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Antipsychotic Drugs: Regulating Their Use in the Private Practice of Medicine

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ANTIPSYCHOTIC DRUGS: REGULATING THEIR USE IN THE PRIVATE PRACTICE OF MEDICINE

I. INTRODUCTION

The discovery of a drug called chlorpromazine[1] marked the beginning of a "therapeutic"[2] revolution in the practice of psychiatry and the widespread use of antipsychotic drugs[3] in the

1. Chlorpromazine, a phenothiazine derivative developed in France, was introduced in the United States in 1953 and marketed under the brandname Thorazine. This was a tremendous breakthrough in psychopharmacology because chlorpromazine was found to have powerful sedative properties, while unlike other tranquilizers available at that time, it was able to tranquilize without impairing consciousness. M. LADER, INTRODUCTION TO PSYCHOPHARMACOLOGY 56 (1980). Thorazine continues to be the most widely prescribed antipsychotic drug. Dubose, *Of the Parens Patriae Commitment Power and Drug Treatment of Schizophrenia: Do the Benefits to the Patient Justify Involuntary Treatment?* 60 MINN. L. REV. 1149, 1169 (1976); ASSEMBLY OFFICE OF RESEARCH CALIFORNIA LEGISLATURE, THE USE AND MISUSE OF PSYCHIATRIC DRUGS IN CALIFORNIA'S MENTAL HEALTH PROGRAMS 21 (1977) [hereinafter cited as PSYCHIATRIC DRUGS].

2. There continues to be controversy over psychiatry's reliance on antipsychotic drugs in that these drugs do not "cure" psychosis (the primary therapeutic indication being schizophrenia) but produce remission of psychotic symptoms rather than altering the course of the disorder itself. PSYCHIATRIC DRUGS, *supra* note 1, at 14. There are those in the profession who feel the benefits of these drugs are exaggerated, and that since it is easier to prescribe drugs than try and find the reasons why a patient has developed to the point when the label "schizophrenia" has been given, psychiatrists are unwilling to try to find alternative methods of treatment. *See generally,* P. BREGGIN, PSYCHIATRIC DRUGS: HAZARDS TO THE BRAIN (1983); Bierer, *Medicine or "Manslaughter,"* 29 INT'L J. SOC. PSYCHIATRY 247, 248 (1983), whereupon returning from the World Congress of Psychiatrists, the author labels the whole Congress as one huge Drug Factory. On the other hand, other psychiatrists claim that without these medications, the patient would not become amenable to other forms of treatment, such as psychotherapy. Brooks, *The Constitutional Right to Refuse Antipsychotic Medications,* 8 BULL. AM. ACAD. PSYCHIATRY & LAW 179, 183 (1980).

3. It has been estimated that three million Americans are currently taking antipsychotic drugs, and that 925,000 new patients receive such medication each year. Gualtieri & Sprague, *Preventing Tardive Dyskinesia and Preventing Tardive Dyskinesia Litigation,* 20 PSYCHOPHARMACOLOGY BULL. 346, 347 (1984). The term "antipsychotic drug" is preferable to expressions of "major tranquilizer," or "neuroleptic" because antipsychotic indicates the type of clinical action of these drugs. Although such a drug has a tranquilizing effect, it is possible that a patient can build a tolerance to the sedation, while the antipsychotic effects remain constant. The term neuroleptic can be considered less appropriate than antipsychotic as well, because it focuses on the extrapyramidal effects (abnormalities in motor activity) which can occur in patients receiving this drug rather than the clinical action. M. LADER, *supra* note 1, at 51; L. SEIDEN & L. DYKSTRA,

clinical management of patients diagnosed as suffering from major psychiatric disorders.[4] The ability of these drugs to reduce the manifest symptomatology and behavioral deviances of the psychotic individual[5] contributed greatly to the deinstitutionalization of the chronic psychotic and his assimilation into the community.[6] However, these powerful drugs[7] have a high probability of producing a wide variety of undesirable side ef-

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PSYCHOPHARMACOLOGY: A BIOCHEMICAL AND BEHAVIORAL APPROACH 198 (1977). *See infra* notes 35-58 and accompanying text for discussion of extrapyramidal effects.

4. The major psychiatric disorders for which the use of these drugs ought to be reserved include: schizophrenia, mania, acute organic brain syndrome (delirium), chronic organic brain syndrome (dementia), psychoses and behavioral problems associated with mental retardation and depression. Pirodsky, *The Rational Use of Antipsychotic Drugs*, in TARDIVE DYSKINESIA AND RELATED INVOLUNTARY MOVEMENT DISORDERS: THE LONG-TERM EFFECTS OF ANTIPSYCHOTIC DRUGS 59, 60 (J. De Veaugh-Geiss ed. 1982). *See id.* (Table 6-1) for a more extensive list of indications of major psychiatric disorders.

