.

336. 3 PERLIN, *supra* note 4, at 354–55 (2000); Kaye & Reed, *supra* note 210, at 331.

337. See, e.g., Julio Bobes et al., *Risperidone: A Real Alternative to Depot Neuroleptic Treated Patients*, 28 ACTAS ESP. PSIQUIATR. 367 (2000) (reporting that risperidone improved disability, psychotic symptoms, and tolerability in patients); John G. Csernansky et al., *A Comparison of Risperidone and Haloperidol for the Prevention of Relapse in Patients with Schizophrenia*, 346 NEW ENG. J. MED. 16, 18 (2002) (reporting that patients treated with risperidone had a lower risk of relapse, and were less likely to stop treatment, than were patients taking haloperidol); N.M. Desai et al., *Switching from Depot Antipsychotics to Risperidone: Results of a Study of Chronic Schizophrenia*, 16 ADVANCES THERAPY 78 (1999) (stating that patients previously taking depot neuroleptics benefited from, complied with, and preferred risperidone).

This evidence is not unanimous. A study of prescription refill patterns suggests that outpatients' compliance with most oral atypicals is no better than with neuroleptics. Mark Vanelli et al., *Refill Patterns of Atypical and Conventional Antipsychotic Medications at a National Retail Pharmacy Chain*, 52 PSYCHIATRIC SERVICES 1248, 1249 (2001). The exception was clozapine, where the demands for frequent blood drawing required eight pharmacy visits per month, plus additional visits to psychiatrists. "This process may have resulted in better patient engagement," or it may have been the case that the patients doctors selected to receive clozapine were more compliant patients or patients with good social support. *Id.*

committing suicide³³⁸ and have an increased risk of acting violently toward others.³³⁹ Self-harming behavior that results in serious injury and aggression by patients towards others are well known sources of malpractice litigation for psychiatrists.³⁴⁰ In 1999, Pinals and Buckley described published reports on the superiority of novel antipsychotic agents in reducing patients' aggressiveness.³⁴¹ Recent studies have found that arrest rates fall after patients began receiving clozapine³⁴² and

338. Herz et al., *supra* note 143, at 5 (“[S]uicide . . . occurs in up to 10% of patients” with schizophrenia).

339. See, e.g., Louise Arseneault et al., *Mental Disorders and Violence in a Total Birth Cohort: Results from the Dunedin Study*, 57 ARCHIVES GEN. PSYCHIATRY 979, 982 (2000) (reporting that persons with schizophrenia are 2.5 times more likely to become violent than nondisordered persons and persons with schizophrenia and marijuana dependence had far higher rates of violence); Patricia A. Brennan et al., *Major Mental Disorders and Criminal Violence in a Danish Birth Cohort*, 57 ARCHIVES GEN. PSYCHIATRY 494, 494 (2000) (“Individuals hospitalized for schizophrenia and men hospitalized with organic psychosis have higher rates of arrests for violence than those never hospitalized.”); Sheilagh Hodgins et al., *Mental Disorder and Crime: Evidence From a Danish Birth Cohort*, 53 ARCHIVES GEN. PSYCHIATRY 489, 489 (1996) (“Women and men who had been hospitalized in psychiatric wards were more likely to have been convicted of a criminal offense than persons with no history of psychiatric hospitalization.”); Bruce G. Link et al., *The Violent and Illegal Behavior of Mental Patients Reconsidered*, 57 AM. SOC. REV. 275, 275 (1992) (reporting that the risk of violence stems from active symptoms of the disorder, not from having the disorder per se); Jeffrey W. Swanson et al., *Psychotic Symptoms and Disorders and the Risk of Violent Behaviour in the Community*, 6 CRIM. BEHAV. & MENTAL HEALTH 309, 317 (1996) (reporting that the risk of violence stems from active symptoms of the disorder, not having the disorder per se); Jeffrey W. Swanson et al., *Violence and Psychiatric Disorder in the Community: Evidence from the Epidemiologic Catchment Area Surveys*, 41 HOSP. & COMMUNITY PSYCHIATRY 761, 769 tbl.7 (1990) (reporting that schizophrenia increases the risk by approximately six times); Jari Tiihonen et al., *Specific Major Mental Disorders and Criminality: A 26-Year Prospective Study of the 1966 Northern Finland Birth Cohort*, 154 AM. J. PSYCHIATRY 840, 840 (1996) (“[The] risk of criminal behavior was significantly higher among subjects with psychotic disorders, even though the socioeconomic status of the childhood family was controlled.”).

340. Douglas Mossman & Marshall B. Kapp, *Malpractice and the Psychiatrist: A Primer for Residents*, 21 ACADEMIC PSYCHIATRY 11 (1997). Under a variety of circumstances, psychiatrists face potential malpractice liability for wrongful death claims stemming from a patient's suicide. See 3 PERLIN, *supra* note 4, § 7A–8 (2000) (discussing suicide cases and related commentary). The leading case finding therapist liability for failing to protect the potential victim of his patient is *Tarasoff v. Regents of the University of California*, 551 P.2d 334 (Cal. 1976). For a discussion of *Tarasoff*, its case law progeny, and related commentary by legal scholars and mental health professionals, see 3 PERLIN, *supra* note 4, § 7C–2 (2000).

341. Debra A. Pinals & Peter F. Buckley, *Novel Antipsychotic Agents and Their Implications for Forensic Psychiatry*, 27 J. AM. ACAD. PSYCHIATRY L. 7, 7 (1999).

342. W. Gordon Frankle et al., *Clozapine-Associated Reduction in Arrest Rates of Psychotic Patients with Criminal Histories*, 158 AM. J. PSYCHIATRY 270, 273 (2001)

that olanzapine reduced scores on a scale measuring intentional aggressive behavior.³⁴³ Conceivably, following violence done to a third party by a neuroleptic treated patient, especially a patient who previously had exhibited behavior indicative of a propensity to act aggressively,³⁴⁴ the injured party or his relatives might sue the patient's psychiatrist, alleging that by not prescribing a novel antipsychotic, the clinician had negligently failed to take reasonable measures to reduce a foreseeable risk.³⁴⁵ Family members of a neuroleptic treated patient who committed suicide and had exhibited depressive symptoms might lodge a similar claim against their relative's psychiatrist. To support their claim, they could cite prominent psychiatrists' beliefs that atypical agents reduce schizophrenic patients' depressive symptoms and risk of suicide.³⁴⁶

("[A]rrest rates of the patients taking clozapine were significantly lower while they were taking the drug than before they were given the drug.")

343. Narendran et al., *supra* note 50, at 515.

344. See RESTATEMENT (SECOND) OF TORTS § 319 (1965) ("One who takes charge of a third person whom he knows or should know to be likely to cause bodily harm to others if not controlled is under a duty to exercise reasonable care to control the third person to prevent him from doing such harm."). That doctors have a long recognized legal duty to protect persons from a patient with a known propensity toward violence is illustrated in *University of Louisville v. Hammock*, 106 S.W. 219 (Ky. 1907). In *Hammock*, the court stated that a patient's

disease being known, as it was, to a physician of the institution [and other personnel], . . . and their further knowledge, especially that of the physician, that a person so afflicted might reasonably be expected to become violent, uncontrollable, and dangerous at any time, ought to have induced them to take such reasonable precautions with reference to his control or confinement as would have prevented his inflicting injury upon other inmates . . .

Id. at 220.

345. In an article authored before the advent of novel antipsychotic agents, Appelbaum listed administration of medication as one potential option for reducing a patient's risk of violence. See Paul S. Appelbaum, *Tarasoff and the Clinician: Problems in Fulfilling the Duty to Protect*, 142 AM. J. PSYCHIATRY 425, 426 (1985).

346. Paul E. Keck, Jr. et al., *The Efficacy of Atypical Antipsychotics in the Treatment of Depressive Symptoms, Hostility, and Suicidality in Patients with Schizophrenia*, 61 J. CLINICAL PSYCHIATRY 4, 8 (Supp. 3, 2000); Herbert Y. Meltzer et al., *Assessing Cardiovascular Risks Versus Clinical Benefits of Atypical Antipsychotic Drug Treatment*, 63 J. CLINICAL PSYCHIATRY 25, 27 (Supp. 9, 2000); William H. Reid et al., *Suicide Prevention Effects Associated with Clozapine Therapy in Schizophrenia and Schizoaffective Disorder*, 49 PSYCHIATRIC SERVICES 1029, 1032 (1998). *But see* Fontaine et al., *supra* note 238, at 286 (finding absence of data to support claim of decreased mortality associated with clozapine or olanzapine); Michael J. Sernyak et al., *Impact of Clozapine on Completed Suicide*, 158 AM. J. PSYCHIATRY 931, 935 (2001) (reporting that taking clozapine was associated with a decreased death rate but not with a decrease in the suicide rate). For a case involving a therapist's not taking "appropriate preventive measures" prior to a patient's suicide (although ultimately barred due to the statute of limitations), see *Bellah v. Greenson*, 146 Cal. Rptr. 535, 538-39 (Ct. App. 1978).

C. Neuroleptics as Civil Rights Violations and Discrimination

Besides malpractice lawsuits, psychiatrists and treatment agencies that provide care to patients with psychoses must consider two additional types of litigation as possible consequences of administering older neuroleptics: civil rights actions and actions alleging discrimination under the Americans with Disabilities Act.

I. Neuroleptics as Civil Rights Violations

A patient who was involuntarily committed to a government run hospital and who received treatment from hospital employed physicians could file an action under 42 U.S.C. § 1983³⁴⁷ alleging that using neuroleptics as drugs of first choice constituted a violation of his civil rights. The starting point for any analysis of such a claim is *Youngberg v. Romeo*.³⁴⁸

During a two-year stay at the Pennhurst State School and Hospital, Nicholas Romeo, a severely retarded, involuntarily committed resident, sustained scores of bodily injuries that had been inflicted by himself and other residents, including cuts, broken bones, and damaged genitalia.³⁴⁹ His mother filed a next friend civil rights suit alleging that administrators' failure to protect Romeo violated the Eighth and Fourteenth Amendments. After the suit was filed, Romeo was transferred to the facility's hospital for treatment, where he was restrained daily. His mother's suit was subsequently amended to seek relief from excessive restraint and compensation for failure to provide him with treatment.³⁵⁰

In its Fourteenth Amendment analysis of Romeo's claim, the U.S. Supreme Court held that institutionalized individuals in Romeo's position were entitled to "adequate food, shelter, clothing, and medical

347. Every person who, under color of any statute, ordinance, regulation, custom, or usage, of any State or Territory or the District of Columbia, subjects, or causes to be subjected, any citizen of the United States or other person within the jurisdiction thereof to the deprivation of any rights, privileges, or immunities secured by the Constitution and laws, shall be liable to the party injured in an action at law, suit in equity, or other proper proceeding for redress

42 U.S.C. § 1983 (2000).

348. 457 U.S. 307 (1982).

349. *Romeo v. Youngberg*, 644 F.2d 147, 155 (3d Cir. 1980), *vacated*, 457 U.S. 307 (1982). Some skin injuries became infected either because of inadequate attention or failure to clean up human excrement. *Id.*

350. *Youngberg*, 457 U.S. at 311–12.

care,”³⁵¹ and to the substantive due process rights of safe conditions³⁵² and freedom from excessive restraint.³⁵³ In addition, Romeo had a limited right, if not to treatment, then to training that could “ensure his safety and . . . facilitate his ability to function free from bodily restraints.”³⁵⁴

The Court also said, however, that the proper standard for assessing whether these rights had been satisfied was only whether the decision concerning the patient’s care had been that of an appropriate “professional decisionmaker”³⁵⁵ and had reflected “professional judgment.” A decision by an appropriate professional was presumptively valid, and liability could be imposed only if “the decision by the professional [represented] . . . such a substantial departure from accepted professional judgment, practice or standards as to demonstrate that the person responsible actually did not base the decision on such a judgment.”³⁵⁶ Professionals would *not* be liable individually if they could not satisfy their normal professional standards “because of budgetary restraints.”³⁵⁷

Several cases that predated novel antipsychotics established that a psychiatric inpatient might enforce his right to refuse involuntarily administered psychotropic medication through a § 1983 claim, while affirming that professional judgment was the standard against which a violation of that right must be judged.³⁵⁸ With the availability of novel

351. *Id.* at 324. The Court characterized these items as “the essentials of the care that the state must provide,” *id.*, despite Romeo’s having been lawfully committed to Pennhurst.

352. *Id.* at 315–16.

353. *Id.* at 316.

354. *Id.* at 324.

355. *Id.* at 323. The Court defined “professional decisionmaker” as “a person competent, whether by education, training or experience, to make the particular decision at issue. Long-term treatment decisions normally should be made by persons with degrees in medicine or nursing, or with appropriate training . . .” *Id.* at n.30. Moment-to-moment decisions could be made by employees “subject to the supervision of qualified persons.” *Id.* The choices concerning psychotropic medications focused on here clearly are long-term treatment decisions that would be properly made by psychiatrists.

356. *Id.*

357. *Id.*

358. *See, e.g.,* *Walters v. W. State Hosp.*, 864 F.2d 695, 697 (10th Cir. 1988) (stating that the patient’s right to refuse psychotropic drugs was clearly established when the defendants allegedly deprived the plaintiff of this right); *Dautremont v. Broadlawns Hosp.*, 827 F.2d 291, 300 (8th Cir. 1987) (recognizing the right to maintain a § 1983 claim against forced administration of medication); *Johnson v. Silvers*, 742 F.2d 823, 825 (4th Cir. 1984) (stating that forcible administration of antipsychotic drugs to involuntarily committed mental patients violates a constitutionally protected liberty interest in freedom from bodily restraint); *Rennie v. Klein*, 720 F.2d 266, 268 (3rd Cir. 1983) (stating that involuntarily committed patients have a constitutional right to refuse antipsychotic drugs and endorsing the “acceptable professional judgment” standard enunciated in *Youngberg*, 457 U.S. 307 (1982)).

antipsychotics, a new twist has been added: Can administration of conventional neuroleptics, even judicious administration to patients who had not refused antipsychotic drug therapy, generate a successful civil rights claim? Might a court find that it was “a substantial departure from accepted professional judgment, practice, or standards”³⁵⁹ for an institution to make financial rather than clinical considerations the primary factor in its drug selection policies?

In her analysis of this issue, attorney Susan Stefan describes a hypothetical situation in which a public sector psychiatrist did not offer his patient clozapine³⁶⁰ because the state had not budgeted funds for the costly drug. She suggests that “the ‘decision’ not to use Clozaril may not represent a judgment by the professional at all, but a [financial] decision by agency administrators who are not mental health professionals.”³⁶¹ The distinction between “acceptable professional standards based on expertise in diagnosis and treatment” and policies “developed on the basis of state budgetary or resource considerations,” Ms. Stefan argues, was implied in the U.S. Supreme Court’s decision to exempt state professionals from individual liability for financially induced departures from professional judgment.³⁶² The *Youngberg* standard, says Ms. Stefan, implies “that it is not appropriate to consider budgetary constraints”³⁶³ in determining what constitutes the prevailing professional standard. The professional judgment standard contemplates “an assessment of challenged actions at a given institution against professional standards developed nationwide.”³⁶⁴ The proper question to ask is whether the allegedly inadequate treatment “would be among the options offered this patient in a private setting,”³⁶⁵ where patients make decisions for themselves about how much to spend on various alternative therapies. “If so, then the professional judgment standard is met.”³⁶⁶ Accordingly, it would be acceptable for a state not to provide clozapine or, presumably, the other novel agents now available, to all patients who

359. *Youngberg*, 457 U.S. at 323.

360. In 1992, when Ms. Stefan’s article was published, clozapine was the only available novel agent.

361. Stefan, *supra* note 41, at 691.

362. *Id.* at 696 (citing American Psychiatric Association, *Ethical Principles of Psychologists*, 45 AM. PSYCHOLOGIST 390–95 (1989) (discussing *Youngberg*, 457 U.S. at 323)).

363. Stefan, *supra* note 41, at 696 n.277.

364. *Id.* at 697.

365. *Id.*

366. *Id.*

might receive potential benefit from the drug only “if there [we]re other more economical treatments that [we]re sufficiently effective that professionals in the private sector would also prescribe them.”³⁶⁷

If Ms. Stefan’s analysis is correct, then a financially motivated approach to antipsychotic treatment selection probably would *not* represent a violation of a public sector patient’s civil rights. When treating a cost conscious patient, a private psychiatrist might well recommend treatment with an inexpensive conventional agent, with plans to try an atypical antipsychotic agent only if a cheaper medication were inadequately effective or caused intolerable side effects.³⁶⁸

Complete refusal to provide novel drugs at all, even after failed treatment with neuroleptics, might yield a somewhat different result. Due to the fact that clozapine is the first atypical agent to become available in the U.S., the five major decisions concerning institutionalized patients’ access to novel antipsychotics have focused on that drug.³⁶⁹

The first two decisions were issued in the early 1990s following clozapine’s U.S. release. Although these cases did not address the concerns of institutionalized patients only, they clarified a key obligation in the program that pays for many patients’ clozapine treatment, state funded Medicaid. Courts in Kansas³⁷⁰ and New York³⁷¹ found that state

367. *Id.* at 699.

368. Patients may prefer older drugs for reasons besides cost. Although some weight gain is a concomitant of most antipsychotic therapy, the novel agents appear more prone to inducing this problem; the neuroleptic molindone appears to be associated with some weight *loss*. Masand & Gupta, *supra* note 191, at 301. According to one recent review, atypical associated “weight gain . . . is highly distressing to patients, may reduce treatment adherence, and may increase the relative risk for diabetes mellitus and hypertriglyceridemia.” Roger S. McIntyre et al., *Antipsychotic Metabolic Effects: Weight Gain, Diabetes Mellitus, and Lipid Abnormalities*, 46 CANADIAN J. PSYCHIATRY 273, 273 (2001). Also, the pharmacotherapy of schizophrenia can last for decades. Psychiatrists’ experience with risperidone treatment comprises just nine years, and we have even less experience with the other novel agents. Lieberman et al., *supra* note 296, at 1256.

369. A sixth case addresses the rights of a woman who had been jailed for less than 20 hours. *Eres v. County of Alameda*, No. C-96-2094 MHP, 1999 U.S. Dist. LEXIS 1385, at *31–32 (N.D. Cal. Feb. 2, 1999) (finding that failure of county jail personnel to provide an inmate with risperidone was not deliberate indifference). A seventh case, granting summary judgment to prison officials in a case alleging that deliberate indifference led to an inmate’s suicide, discusses the allegation that prison therapists did not administer clozapine because of the drug’s expense. *Pelletier v. Magnusson*, 201 F. Supp. 2d 148, 168 (D. Me. 2002) (stating that plaintiff’s assertion about financial motivation “is nothing more than a theory”). The inmate had been receiving risperidone. *Id.* at 159.

370. *Visser v. Taylor*, 756 F. Supp. 501 (D. Kan. 1990). In *Visser*, the plaintiff’s action was authorized by 42 U.S.C. § 1983, and Kansas Medicaid’s refusal to cover clozapine in its prescription drug program violated 42 C.F.R. § 440.230(c) because it was an arbitrary reduction in services to eligible individuals. *Id.* at 504, 507–08. Furthermore, the court required state Medicaid coverage of clozapine for eligible patients and ordered the drug to be included in the program’s formulary list. *Id.* at 507–08.

Medicaid programs were obligated to include clozapine in formularies and cover the drug's costs. The option to take clozapine had to be available to patients whose physicians believed the drug was necessary and appropriate therapy.³⁷²

Three other decisions have looked at whether particular individuals or classes of patients were entitled to clozapine therapy. In a 1993 unpublished decision, a Massachusetts federal district court dismissed a § 1983 action brought by Sherman Miller, who had been a resident of the Bridgewater (Massachusetts) Treatment Center for Sexually Dangerous Persons (BTC) for about fifteen years following his 1978 conviction for rape.³⁷³ Although Miller had been offered several psychosocial and nonpharmacological therapies, he claimed that "his only hope of release might rest on securing clozapine therapy" and that BTC's failure to prescribe clozapine for him therefore represented inadequate treatment.³⁷⁴ The court of appeals supported the district court's dismissal of Miller's claim, including the lower court's ruling "that, without more, the BTC's mere failure to provide this one recommended treatment was insufficient to demonstrate a genuine issue of material fact."³⁷⁵

In *Gates v. Shinn*, a 1996 decision dealing with California prisoners, the Court of Appeals for the Ninth Circuit held that a 1990 consent decree mandating "appropriate psychiatric care for prisoners" did not obligate the state to make clozapine therapy available to inmates.³⁷⁶ In

371. *Alexander L. v. Cuomo*, 588 N.Y.S.2d 85, 88 (Sup. Ct. 1992) (holding that a mandamus order is an appropriate remedy to compel the state's health commissioner to include clozapine in the Medicaid formulary). "Cost alone, or unique but necessary medical care for Medicaid recipient have not been a bar to Medicaid Coverage." *Id.*

372. Following the *Visser* decision, Pennsylvania officials abandoned that state's lottery system for assigning clozapine therapy three months after a § 1983 action was brought against the practice. *Alliance for the Mentally Ill of Pa., Inc. v. White*, No. 90-6389, 1991 U.S. Dist. LEXIS 15994, at *1-2 (E.D. Pa. Nov. 4, 1991).

373. *Miller v. Dep't of Corr.*, No. 91-2183, 1993 U.S. App. LEXIS 17463, at *1 (1st Cir. July 14, 1993).

374. *Id.* at *9.

375. *Id.* at *17-18.

376. *Gates v. Shinn*, 98 F.3d 463, 464, 472 (9th Cir. 1996). The case originated as a civil rights action under 42 U.S.C. § 1983 and 29 U.S.C. § 794. *Gates v. Gomez*, 60 F.3d 525, 527 (9th Cir. 1995). It challenged the medical care, psychiatric care, and conditions of confinement at the California Medical Facility and Main Northern Reception Center in Vacaville, California, and also challenged the treatment of HIV-infected inmates. *Id.* The case went to trial in September 1989. *Id.* After the plaintiffs rested their case, settlement negotiations culminated in a consent decree that was approved March 8, 1990. *Id.*

reaching this decision, the court cited an affidavit filed several months before the decision by Richard Yarvis, M.D., the prison system's psychiatric expert, whose opinions had been considered in mediation discussions. Dr. Yarvis believed that not treating prisoners with clozapine made sense, because low staffing levels would make it difficult to administer the medication safely. He added, however, that "new medications with potentially less risk are about to come on line in psychiatric practice."³⁷⁷

Finally, a 1997 federal court ruling³⁷⁸ concerning adherence to treatment standards promulgated in the original *Wyatt v. Stickney*³⁷⁹ case criticized Alabama state facilities for sloppy record keeping and for leaving long-term patients "on stagnant medication regimes."³⁸⁰ However, the court declined to fault clinicians for not prescribing clozapine. The court felt it could not, "and should not, fault the defendants for deciding, in their professional judgment, not to use [clozapine]. Moreover, the court's duty does not extend to such minuscule oversight."³⁸¹

These five cases suggest the following conclusions. A financially motivated institutional posture that precluded *any* use of the newer antipsychotics might trigger an ultimately successful § 1983 action. However, U.S. courts have not held that civil rights considerations obligate psychiatrists, institutions, or public agencies to treat a particular patient with a particular drug. Medication choices that reflect professional judgment, including use of old neuroleptics, would pass constitutional muster.³⁸² Courts have not held that psychiatrists or government agencies must use novel antipsychotic drugs rather than neuroleptics as first-line treatment for all patients that need antipsychotic therapy. As long as patients can get novel agents when their doctors think they need them, it seems permissible to make drug choices using a financially

377. *Gates*, 98 F.3d at 470. The medications to which Dr. Yarvis referred are the atypical antipsychotics released since 1994 which, unlike clozapine, do not require frequent blood testing.

378. *Wyatt v. Rogers*, 985 F. Supp. 1356 (M.D. Ala. 1997).

379. 325 F. Supp. 781 (M.D. Ala. 1971). The subsequent history of the *Wyatt* litigation is summarized in *Wyatt*, 985 F. Supp. at 1361–83. For a thorough, perspicacious description of the background, development, and impact of *Wyatt v. Stickney*, see 2 PERLIN, *supra* note 4, §§ 3A-3, 3A-14.2 (1999).

380. *Wyatt*, 985 F. Supp. at 1386.

381. *Id.* at 1396.

382. Failure to offer any reasonable treatment might well be unacceptable, however. If a prisoner could show a serious need for psychiatric treatment and that prison authorities displayed deliberate indifference in declining to provide medical attention, he might successfully litigate a constitutional rights violation under 42 U.S.C. § 1983. *Hudson v. McMillian*, 503 U.S. 1, 8 (1992); *Wilson v. Seiter*, 501 U.S. 294, 297–98 (1991). Merely negligent treatment is not cognizable under § 1983. *Daniels v. Williams*, 474 U.S. 327, 332 (1986). However, such treatment might be the basis for a tort action (unless barred by sovereign immunity). *Id.*

motivated policy of stepped care, that is, trying cheaper drugs first and using atypicals if neuroleptics fail or cause side effects.³⁸³ This would seem particularly acceptable if professional judgment had deemed the policy to represent the best use of limited but adequate treatment resources. Not giving clozapine to prisoners also appears permissible if staffing is not sufficient to make sure that the medication can be administered safely. Lack of staffing would not excuse a prison from not treating inmates with the other atypicals, however, because these drugs are no harder to administer than cheaper, conventional neuroleptics.

Before concluding this section, we must distinguish a judicious, stepped care approach that manages atypicals wisely and provides them when patients need them from a situation that results from a state's failure to allocate sufficient funds to make atypical antipsychotics available *at all*. That the latter scenario, which reflects legislative budgetary decisions and not professional judgment, represents a civil rights violation was endorsed by the Clinton Administration's Justice Department. In an October 6, 1999 letter³⁸⁴ to Virginia Governor James S. Gilmore III that summarized findings of an investigation³⁸⁵ of conditions at Western State Hospital in Staunton, Virginia, Bill Lann Lee, then the Acting Assistant Attorney General for the Justice Department's Civil Rights Division, described what he termed "constitutional and federal statutory violations at Western State."³⁸⁶

383. For a fuller definition of stepped care as used in this Article, see *supra* Part IV.B.6.

384. Letter from Bill Lann Lee, Acting Assistant Attorney General, Civil Rights Division, to the Honorable James S. Gilmore III, Governor of Virginia (n.d.), at <http://www.usdoj.gov/crt/split/documents/westernfl.htm> (last visited Aug. 1, 2002) [hereinafter Letter from Lee]. The state of Virginia agreed to federal monitoring under a consent decree reached May 6, 1999. Press Release, U.S. Dep't of Justice, Virginia Institution for the Mentally Ill Agrees to Improve Conditions Under Justice Department Agreement (May 6, 1999), at <http://www.usdoj.gov/opa/pr/1999/May/175cr.htm> (last visited Sept. 24, 2002).

385. The investigation was conducted pursuant to the Civil Rights of Institutionalized Persons Act, 42 U.S.C. § 1997 (2000).

386. Mr. Lee's letter does not specify which of the problems discussed in his letter are constitutional violations, violations of statutes, or both. His letter mentions the *Olmstead* decision, discussed in Part V.C.2. Letter from Lee, *supra* note 384.

The Justice Department's investigation is mentioned in *Patten v. Nichols*, 274 F.3d 829, 833 (4th Cir. 2001). Interestingly, the *Patten* plaintiff's § 1983 action alleged, inter alia, that allowing an already obese, civilly committed inpatient with respiratory problems to gain thirty-seven pounds while taking clozapine represented a departure from professional judgment. *Id.* at 831. The Court found that the *Youngberg* standard

Mr. Lee noted:

Western State frequently fails to provide necessary psychotropic medications to its patients. Our expert consultants found that the restricted availability of particular psychotropic medications is a significant deficiency in psychopharmacologic practice at Western State. Facility officials and staff report that when a physician determines that a patient requires one of the newer, more effective antipsychotic medications, known as “atypicals,” the required medicine is not available because of budgetary restrictions. As a result, Western State psychiatrists prescribe antipsychotic medications based on budgetary constraints, rather than clinical indications. Physicians on all units indicated that the unavailability of atypicals is a significant impediment to providing appropriate patient care. Western State’s clinical psychopharmacologist confirmed that the budget has allowed no new prescriptions of atypical antipsychotic medication since December 1997. As a result, many Western State patients are not receiving medications that their psychiatrists have determined to be clinically necessary and appropriate. Citing numerous examples of patients who would benefit from atypical medications, our psychiatric consultant concluded that patients deprived of appropriate medications are harmed by suffering prolonged psychotic symptoms, endure unnecessary painful physical side effects, suffer a greater risk of suicide, and are subjected to seclusion and restraint beyond what would be required if appropriate medications were available.³⁸⁷

2. Treatment Selection and the Americans with Disabilities Act

A final source of potential litigation stems from the limited effectiveness of conventional agents in ameliorating negative symptoms and cognitive deficits, which are major sources of long-term disability in schizophrenia.³⁸⁸ A patient who received treatment only with conventional agents might allege that an atypical antipsychotic drug could have permitted him to live successfully in a less restrictive setting or to achieve greater success in a community setting. To support this claim, the patient could cite the opinion of many clinicians that medication induced improvements in cognition can lead to better overall social functioning³⁸⁹ as well as studies suggesting that the newer drugs improve cognitive functioning³⁹⁰ and do more to reduce negative symptoms than do the neuroleptics.³⁹¹

was applicable, but that the defendants’ alleged conduct constituted (at most) negligence, rather than a failure to exercise professional judgment. *Id.* at 845–46.

387. Letter from Lee, *supra* note 384.

388. *See supra* Part III.D.2.

389. It is becoming increasingly apparent that cognitive impairment and the possible therapeutic reduction of this impairment will have an important contribution to the emotional, interpersonal, and vocational implications of schizophrenia. . . . An improved cognitive profile is likely to contribute to educational and occupational opportunities that may also require the simultaneous addition of creative rehabilitative and psychotherapeutic strategies directed toward full reintegration.

Purdon et al., *supra* note 207, at 257.

390. *See supra* note 207.

391. *See supra* note 206.

Accumulating data showing that the atypicals improve the long-term prospects of schizophrenic patients may soon provide scientific justification for a lawsuit alleging failure to provide the pharmacological means to allow good community functioning.³⁹² Such a claim might be grounded on assertions about psychiatric patients' rights under the Americans with Disabilities Act³⁹³ (ADA) as construed by the U.S. Supreme Court in *Olmstead v. L.C.*³⁹⁴

Olmstead concerned two institutionalized, mentally retarded women who sued various Georgia officials for failing to place them in community settings that their doctors believed could provide appropriate care. The state, which had paid for the plaintiffs' care and had cited limited funding for such placements, claimed that the women had not been denied community placements and services "by reason of" their disabilities, and had therefore not experienced disability based discrimination.³⁹⁵ The Supreme Court disagreed, holding "that unjustified institutional isolation of persons with disabilities is a form of discrimination"³⁹⁶ under the ADA for two reasons:

First, institutional placement of persons who can handle and benefit from community settings perpetuates unwarranted assumptions that persons so isolated are incapable or unworthy of participating in community life. Second, confinement in an institution severely diminishes the everyday life activities of individuals, including family relations, social contacts, work options, economic independence, educational advancement, and cultural enrichment.³⁹⁷

Justice Ginsburg's plurality opinion in *Olmstead* addressed Georgia's claim that an ADA-based mandate to place plaintiffs in the least restrictive setting possible would require the State to expend funds and would therefore constitute a violation of established principles of federalism. After examining the Justice Department regulation concerning

392. See, e.g., Meyer et al., *supra* note 204, at 108 (stating that a study evaluating ability to work in patients treated with neuroleptics and atypicals found that: "[The] type of medication prescribed was associated with better symptom control but not better work status. The association between symptoms and work status, however, may suggest an indirect link favoring atypical antipsychotics for achieving paid employment.").

393. Americans with Disabilities Act of 1990, Pub. L. No. 101-336, 104 Stat. 327 (codified as amended in scattered sections of 29 U.S.C., 42 U.S.C., 47 U.S.C.).

394. 527 U.S. 581 (1999).

395. *Id.* at 598.

396. *Id.* at 600.

397. *Id.* at 600-01 (citations omitted). The Supreme Court noted that the ADA and its regulations do not mandate community placements of persons who cannot function as outpatients; also, persons who do not desire community placements may not be forced to accept them. *Id.* at 601-02.

reasonable modifications,³⁹⁸ Justice Ginsburg concluded that states must have some flexibility in complying with the ADA's integration mandate³⁹⁹ and that courts must consider costs when determining the appropriate remedy for a state's failure to comply with that mandate. Nonetheless, Title II of the ADA requires states

to provide community-based treatment for persons with mental disabilities when the State's treatment professionals determine that such placement is appropriate, the affected persons do not oppose such treatment, and the placement can be reasonably accommodated, taking into account the resources available to the State and the needs of others with mental disabilities.⁴⁰⁰

Olmstead's ultimate impact will be a function of how lower courts interpret and apply its general principles; funding decisions by local governments; and the behavior of local, state, and federal agencies that actually help patients obtain services that allow them to function in community placements.⁴⁰¹

In a few cases, plaintiffs with mental disabilities have cited *Olmstead* as a basis for claiming that *private*, employer sponsored health benefits for psychiatric illnesses should equal the health benefits for other medical illnesses.⁴⁰² Courts have dismissed these claims,⁴⁰³ pointing out

398. "A public entity shall make reasonable modifications in policies, practices, or procedures when the modifications are necessary to avoid discrimination on the basis of disability, unless the public entity can demonstrate that making the modifications would fundamentally alter the nature of the service, program, or activity." General Prohibitions Against Discrimination, 28 C.F.R. § 35.130(b)(7) (2000).

399. If, for example, the State were to demonstrate that it had a comprehensive, effectively working plan for placing qualified persons with mental disabilities in less restrictive settings, and a waiting list that moved at a reasonable pace not controlled by the State's endeavors to keep its institutions fully populated, the reasonable modifications standard would be met.
Olmstead, 527 U.S. at 605–06.

400. *Id.* at 607.

401. For a brief summary of recent developments, see Kate Mulligan, *States Slow to Implement Community-Care Mandate*, PSYCHIATRIC NEWS, MAY 17, 2002, at 4, 20. President George W. Bush accurately summarized the current state of affairs when he stated: "*Olmstead* has yet to be fully implemented." GEORGE W. BUSH, NEW FREEDOM INITIATIVE 20 (2001), available at <http://www.whitehouse.gov/news/freedominitiative/freedominitiative.html>.

402. See also *Ford v. Schering-Plough Corp.*, 145 F.3d 601, 608 (3d Cir. 1998) ("So long as every employee is offered the same plan regardless of that employee's contemporary or future disability status, then no discrimination has occurred even if the plan offers different coverage for various disabilities."). But see *Boots v. Northwestern Mut. Life Ins. Co.*, 77 F. Supp. 2d 211, 220 (D.N.H. 1999) (concluding that providing disparate long-term disability benefits to physically and mentally disabled insured persons may violate the ADA).

403. See, e.g., *Weyer v. Twentieth Century Fox Film Corp.*, 198 F.3d 1104, 1117–18 (9th Cir. 2000) ("*Olmstead* does not speak to insurance classifications . . . and Congress's clear instruction in the insurance safe harbor [shows] that the Act was not intended to reach common insurance practices such as underwriting of risks."); *El-Hajj v. Fortis Benefits Ins. Co.*, 156 F. Supp. 2d 27, 32 (D. Me. 2001) (holding that the ADA does not

that *Olmstead* concerned Title II of the ADA, which concerns public accommodations,⁴⁰⁴ rather than employment matters, which are addressed by Title I.⁴⁰⁵ At least two cases have looked at the extent to which the ADA's "integration mandate" requires state Medicaid programs to modify their programs and services. A federal district court ruled, in *Makin v. Hawaii*, that using a wait list to implement a housing program for individuals with mental retardation

could potentially force Plaintiffs into institutions in violation of the ADA's non-discrimination policy Since the State provides the [housing] services, it

create a cause of action against insurers that provide lower levels of coverage for mentally disabled persons versus persons with physical disabilities); *Pelletier v. Fleet Fin. Group, Inc.*, No. 99-245-B, 2000 U.S. Dist. LEXIS 16456, at *10-11 (D.N.H. Sept. 19, 2000) (stating that the reasoning underlying *Olmstead* did not invalidate private employer's disability insurance policy that limited the benefit period for mental illness); *see also Witham v. Brigham & Women's Hosp., Inc.*, No. 00-268-M, 2001 U.S. Dist. LEXIS 7027, at *7, *11 (D. N.H. May 31, 2001) (following *Pelletier*); *Morrill v. Lorillard Tobacco Co.*, No. 00-214-B, 2000 U.S. Dist. LEXIS 18810, at *5-8 (D. N.H. Dec. 7, 2000) (following *Pelletier* and holding that an employer health plan that provided less favorable coverage for outpatient psychotherapy than for other forms of outpatient treatments did not violate the ADA); *Wilson v. Globe Specialty Prods., Inc.*, 117 F. Supp. 2d 92, 97 (D. Mass. 2000) (stating that the ADA does not require a private employer sponsored disability plan to provide equal benefits for mental and physical disabilities and distinguishing *Olmstead* as involving ADA provisions which govern reasonable accommodation by public entities); *Hess v. Allstate Ins. Co.*, No. 99-384-P-C, 2000 U.S. Dist. LEXIS 12258, at *26 (D. Me. Aug. 2, 2000) (stating that there is "no requirement under the ADA that insurance policies provide the same benefits to all categories of disabled people"). For additional citations with similar findings, see *Pelletier*, 2000 U.S. Dist. LEXIS 16456, at *7 (citing other circuits' decisions, including several that were issued before *Olmstead*).

404. *See* 42 U.S.C. § 12132 (2000) (stating that "no qualified individual with a disability shall, by reason of such disability . . . be subjected to discrimination by any [public] entity").

405. *Cf. id.* § 12112 (setting forth numerous definitions of disability discrimination in employment matters covered under Title I of the ADA). For example, in *Equal Employment Opportunity Commission v. Staten Island Savings Bank*, the court concluded that: (1) Title I does not explicitly prevent an employer from adopting a disability plan that provides reduced benefits for mental illness, (2) the ADA's legislative history strongly suggests that Congress did not intend to restrict an employer's ability to impose special limitations on disability insurance coverage for mental illness, (3) the inclusion of a safe harbor provision in the ADA, 42 U.S.C. § 12201, suggests that disability plans may lawfully place special limitations on mental illness coverage, (4) the reasoning in *Olmstead* does not invalidate the type of disability insurance policy that is at issue in this case, and (5) Congress would have spoken more clearly had it intended to prohibit the well-established practice of provided differential (lesser) benefits for mental illness. 207 F.3d 144, 149-153 (2d Cir. 2000). Thus, the court held that the Bank's long-term disability plan did not violate Title I of the ADA even though it authorized two years of disability benefits for psychiatric conditions, but more extended benefits for other types of disabilities. *Id.* at 152-53.

cannot discriminate against the disabled by denying them services in an 'integrated' setting since that could constitute unjustified isolation. . . . if a state is found to have discriminated against disabled individuals through the administration of a program, it must modify the program to remedy the situation unless it can prove that any modification would fundamentally alter the program.⁴⁰⁶

By contrast, the Second Circuit held, in *Rodriguez v. New York*, that providing "safety-monitoring" services for a mentally disabled person was not required by the ADA, notwithstanding the plaintiffs' claims that they needed such services to remain able to live in the community.⁴⁰⁷ The court held that the plaintiffs were requesting new services, whereas *Olmstead* had held only that "[s]tates must adhere to the ADA's nondiscrimination requirements with regard to the services they in fact provide."⁴⁰⁸

Moreover, in *Board of Trustees v. Garrett*, a decision issued in February 2001, the U.S. Supreme Court held that, absent "a pattern of discrimination by the States which violates the Fourteenth Amendment," the U.S. Constitution's Eleventh Amendment barred state employees from seeking money damages in federal court for a state's alleged failure to comply with Title I of the ADA.⁴⁰⁹

The influence of *Garrett* on lower court decisions is not yet clear regarding cases that involve treatment or services provided by entities operated by states and their subdivisions that fall under the ADA's Title II. For example, in *Smith-Berch, Inc. v. Baltimore County*,⁴¹⁰ a federal district court's pre-*Garrett* reading of the ADA led to its refusing to dismiss a claim alleging that Baltimore County, Maryland's zoning regulations discriminated against the subgroup of substance abuse patients that needed to take methadone. The court cited Justice Department regulations that prohibit public entities from providing some qualified individuals with opportunities and services not equal to those given to other qualified individuals, from limiting qualified individuals' access to benefits or services, or from administering services that subject qualified individuals to disability related discrimination.⁴¹¹ The same regulations, the court noted, prevent public entities from imposing or applying unnecessary eligibility criteria that might prevent persons with disabilities from taking advantage of services or programs⁴¹² and require

406. *Makin v. Hawaii*, 114 F. Supp. 2d 1017, 1034 (D. Haw. 1999) (interpreting *Olmstead*, 527 U.S. 581, 605–606 (1999)).