5. Clinically, psychotic symptoms such as anxiety, delusions, hallucinations, paranoid ideation, catatonia, social withdrawal, and autonomic nervous system dysfunctions are suppressed so as to facilitate the patient's tendency and capacity for social and familial adjustment. PSYCHIATRIC DRUGS, *supra* note 1, at 14.

6. Deinstitutionalization was also considerably accelerated by two federal legislative acts in 1963. Aid to the Disabled (ATD) became available to the mentally ill. Thus psychiatric patients, and mental health professionals acting on their behalf, were eligible for federal grants-in-aid which enabled patients to support themselves or be supported either at home or in facilities such as board and care homes or old hotels. Money available to patients under ATD was sufficient to maintain a low standard of living in the community. Consequently, it cost far less for the states to maintain patients in the community than in the hospital. (ATD is now administered by the Social Security Administration and called Supplemental Security Income or SSI). A second significant federal development was the Mental Retardation Facilities and Community Mental Health Centers Construction Act, amended in 1965, which provides grants for the initial costs of staffing newly constructed community mental health centers. This acted as a strong incentive for the development of community programs to treat patients whose main resource had been in the state hospitals. Lamb, *Deinstitutionalization and the Homeless Mentally Ill*, 35 HOSP. & COMMUNITY PSYCHIATRY 899, 902 (1984). *See* 42 U.S.C. §§ 1381-1385 (1982) for present codification of SSI for the mentally disabled. *See also* Mental Retardation Facilities and Community Mental Health Centers Construction Act of 1963, Pub. L. No. 88-164, §§ 200-07, 401-07, 77 Stat. 282, 290-94, 296-99, *amended by* Mental Retardation Facilities and Community Mental Health Centers Construction Act Amendments of 1965, Pub. L. No. 89-105, §§ 220-24, 408, 79 Stat. 427, 428-30 (codified as amended in scattered sections of 42 U.S.C.). The number of state hospital patients in the United States has dropped from 559,000 in 1955 to approximately 132,000 today. *See* Lamb, *supra*, at 902.

7. There are three major generic classes of antipsychotic agents. Phenothiazines (chief brand names are Thorazine, Mellaril, Prolixin and Stelazine); thioxanthenes (chief brand names Taractan and Navane); and butyrophones (chief brand name Haldol). Callaway & Paull, *Mental Disabilities Law Issues—Legal Awareness of Tardive Dyskinesia*, 10 COL. LAW. 788 (M. Dice ed. 1981). *See* M. LADER, *supra* note 1, at 63 (Table 5-2) and D. PIRODSKY, PRIMER OF CLINICAL PSYCHOPHARMACOLOGY: A PRACTICAL GUIDE (1981) *reprinted in* Pirodsky, *supra* note 4, at 63 (Table 6-3) for a more extensive classification of most of the antipsychotics currently available in the U. S.

fects.[8] In a generally unsuccessful attempt to improve the therapeutic ratio between wanted and unwanted side effects, over thirty different antipsychotic drugs of differing chemical structures have been introduced into the market.[9]

The manifest risk that the administration of antipsychotic drugs may lead to harmful side effects, as well as alarming evidence in some cases of negligent and abusive medication practices in state institutions,[10] has motivated courts to hold that involuntarily committed patients have a qualified constitutional right to refuse antipsychotic medication.[11] Although antipsy-

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8. Taub, *Psychiatric Malpractice in the 1980's: A Look at Some Areas of Concern*, 11 LAW, MEDICINE, & HEALTH CARE 97, 102 (1983). *See infra* notes 31-69 and accompanying text for a discussion of these side effects.

9. Blackwell, *Schizophrenia and Neuroleptic Drugs: A Biopsychosocial Perspective*, in REFUSING TREATMENT IN MENTAL HEALTH INSTITUTIONS - VALUES IN CONFLICT 13, 15 (A. Doudera & J. Swazey eds. 1982) [hereinafter cited as VALUES IN CONFLICT]. This text is a compilation of papers and discussions derived from a national conference by the same name in November 1980; M. LADER, *supra* note 1, at 63. The drugs still in use are those that have been available the longest. Blackwell, *supra*, at 15.

10. *See* Rogers v. Comm'r of the Dept. of Mental Health, 390 Mass. 489 ___, 458 N.E.2d 308, 320-21 (1983) (citing literature and cases where antipsychotic medication has been found to be used for the convenience of the staff rather than treatment); Brooks, *supra* note 2, at 188-89. Antipsychotic drugs may also be used to compensate for personnel shortages in that administering drugs only takes a few minutes of professional time, as well as being inexpensive in comparison to having adequate staffing levels. Rogers, 390 Mass. at ___, 458 N.E.2d at 318 n.19; L.A. Daily J., May 16, 1983, at 1, col. 4. It has also been asserted that *pro re nata* prescriptions (according as the circumstances may require) which allow nurses and technicians to determine the need for antipsychotics from a doctor's open-ended prescription may be used for punishment or control of patients by staff members not adequately trained to make treatment decisions. Bishop, *The Expanding Rights of Mental Patients*, 2 CAL. LAW., Sept. 9, 1982 at 108.