407. *Rodriguez v. New York*, 197 F.3d 611, 613–14 (2d Cir. 1999).

408. *Id.* at 619 (citing *Olmstead*, 527 U.S. at 603 n.14).

409. *Bd. of Trs. of the Univ. of Ala. v. Garrett*, 531 U.S. 356, 374 (2001).

410. 68 F. Supp. 2d 602 (D. Md. 1999).

411. *Id.* at 620 (citing 28 C.F.R. §§ 35.130(b)(1)(ii), (vii), (b)(3)(i) (2001)).

412. *Id.* (citing 28 C.F.R. § 35.130(b)(8)).

public entities to make “reasonable modifications in policies, practices, or procedures” unless doing so “would fundamentally alter” the services or programs.⁴¹³ The court concluded that even if the zoning policy had a rational basis, the county’s special methadone policy placed “disproportionate burdens on . . . opiate addicts who require methadone therapy” and unless it could not be eliminated through “reasonable modifications,” it would violate the ADA.⁴¹⁴

This case and the quoted regulatory language suggest that limiting public sector patients’ access to novel antipsychotic medications might be suspect under the ADA. Patients who did not get the newer drugs might be deemed not to have received services and opportunities equal to those who did get them. To date, no published decision has addressed this issue concerning atypicals, but it is endorsed by the Bazelon Center,⁴¹⁵ which, in its interpretation of *Olmstead*, concluded,

An important part of the treatment for a mental illness is access to the newer “atypical” medications for psychiatric disorders. These drugs have significantly fewer and less severe side effects; they are also more effective than older antipsychotics.

. . . .
In addition to being in violation of the Medicaid statute, a state that fails to provide adequate access to the atypical medications in compliance with these federal Medicaid rules will have weakened its defense under the ADA that it is unable to provide necessary services for all individuals who are or are at risk of unnecessary institutionalization.⁴¹⁶

However, the holding in *Frederick L. v. Department of Public Welfare*⁴¹⁷ suggests that after *Garrett*, courts may not be favorably inclined toward ADA-related arguments about psychiatric patients who take antipsychotic drugs. *Frederick* concerned four adults hospitalized at Norristown State Hospital (NSH) who had sued a state agency (DPW) and the Secretary of Public Welfare, alleging § 1983 violations,

413. *Id.* at 620–21 (quoting 28 C.F.R. § 35.130(b)(7)).

414. *Id.* at 621–22 (citing *Oconomowoc Residential Programs, Inc. v. City of Greenfield*, 23 F. Supp. 2d 941, 953 (E.D. Wis. 1998) (stating that the ADA confers “protected class” status to disabled persons, so a “rational basis [argument] will no longer support a law which burdens the disabled”).

415. It may also have been implicitly endorsed by the Clinton Administration’s Justice Department. *See supra* note 384 and accompanying text.

416. Bazelon Center for Mental Health Law, *Under Court Order: What the Community Integration Mandate of the Supreme Court Ruling in Olmstead v. L.C. Means for People with Mental Illness*, at <http://www.bazelon.org/lcruling.html> (last visited Aug. 14, 2002).

417. 157 F. Supp. 2d 509, 512–14 (E.D. Pa. 2001).

violations of the ADA's Title II, and section 504 of the Rehabilitation Act of 1973.⁴¹⁸ The plaintiffs, suing on behalf of themselves and other patients at NSH, challenged their needless institutionalization and the state's failure to provide them with treatment in the community. The problem was summarized by the court as follows:

The DPW has the authority to shift funds used for institutionalized care to community care. The counties make annual requests to the DPW for funds needed to provide appropriate community-based services. The DPW, however, has consistently failed to satisfy the requests of those counties whose residents are institutionalized at NSH (Bucks, Chester, Delaware, Montgomery, and Philadelphia). As a result, all of the individuals with mental disabilities who could be appropriately served in the community cannot be accommodated and remain unnecessarily institutionalized where they are either not recommended for discharge or placed on waiting lists for community care indefinitely.⁴¹⁹

The suit alleged that the defendants unlawfully had failed to "properly assess the Plaintiffs' community service needs and fund sufficient appropriate community-based programs to serve them," and sought "an injunction compelling the Defendants to remedy the ongoing violations of federal law."⁴²⁰ The DPW and the Secretary moved to dismiss, arguing that the plaintiffs' claims were barred by the Eleventh Amendment and that plaintiffs had otherwise failed to state a claim upon which relief can be granted.⁴²¹

In a complex decision,⁴²² the court held that the plaintiffs could proceed on their section 504 and § 1983 claims against the DPW and the official, but it dismissed the ADA claims against the DPW.⁴²³ Concerning the section 504 claims, the court cited statutory language,⁴²⁴ *Lane v. Pena*,⁴²⁵ and several decisions by courts of appeals,⁴²⁶ to "conclude that

418. *Id.* at 512.

419. *Id.* at 513.

420. *Id.* at 514.

421. *Id.* at 512.

422. Reflecting this, District Judge Schiller concluded his decision:

The fact that federal judges have a great many constitutional powers and duties which enable them to resolve difficult issues with authority is put to the test in a situation like this where the law is developing and many of the principles are amorphous. Even had I the benefit of the Oracle at Delphi some of these issues will be finally resolved in another forum. Nonetheless, I believe that at this stage of the pleadings plaintiffs are entitled to proceed on several of their claims.

Id. at 541.

423. *Id.* at 512.

424. "A State shall not be immune under the Eleventh Amendment of the Constitution of the United States from suit in Federal court for a violation of section 504 of the Rehabilitation Act of 1973 . . ." *Id.* at 520 (quoting 42 U.S.C. § 2000d-7(a)(1) (2000)).

425. 518 U.S. 187, 200 (1996) (stating that in enacting 42 U.S.C. § 2000d-7(a)(1), Congress unmistakably expressed its intent to waive the states' sovereign immunity but not the federal government's).

section 504 unambiguously expresses Congress' intent to condition the grant of federal funds on a States' [sic] consent to suit"⁴²⁷

Concerning the ADA claim, and with *Garrett* expressly in mind, the *Frederick* court held that Congress had not sufficiently identified a "history and pattern" of discrimination by states against persons with mental disabilities that would make the ADA applicable.⁴²⁸ Even if Congress had done so, the court said, the plaintiffs would still have to show that their sought-after remedy met the "congruence and proportionality" test set out in *Garrett* regarding the rights and remedies created by Title II.⁴²⁹ The plaintiffs' proposed remedy exceeded what was constitutionally required:

State public welfare agencies are not constitutionally required to undergo a comprehensive modification of their rules, policies, and practices in order to accommodate all disabled individuals. . . . [E]nforcement of the substantive due process right asserted here by the Plaintiffs may require modification of State policies that irrationally interfere with the provision of treatment recommended by professionals, but the Constitution does not require the State to make *all* modifications necessary to prevent discrimination.⁴³⁰

Similarly, an Oregon court held that a state's health plan⁴³¹ that refused to pay for a combined lung and liver transplant did not violate the ADA's nondiscrimination mandates. *Stroeder v. Office of Medical Assistance Programs* found that *Olmstead* "held only that 'States must adhere to the ADA's nondiscrimination requirement with regard to the

426. *Frederick*, 157 F. Supp. at 521 (citing *Jim C. v. United States*, 235 F.3d 1079, 1082 (8th Cir. 2000); *Stanley v. Litscher*, 213 F.3d 340, 344 (7th Cir. 2000); *Pederson v. La. State Univ.*, 213 F.3d 858, 875–76 (5th Cir. 2000)).

427. *Id.*

428. *Id.* at 528.

429. *Id.*

430. *Id.* at 530 (emphasis added). The Court also noted that the ADA's implementing regulations state that "[a] public entity shall make reasonable modifications in policies, practices, or procedures when the modifications are necessary to avoid discrimination on the basis of disability, *unless the public entity can demonstrate that making the modifications would fundamentally alter the nature of the service, program, or activity.*" *Id.* at 529–30 (quoting 28 C.F.R. § 35.130(b)(7) (2000)) (alteration in original) (emphasis added).

431. In Oregon, the Office of Medical Assistance Programs coordinates the state's Medical Assistance Program, which provides for payment for health care services to Oregonians eligible for Medicaid and other state and federally funded assistance programs. *See* OR. ADMIN. R. 410-120 (LEXIS through 2002 filings); *see also* 42 USC § 1396(a)(5) (2000) (authorizing the creation of state agencies to administer state plans of medical assistance).

services *they in fact provide.*”⁴³² The administrative regulation governing treatment for the claimant’s condition “does not provide coverage for a combined lung and liver transplant for *any* Oregon Health Plan recipient. Thus, . . . claimant cannot demonstrate that . . . denial of that benefit or service to her has discriminated against her on the basis of any disability she may have.”⁴³³

Finally, courts considering *Olmstead* claims of discrimination appear very sensitive to the decision’s focus on costs as a factor in the defendants’ decisionmaking. Two cases illustrate this.

First, *Sanon v. Wing*⁴³⁴ concerned three elderly women plaintiffs with multiple medical disabilities who had received Medicaid funded twenty-four hour home care from New York City and state health agencies. The agencies decided to terminate the home care, which would likely necessitate having the women go to nursing home for the care they needed. In response to the plaintiff’s claim that the decision to terminate home care violated the ADA, the defendants argued that the cost of continuing home care would fundamentally alter the state’s Medicaid program. The court reversed the agencies’ decision,⁴³⁵ saying that the defendant agencies could not merely assert that an increase in cost would create a fundamental alteration; the agencies would have to make some factual showing that a fundamental alteration would occur.⁴³⁶ However, the court found

no indication in the record that any factual inquiry took place here Nor has DSS [a defendant agency] demonstrated that there would be a “massive” change in the program.

Before that determination can be made, DSS must demonstrate what the cost of such an undertaking would be with respect to the system as a whole and not just the comparative cost with respect to the individual. . . . Unless respondents can demonstrate that accommodating Medicaid recipients who otherwise qualify for 24-hour home care would result in a fundamental alteration in the Medicaid program, respondents must provide services in “the most integrated setting appropriate to the needs of” petitioners.⁴³⁷

Second, in *Williams v. Wasserman*,⁴³⁸ a case that raised “complex medical, social and fiscal issues not easily addressed by litigation,”⁴³⁹ twelve brain injured or developmentally disabled patients brought claims under

432. *Stroeder v. Office of Med. Assistance Programs*, 37 P.3d 1012, 1021 (Or. Ct. App. 2001) (quoting *Rodriguez v. City of New York*, 197 F.3d 611, 618–19 (2d Cir. 1999); *Olmstead v. L.C.*, 527 U.S. 581, 603 n.14 (1999)).

433. *Id.*

434. No. 403296/98, 2000 N.Y. Misc. LEXIS 139 (Sup. Ct. Feb. 25, 2000).

435. *Id.* at *23–24.

436. *Id.* at *18.

437. *Id.* at *18–20 (quoting 28 C.F.R. § 35.130(d) (2001)) (other citations omitted).

438. 164 F. Supp. 2d 591 (D. Md. 2001).

439. *Id.* at 595.

the Due Process Clause, 42 U.S.C. § 1983, and the ADA, seeking relief for Maryland's failure to provide them community placements rather than inpatient treatment in state institutions. After finding that "the staffs at the state hospitals were [not] so undertrained as to deprive the patients of their due process rights,"⁴⁴⁰ the court addressed the plaintiff's *Olmstead* based contention that their continued institutionalization violated their rights under the ADA.⁴⁴¹ Against this claim, Maryland offered a cost-based defense, arguing that placing the patients in the community would require added expenses. The hospital would need additional monies to house the placed patients but still would have to preserve the availability of hospital beds for persons that needed them.⁴⁴² Noting the state's significant progress at reducing the number of mental patients persons treated in hospitals,⁴⁴³ the court concluded that *Olmstead* supported Maryland's claim that the cost of immediately placing patients in the community would constitute a "fundamental alteration of the State's provision of services,"⁴⁴⁴ and entered a judgment in favor of the defendants.

Taken together, what can *Olmstead*, *Garrett*, and the other previously discussed cases tell us about how a federal court would respond to a lawsuit seeking relief under the ADA concerning a state agency's financially motivated, stepped care drug policy? Following *Olmstead*, the agency could defend the policy by showing that using the more expensive, novel antipsychotic drugs could not "be reasonably accommodated, taking into account the resources available to the State and the needs of others with mental disabilities."⁴⁴⁵ Certainly, providing the newer drugs to all eligible patients would not "fundamentally alter" pharmacological treatment in the public sector to nearly the same degree that finding hospitalized patients a community placement alters patterns of overall psychiatric care. However, the agency might reasonably argue that paying for more expensive medicines would critically compromise the other nonpharmacological services being provided to its clientele. The agency also might argue, following *Garrett*, that providing patients

440. *Id.* at 627.

441. *Id.* at 630.

442. *Id.* at 637. The case offers a nice example of the complex calculations needed to determine whether clinical intervention, applied to a healthcare system, actually saves money in the short or long term. *Id.* at 637–38.

443. *Id.* at 634–36.

444. *Id.* at 638.

445. *Olmstead v. L.C.*, 527 U.S. 581, 607 (1999).

with free neuroleptic therapy did not constitute a “history and pattern” of discrimination, especially when those drugs were standard therapy in the mid-1990s and remain the predominant therapy in Europe, and especially when the atypical agents were available to patients who could not tolerate or benefit from neuroleptics. Finally, if the policy applied to *all* patients in a state program, the agency might argue that no ADA prohibited discrimination based on disability had taken place because the stepped care policy applied to everyone, not just persons who had a mental disability.

What about situations in which a state’s asserted inability to fund expensive new drugs stems from a less than adequate apportionment of total tax dollars to mental disability care and treatment? What part of a state’s *total* budget might come under scrutiny in assessing its ADA related obligations to improve patients’ chances for integrated community life? In *Helen L. v. DiDario*,⁴⁴⁶ a pre-*Olmstead* decision that found an ADA violation where a Pennsylvania plaintiff was confined to a nursing home despite needing only home health care, the Court of Appeals for the Third Circuit commented:

It is not now up to us to invent a funding mechanism whereby the Commonwealth can properly finance its nursing home and attendant care programs. However, the ADA applies to the General Assembly of Pennsylvania, and not just to DPW [the Pennsylvania Department of Public Welfare]. DPW can not rely upon a funding mechanism of the General Assembly to justify administering its attendant care program in a manner that discriminates and then argue that it can not comply with the ADA without fundamentally altering its program.⁴⁴⁷

The Third Circuit’s reading of the ADA suggested that, at least in some evaluations of whether increased funding constituted a “reasonable accommodation,” a court could look to a state’s entire budget as a resource for rectifying discrimination. *Olmstead*, however, indicated that in deciding whether making a proposed accommodation was “reasonable” or would pose an “undue hardship” to the state, a court’s inquiry should only examine the particular program under which a recipient was receiving treatment.⁴⁴⁸ Having “a waiting list that moved

446. 46 F.3d 325 (3d Cir. 1995).

447. *Id.* at 338.

448. In a footnote, the plurality opinion noted that Congress had required the Attorney General to make ADA TITLE II regulations consistent with the regulations that implement section 504 of the Rehabilitation Act. Justice Ginsburg wrote:

The § 504 regulation upon which the reasonable modifications regulation is based provides now, as it did at the time the ADA was enacted:

“A recipient shall make reasonable accommodation to the known physical or mental limitations of an otherwise qualified handicapped applicant or employee unless the recipient can demonstrate that the accommodation would impose an undue hardship on the operation of its program.” 28 CFR § 41.53 (1990 and 1998 eds.).

at a reasonable pace not controlled by the State's endeavors to keep its institutions fully populated" would be a reasonable accommodation, Justice Ginsburg wrote.⁴⁴⁹ In his concurring opinion, Justice Kennedy was even more explicit about the degree to which courts could influence states' funding choices. States are free to apportion their limited resources as they see fit, he wrote, and "must make hard decisions on how much to allocate to treatment of diseases and disabilities. . . . [Such decisions] may be unfortunate. The judgment, however, is a political one and not within the reach of the statute."⁴⁵⁰ A state may not be forced to create programs where they do not exist, wrote Justice Kennedy.⁴⁵¹ Moreover, "[t]he State is entitled to wide discretion in adopting its own systems of cost analysis, and, if it chooses, to allocate health care resources based on fixed and overhead costs for whole institutions and programs."⁴⁵²

* * * * *

Malpractice suits, civil rights claims, and ADA related challenges to medication practices are nascent areas of litigation that may someday affect patients that take antipsychotic drugs and caregivers that administer those medications. By contrast, several cases have already addressed how the distinctive properties of novel antipsychotics may influence judicial decisions about forcing persons to take psychotropic drugs. It is to an examination of these cases that we now turn.

While the part 41 regulations do not define "undue hardship," other § 504 regulations make it clear that the "undue hardship" inquiry requires not simply an assessment of the cost of the accommodation in relation to the recipient's overall budget, but a "case-by-case analysis weighing factors that include: (1) [t]he overall size of the recipient's program with respect to number of employees, number and type of facilities, and size of budget; (2) [t]he type of the recipient's operation, including the composition and structure of the recipient's workforce; and (3) [t]he nature and cost of the accommodation needed." 28 CFR § 42.511(c) (1998); see 45 CFR § 84.12(c) (1998) (same).

Olmstead, 527 U.S. at 606 n.16 (alterations in original).

449. *Id.* at 606.

450. *Id.* at 612 (Kennedy, J., concurring).

451. *Id.* at 613.

452. *Id.* at 615.

VI. THE RIGHT TO REFUSE TREATMENT: CHANGING JUDICIAL ATTITUDES

A. Background

No issue in mental disability law has more polarized psychiatrists and legal academics⁴⁵³ than the right of involuntarily institutionalized patients to refuse treatment with antipsychotic medication.⁴⁵⁴ On one side are most psychiatrists, whose professional ethos, medical school socialization, and training experiences lead them to see patients as sick persons with diseases that can and must be treated.⁴⁵⁵ Psychiatrists regard psychotropic medication as an effective means for improving patients' functioning and for reducing the risk patients pose to themselves and other persons. Psychiatrists also point out that without medication, many patients who undergo involuntary hospitalization would be subject to long-term institutionalization and, potentially, long-term use of physical restraints.⁴⁵⁶ On the other side, some legal scholars and patient advocates, while acknowledging, sometimes only in passing,⁴⁵⁷ that antipsychotic medication is effective, have emphasized that antipsychotic drugs can cause serious side effects⁴⁵⁸ and that

453. Cichon, *supra* note 35, at 286 ("The right to refuse antipsychotic drugs soon became the most controversial and divisive issue between the medical and legal professions."); Sheldon Gelman, *Mental Hospital Drugging—Atomistic and Structural Remedies*, 32 CLEV. ST. L. REV. 221, 222 (1983–84) (stating that lawsuits have been "unusually contentious"); Jonathan Brant, *Pennhurst, Romeo and Rogers: The Burger Court and Mental Health Law Reform Litigation*, 4 J. LEGAL MED. 323, 345 (1983) (stating that the right to refuse was "the most controversial issue in forensic psychiatry today"); 2 PERLIN, *supra* note 4, at 166 n.28 (1999) (stating that "[t]he rhetoric has certainly been contentious" and citing examples).

454. Although lawsuits and other legal actions might, in principle, have involved involuntary use of *any* psychotropic medication, all the major litigation in this area has focused on antipsychotic medication. Perlin lists several interrelated reasons for this focus, including the risk of wrongful administration of these drugs arising from incorrect diagnoses, the high percentage of state hospital patients that received them, and the use of the drugs for purposes other than treatment of psychiatric problems (for example, for behavioral control). Yet the main reason, Professor Perlin suggests, was the uniquely toxic neurological effects of phenothiazines and other older antipsychotic medications. 2 PERLIN, *supra* note 4, at 157–65 (1999).

455. Cichon, *supra* note 35, at 284; Thomas G. Gutheil, *In Search of True Freedom: Drug Refusal, Involuntary Medication, and "Rotting with Your Rights On,"* 137 AM. J. PSYCHIATRY 327, 327 (1980).

456. GARY B. MELTON ET AL., *PSYCHOLOGICAL EVALUATIONS FOR THE COURTS: A HANDBOOK FOR MENTAL HEALTH PROFESSIONALS AND LAWYERS* 350 (2d ed. 1997).

457. *See, e.g.*, 2 PERLIN, *supra* note 4, at 159 (1999) (mentioning the benefits of antipsychotic medication in one sentence, while misuse, limitations, and drawbacks are discussed over nine pages).

458. *See, e.g.*, *State v. Perry*, 610 So. 2d 746, 758–60 (La. 1992) (describing the purpose and benefits of neuroleptics in twenty-eight words, and devoting nearly thirty times as much space to the drugs' side effects); *In re Guardianship of Roe*, 421 N.E.2d

unwanted administration of medications automatically raises a host of legal issues.⁴⁵⁹ At the core of these issues is the “sacred . . . [and] carefully guarded . . . right of every individual to the possession and control of his own person, free from all restraint or interference of others, unless by clear and unquestionable authority of law.”⁴⁶⁰ As Cichon has succinctly expressed: “The professional discord surrounding the right to refuse antipsychotic drugs reflects the inherent tension between the law’s respect for the values of self-determination and bodily integrity and the medical profession’s concern for the treatment and care of the mentally ill.”⁴⁶¹

Common law rules preventing unwanted medical treatment would seem applicable *in toto* to persons undergoing psychiatric hospitalization,⁴⁶² and rules requiring informed consent⁴⁶³ would seem as appropriate to psychiatric care as to any other type of medical treatment. When the seminal “right to refuse treatment” cases were litigated, however, courts

40, 52–54 (Mass. 1981) (using twelve words to acknowledge the benefits of antipsychotic drugs and devoting 1400 words to potential adverse effects); Cichon, *supra* note 35, at 292–310 (summarizing the drugs’ benefits in approximately 220 words and the limitations and detailing side effects in approximately 3400 words); *cf.* Rennie v. Klein, 462 F. Supp. 1131, 1136–38 (D.N.J. 1978) (devoting more than 700 words to the benefits of neuroleptics and approximately 460 words to their side effects), *suppl.*, 476 F. Supp. 1294 (D.N.J. 1979), *modified*, 653 F.2d 836 (3d Cir. 1981), *vacated and remanded*, 458 U.S. 1119 (1982); HYMAN ET AL., *supra* note 9, at 14–40 (discussing antipsychotic drugs in their 1995 psychopharmacology text and emphasizing neuroleptics’ toxicity, discussing then available alternative treatments for psychoses, and devoting eight pages to indications for neuroleptics, nine pages to their therapeutic usage, and eight pages to side effects).

459. MELTON, *supra* note 456, at 350.

460. Union Pac. Ry. Co. v. Botsford, 141 U.S. 250, 251 (1891).

461. Cichon, *supra* note 35, at 288.

462. Ordinarily, the mere apprehension of a harmful or offensive contact by another is actionable in tort. PROSSER AND KEETON ON THE LAW OF TORTS § 9 (W. Page Keeton ed., 5th ed. 1984).

463. The doctrine of informed consent establishes a prohibition against unwanted medical treatment. There are several important cases establishing that nonconsensual treatment is battery. Cobbs v. Grant, 502 P.2d 1, 7 (Cal. 1972); *In re Quackenbush*, 383 A.2d 785, 789 (Morris County Ct. 1978); Schloendorff v. Soc’y of N.Y. Hosp., 105 N.E. 92, 93 (N.Y. 1914) (“Every human being of adult years and sound mind has a right to determine what shall be done with his own body . . .”). Other leading cases discuss the requirements for valid consent. Canterbury v. Spence, 464 F.2d 772, 778 (D.C. Cir.) (stating that a doctor must disclose all “material” risks relevant to a patient’s decision about a treatment); Salgo v. Leland Stanford Jr. Univ. Bd. of Trustees, 317 P.2d 170, 181 (Cal. Dist. Ct. App. 1957) (holding that a provider’s duty includes disclosing “any facts which are necessary to form the basis of an intelligent consent by the patient”); Natanson v. Kline, 350 P.2d 1093, 1106 (Kan. 1960) (stating that a provider must disclose the nature of proposed treatment, probability of success, alternative treatments, and risks).

had not previously held that these traditional tort remedies were available to institutionalized persons.⁴⁶⁴ Instead, mentally disabled inpatients were regarded as “*per se* incompetent to make rational treatment decisions.”⁴⁶⁵ Therefore, lawyers that represented institutionalized patients offered arguments that saw “the Constitution as a potential source of a right to refuse treatment.”⁴⁶⁶ When courts accepted the arguments of patient advocates, it was often the potential side effects of antipsychotic drugs, rather than a principled opposition to nonconsensual medical treatment *per se*, that gave force to a patient’s constitutionally based right to refuse treatment.⁴⁶⁷

Because neuroleptic side effects played such a pivotal role in earlier decisions about refusing antipsychotic therapy, one might wonder whether the availability of less noxious medications might now make courts more favorably disposed toward involuntary treatment. At least two courts suggested that this might occur. Following a highly critical description of then-available antipsychotic drugs, Chief Justice Hennessey of the Massachusetts Supreme Judicial Court wrote, in *In re Guardianship of Roe*:⁴⁶⁸

We admit the possibility and express the hope that future medical advances may produce antipsychotic drugs free from the severe adverse side effects we have described above. At the same time, it must be noted that the intended effect of the medication—to alter mental processes—by definition cannot be eliminated from those drugs we have described as “antipsychotic.” Nevertheless, we do not foreclose reconsideration of these issues when and if it can be shown that the characteristics of antipsychotic drugs have changed.⁴⁶⁹

In his concurring opinion in *Riggins v. Nevada*,⁴⁷⁰ Justice Kennedy argued that society might have to forego prosecution of some psychotic defendants because side effects of the antipsychotic medications then

464. 2 PERLIN, *supra* note 4, at 168–70 (1999).

465. Cichon, *supra* note 35, at 315; *see, e.g.*, Price v. Sheppard, 239 N.W.2d 905, 911 (Minn. 1976) (relying on “the need for the state to assume the decision-making role regarding the psychiatric treatment for one who, presumptively, based on the fact of commitment on the grounds of mental illness, is unable to *rationaly* do so for himself” (footnote omitted)); Denny v. Tyler, 85 Mass. (3 Allen) 225, 227, 228–29 (1861) (holding that involuntarily hospitalized patient cannot form “a judgment concerning his own condition,” and “abstract” liberty guarantees “can have no legitimate application where . . . the person who is alleged to be . . . restrained of his liberty is insane”).

466. 2 PERLIN, *supra* note 4, at 170 (1999) (footnotes omitted).

467. *See, e.g.*, Davis v. Hubbard, 506 F. Supp. 915, 929–32 (N.D. Ohio 1980) (describing common law bases for a right to refuse treatment, but ultimately grounding the right in the Fourteenth Amendment’s substantive due process guarantee). *But see* Rivers v. Katz, 495 N.E.2d 337, 341 (N.Y. 1986) (grounding the right to refuse psychotropic medication in common law principles, New York case law, and New York statutes that affirm a competent patient’s right to decline medical treatment even when “the recommended treatment may be beneficial or even necessary to preserve the patient’s life”).

468. 421 N.E.2d 40 (Mass. 1981).

469. *Id.* at 54 n.12.

470. 504 U.S. 127 (1990).

used to restore competence could compromise their right to a fair trial.⁴⁷¹ Yet, he noted: “The state of our knowledge of antipsychotic drugs and their side effects is evolving and may one day produce effective drugs that have only minimal side effects.”⁴⁷²

As the twenty-first century commences, atypical antipsychotics are indeed shifting judicial attitudes about refusals of antipsychotic medication by mentally disabled persons. Decisions issued before wide use of novel agents often contain scathing descriptions of the horrors of then standard psychiatric treatment of psychotic disorders. Part VI.B provides summaries and examples of such cases, organized according to the various types of federal and state constitutional rights putatively implicated by drug side effects. Part VI.C contains examples of published holdings from the last decade in which trial level and appellate court judges have demonstrated an awareness of the advantages of atypical agents. These cases express less concern about potential side effects and often emphasize the advantages of antipsychotic medications to patients that might receive them involuntarily.

B. Constitutional Arguments from the Neuroleptic Era

1. Side Effects and the First Amendment

Professor Bruce J. Winick has argued that involuntary administration of antipsychotic medication necessarily implicates the First Amendment’s free expression guarantee⁴⁷³ because psychotropic medications influence emotions and change how patients think.⁴⁷⁴ Although *State v. Perry*⁴⁷⁵ was decided on *state* constitutional grounds, this decision invoked freedom of thought as one of several grounds for barring involuntary treatment to restore competence for execution. The Louisiana Supreme Court described involuntarily medicating a condemned inmate as an

471. *Id.* at 142.

472. *Id.* at 145.

473. The First Amendment states that “Congress shall make no law . . . abridging the freedom of speech . . .” U.S. CONST. amend. I. The First Amendment was found applicable to the states in *Gitlow v. New York*, 268 U.S. 652, 666 (1925). The Supreme Court has held that the free speech clause contains protections for related activities, including the freedom to think about what one wishes. Thus, in ruling unconstitutional a Georgia law prohibiting private possession of pornographic materials, the Court wrote: “Our whole constitutional heritage rebels at the thought of giving government the power to control men’s minds.” *Stanley v. Georgia*, 394 U.S. 557, 565 (1969).

474. Winick, *supra* note 18, at 103.

475. 610 So. 2d 746 (La. 1992).

“invasion of his brain and body[,] . . . the seizure of control of [the prisoner’s] mind and thoughts, and the usurpation of his right to make decisions,”⁴⁷⁶ the “chemical[] alter[ation of] his mind and will,”⁴⁷⁷ and as compelling the prisoner “to yield control of his thoughts and will to the state.”⁴⁷⁸ The court deemed involuntary psychotropic treatment equivalent to governmental “thought control” prohibited by *Stanley v. Georgia*. “Government does not have ‘the power to control men’s minds’ or ‘the right to control the moral content of a person’s thought.’”⁴⁷⁹

Though a treatment that could change someone’s thoughts, feelings, mood, and attitudes might seem to raise First Amendment issues, most courts have generally not taken Winick’s view. That is, although *side effects* of medication could be violative of an individual’s First Amendment rights, courts have not held that psychotic thinking deserves First Amendment protection from the intended, *beneficial* effects of antipsychotic drugs.⁴⁸⁰ This makes sense for two reasons. First, persons who are psychotic have severely impaired thinking abilities, and antipsychotic medications can, by reducing this impairment, *improve* thinking and thereby confer greater freedom of expression on their recipients. As Gutheil points out: “[P]sychosis is *itself* involuntary mind control of the most extensive kind and itself represents the most severe ‘intrusion on the integrity of a human being.’ The physician seeks to liberate the patient from the chains of illness”⁴⁸¹ Some forms of psychosis render meaningful expression impossible. During the acute phase of catatonic schizophrenia, for example,

patients may demonstrate marked negativism or mutism, profound psychomotor retardation or severe psychomotor agitation, echolalia (repetition of words or phrases in a nonsensical manner), echopraxia (mimicking the behaviors of others), or bizarreness of voluntary movements and mannerisms. . . . Patients with catatonic stupor . . . may remain in the same position for weeks at a time.⁴⁸²

Second, psychotropic medications do not alter a patient’s thoughts

476. *Id.* at 747.

477. *Id.* at 758.

478. *Id.* at 760.

479. *Id.* at 758 (quoting *Stanley v. Georgia*, 394 U.S. 557, 565–66 (1969)).

480. Cichon, *supra* note 35, at 321–24 (noting that “courts have been hesitant to extend First Amendment protection to disordered thoughts,” but discussing several cases in which courts found that potential side effects raised First Amendment issues).

481. Gutheil, *supra* note 455, at 327. Similar reasoning led Judge Brotman to conclude that in treating a patient who wished “to be cured, not warehoused,” a hospital’s administration of medication to “alter his thinking disorder cannot be seen as a first amendment violation.” *Rennie v. Klein*, 462 F. Supp. 1131, 1144 (D.N.J. 1978), *suppl.*, 476 F. Supp. 1294 (D.N.J. 1979), *modified*, 653 F.2d 836 (3d Cir. 1981), *vacated and remanded*, 458 U.S. 1119 (1982).

482. Pinals & Breier, *supra* note 52, at 931–32.

about specific political or social issues. Properly administered, they improve a psychotic patient's ability to think about whatever he wishes. Antipsychotic medications "restore existing imbalance toward the balanced norm . . . [and] are generally incapable of creating thoughts, views, ideas or opinions de novo, or of permanently inhibiting the process of thought generation."⁴⁸³ As the author has pointed out elsewhere in discussing the majority's flawed First Amendment reasoning in *Perry*:

The majority opinion analyzes "positive symptoms" such as hallucinations and delusions as though they were unpopular moral viewpoints or expressions of individual privacy that neuroleptics "suppress." When neuroleptics alleviate schizophrenic hallucinations and delusions, however, the drugs do not act on the basis of the peculiar moral or intellectual content of psychotic thoughts. Thus, when antipsychotic medications restore patients' ability to think logically, entertain doubts about or evidence that conflicts with delusional beliefs, consider alternatives, formulate coherent sets of wishes, and make those wishes known, the action of antipsychotic drugs should not be construed as performing the intrapsychic equivalent of "banning books" or abolishing specific thoughts because their content is objectionable.

In altering neuronal transmission, antipsychotic medications do not "censor" *particular* thoughts, "seize control" of patients' minds, nor "alter" patients' will. Medications also do not let the state "usurp" one's *right* to make decisions. . . . When an individual's very ability to make (legally cognizable) decisions does not *exist* without medication, it makes little sense to suggest that medication could usurp his "ability to control his own mind and thoughts." Neuroleptics are to psychosis what eye glasses are to myopia: both interventions remove impediments to perception; neither proscribes *particular* thoughts or actions, though both may enhance decision-making and the ability to respond.⁴⁸⁴

When courts have accepted First Amendment arguments against involuntary antipsychotic therapy, they usually have done so because of the drugs' potential adverse *side effects*, rather than their therapeutic impact on thinking.⁴⁸⁵ For example, in an appellate decision reversing the district court's dismissal of an involuntary medication case, the Third Circuit found that "involuntary administration of drugs which affect mental processes, . . . could amount . . . to an interference with [the plaintiff's] rights under the first amendment."⁴⁸⁶ In *Rogers v. Okin*,⁴⁸⁷

483. Paul S. Appelbaum & Thomas G. Gutheil, "Rotting with their Rights On": *Constitutional Theory and Clinical Reality in Drug Refusal by Psychiatric Patients*, 7 BULL. AM. ACAD. PSYCHIATRY & L. 306, 308 (1979) (footnote omitted).

484. Douglas Mossman, *Denouement of an Execution Competency Case: Is Perry Pyrrhic?*, 23 BULL. AM. ACAD. PSYCHIATRY & L. 269, 274 (1995) (footnote omitted).

485. Cichon, *supra* note 35, at 320-22.

486. *Scott v. Plante*, 532 F.2d 939, 946 (3d Cir. 1976).

487. 478 F. Supp. 1342 (D. Mass. 1979), *rev'd in part*, 634 F.2d 650 (1st Cir. 1980).

one of the seminal “right to refuse” cases, the district court declared that “[t]he right to produce a thought . . . is a fundamental element of freedom.”⁴⁸⁸ Similarly, the potential side effects of neuroleptics, including their “capacity to severely and even permanently affect an individual’s ability to think and communicate,”⁴⁸⁹ led the Tenth Circuit to rule that “less restrictive courses of action” should be considered before medication was forced on a pretrial inmate.⁴⁹⁰

In some cases, courts have explicitly considered whether side effects interfere with First Amendment rights, but have rejected this as a basis for the right to refuse treatment with antipsychotic drugs. *Davis v. Hubbard* cited First Amendment cases as a conceivable basis for a constitutional right to refuse, but ultimately grounded the right in the Fourteenth Amendment’s substantive due process protections.⁴⁹¹ In *Rennie v. Klein*, the district court held that a medication that induced “temporary dulling of the senses” did not constitute a First Amendment violation.⁴⁹²

2. Side Effects and the Eighth Amendment

In cases litigated before *Bell v. Wolfish*,⁴⁹³ some courts held that neuroleptic side effects could, under some circumstances, give rise to a violation of the Eighth Amendment’s prohibition of cruel and unusual punishment,⁴⁹⁴ particularly if the drugs were used inappropriately in correctional settings. For example, the Seventh Circuit concluded that the Eighth Amendment applied in a case involving a juvenile correctional facility where antipsychotic drugs were administered without adequate medical guidance and were used “not as part of an ongoing psychotherapeutic program, but for the purpose of controlling excited behavior.”⁴⁹⁵

488. *Id.* at 1367.

489. *Bee v. Greaves*, 744 F.2d 1387, 1394 (10th Cir. 1984).

490. *Id.* at 1396.

491. *Davis v. Hubbard*, 506 F. Supp. 915, 929 (N.D. Ohio 1980). In declining to ground the protection of “a person’s interest in being free to use his mind as he so desires” in the First Amendment, the *Davis* court stated: “It is enough to observe that ‘the power to control men’s minds’ is ‘wholly inconsistent’ not only with the ‘philosophy of the first amendment but with virtually any concept of liberty.’” *Id.* at 933 (quoting *Stanley v. Georgia*, 394 U.S. 557, 565–66 (1964)).

492. *Rennie v. Klein*, 462 F. Supp. 1131, 1144 (D.N.J. 1978), *suppl.*, 476 F. Supp. 1294 (D.N.J. 1979), *modified*, 653 F.2d 836 (3d Cir. 1981), *vacated and remanded*, 458 U.S. 1119 (1982).

493. 441 U.S. 520 (1979).

494. “Excessive bail shall not be required, nor excessive fines imposed, nor cruel and unusual punishments inflicted.” U.S. CONST. amend. VIII. *Louisiana ex rel. Francis v. Resweber* makes the Eighth Amendment applicable to states. 329 U.S. 459, 463 (1947).

495. *Nelson v. Heyne*, 491 F.2d 352, 356 (7th Cir. 1974); *see also* *Scott v. Plante*,

Whether the Eighth Amendment's prohibition of "cruel and unusual punishment" applies *outside* correctional settings is unclear.⁴⁹⁶ In 1977, the U.S. Supreme Court avoided the issue, holding that a case addressing whether the Eighth Amendment applied to corporal punishment administered in schools⁴⁹⁷ provided "no occasion . . . to consider whether or under what circumstances persons involuntarily confined in mental or juvenile institutions can claim the protection of the Eighth Amendment."⁴⁹⁸ Two years later, in *Bell v. Wolfish*, the Supreme Court held that the Due Process Clause, not the Eighth Amendment, was the appropriate vehicle for evaluating constitutional claims about a jail's living conditions and restrictions for pretrial detainees.⁴⁹⁹ In a pre-*Bell* decision, the district court ruled that the Eighth Amendment could apply to psychotropic medication if it were "found to have no proven therapeutic value and its use was not recognized as acceptable medical practice, . . . [or] the adverse effects seemed *unnecessarily* harsh," or it were "used improperly and for punishment rather than as part of an ongoing psychotherapeutic program."⁵⁰⁰ Three years later, however, when the court of appeals issued its decision in the same case, it relied on *Bell* to reject the Eighth Amendment as a standard against which to assess involuntary treatment.⁵⁰¹ Patients, the court said, were "entitled to more humane consideration"⁵⁰² than convicts. Cichon pointed out, however, that "[t]he Court [in *Bell*] did not hold that the Eighth Amendment protects *only* those convicted of crimes."⁵⁰³ The Oklahoma Supreme Court ruled, in *In re K.K.B.*, that it was a violation of the Eighth Amendment to use drug treatment on an involuntary patient "for control or punishment, rather than as part of an on-going psychotherapeutic

532 F.2d 939, 946–47 (3d Cir. 1976) (reinstating an involuntary medication complaint, citing "conceivable constitutional deprivations," including "an eighth amendment issue"), *vacated by*, 458 U.S. 1101 (1982).