11. *See* Rennie v. Klein, 653 F.2d 836, 844-45 (3d Cir. 1981), *vacated and remanded*, 458 U. S. 1119 (1982) *aff'd*, 720 F.2d 266 (3d Cir. 1983) (patient has a constitutional right to be free from treatment that poses substantial risks to his well-being); Rogers v. Okin, 634 F.2d 650, 653 (1st Cir. 1980), *cert. granted*, 451 U.S. 906 (1981), *vacated and remanded sub nom.*, Mills v. Rogers, 457 U.S. 291 (1982), *aff'd on other grounds*, Rogers v. Comm'r of the Dept. of Mental Health, 390 Mass. at ___, 458 N.E.2d at 308 (constitutionally protected interest in being left free by the state to decide whether to submit to the serious and potentially harmful medical treatment that is represented by the administration of antipsychotic drugs); Project Release v. Prevost, 722 F.2d 960 (2nd Cir. 1983) (constitutional liberty interest in refusing antipsychotic medication); Jamison v. Farabee, No. C 780445, WHO (N.D. Cal. April 26, 1983) (settlement approved by federal district court judge recognized that mental patients have a substantial right to refuse medication); Colorado *ex rel.* Medina, 662 P.2d 184 (Colo. Ct. App. 1982); Anderson v. Arizona, 135 Ariz. 578, 663 P.2d 570 (1982) (concluded that right to refuse medication based on state statute exceeded constitutional minima). Although the above cases all acknowledged a qualified constitutional right to refuse antipsychotic medication, the decisions differed in the standards and procedures employed to protect the involuntarily committed patient's right when determining when the state may override a patient's refusal.

chotic drugs may be beneficial,[12] the fact that harmful side effects do occur[13] warranted the court's intervention to protect involuntarily committed patients. The rationale being that this harm was being imposed by the exercise of the state's police power in deciding to involuntarily commit a patient.[14]

In addition to affording the involuntarily committed patient a right to refuse, these litigations,[15] along with legislative inquiries[16] and newspaper accounts,[17] revealed that improper, excessive, or inappropriate use of antipsychotic medication frequently occurred in psychiatric hospitals and institutions in the public sector.[18] Consequently, a number of states have taken affirma-

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See, e.g., Rennie v. Klein, 720 F.2d at 269 (medication refusal can only be overcome if, in the exercise of professional judgment, administration of antipsychotics is necessary to prevent the patient from endangering himself or others); Roger v. Comm'r of the Dept. of Mental Health, 390 Mass. at ___, 458 N.E.2d at 321-22 (medication refusal can only be overridden in an emergency when the patient poses imminent threat of harm to himself or others, or to prevent immediate, substantial, and irreversible deterioration of a serious mental illness, and where a patient has been specifically ajudicated incompetent to make treatment decisions, a substitute judgment by way of court approval is necessary to override the patient's objection); Jamison v. Farabee, *supra* (medication refusal overridden in the event of either: 1) an emergency; 2) the patient is substantially deteriorating; or 3) upon approval of an independent reviewer where court appointed conservator). Portions of the Jamison settlement and exhibits *reprinted in California Consent Decree Gives Right to Refuse Antipsychotic Medication*, 7 MENTAL DISABILITY L. REP. 437 (1983).

12. A study by the National Institute of Mental Health found that 75% of the patients treated with antipsychotic drugs showed marked degrees of improvement within six weeks after being hospitalized, while only 23% of the placebo groups were rated as showing marked or moderate improvement. Roth & Appelbaum, *What We Do and Do Not Know About Treatment Refusals in Mental Institutions*, in VALUES IN CONFLICT, *supra* note 9, at 179, 182-83.

13. Dangerous side effects occur even where antipsychotics are prescribed and administered in accordance with competent and responsible clinical practice. However, the distress on the part of the patients as a result of these side effects may be significantly worse where these drugs are administered negligently or abusively. Brooks, *supra* note 2, at 183. *See infra* notes 65-69 and accompanying text.

14. Consequently, the courts were required to pursue their traditional role of ensuring the individual is protected against harmful state interventions without regard to the state's good intentions in deciding that hospitalization is necessary to provide cure and treatment. Brooks, *supra* note 2, at 182.

15. *See supra* note 11.