496. Cichon, *supra* note 35, at 318.

497. The majority ruled that the Eighth Amendment did not apply in this setting. *Ingraham v. Wright*, 430 U.S. 651, 664 (1977) (stating that the Eighth Amendment "was designed to protect those convicted of crimes").

498. *Id.* at 669 n.37.

499. *Bell v. Wolfish*, 441 U.S. 520, 535 (1979).

500. *Rennie v. Klein*, 426 F. Supp. 1131, 1143 (D.N.J. 1978), *suppl.*, 476 F. Supp. 1294 (D.N.J. 1979), *modified*, 653 F.2d 836 (3d Cir. 1981), *vacated and remanded*, 458 U.S. 1119 (1982).

501. *Rennie*, 653 F.2d at 844 n.10.

502. *Id.* at 844.

503. Cichon, *supra* note 35, at 319 n.215 (emphasis added).

program designed to aid the patient.”⁵⁰⁴

Although *State v. Perry* was decided on *state* constitutional grounds, the Louisiana Supreme Court certainly characterized the effects and side effects of competence restoring treatment for a condemned inmate as cruel and unusual punishment. The court said that after receiving neuroleptics, the prisoner

will be forced to linger for a protracted period, stripped of the vestiges of humanity and dignity usually reserved to death row inmates, with the growing awareness that the state is converting his own mind and body into a vehicle for his execution.

...
Unlike sane death row prisoners who retain dignity until the end, Perry would . . . experience an indefinite period of indignity, anxiety and fear, assimilating unwanted antipsychotic drugs into his brain and body against his will at the risk of harmful and fatal side effects. . . . These circumstances . . . [would] degrade human dignity and reach a sum in which there is something inhuman, barbarous, and analogous to torture.⁵⁰⁵

3. *Side Effects and the Due Process Protections of the Fifth and Fourteenth Amendments*

In *Youngberg v. Romeo*⁵⁰⁶ and *Vitek v. Jones*,⁵⁰⁷ the U.S. Supreme Court recognized that mentally disabled patients and prison inmates retain a liberty right to freedom from certain government intrusions⁵⁰⁸ despite their having been legally confined. In two later cases, *Washington v. Harper*⁵⁰⁹ and *Riggins v. Nevada*,⁵¹⁰ drug side effects led the Supreme Court to recognize that convicted prisoners and pretrial detainees retained liberty rights to avoid unwanted administration of antipsychotic medication.

504. 609 P.2d 747, 751 (Okla. 1980).

505. *State v. Perry*, 610 So. 2d 746, 766, 768 (La. 1992).

506. 457 U.S. 307, 315–16 (1982) (stating that institutionalized persons retain a substantive due process right of freedom from excessive restraint).

507. 445 U.S. 480, 492–93 (1980) (stating that the transfer of a prisoner to a mental hospital for treatment without a hearing violates the Due Process Clause because the prisoner retains the “right to be free from, and to obtain judicial relief for, unjustified intrusions on personal security” (quoting *Ingraham v. Wright*, 430 U.S. 651, 673 (1977))).

508. The Supreme Court’s *Vitek* decision notes explicitly that at the hospital, the prisoner might have to undergo a “mandatory behavior modification [program] as a treatment for mental illness,” but does not describe the program. *Id.* at 494. According to the brief filed by Jones’s counsel, the treatment included involuntary administration of the neuroleptic Thorazine® (chlorpromazine). Brief of Appellee Larry D. Jones at 16, *Vitek v. Jones*, 445 U.S. 480 (1980) (No. 78–1155).

509. 494 U.S. 210, 221–22 (1990) (stating that a convicted prisoner “possesses a significant liberty interest in avoiding the unwanted administration of antipsychotic drugs under the Due Process Clause of the Fourteenth Amendment”).

510. 504 U.S. 127, 138 (1992).

Washington v. Harper examined the propriety of a state prison procedure that allowed involuntary medication to be given following a finding by a three member administrative panel that the drug was a medically appropriate remedy for the inmate's grave disability or risk of harm.⁵¹¹ Harper contended that the prison's procedure was an unconstitutional violation of his due process rights and that forcible medication should occur only after a judicial finding that he was incompetent to refuse treatment.⁵¹² The majority opinion recognized the drugs' potentially "serious, even fatal" adverse effects and concluded that "forcible injection of medication into a nonconsenting person's body represents a substantial interference with that person's liberty."⁵¹³ Though the majority holding and the dissent in *Harper* disagreed on the type of procedural protections that were constitutionally required, both opinions agreed that because of the risk and severity of side effects, some sort of systematic review was necessary before a prisoner could receive antipsychotic medication over his objection.⁵¹⁴

511. The panel consisted of a psychiatrist, psychologist, and associate superintendent of corrections. For a description of the prison's policy, see *Harper*, 494 U.S. at 215–16.

512. The Washington Supreme Court had agreed partially with Harper, stating that: [A] judicial hearing must be held to determine whether the State can treat a prisoner with antipsychotic drugs against his will. A court may order imposition of antipsychotic drug treatment upon a nonconsenting prisoner when the State proves (1) a compelling state interest to administer antipsychotic drugs, and (2) the administration of the drugs is both necessary and effective for furthering that interest. *Harper v. State*, 759 P.2d 358, 364 (Wash. 1988) (en banc), *rev'd*, 494 U.S. 210 (1990). Notice that the Washington Supreme Court did *not* require the state to prove that an inmate is incompetent to make treatment decisions. *See id.*

513. *Harper*, 494 U.S. at 229.

514. The majority concluded that the prison's internal review procedure struck an acceptable balance between the prisoner's liberty interests and the prison's need to maintain order and protect inmates. *Id.* at 229–31. Justice Stevens's dissent maintained that this procedure was inadequate, because the panel members would be subject to internal pressure from colleagues and because institutional interests of jail personnel would undermine their professional judgment about the inmate's medical condition. *Id.* at 251–53 (Stevens J., dissenting). He concluded:

[I]t is difficult to imagine how a committee convened under [the prison's] Policy . . . could conceivably discover, much less be persuaded to overrule, an erroneous or arbitrary decision to medicate or to maintain a specific dosage or type of drug. Institutional control infects the decisionmakers and the entire procedure. . . . I would affirm the decision of the Washington Supreme Court requiring a judicial hearing, with its attendant procedural safeguards, as a remedy in this case.

Id. at 257 (citation omitted).

In *Riggins*, the Supreme Court overturned the conviction and death sentence of a Nevada prisoner who contended that the antipsychotic drug Mellaril he received before and during his trial for capital murder had compromised his right to a fair trial.⁵¹⁵ The majority quoted *Harper*'s view that forced medication is a substantial interference with liberty. Citing *Harper*'s descriptions of the adverse effects of antipsychotic drugs,⁵¹⁶ the *Riggins* court noted that the interference with a person's liberty caused by "antipsychotic drugs like Mellaril . . . is particularly severe."⁵¹⁷ Comparing Harper's situation to that of Riggins, the Court concluded that a pretrial detainee deserved "at least as much protection" as a prisoner before receiving involuntarily administered drugs.⁵¹⁸ The state could meet its burden by demonstrating that administering a drug was medically appropriate and necessary for the safety of the inmate or others, or that there was no less intrusive means for the state to make the prisoner able to proceed with criminal adjudication.⁵¹⁹

Although the Supreme Court has not yet stated what procedural protections are due to persons institutionalized outside of correctional settings, many lower court decisions have, again concluding that the side effects of medications implicate liberty interests that require some sort of procedural protection. In *Davis v. Hubbard*,⁵²⁰ a federal district court examined conditions of treatment at the Lima State Hospital in Ohio.⁵²¹

As was the case with the Washington Supreme Court's ruling, the U.S. Supreme Court's *Harper* ruling permits involuntary administration of medication irrespective of the inmate's capacity to make informed treatment decisions. *Harper*, 494 U.S. at 226. Thus, the *Harper* majority countenances administering antipsychotic drugs over the objections of competent inmates.

515. Throughout his trial, Riggins received the maximum FDA-approved dose (800 milligrams/day) of the antipsychotic medication thioridazine (trade name Mellaril®). *Riggins v. Nevada*, 504 U.S. 127, 131 (1992). Among conventional antipsychotic medications, thioridazine has a high potential to cause sedation. HYMAN ET AL., *supra* note 9, at 8.

516. *Riggins*, 504 U.S. at 134 (quoting *Harper*, 494 U.S. at 229–30).

517. *Id.*

518. *Id.* at 135.

519. *Id.*

520. 506 F. Supp. 915 (N.D. Ohio 1980).

521. In addition to evincing concern about neuroleptics' side effects, the *Davis* court was troubled by *how* the drugs were being used:

Psychotropic drugs are not only overprescribed; they are also freely prescribed. They are prescribed by both licensed and unlicensed physicians. Both licensed and unlicensed physicians regularly prescribe drugs for any patient in the institution without regard to whether he is personally assigned to the patient or whether he has even seen the patient. It is not unusual for attendants to recommend a certain dosage or increased dosage. Such recommendations are often accepted by the physician without having examined the patient. Further, when dealing with an especially disturbed patient, attendants can obtain additional medication by submitting appropriate forms to the pharmacy when there is no physician available. . . . [P]atients are

After reviewing the side effects associated with neuroleptics, the court concluded that a right to refuse treatment derived from each patient's constitutional entitlement to "substantive due process, or phrased differently, as an aspect of 'liberty' guaranteed by the due process clause of the Fourteenth Amendment."⁵²²

Similarly, the final ruling in *Rennie v. Klein*⁵²³ specified that although exercise of professional judgment was sufficient to override an involuntary patient's Fourteenth Amendment right to refuse treatment, doctors must consider "whether and to what extent the patient will suffer harmful side effects."⁵²⁴ Although *Project Release v. Prevost*⁵²⁵ ultimately concluded that then-existing New York state regulations were adequate to protect patients' due process rights, drug side effects were again cited as the source of a constitutionally significant liberty.⁵²⁶ In *Johnson v. Silvers*,⁵²⁷ the Fourth Circuit relied on *Project Release* in reaching its similar conclusion that the side effects of antipsychotic medication were sufficiently intrusive to implicate protected liberty interests.⁵²⁸

4. Side Effects and Privacy Protections

As the U.S. Supreme Court noted in *Cruzan v. Director, Missouri Department of Health*, "many state courts have held that a right to refuse treatment is encompassed by a generalized constitutional right of

generally not given the opportunity to refuse psychotropic drugs, although roughly 85% of the patients are capable of rationally deciding whether to consent to their use.

Id. at 926–27. Besides medication issues, the *Davis* court examined the hospital's staffing, treatment planning, and physical plant. *Id.* at 917–22.

522. *Id.* at 929.

523. 720 F.2d 266 (1983).

524. *Id.* at 269. In his concurrence, Judge Seitz noted the "dangerous and irreversible side effects" of then-available antipsychotic drugs as grounds for explicitly holding "that the Due Process Clause at a minimum requires the authorities to administer antipsychotic drugs to an unwilling patient" only when such administration derives from a professional judgment about the patient's welfare. *Id.* at 273–74 (Seitz, C.J., concurring).

525. 722 F.2d 960 (2d Cir. 1983).

526. *Id.* at 978–80. In *Rivers*, a New York appellate court held that *state* constitutional guarantees required more extensive procedural protections before involuntary medication could be administered, including a judicial hearing and determination of incompetence by clear and convincing evidence. *Rivers v. Katz*, 495 N.E.2d 337, 341 (N.Y. 1986).

527. 742 F.2d 823 (4th Cir. 1984).

528. *Id.* at 825.

privacy.”⁵²⁹ Privacy was first recognized as an implicit constitutional right in *Griswold v. Connecticut*, a 1965 U.S. Supreme Court case holding that state law could not preclude a person’s use of contraception.⁵³⁰ In those court decisions that rely on privacy rights as reasons for precluding automatic administration of antipsychotic drugs to nonconsenting persons, side effects are often cited as the source of this potential constitutional violation. For example, in *Bee v. Greaves*,⁵³¹ the Court of Appeals of the Tenth Circuit characterized antipsychotic medications as “potentially dangerous drugs” in concluding “that the decision whether to accept treatment with antipsychotic drugs is of sufficient importance to fall within this category of privacy interests protected by the Constitution.”⁵³² The characterization of antipsychotic therapy as a “potentially dangerous treatment”⁵³³ supported the view of the Court of Appeals of the First Circuit that “a person has a constitutionally protected interest in being left free by the state to decide for himself” whether to receive such medication.⁵³⁴ A scathing description of antipsychotic drug therapy led the Massachusetts Supreme Judicial Court to recognize a constitutionally protected privacy interest as the source of the right of patients or guardians to decide whether to permit treatment with antipsychotic medication.⁵³⁵

5. Side Effects and State Constitutional Justifications

In a number of cases, state courts have held that individuals enjoy

529. 497 U.S. 261, 279 n.7 (1990). The Court continued, however, that “we have never so held. We believe this issue is more properly analyzed in terms of a Fourteenth Amendment liberty interest.” *Id.*

530. 381 U.S. 479, 485 (1965). In his plurality opinion, Justice Douglas argued that “specific guarantees in the Bill of Rights have penumbras” that give citizens “zones of privacy” protected from state intrusion by the Fourteenth Amendment. *Id.* at 484. Justice Goldberg’s concurrence finds that privacy is a nonenumerated right preserved by the Ninth Amendment. *Id.* at 487 (Goldberg, J., concurring). Justice Harlan, however, stated that privacy is “implicit in the concept of ordered liberty,” and found its basis in the Fourteenth Amendment’s Due Process Clause. *Id.* at 500 (Harlan, J., concurring) (quoting *Palko v. Connecticut*, 302 U.S. 319, 325 (1937)).

531. *Bee v. Greaves*, 744 F.2d 1387 (10th Cir. 1984).

532. *Id.* at 1392–93.

533. *Id.* at 1395.

534. *Rogers v. Okin*, 634 F.2d 650, 653 (1st Cir. 1980), *vacated*, *Mills v. Rogers*, 457 U.S. 291 (1982).

535. *In re Guardianship of Roe*, 421 N.E.2d 40, 51 n.9 (Mass. 1981). The Court deemed antipsychotic therapy an “extraordinary medical treatment.” *Id.* at 51. The Court further noted: “We can identify few legitimate medical procedures which are more intrusive than the forcible injection of antipsychotic medication. . . . [W]e treat these drugs in the same manner we would treat psychosurgery or electroconvulsive therapy. . . . [T]he impact of the chemical upon the brain is sufficient to undermine the foundations of personality.” *Id.* at 52–53 (footnote omitted).

additional substantive and procedural protections beyond those that federal constitutional law requires.⁵³⁶ Here again, the side effects of antipsychotic drugs have figured prominently in state appellate courts' deliberations. After summarizing the benefits and adverse effects of neuroleptic medication,⁵³⁷ the court of appeals in *Rivers v. Katz* concluded that New York's state constitution "affords involuntarily committed mental patients a fundamental right to refuse antipsychotic medication."⁵³⁸ The court directed judicial decisionmakers to consider "adverse side effects associated with the treatment and any less intrusive alternative treatments" in determining whether the state had shown, by clear and convincing evidence, that "the proposed treatment is narrowly tailored to give substantive effect to the patient's liberty interest."⁵³⁹ Similarly, the Minnesota Supreme Court, after noting that "the final decision to accept or reject a proposed medical procedure and its attendant risks is ultimately *not* a medical decision, but a personal choice," found that the intrusive side effects of neuroleptics implicated a state constitutional right to privacy. This right, the court claimed, could be protected only by requiring that doctors get judicial approval before administering medication over a patient's objection.⁵⁴⁰

C. Case Law Since the Arrival of Atypical Agents

Since the arrival of novel antipsychotic agents, several courts have held that the substantive and procedural protections owed to patients who wished to refuse treatment with neuroleptics also applied to patients who wished to refuse atypical antipsychotic agents. Some cases discuss older and newer antipsychotic agents together without mentioning the special features or more benign side effect profiles of the newer drugs.⁵⁴¹

536. The U.S. Supreme Court noted this with specific reference to antipsychotic medication in *Mills v. Rogers*, 457 U.S. 291, 299–300 (1982).

537. *Rivers v. Katz*, 495 N.E.2d 337, 339 n.1 (1986).

538. *Id.* at 341.

539. *Id.* at 344.

540. *Jarvis v. Levine*, 418 N.W.2d 139, 145, 148–49 (Minn. 1988).

541. See, e.g., *In re Locks*, 94 Cal. Rptr. 2d 495, 500 (Ct. App. 2000) (stating that the petitioner being held and treated at state mental hospital for insanity while habeas relief was sought was not entitled to a hearing to determine his competence to refuse treatment with haloperidol or olanzapine); *State v. Kotis*, 984 P.2d 78, 93 (Haw. 1999) (applying the three-fold test articulated in *Riggins v. Nevada* to pretrial medication with novel antipsychotic drugs); *In re Frances K.*, 749 N.E.2d 1082, 1087 (Ill. App. Ct. 2001) (using the same statutorily prescribed seven-factor test in jury trial concerning the administration of psychotropic medication against a patient's will), *appeal denied*, 763

*In re Gwendolyn N.*⁵⁴² reversed a trial courts' involuntary medication order for older and newer agents because the order did not specify drugs and dosages. This decision noted that newer antipsychotic "drugs have fewer side effects" but noted that "death" remains a possible side effect of the atypicals.⁵⁴³ In *Steinkruger v. Miller*, the South Dakota Supreme Court found that previous federal and state case law applied to refusals of novel antipsychotics, despite its explicit recognition of the advantages of novel agents. After citing the list of neuroleptic side effects found in Justice Stevens's *Harper* concurrence,⁵⁴⁴ the *Steinkruger* court stated: "We recognize that pharmaceutical advancements have brought into use new medications with fewer side effects, but adverse reactions have not been eliminated."⁵⁴⁵ The *Steinkruger* court concluded: "As forced medication intrudes on a patient's basic rights, due process requires that psychotropic drugs not only be deemed medically appropriate, but before approving their forced administration the court must also consider 'less intrusive alternatives.'"⁵⁴⁶

In contrast to the often harsh descriptions of antipsychotic therapy that one finds in decisions on forced treatment with neuroleptics, a few appellate decisions concerning involuntary administration of atypical antipsychotics have described these newer drugs favorably. Moreover, the reduced risk and superior effectiveness of the novel antipsychotics have, on occasion, been factors that convinced courts to favor involuntary treatment.

N.E.2d 318 (Ill. 2001); *In re Len P.*, 706 N.E.2d 104, 108–09 (Ill. App. Ct. 1999) (stating that specifying the type and dosage of antipsychotic medication implicated a substantive right and was not a mere procedural formality and that failure to specify the dose justified the reversal of the trial court's medication order); *In re Edward S.*, 698 N.E.2d 186, 189 (Ill. App. Ct. 1998) (stating that because the state did not make a diligent effort to tell the patient about the risks and benefits of psychotropic medication, the order to medicate was manifestly erroneous); *In re Mental Commitment of Laura J.M.*, No. 01-1174-FT, 2001 Wisc. App. LEXIS 832, at *1 (Ct. App. Aug. 15, 2001) (unpublished opinion) (reversing the involuntary medication order and remanding because the trial court failed to make the findings required by *Virgil D. v. Rock County*, 524 N.W.2d 894 (1994)).

Haloperidol is the generic name for the conventional neuroleptic marketed under the trade name Haldol®. HYMAN ET AL., *supra* note 9, at 8.

542. 760 N.E.2d 575, 578–79 (Ill. App. Ct. 2001).

543. *Id.* at 577.

544. *Harper*, 494 U.S. at 240 (Stevens, J., concurring) (stating that neuroleptic "reactions include drowsiness, excitement, restlessness, bizarre dreams, hypertension, nausea, vomiting, loss of appetite, salivation, dry mouth, perspiration, headache, constipation, blurred vision, impotency, eczema, jaundice, tremors, and muscle spasms").

545. *Steinkruger v. Miller*, 612 N.W.2d 591, 598 (S.D. 2000).

546. *Id.* at 599 (quoting *Riggins v. Nevada*, 504 U.S. 127, 135 (1992)).

1. Involuntary Administration of Atypicals to Civil Patients

a. Minnesota Appellate Cases

In a series of Minnesota cases, the advantages of atypicals have been noted explicitly by appeals courts, and in some instances have served as reasons for involuntarily administering novel agents, particularly clozapine. First, *In re Stewart*⁵⁴⁷ involved an appeal of an involuntary medication order in which the trial court authorized either the conventional neuroleptic loxapine or clozapine. However, Stewart wished to be treated only with clozapine. Although the appeals court ruled that the trial court properly left the choice of medication “to the discretion of the medical professionals,”⁵⁴⁸ it also noted that the trial court had “recognized that the use of Clozaril would further reduce the risk of tardive dyskinesia.”⁵⁴⁹

Next, *Dibley v. Gomez*⁵⁵⁰ concerned a long-term inpatient who denied that he was mentally ill, but also objected to antipsychotic therapy because of its side effects. Despite its decision to affirm the trial court’s involuntary medication order, the appeals court was

concerned about the hospital’s failure to . . . use the newer medications that do not precipitate the adverse side effects associated with the older neuroleptics. . . . Clozaril or other new medication may forever eliminate the need for Dibley to confront the regrettable side effects of traditional neuroleptics. We must, however, leave to the treating professionals the decision of how best to proceed.⁵⁵¹

*In re Tyler*⁵⁵² reviewed a trial court’s authorization of antipsychotic medication for a patient who had suffered from delusions that ceased during treatment with the neuroleptic fluphenazine (Prolixin®), but whose aggressiveness had not sufficiently diminished. His doctors wanted to prescribe clozapine. In affirming the trial court’s order, the appeals court noted:

547. No. C3-91-439, 1991 Minn. App. LEXIS 697 (Ct. App. July 10, 1991) (unpublished opinion).

548. *Id.* at *5.

549. *Id.* at *3.

550. No. C4-94-870, 1994 Minn. App. LEXIS 801 (Ct. App. Aug. 16, 1994) (unpublished opinion).

551. *Id.* at *6–7.

552. No. C4-95-1432, 1995 Minn. App. LEXIS 1403 (Ct. App. Nov. 14, 1995) (unpublished opinion).

Clozaril is known to be more effective with some patients than other neuroleptics, and he may not experience many of the side effects which Prolixin causes. . . . There is a possibility that an atypical neuroleptic such as [r]isperidone or Clozaril may better treat appellant's remaining problematic behaviors, and there is little disadvantage to either medication.⁵⁵³

In addition, the superiority of clozapine figured importantly in two appellate court decisions to allow administration of medication by nasogastric tube, which would require passing a tube through the patient's nose and down his esophagus, if the patient refused to swallow it.

*In re Witthans*⁵⁵⁴ concerned a patient who would take haloperidol and risperidone, but refused clozapine. The patient's doctors had recommended clozapine because the patient was not responding to his medication. Because clozapine cannot be administered by injection, Witthans's doctors sought and received the trial court's permission to administer the drug via nasogastric tube if Witthans would not swallow it. The appellate court backed the trial court's decision. Witthans was not participating adequately in psychosocial treatments,⁵⁵⁵ and the appeals court recognized that "Clozaril can produce significant improvement in individuals who do not respond to typical neuroleptics."⁵⁵⁶ The appeals court agreed with the trial court that

the use of a nasogastric tube to administer the Clozaril . . . [is] a routine medical procedure involving no significant risk of serious harm. . . . If appellant continues his refusal to take it orally, the only alternative is to use a nasogastric tube. Since there is present medical necessity for the Clozaril, the trial court did not clearly err in authorizing the use of a nasogastric tube to administer it.⁵⁵⁷

Involuntary nasogastric tube administration of clozapine was the chief issue examined in *In re Martin*.⁵⁵⁸ Based on evidence heard by the trial court that clozapine decreased Martin's delusional preoccupations and aggressiveness, the appellate court concluded:

Clozaril is a better medication for Martin because it greatly reduces his symptoms of mental illness and makes him more amenable to other treatment while avoiding the risk of tardive dyskinesia. . . .

. . . .
. . . If the medication is medically necessary, the means to administer it must be medically necessary as well. The trial court's weighing of the extent of the intrusion of the tube, and authorization of the procedure, were not clearly erroneous.⁵⁵⁹

553. *Id.* at *6–7. Although this decision refers to the novel agents clozapine and risperidone as "neuroleptics," psychiatrists usually reserve this term for older, "typical" antipsychotic drugs.

554. No. CX-94-1280, 1994 Minn. App. LEXIS 934 (Ct. App. Sept. 27, 1994) (unpublished opinion).

555. *Id.* at *2–3.

556. *Id.* at *8.

557. *Id.* at *8–9.

558. 527 N.W.2d 170 (Minn. Ct. App. 1995).

559. *Id.* at 172–73.

b. Appellate Cases from Other States

In a New York appellate opinion that approved a trial court's involuntary medication order, the advantages and diminished side effect burden of atypicals was acknowledged, and indeed, exaggerated. The opinion said that giving an incompetent patient antipsychotic therapy "in turn would allow him to take newer antipsychotic drugs which have no side effects and to participate in schooling and training programs which would allow reentry into the community."⁵⁶⁰

*In re R.A.J.*⁵⁶¹ reviewed a trial court's involuntary medication order that authorized administering either "Haldol and Tegretol or Risperdal and Tegretol."⁵⁶² But because risperidone has fewer side effects than haloperidol, the appeals court stated that

the least restrictive combination of medications for R.A.J. is oral Risperdal and Tegretol, and that the combination of injectable Haldol and Tegretol is to be given only if R.A.J. should change his mind and refuse Risperdal. Accordingly, we direct modification of the order to authorize the combination of Haldol with Tegretol only if R.A.J. should refuse Risperdal while it is prescribed. . . .
So modified, we affirm the forced medication order.⁵⁶³

The potential advantages of novel agents in a risk benefit calculus became the key issue in *In re Nancy M.*,⁵⁶⁴ which examined an Illinois jury's decision to authorize forced medication with haloperidol, risperidone, and olanzapine. At trial, the patient's doctor testified that haloperidol had more risk of neurological side effects than did the other drugs. The doctor had requested haloperidol only because the newer drugs were not injectable, and therefore could not be given to a patient who might refuse oral therapy.⁵⁶⁵ In her trial testimony, the patient denied having a mental illness, but said she would take the novel agents if ordered because they were less dangerous than Haldol.⁵⁶⁶

Using a form that did not name any particular drug, the jurors "returned a general verdict" saying the patient met Illinois's criteria for receiving involuntary medication, and the trial court judge authorized all

560. *Mausner v. William E.*, 694 N.Y.S.2d 165, 166 (App. Div. 1999).

561. 554 N.W.2d 809 (N.D. 1996).

562. *Id.* at 812. Tegretol® (generic name carbamazepine) is an antiseizure medication that is sometimes used by psychiatrists to treat emotional and behavioral conditions, including mania and aggressiveness. HYMAN ET AL., *supra* note 9, at 131–35.

563. *In re R.A.J.*, 554 N.W.2d at 812–13.

564. 739 N.E.2d 607 (Ill. App. Ct. 2000).

565. *Id.* at 610.

566. *Id.* at 611.

three medications.⁵⁶⁷ The appeals court ruled that this was improper. After reviewing the doctor's trial "testimony that the medications were very different," the appeals court reversed the trial court's order, citing the failure of

the verdict forms . . . [to] distinguish the medications. Based on the testimony presented, the jury reasonably could have found that the benefits of administering either [o]lanzapine or Risperdal to respondent outweighed the harm and that the benefit of administering Haldol to respondent did not outweigh the harm to her. However, the jury's verdict simply states that respondent qualifies for the involuntary administration of psychotropic medication. The verdict does not show that the jury found that the benefits of administering Haldol to respondent outweighed the harm it would pose to her, nor does it show that the benefits of administering Risperdal or [o]lanzapine to respondent outweighed the harm. The verdict here fails to show that the jury clearly intended to authorize the involuntary administration of all three medications.⁵⁶⁸

2. *Involuntary Administration of Atypicals to Pretrial Detainees*⁵⁶⁹

The relatively benign side effect profile of the newer antipsychotic drugs figures importantly in at least three federal court decisions that concern the involuntary administration of antipsychotic drugs to restore competence to stand trial. Two⁵⁷⁰ of these decisions involve Russell Eugene Weston, Jr., the man charged with killing two Capitol police officers in July 1998.⁵⁷¹

In April 1999, the district court found Weston incompetent to stand trial and ordered him to undergo competence restoring treatment at a federal correctional hospital.⁵⁷² Later that year, the district court approved involuntary medication for Weston. In March 2000, the D.C. Circuit Court of Appeal remanded the case to the district court to consider whether medication was medically appropriate, necessary to

567. *Id.*

568. *Id.* at 615–16.

569. This section focuses on the *Weston* courts' recognition of the special properties of novel agents, and how that recognition has influenced decisionmaking. For a summary of developments in Weston's case through March 2000, see Siegel et al., *supra* note 35, at 308–12.

570. *United States v. Weston*, 134 F. Supp. 2d 115 (D.D.C. 2001), *aff'd*, 255 F.3d 873 (D.C. Cir. 2001); *United States v. Weston*, 255 F.3d 873 (D.C. Cir. 2001).

571. On December 10, 2001, the U.S. Supreme Court declined to hear Weston's appeal of the D.C. Circuit Court's decision. *Weston*, 122 S. Ct. 670 (2001). Therefore, after going three years without antipsychotic medication, Weston finally began receiving treatment that could permit him to undergo trial. Neely Tucker, *High Court Passes on Capitol Suspect: Decision Clears Way for Medicating Weston*, WASH. POST, Dec. 11, 2001, at B01. For a recent case that follows the D.C. Circuit's reasoning, see *United States v. Arena*, No. 00 CR. 398(JFK), 2001 U.S. Dist. LEXIS 17522 (S.D.N.Y. Oct. 29, 2001). As of early August 2002, Weston continued to receive antipsychotic medication, but had not achieved competence to stand trial. *Judge Rules Capitol Gunman Can Be Forced to Take Medicine*, NEW YORK TIMES, Aug. 3, 2002, at A11.

572. *Weston*, 134 F. Supp. 2d at 117.

restore Weston's competence, and could be administered without unacceptably compromising Weston's fair trial rights.⁵⁷³ In his latest ruling, district court Judge Sullivan concluded that involuntary administration of antipsychotic medication to Weston could be accomplished in a manner that met all these tests.

Judge Sullivan's latest decision contains an extensive⁵⁷⁴ discussion of the properties of older and newer antipsychotic drugs. He noted that:

Atypical antipsychotics have a more favorable side effect profile and are better tolerated by the average patient. . . . Dr. Zonana testified that atypicals have so few side effects that studies use them on individuals who have not yet been diagnosed with schizophrenia, but who only have symptoms that suggest they might develop the disease. . . . In short, "there is a world of difference" between the antipsychotic medications described in the judicial opinions of the early 1990s and the current atypical antipsychotic medications now available.⁵⁷⁵

This helped "persuade the [c]ourt that antipsychotic medication is appropriate, notwithstanding the potential side effects since they can be managed with close oversight."⁵⁷⁶

The district court also considered whether the side effects of competence-restoring antipsychotic therapy might impair Weston's ability to undergo trial and adversely affect his demeanor and appearance before a jury. The court noted that drug therapy probably would *improve* many trial related abilities, including Weston's abilities to consult with counsel, pay attention, and concentrate.⁵⁷⁷ However, the advantages of atypicals were central to the court's conclusions about how medication would affect Weston's presentation. Citing psychiatrists' testimony at hearings concerning the newer medications, Judge Sullivan specifically addressed the concerns about side effects expressed in Justice Kennedy's *Riggins* concurrence⁵⁷⁸ as follows:

Advances in the primary antipsychotic medications and adjunct therapies make such side effects less likely. Additionally, medications that help control side effects are available and Weston will be very closely monitored. In fact, antipsychotic medication is likely to make Weston's affect more, rather than less, appropriate.⁵⁷⁹

573. *United States v. Weston*, 206 F.3d 9, 13–14 (D.C. Cir. 2000).

574. The discussion extends for approximately 1000 words, and describes the benefits and side effects in detail. *Weston*, 134 F. Supp. 2d at 123–25.

575. *Id.* at 124 (citations omitted) (quoting Dr. Sally Johnson).

576. *Id.* at 125.

577. *Id.* at 133.

578. *Riggins v. Nevada*, 504 U.S. 127, 138–43 (1992) (Kennedy, J., concurring).

579. *Weston*, 134 F. Supp. 2d at 134 (citation omitted).

In a decision issued July 27, 2001, a panel of the D.C. Circuit Court of Appeals affirmed the district court's decision.⁵⁸⁰ After summarizing the side effects of "typical antipsychotics" and atypical agents in a footnote,⁵⁸¹ the circuit court panel cited the benefits of antipsychotic therapy as a factor favoring its administration to Weston.

[T]he record [of medical testimony heard by the district court] indicates that medication will likely enhance rather than impair Weston's right to a fair trial. . . . The possibility of side effects from anti-psychotic medication is undeniable, but the ability of Weston's treating physicians and the district court to respond to them substantially reduces the risk they pose to trial fairness."⁵⁸²

The panel quoted the favorable views of novel agents offered by the district court's independent psychiatric expert⁵⁸³ and commented that "[a]ntipsychotic drugs have progressed since Justice Kennedy discussed their side effects in *Riggins*. There is a new generation of medications having better side effect profiles."⁵⁸⁴

The "better side effect profiles" of the atypicals also figured importantly in recent thinking about competence restoration articulated by the Court of Appeals of the Second Circuit. Like the *Weston* cases, *United States v. Gomes*⁵⁸⁵ concerned a defendant whose lawyers wished to have their client avoid involuntarily administered antipsychotic medication, the purpose of which was to restore competence to proceed with adjudication.⁵⁸⁶ The appellate court articulated a five-factor standard for administering antipsychotic medication under these circumstances, and sent the case back to the district court for further fact finding related to these factors.⁵⁸⁷ However, the court of appeals clearly saw the

580. *Weston*, 255 F.3d 873, 887 (D.C. Cir. 2001).

581. *Id.* at 877 n.3.

582. *Id.* at 885.

583. "General experience with antipsychotics, particularly the newer medications, indicates that given their benefits they are reasonably safe and well-tolerated." *Id.* at 886 (quoting report of Dr. David G. Daniel, M.D.).

584. *Id.* at 886 n.7. The panel went on to quote from an article by attorney Paul Nidich and psychiatrist Jacqueline Collins:

[I]n light of the progress made in the development of new antipsychotic medications since the Supreme Court's *Riggins* decision in 1992, the courts should revisit this issue with an open mind. . . . [Because of new atypicals,] the fear of side effects should not weigh heavily in the decision whether to treat pretrial detainees or civilly committed persons with antipsychotic medication against their will when that treatment is medically appropriate.

Id. (alteration in original) (quoting Paul A. Nidich & Jacqueline Collins, *Involuntary Administration of Psychotropic Medication: A Federal Court Update*, 11 HEALTH LAW., May 1999, at 12, 13).

585. 289 F.3d 71 (2d Cir. 2002).

586. *Id.* at 75.

587. The five factors are: (1) the government's interest in prosecuting the defendant versus the defendant's interest in being free of medication, (2) the medical appropriateness of the defendant's proposed treatment, (3) whether medicating the

availability of atypicals in much the same light as did the *Weston* courts:

[W]e first note that significant improvements have been made in antipsychotic medication in the decade since Justice Kennedy expressed his misgivings in *Riggins*. Justice Kennedy himself presciently acknowledged then that “[t]he state of our knowledge of antipsychotic drugs and their side effects is evolving and may one day produce effective drugs that have only minimal side effects.” As the American Psychiatric Association has pointed out [in an amicus brief filed in the case], a new generation of antipsychotic drugs “largely post-dating *Riggins*” and with a “more favorable side effect profile” has appeared. The American Psychological Association agrees, stating [in an amicus brief filed in the case] that these new drugs, called atypicals, “generally exhibit equal or improved therapeutic efficacy in comparison to the traditional or conventional agents, yet they have a more favorable side effect profile.” Most of the atypicals present relatively low risks of the serious side effects associated with conventional drugs such as Mellaril, the drug at issue in *Riggins*.

Gomes’s effort to discount the significance of the atypicals is not convincing.⁵⁸⁸

D. Observations and Comments

Although several years have passed since risperidone became

defendant was necessary because less invasive means of restoring competency are not available, (4) the need for continued monitoring of the defendant to assess the actual effects of medication on the defendant’s ability to stand trial, and (5) the impact of medication on a defendant’s ability to mount an insanity defense. *Id.* at 85–88. The court of appeals reasoned that the lower court’s decision to permit involuntary medication had not adequately addressed the first four of these factors. *Id.* at 85.

In articulating this standard, the *Gomes* court determined, as did the court in *Weston*, that heightened scrutiny was the appropriate standard for evaluating whether involuntary medication would adversely affect a pretrial detainee’s due process rights. *Id.* at 82; *Weston*, 255 F.3d at 880. By contrast, in a case involving use of antipsychotic drugs to restore competence of a defendant charged with mailing a threatening letter, the Sixth Circuit held that courts must apply a strict scrutiny standard when the state wishes to forcibly medicate a nondangerous pretrial detainee. *United States v. Brandon*, 158 F.3d 947, 960 (6th Cir. 1998). In a case involving a dentist charged with filing false Medicaid and private insurance claims, the Eighth Circuit adopted heightened scrutiny as its standard, and explicitly rejected the strict scrutiny approach taken in *Brandon*. *United States v. Sell*, 282 F.3d 560, 567–68 (8th Cir. 2002). On November 4, 2002, the U.S. Supreme Court agreed to review the *Sell* decision solely on “the following question: Whether the Court of Appeals erred in rejecting petitioner’s argument that allowing the government to administer antipsychotic medication against his will solely to render him competent to stand trial for non-violent offenses would violate his rights under the First, Fifth, and Sixth Amendments.” *Sell v. United States*, No. 02-5664, 2002 U.S. LEXIS 8315, at *1 (Nov. 4, 2002). One may expect that the Supreme Court’s decision will resolve the conflicting standards for reviewing involuntary competence; it will be interesting to see whether the availability and properties of novel antipsychotics play a role in the Court’s opinion.

588. *Gomes*, 289 F.3d at 83 (citations omitted).

available in the U.S. as a first-line therapy for psychosis, the ultimate impact of current and future novel agents on “right to refuse treatment” litigation remains unclear. For several reasons, it seems very unlikely that courts will undo the cautions and procedural protections embodied in litigation that addressed involuntary treatment with older, more noxious antipsychotic drugs. First, the newer drugs, though much more tolerable, still carry some risk of the neurological side effects that alarmed courts in the 1970s and 1980s. Second, the newer drugs appear to place patients at more risk than neuroleptics of developing troublesome metabolic conditions, including obesity, alterations in lipid metabolism, and diabetes mellitus.⁵⁸⁹ Though these conditions are not as uncomfortable as the acute neurological side effects induced by neuroleptics, they are sources of concern for doctors and patients and should receive courts’ consideration as well.⁵⁹⁰ Third, when the new drugs serve their intended purpose, they lead to changes in the way patients think. Almost any reasonable observer would characterize quelling psychosis as a desirable outcome of medical treatment. Yet this means that novel antipsychotic drugs are indeed “mind altering,” and their unwanted administration therefore should raise legally significant questions about intrusions into a person’s privacy. Finally, current legal rules and procedures concerning involuntary drug therapy may, and probably should, be preserved because they serve a valuable ethical purpose beyond protecting patients from side effects. Even if legal barriers to automatic administration of unwanted medication were initially justified in consequentialist terms, these protections also serve the nonconsequentialist purpose of respecting the personhood of patients. This is especially true in those states that require a judicial finding of incompetence before authorization of involuntary medication.

Though courts can be expected to preserve currently existing legal barriers against automatic treatment of drug refusing psychotic patients, *In re Tyler*, *In re Martin*, *In re Nancy M.*, *Gomes*, and the *Weston* decisions may show us *how* future courts will evaluate and make decisions about involuntary administration of antipsychotic drugs. In these cases and others discussed in the previous Part, the flaws of antipsychotic medications are often noted, but so are their benefits. Gone are extensive judicial diatribes about horrible side effects that all but ignore the benefits of medication and the horror of being psychotic. In some cases, courts have even endorsed the values of antipsychotic therapy, and because such treatment

589. See *supra* notes 236–38 and accompanying text.

590. Both of the *Weston* decisions did so explicitly. See *United States v. Weston*, 134 F. Supp. 2d 115, 124 (D.D.C. 2001), *aff’d*, 255 F.3d 873 (D.C. Cir. 2001); *Weston*, 255 F.3d at 877 n.3.

can be delivered with less risk to a patient's nervous system, judges have seemed more willing to approve of its involuntary administration.

The cases discussed in Part VI.C also demonstrate that at least some courts are capable of receiving and understanding complicated, nuanced scientific information about currently available antipsychotic therapy. This should encourage psychiatrists and other medical experts who testify or otherwise provide information about treatment to courts. Psychiatrists have always had an obligation, when presenting information to courts, to provide legal decisionmakers with up-to-date, detailed information on newly developed treatments. Recent legal developments give psychiatrists reason to believe that when judges consider information about antipsychotic therapy, they now may be more inclined to accept physicians' generally pro-treatment position and less persuaded by the antim medication views of some patient advocates.

VII. CASES MENTIONING NOVEL ANTIPSYCHOTICS: A SHORT QUANTITATIVE SUMMARY

The previous Parts review legal issues concerning novel antipsychotic agents that have been addressed in cases published as of late June 2002. Can we gain additional insight into these cases by examining them as a group?

Figures 1 and 2 address this question by summarizing information from cases listed in this Article's Appendix, which constitute all cases as of October 1, 2002 in the LEXIS database of federal and state cases after 1944⁵⁹¹ discovered using the search strategy described earlier.⁵⁹² Figure 1 describes the frequency with which cases mention the various atypical agents.⁵⁹³ Most cases mention a single drug. Olanzapine and risperidone are the drugs most frequently named, appearing in fifty-five and ninety-nine cases, respectively. This finding in part reflects the fact that these drugs were the first two first-line atypical antipsychotics approved in the U.S.⁵⁹⁴ At least five cases contain language referring to the special

591. This database provides all available case law decided since 1945, including decisions by the U.S. Supreme Court, federal courts of appeals, federal district courts and state cases. It also includes decisions of specialty courts dealing with military appeals, customs, patents, tax law, trade, commerce, veterans' appeals, and bankruptcy.

592. *See supra* note 28.

593. In both Figures, "clz" refers to a case that mentions clozapine, "rsp" to one that mentions risperidone, "olz" to olanzapine, and "que" to quetiapine. No case had yet mentioned the latest novel agent, ziprasidone. The abbreviation "atyp" designates cases that discuss the properties of atypical agents in general, independent of mentioning a specific drug.

594. *See supra* Parts III.D.1, III.D.2.

properties of atypical antipsychotics, either from testifying physicians,⁵⁹⁵ or from the court itself.⁵⁹⁶

Figure 2 shows the frequency with which each drug has been mentioned since atypical agents became available.⁵⁹⁷ Looked at this way, the corpus of cases suggest the following trends.

First, with one exception (1997), no more than six cases mentioning clozapine have appeared each year, and such cases do not seem to be increasing in frequency. One reason for this is that clozapine's use is largely restricted to patients that cannot tolerate or benefit from other antipsychotic agents.⁵⁹⁸ Therefore, only a fraction of patients who need antipsychotic therapy take clozapine, and the drug receives a limited number of mentions. However, as the discussions in previous Parts of this Article have shown, many cases that refer to clozapine have addressed major legal issues concerning the use or availability of atypical agents.⁵⁹⁹ When courts address important principles related to antipsychotic therapy, clozapine often gets mentioned. Yet, courts hear just a few cases each year that raise such issues, and the rate at which this occurs has been fairly constant.

Second, an increasing number of cases are mentioning novel antipsychotic agents. Cases mentioning risperidone first appear in 1994, the year of the drug's U.S. release, and increase steadily in frequency after that.

595. *United States v. Gigante*, 996 F. Supp. 194, 211 (E.D.N.Y. 1998) (quoting psychiatric testimony that “[m]odern day atypical anti-psychotic medication has completely destroyed th[e] myth” that “[c]onsistent deterioration of personality functioning is . . . the rule when talking about psychotic disorders such as schizophrenia”), *amended by* 989 F. Supp. 436 (1997), *aff'd*, 166 F.3d 75 (2d Cir. 1999); *State v. Jung*, 724 N.E.2d 1262, 1263 (Ohio Ct. App. 1999) (quoting psychiatrist Douglas Songer as asserting “that there are several newer medications which have fewer side effects” than neuroleptics which had bothered the patient).

596. *United States v. Weston*, 255 F.3d 873, 877 n.3 (D.C. Cir. 2001) (differentiating atypicals and typical agents, that is, neuroleptics); *United States v. Weston*, 134 F. Supp. 2d 115, 124 (D.D.C. 2001), *aff'd*, 255 F.3d 873 (D.C. Cir. 2001) (“‘[T]here is a world of difference’ between the antipsychotic medications described in the judicial opinions of the early 1990s and the current atypical antipsychotic medications now available.” (quoting Dr. Sally Johnson)); *Mausner v. William E.*, 694 N.Y.S.2d 165, 166 (App. Div. 1999) (discussing “newer antipsychotic drugs which have no side effects”).

597. Although clozapine became available in late 1989, no case mentioned any atypical agent until 1990. Data shown for 2002 represent those cases that had been placed in the LEXIS database of federal and state cases after 1944, as of October 7, 2002.

598. *See supra* Part III.D.1.

599. *See, e.g.*, *Gates v. Shinn*, 98 F.3d 463, 470 (9th Cir. 1996) (prisoners' access to clozapine); *Visser v. Taylor*, 756 F. Supp. 501, 507 (D. Kan. 1990); *O'Keefe v. Orea*, 731 So. 2d 680, 686 (Fla. Dist. Ct. App. 1998) (requiring a psychiatrist to disclose clozapine as a treatment option); *Alexander L. v. Cuomo*, 588 N.Y.S.2d 85, 88 (Sup. Ct. 1992) (inclusion of clozapine in Medicaid formulary); *supra* Part VI.C.1.a (discussing five cases mentioning clozapine while discussing special properties of atypicals as they relate to the involuntarily administered therapy).

FIGURE 1

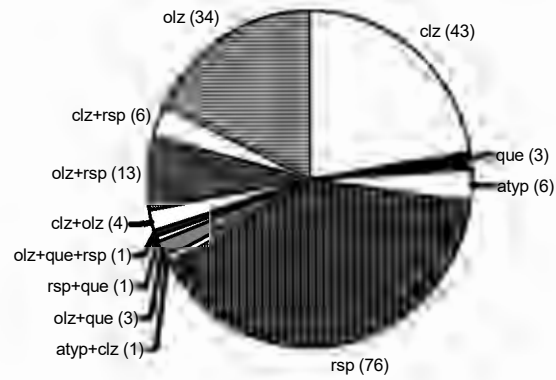
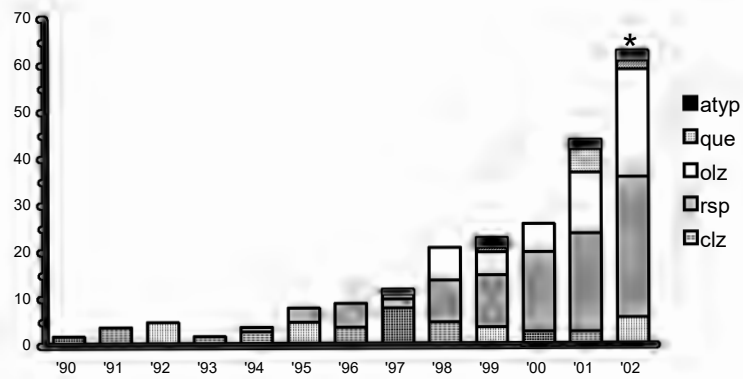


FIGURE 2



* Updated through October 1, 2002.

A similar pattern obtains for olanzapine, and perhaps for quetiapine, which psychiatrists appear to have used less than the two other first-line novel agents. In contrast to what one finds in the clozapine cases, many cases that mention the other novel agents are not concerned with medication issues themselves. The drugs' names simply appear in descriptions of the treatment received by persons with psychiatric disorders. Exceptions to this finding are found in cases that mention more than one atypical agent. Often, for example, olanzapine and risperidone occur together as examples of new antipsychotics that are recognized to have different and usually more desirable properties when compared to the older antipsychotic drugs.⁶⁰⁰

A third point emerges when one determines what fraction of *all* cases discuss antipsychotic drugs discuss novel agents. A search of the LEXIS database of federal and state cases after 1944 for the years 2000 and 2001, using a strategy that contained names of the most commonly used neuroleptics as well as novel antipsychotic drugs⁶⁰¹ yielded 265 cases that mentioned an antipsychotic drug by name. Sixty-five of these cases included the name of one or more atypical antipsychotics. In other words, at a time when an estimated three-fourths of U.S. antipsychotic drug prescriptions were for novel agents,⁶⁰² fewer than one quarter of the published cases mentioning antipsychotic therapies referred to atypicals. Clearly, the frequency with which various drugs are mentioned in U.S. case law does not reflect American psychiatrists' current pattern of drug selection.

600. See, e.g., *In re Nancy M.*, 739 N.E.2d 607, 610, 615 (Ill. App. Ct. 2000) (finding that with the doctor's testimony that risperidone and olanzapine "have the same possible neurological side effects [as neuroleptics] but at a substantially reduced rate," the jury reasonably could have concluded that the benefits of atypicals outweighed their risks, but that the opposite was true for haloperidol); *In re Len P.*, 706 N.E.2d 104, 106 (Ill. App. Ct. 1999) (stating that the newer drugs "have fewer side effects"); *Baer v. Baer*, 738 A.2d 923, 926 n.2 (Md. Ct. Spec. App. 1999) (doctor recommends risperidone or olanzapine as "safe medicines"); *Commonwealth v. Brown*, No. 96-11156(001-004), 1998 Mass. Super. LEXIS 664, at *3 (Dist. Ct. Dec. 18, 1998) (noting that pretrial detainee regained competence with risperidone, "an atypical antipsychotic medication," after treatment with a neuroleptic had been unsuccessful).

601. The search strategy was: "cloza! or risperid! or resperid! or respirid! or risperd! or resperd! or respird! or olanzap! or zyprexa or quetiapine or seroquel or ziprasidone or geodon or haldol or haloperidol or navane or thiothixene or mellaril or thioridazine or trilafon or perphenazine or molindone or moban or stelazine or trifluoperazine or prolixin or fluphenazine or loxitane or loxapine or thorazine or chlorpromazine and date(geq (01/01/2000) and leq (01/01/2002))."

602. Kapur & Remington, *supra* note 204, at 1361.

VIII. CONCLUSIONS

For patients who need antipsychotic therapy and for the psychiatrists who provide their care, the arrival of novel antipsychotic drugs has had enormous therapeutic significance. Older antipsychotic agents clearly helped most psychotic patients who took them and freed many psychotic patients from the horrors of their illness. Yet for many persons, neuroleptic therapy was an unpleasant experience fraught with uncomfortable side effects and risk to the nervous system, and, for a small fraction of the millions of patients who took the older antipsychotic drugs, their experience could rightfully be likened to being placed in a chemical straitjacket.⁶⁰³ Atypical agents have all the antipsychotic benefits of the older drugs but are more easily administered at doses that cause few or no extrapyramidal side effects.⁶⁰⁴ In addition, investigators are developing and accumulating evidence that these drugs, when administered to persons with schizophrenia, may rectify some of the neuropsychological dysfunction that underlies and contributes to the disability associated with the disorder.⁶⁰⁵

Because antipsychotic therapy is, in so many situations, a legally as well as medically significant phenomenon, current trends in the psychopharmacology of psychotic disorders are important to attorneys who represent and judges who hear cases concerning mentally disabled litigants. Moreover, an understanding of what schizophrenia is and of how its current treatment works is vital to the work of scholars and academics who supply legal decision makers with perspectives on the issues faced by litigants who take antipsychotic drugs. This Article has endeavored to explain to legal readers how psychiatrists think about antipsychotic medications and the illnesses they treat. The Article has also tried to suggest several ways in which an important development in psychiatric medicine has a growing legal significance, that is, has altered the way attorneys and courts should think about the actions and legal ramifications of antipsychotic drugs.

603. This experience was, for the vast majority of patients, avoidable through the skillful prescription and monitoring of medication. Unfortunately, psychiatrists' dosing practices typically fell far short of the ideal. See Mossman, *supra* note 227, at 66, 71–72 (describing psychiatrists' ham-handed dosing of neuroleptics and their nonclinical reasons for using needlessly large amounts of these drugs).

604. Jibson & Tandon, *supra* note 20, at 223.

605. See *supra* Part II.A.3.e (discussing cognitive dysfunction in schizophrenia); *supra* notes 206–07 (citing studies concerning partial reversal of deficits using novel agents).

To summarize this Article's major points:

- (1) As of October 2002, nearly 200 published cases had mentioned novel antipsychotic agents. These cases feature discussions of informed consent, the right to refuse treatment, and the rights of Medicaid patients and prisoners to have these drugs available.
- (2) Psychiatry's perception of what schizophrenia is changed markedly in the last three decades of the twentieth century. During that period, scientists accumulated a huge body of evidence from sources such as genetic studies, population studies, and brain imaging procedures, which shows that schizophrenia is a brain-based disorder. The crazy beliefs, hearing voices, social withdrawal, apathy, and other clinically detectable symptoms of schizophrenia reflect faulty brain circuitry. Although signs and symptoms vary enormously over time and among persons with schizophrenia, persons with the disorder typically have distinctive problems in performing discrete, precisely measurable neuropsychological tasks.
- (3) The novel antipsychotic agents appear to have several advantages over older neuroleptics. These include reduced neuromotor side effects, lower risk of tardive dyskinesia, fewer drug-induced negative symptoms, and the potential to alleviate cognitive deficits and improve patients' social functioning. Also, patients who have taken both types of medication typically prefer the newer drugs.
- (4) Novel agents are not free of side effects. As a group, they appear more likely than older neuroleptics to induce weight gain and related metabolic problems, including diabetes mellitus and hyperlipidemia.
- (5) At present, the chief disadvantage of novel agents is their high acquisition cost relative to oral neuroleptics. Because of this, third party payers, including public sector hospitals and employer funded managed care organizations, have a financial incentive to limit access to the newer drugs. This does not mean, however, that payers will act on these incentives.
- (6) Despite the claims of several extant pharmacoeconomic studies, prescribing novel agents may not yield enough savings to completely offset the higher cost of the new drugs.
- (7) A growing number of American psychiatrists believe that

novel agents should be the first-line therapy for patients that need antipsychotic medication. A respectable minority of psychiatrists has questioned this recommendation, however, and it remains the case that a substantial fraction of prescriptions for antipsychotic medications are written for neuroleptics. Despite suggestions from some psychiatrists and attorneys to the contrary, psychiatrists appear not to be at risk of being held liable simply because they have continued to prescribe conventional antipsychotics.

- (8) Damages that stem from failing to properly inform patients about the option of taking newer medications appear more likely to give rise to successful malpractice litigation.
- (9) Conceivably, plaintiffs might also sue doctors for failing to minimize risk of harm to self or others. Reports suggesting that atypicals reduce aggression and lower the likelihood of suicide might support such claims.
- (10) Lack of access to atypicals has attracted the attention of legal scholars as a potential source of civil rights claims or claims under the Americans with Disabilities Act. Extant litigation and several published appellate decisions have already signified that these areas, rather than malpractice cases, could become a major source of medication-related liability.
- (11) Cases litigated before the early 1990s often contain severe criticisms of antipsychotic therapies. By contrast, in several recently decided cases that mention novel agents, one detects less judicial concern about drug side effects and more recognition of the benefits of antipsychotic medications to patients who might receive them involuntarily.
- (12) These recently decided cases also show that some courts can receive and assimilate complicated, nuanced scientific information about currently available antipsychotic therapy. This should encourage psychiatrists and give them reason to believe that courts may be more sympathetic to physicians' pro-treatment positions than to the frequently asserted anti-medication views of some patient advocates.
- (13) Although the names of novel agents are appearing with

increased frequency in U.S. case law, older agents still account for the majority of instances in which published decisions discuss antipsychotic therapy.

Chemical straitjacketing is rapidly becoming an unusual phenomenon for patients who take antipsychotic medication. The last decade's advances in psychopharmacology require courts and legal scholars to re-evaluate the role and value of antipsychotic drugs without being misled by distorted and increasingly outdated views found in existing case law and secondary legal sources.

IX. APPENDIX

CASES MENTIONING NOVEL ANTIPSYCHOTIC AGENTS

SEARCH COMPLETED JULY 1, 2002

CASE NAME	CITE
1. <i>In re</i> Ingram	No. C2-90-700, 1990 Min. App. LEXIS 723 (Minn. Ct. App. July 24, 1990).
2. Visser v. Taylor	756 F. Supp. 501 (D. Kan. 1990).
3. Alliance for the Mentally Ill, Inc. v. White	No. 90-6389, 1991 U.S. Dist. LEXIS 15994 (E. D. Pa. Nov. 4, 1991).
4. <i>In re</i> M.H.	475 N.W.2d 552 (N.D. 1991).
5. <i>In re</i> Reinhold	No. C1-90-2650, 1991 Minn. App. LEXIS 314 (Minn. Ct. App. Apr. 2, 1991).
6. <i>In re</i> Stewart	No. C3-91-439, 1991 Minn. App. LEXIS 697 (Minn. Ct. App. July 16, 1991).
7. Adelson v. GTE Corp.	790 F. Supp. 1265 (D. Md. 1992).
8. Alexander L. v. Cuomo	588 N.Y.S.2d 85 (Sup. Ct. 1992).
9. Alliance for the Mentally Ill, Inc. v. White	No. 90-6389, 1992 U.S. Dist. LEXIS 13191 (E.D. Pa. Aug. 27, 1992).
10. Holmes v. Kizer	13 Cal. Rptr. 2d 746 (Ct. App. 1992).
11. <i>In re</i> Welsh	No. 6666, 1992 Del. Ch. LEXIS 223 (Del. Ch. Sept. 17, 1992).
12. Lafleur v. Hogan	No. CV 89-0370170 S, 1993 Conn. Super. LEXIS 2673 (Conn. Super. Ct. Oct. 13, 1993).
13. Miller v. Dep't of Corr.	998 F.2d 1001 (1st Cir. 1993) (unpublished table decision).
14. Dibley v. Gomez	No. C4-94-870, 1994 Minn. App. LEXIS 801 (Minn. Ct. App. Aug. 16, 1994).
15. <i>In re</i> Witthans	No. CX-94-1280, 1994 Minn. App. LEXIS 934 (Minn. Ct. App. Sept. 27, 1994).
16. People v. Bell	36 Cal. Rptr. 2d 746 (Ct. App. 1994).
17. Hanafin v. United States	No. 1:95:CV:128, 1995 U.S. Dist. LEXIS 14450 (W.D. Mich. Aug. 14, 1995).

18. <i>In re</i> Herbolsheimer	650 N.E.2d 287 (Ill. App. Ct. 1995).
19. Hertwig-Brilliant v. Wright	622 N.Y.S.2d 450 (App. Div. 1995).
20. <i>In re</i> Martin	527 N.W.2d 170 (Minn. Ct. App. 1995).
21. <i>In re</i> Tyler	No. C4-95-1432, 1995 Minn. App. LEXIS 1403 (Minn. Ct. App. Nov. 14, 1995).
22. Lopez v. Chater	No. 94 C 832, 1995 U.S. Dist. LEXIS 18136 (N.D. Ill. Dec. 1, 1995).
23. Allen v. Wray	No. 01A01-9511-CH-00505, 1996 Tenn. App. LEXIS 374 (Tenn. Ct. App. June 19, 1996).
24. Gates v. Shinn	98 F.3d 463 (9th Cir. 1996).
25. <i>In re</i> Bradshaw	No. C4-95-2225, 1996 Minn. App. LEXIS 77 (Minn. Ct. App. Jan. 23, 1996).
26. <i>In re</i> R.A.J.	554 N.W.2d 809 (N.D. 1996).
27. Bisch v. Lindquist	542 N.W.2d 138 (S.D. 1996).
28. <i>In re</i> Israel	664 N.E.2d 1032 (Ill. App. Ct. 1996).
29. State v. Martin	No. 02-C01-9512-CR-00374, 1996 Tenn. Crim. App. LEXIS 745 (Tenn. Crim. App. Dec. 2, 1996).
30. State of Pallotolo	No. CR21-21986, 1996 Conn. Super. LEXIS 29 (Conn. Super. Ct. Jan. 9, 1996).
31. Clements v. Clements	No. FA 95328252, 1997 Conn. Super. LEXIS 2036 (Conn. Super. Ct. July 24, 1997).
32. DeSario v. Thomas	963 F. Supp. 120 (D. Conn. 1997).
33. <i>In re</i> Joseph O.	666 N.Y.S.2d 322 (N.Y. App. Div. 1997).
34. <i>In re</i> G.B.R.	953 S.W.2d 391 (Tex. App. 1997).
35. Jurasek v. Payne	959 F. Supp. 1441 (D. Utah 1997).
36. Presto v. Charter Peachford Behavioral Health Sys., Inc.	494 S.E.2d 377 (Ga. Ct. App. 1997).
37. Presto v. Sandoz Pharms. Corp.	487 S.E.2d 70 (Ga. Ct. App. 1997).
38. Suel v. Sec'y of Health & Human Servs.	No. 90-935V, 1997 U.S. Claims LEXIS 210 (Fed. Cl. Sept. 22, 1997).
39. U.S. v. Gigante	996 F. Supp. 194 (E.D.N.Y. 1998).
40. U.S. v. Moses	106 F.3d 1273 (6th Cir. 1997).
41. Wyatt v. Rogers	985 F. Supp. 1356 (M.D. Ala. 1997).
42. Commonwealth v. Brown	No. 96-11156(001-004), 1998 Mass. Super. LEXIS 664 (Mass. Sup. Ct. Dec. 18, 1998).

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| 43. Dinardo v. State | 742 So. 2d 287 (Fla. Dist. Ct. App. 1998). |
| 44. Dunson v. Stricklin | No. 96-0072-CB-S, 1998 U.S. Dist. LEXIS 11082 (S.D. Ala. July 7, 1998) |
| 45. Hesler v. Osawatomie State Hosp. | 971 P.2d 1169 (Kan. 1999). |
| 46. Hurt v. State | 694 N.E.2d 1212 (Ind. Ct. App. 1998) |
| 47. <i>In re</i> Anonymous | 1998 Pa. D. & C. LEXIS 20 (Pa. July 15, 1998). |
| 48. <i>In re</i> J.V.N. | 1998 Pa. D. & C. LEXIS 147 (Berks County, Oct. 29, 1998). |
| 49. O'Keefe v. Orea | 731 So. 2d 680 (Fla. Dist. Ct. App. 1998). |
| 50. People v. Barichello | 711 N.E.2d 406 (Ill. App. Ct. 1999). |
| 51. <i>In re</i> Barry B. | 693 N.E.2d 882 (Ill. App. Ct. 1998). |
| 52. <i>In re</i> Edward S. | 698 N.E.2d 186 (Ill. App. Ct. 1998). |
| 53. People v. Harris | 70 Cal. Rptr. 2d 689 (Ct. App. 1998). |
| 54. <i>In re</i> J.J.C. | 689 N.E.2d 1172 (Ill. Ct. App. 1998). |
| 55. <i>In re</i> Perona | 690 N.E.2d 1058 (Ill. Ct. App. 1998). |
| 56. Roth v. Blue Cross | No. 95-CV-1332, 1998 U.S. Dist. LEXIS 15554 (N.D.N.Y. Sept. 29, 1998). |
| 57. Smyrski v. Weber | No. 32942, 1998 Conn. Super. LEXIS 1218 (Conn. Super. Ct. May 1, 1998). |
| 58. United States v. Cochran | No. 97-6314, 1998 U.S. App. LEXIS 2889 (4th Cir. 1998). |
| 59. Baer v. Baer | 738 A.2d 923 (Md. Ct. Spec. App. 1999). |
| 60. Baker v. Lane County | 33 F. Supp. 2d 1291 (D. Or. 1999). |
| 61. Best v. Best | No. A-98-632, 1999 Neb. App. LEXIS 107 (Neb. Ct. App. Apr. 6, 1999). |
| 62. Closs v. Weber | 87 F. Supp. 2d 921 (D.S.D. 1999). |
| 63. Dion v. O'Keefe | No. C2-99-191, 1999 Minn. App. LEXIS 818 (Minn. Ct. App. July 20, 1999). |
| 64. Dunbar v. Brown | No. 97-951, 1999 U.S. Dist. LEXIS 4441 (E.D. La. Mar. 29, 1999). |
| 65. Eres v. County of Alameda | No. C-96-2094, 1999 U.S. Dist. LEXIS 1385 (N.D. Cal. Feb. 2, 1999). |

66. <i>In re</i> M.M.	No. 09-98-234, 1999 Tex. App. LEXIS 1502 (Tex. App. Mar. 4, 1999).
67. <i>In re</i> TT Boat Corp.	No. 98-0494, 1999 U.S. Dist. LEXIS 19541 (E.D. La. Dec. 21, 1999).
68. Kevin S.E. v. Diana M.E.	520 S.E.2d 197 (W. Va. 1999).
69. Mausner v. William E.	694 N.Y.S.2d 165 (N.Y. App. Div. 1999).
70. Ohene Boakye-Yiadom v. City & County of San Francisco	No. C-99-0574, 1999 U.S. Dist. LEXIS 12981 (N.D. Cal. Aug. 18, 1999).
71. People v. Callahan	87 Cal. Rptr. 2d 838 (Ct. App. 1999).
72. <i>In re</i> Len P.	706 N.E.2d 104 (Ill. App. Ct. 1999).
73. Pudlo v. Pudlo	No. 016336, 1999 Conn. Super. LEXIS 3110 (Conn. Super. Ct. Nov. 16, 1999).
74. Sobowitz v. Sobowitz	No. FA 980719025, 1999 Conn. Super. LEXIS 2758 (Conn. Super. Ct. Oct. 13, 1999).
75. State v. Jung	724 N.E.2d 1262 (Ohio Ct. App. 1999).
76. State v. Kotis	984 P.2d 78 (Haw. 1999).
77. State v. Williams	No. 98-CA-1, 1999 Ohio App. LEXIS 6426 (Ohio Ct. App. Dec. 21, 1999).
78. Steadman v. Newhart	No. 2:98CV260, 1999 U.S. Dist. LEXIS 11768 (E.D. Va. July 1, 1999).
79. Blackston v. Warner-Lambert Co.	No. CV-98-P-2974-S, 2000 U.S. Dist. LEXIS 1114 (N.D. Ala. Jan. 25, 2000).
80. Consilvio v. Diana W.	703 N.Y.S.2d 144 (N.Y. App. Div. 2000).
81. <i>In re</i> Moenisha B.	2000 Conn. Super. LEXIS 1241 (Conn. Super. Ct. May 19, 2000).
82. Floyd v. State	No. M2000-00318-CCA-R3-CD 2000 Tenn. Crim. App. LEXIS 991 (Tenn. Crim. App. Dec. 28, 2000).
83. <i>In re</i> Breanna R.	2001 Conn. Super. LEXIS 766 (Conn. Super. Ct. Mar. 13, 2001).
84. <i>In re</i> Campbell	116 F. Supp. 2d 937 (M.D. Tenn. 2000).
85. <i>In re</i> Curtis	No. 9-99-74, 2000 Ohio App. LEXIS 1708 (Ohio Ct. App. Apr. 20, 2000).
86. <i>In re</i> E.L.	736 N.E.2d 1189 (Ill. Ct. App. 2000).
87. <i>In re</i> Erin B.	751 So. 2d 946 (La. Ct. App. 2000).
88. <i>In re</i> Locks	87 Cal. Rptr. 2d 303 (Ct. App. 1999).

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| 89. <i>In re</i> Locks | 94 Cal. Rptr. 2d 495 (Ct. App. 2000). |
| 90. <i>In re</i> Samuel P. | No. L-99-1153, 2000 Ohio App. LEXIS 1626 (Ohio Ct. App. Apr. 14, 2000). |
| 91. <i>In re</i> D.L.M. | 31 S.W.3d 64 (Mo. Ct. App. 2000). |
| 92. Logerquist v. McVey | 1 P.3d 113 (Ariz. 2000). |
| 93. McClellan v. Apfel | No. 98-1288-WEB, 2000 U.S. Dist. LEXIS 5333 (D. Kan. Apr. 12, 2000). |
| 94. Montgomery v. State | 781 So. 2d 1007 (Ala. Crim. App. 2000). |
| 95. Nevis v. Apfel | No. C 98-04953 SI, 2000 U.S. Dist. LEXIS 4174 (N.D. Cal. Mar. 23, 2000). |
| 96. People v. Melka | 744 N.E.2d 290 (Ill. App. Ct. 2000). |
| 97. <i>In re</i> Nancy M. | 739 N.E.2d 607 (Ill. App. Ct. 2000). |
| 98. <i>In re</i> Rayshawn P. | 2000 Conn. Super. LEXIS 3346 (Conn. Super. Ct. Nov. 27, 2000). |
| 99. Saltzman v. Apfel | 125 F. Supp. 2d 1014 (C.D. Cal. 2000). |
| 100. State v. Goldsberry | 2000 Del. Super. LEXIS 115 (Del. Super. Ct. Apr. 26, 2000). |
| 101. Thompson v. State | No. 14-98-00643-CR, 2000 Tex. App. LEXIS 3581 (Tex. Ct. App. June 1, 2000). |
| 102. United States v. Keeven | 115 F. Supp. 2d 1132 (E.D. Mo. 2000). |
| 103. Allen v. Apfel | No. 00-0705, 2001 U.S. Dist. LEXIS 2940 (E.D. La. Mar. 13, 2001). |
| 104. Bolling v. Massanari | No. 00 C 6717, 2001 U.S. Dist. LEXIS 9203 (N.D. Ill. June 26, 2001). |
| 105. Brown v. United States | 766 A.2d 530 (D.C. 2001). |
| 106. Collier v. Ram Partners, Inc. | 159 F. Supp. 2d 889 (D. Md. Aug. 21, 2001). |
| 107. Commonwealth v. Morasse | No. 9977CR1999-01420, 2001 Mass. Super. LEXIS 511 (Mass. Dec. 4, 2001). |
| 108. DeBuhr v. Barnhart | No. C01-4018-MWB, 2001 U.S. Dist. LEXIS 23455 (N.D. Iowa Dec. 18, 2001). |
| 109. Dixon v. Hensley | No. 3:99-CV-1513, 2001 U.S. Dist. LEXIS 1952 (D. Conn. Feb. 16, 2001). |
| 110. <i>In re</i> Jacob R. | 2001 Conn. Super. LEXIS 2739 (Conn. Super. Ct. Sept. 21, 2001). |
| 111. <i>In re</i> Laura J.M. | 635 N.W.2d 28 (Wis. Ct. App. 2001) (unpublished table decision). |

112. <i>In re</i> Oliver	No. CA2001-01-006, 2001 Ohio App. LEXIS 3462 (Ohio Ct. App. Aug. 6, 2001).
113. <i>In re</i> P.G.R.	No. C7-01-396, 2001 Minn. App. LEXIS 1053 (Minn. Ct. App. Sept. 18, 2001).
114. Jones 'El v. Berge	164 F. Supp. 2d 1096 (W.D. Wis. 2001).
115. Kujawski v. United States Filter Wastewater Group, Inc.	No. 00-1151, 2001 U.S. Dist. LEXIS 17578 (D. Minn. Aug. 7, 2001).
116. LaSalle v. Benson Car Co.	783 So. 2d 404 (La. Ct. App. 2001).
117. McCollom v. State	No. 07-00-0282-CR, 2001 Tex. App. LEXIS 959 (Tex. Ct. App. Feb. 13, 2001).
118. Patten v. Nichols	274 F.3d 829 (4th Cir. 2001).
119. <i>In re</i> Frances K.	749 N.E.2d 1082 (Ill. App. Ct. 2001).
120. <i>In re</i> Gwendolyn N.	760 N.E.2d 575 (Ill. App. Ct. 2001).
121. People v. Kirchner	743 N.E.2d 94 (Ill. 2000).
122. People v. Simmons	No. B149356, 2001 Cal. App. Unpub. LEXIS 975 (Cal. Ct. App. Dec. 6, 2001).
123. Rector v. Bridgestone (U.S.A.), Inc.	No. M1999-02284-WC-R3-CV, 2001 Tenn. LEXIS 496, (Tenn. June 11, 2001).
124. Ricci v. Apfel	No. 00-2253, 2001 U.S. Dist. LEXIS 5650 (E.D. Pa. Mar. 15, 2001).
125. Salvador L. v. Superior Court of Orange County 2001	No. G029690, 2001 Cal. App. Unpub. LEXIS 668 (Ct. App. Dec. 18, 2001).
126. San Diego Trolley v. Superior Court	105 Cal. Rptr. 2d 476 (Ct. App. 2001).
127. Smith v. Mann	No. 0206-01-2, 2001 Va. App. LEXIS 703 (Va. Ct. App. Dec. 18, 2001).
128. State v. Hutchins	No. 1-325/99-1959, 2001 Iowa App. LEXIS 474 (Iowa Ct. App. July 18, 2001).
129. State v. Muncie	746 N.E.2d 1092 (Ohio 2001).
130. Turnage v. Massanari	No. 00-6110, 2001 U.S. Dist. LEXIS 15731 (E.D. Pa. July 18, 2001).
131. United States v. Arena	No. 00 Cr. 398, 2001 U.S. Dist. LEXIS 17522 (S.D.N.Y. Oct. 29, 2001).
132. United States v. Jiminez-Villasenor	270 F.3d 554 (8th Cir. 2001).
133. United States v. Juvenile Male N.R.	No. 01-1489, 2001 U.S. App. LEXIS 25931 (8th Cir. Dec. 3, 2001).
134. United States v. Weston	134 F. Supp. 2d 115 (D.D.C. 2001).
135. United States v. Weston	255 F.3d 873 (D.C. Cir. 2001).

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| 136. Vanisi v. State | 22 P.3d 1164 (Nev. 2001). |
| 137. Waldron v. State | No. M2000-00772-CCA-R3-PC, 2001 Tenn. Crim. App. LEXIS 417 (Tenn. Crim. App. June 1, 2001). |
| 138. Watson v. Massanari | No. 00-3621, 2001 U.S. Dist. LEXIS 15863 (E.D. Pa. Sept. 5, 2001). |
| 139. Anderson v. State | 43 P.3d 108 (Wyo. 2002). |
| 140. Brockman v. State | No. 05-01-00064-CR, 2002 Tex. App. LEXIS 139 (Tex. Ct. App. Jan. 10, 2002). |
| 141. <i>In re</i> E.S. | 762 N.E.2d 1287 (Ind. Ct. App. 2002). |
| 142. Guiteras v. Barnhart | No. 01-242, 2002 U.S. Dist. LEXIS 3005 (E.D. Pa. Feb. 21, 2002). |
| 143. Guiteras v. Massanari | No. 01-242, 2002 U.S. Dist. LEXIS 5617 (E.D. Pa. Jan. 3, 2002). |
| 144. Hastings v. Yukins | 194 F. Supp. 2d 659 (E.D. Mich. 2002). |
| 145. <i>In re</i> Alexandra C. | 2002 Conn. Super. LEXIS 917 (Conn. Super. Ct., Mar. 22, 2002). |
| 146. <i>In re</i> Anthony M. | 2002 Conn. Super. LEXIS 1479 (Conn. Super. Ct., Apr. 29, 2002). |
| 147. <i>In re</i> Joseph B.W. | 2002 Conn. Super. LEXIS 186 (Conn. Super. Ct. Jan. 15, 2002). |
| 148. <i>In re</i> Nem | No. 99-4546, 2002 R.I. Super. LEXIS 40 (R.I. Mar. 12, 2002). |
| 149. <i>In re</i> Victoria B. | 2002 Conn. Super. LEXIS 1786 (Conn. Super. Ct. Apr. 30, 2002). |
| 150. <i>In re</i> C.F. | No. 13-01-025-CV, 2002 Tex. App. LEXIS 2454 (Tex. App. Apr. 4, 2002). |
| 151. Jonathan W. v. Georgia W. | No. H022874, 2002 Cal. App. Unpub. LEXIS 2760 (Cal. Ct. App. Mar. 25, 2002). |
| 152. <i>In re</i> M. R. | No. C039776, 2002 Cal. App. Unpub. LEXIS 5718 (Cal. Ct. App. June 24, 2002). |
| 153. Meinders v. Barnhart | 195 F. Supp. 2d 1136 (S.D. Iowa 2002). |
| 154. Orben v. Barnhart | 208 F. Supp. 2d 107 (D.N.H. 2002). |
| 155. Ortiz v. Barnhart | No. 9171, 2002 U.S. Dist. LEXIS 4734, (S.D.N.Y. March 22, 2002). |

156. Pelletier v. Magnusson	195 F. Supp. 2d 214 (D. Me. 2002).
157. Pelletier v. Magnusson	201 F. Supp. 2d 148 (D. Me. 2002).
158. People v. D'Adamo	742 N.Y.S.2d 394 (App. Div. 2002).
159. People v. Hoover	No. A094036, 2002 Cal. App. Unpub. LEXIS 4217 (Cal. Ct. App. Feb. 5, 2002).
160. People v. Hopkins	No. A093455, 2002 Cal. App. Unpub. LEXIS 4938 (Cal. Ct. App. Jan. 14, 2002).
161. People v. McCowan	No. F034999, 2002 Cal. App. Unpub. LEXIS 3902 (Cal. Ct. App. Feb. 15, 2002).
162. People v. Wu	No. F036600, 2002 Cal. App. Unpub. LEXIS 182 (Cal. Ct. App. Apr. 18, 2002).
163. Rhonda S. v. Superior Court of Los Angeles	No. B154426, 2002 Cal. App. Unpub. LEXIS 2613 (Cal. Ct. Mar. 27, 2002).
164. Robicheaux v. Adly	No. 2002-37, 2002 La. App. LEXIS 1910 (La. Ct. App. June 12, 2002).
165. State v. Kelley	No. M2001-00461-CCA-R3-CD, 2002 Tenn. Crim. App. LEXIS 424 (Tenn. Crim. App. May 7, 2002).
166. United States v. Golden	No. 02-6106, 2002 U.S. App. LEXIS 12125 (4th Cir. June 19, 2002).
167. United States v. Gomes	289 F.3d 71 (2d Cir. 2002).
168. United States v. Sell	282 F.3d 560 (8th Cir. 2002).
169. Walls v. Barnhart	No. 01-2361, 2002 U.S. Dist. LEXIS 5558 (E.D. Pa. Mar. 28, 2002).
170. Wengerd v. Gary B.	No. F038659, 2002 Cal. App. Unpub. LEXIS 711 (Cal. Ct. App. May 2, 2002).
171. Williams v. Larpenter	No. 01-3694, 2002 U.S. Dist. LEXIS 11174 (E.D. La. June 14, 2002).