16. *See, e.g.*, PSYCHIATRIC DRUGS, *supra* note 1 (legislative investigation finding large-scale irrational prescribing and administration of antipsychotic medication in California's mental health programs) and *New York Commission Finds Significant Problems in Psychotherapeutic Drug Usage in State Mental Hospitals*, 8 MENTAL & PHYSICAL DISABILITY L. REP. 139 (1984).

17. *See, e.g.*, Sobel, *Psychiatric Drugs Widely Misused, Critics Charge*, N.Y. Times, June 3, 1980, at C1, col. 5.

18. Brooks, *supra* note 2, at 183. *See supra* note 10.

tive action imposing antipsychotic medication guidelines[19] in an effort to minimize the temptation of staff to abuse the "management" potential of these drugs for their own convenience in state facilities.

These safeguards being implemented in state facilities, however, only serve to monitor medication regimens of a relatively small number of individuals in comparison to the numbers who receive antipsychotic drugs outside of state institutions.[20] Furthermore, the exodus of the chronic mentally ill into the community as a result of deinstitutionalization placed many of these individuals outside the closed environment of any hospital.[21]

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19. *E.g.*, the New York State Office of Mental Health has established clinical policy on the appropriate methods of prescribing and administering drugs for patients in facilities within the jurisdiction of the Office of Mental Health. The guidelines have been incorporated into a computerized drug ordering system and a computerized drug exception system for automated review. COMMITTEE ON THERAPEUTICS, N.Y. STATE OFFICE OF MENTAL HEALTH, PSYCHOTHERAPEUTIC DRUG MANUAL (2d ed. 1981). *See* Laska, Siegel & Simpson, *Automated Review System for Orders of Psychotropic Drugs*, 37 ARCH GEN. PSYCHIATRY 824-27 (1980) for a further explanation of the operation of this drug exception system which acts as a check on improper drug therapy. Texas state mental hospitals are now required to administer psychotropic drugs according to a set of guidelines established pursuant to a settlement approved by a federal district court. R.A.J. v. Miller, No. C-A-3-74-394-M (N.D. Tex. Feb. 14, 1983). *See* Am. Med. News, March 4, 1983, at 24, col. 2 for a discussion of these guidelines. In California, pursuant to Jamison v. Farabee, No. C780445 WHO (N.D. Cal. April 26, 1983) a Therapeutic Review Committee was established to review medication decisions that fall outside drug guidelines determined by a Sub-Committee of the Therapeutic Review Committee. Although the settlement applied to one state hospital (Napa State Hospital), the terms of the agreement provided that after a one year pilot of having a Therapeutic Review Committee at Napa, such a uniform drug monitoring system would extend to all state facilities in April 1985. Telephone interview with Dr. Steve Schone, Deputy Director of Clinical Services, Cal. Dept. of Mental Health (November 6, 1984).

20. The dimensions of this problem are revealed by the numbers. Although it is estimated that three million Americans are receiving antipsychotic drugs, only approximately 132,000 of these individuals are patients in state hospitals. *See supra* notes 3 and 6.

21. In the initial years following deinstitutionalization in the 1960's, approximately two thirds of discharged mental patients aged 18 to 65 returned home to their families. In states which have a high number of persons who are without families (which is the case in California), this figure is probably closer to 50 percent. Lamb, *supra* note 6, at 902. Many of those over 65 years old failed to survive the trauma of the transfer from state hospitals to nursing homes. *See generally*, P. AHMED & S. PLOG, STATE MENTAL HOSPITALS, WHAT HAPPENS WHEN THEY CLOSE (1976). Today a large proportion of the chronic psychotic population aged 18 to 65 live in community facilities such as board and care homes. Lamb, *supra* note 6, at 903. One repercussion of leaving a closed hospital environment is that if a person is being maintained on a drug regimen contrary to good clinical practice, the likelihood that inappropriate prescribing will be noticed appears far greater in the closed environment of a hospital. *See* PSYCHIATRIC DRUGS, *supra* note 1, at

This is of particular importance because it is the chronic mentally ill who often are ultimately the most susceptible to irreversible side effects as the result of extended drug exposure.[22] Given psychiatry's continued reliance on antipsychotic drugs as a major mode of treatment for many chronically ill individuals,[23] and the apparently unavoidable propensity of these drugs to produce side effects, it is essential that these drugs be prescribed cautiously only to those individuals who absolutely require them. Thus, similar safeguards in insuring that the safest and most efficient medication procedures are being followed in the

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22. *See infra* notes 50, 51, 56 and accompanying text. Also, the value of antipsychotic medication to treat the chronically mentally ill, as opposed to treating acute patients, is not as clear, in that the harm resulting from the medication outweighs the benefit for a significant number of medicated persons. *See infra* notes 17-28 and accompanying text for drug efficiency in treating acute patients and *infra* note 29 for the efficiency of continued antipsychotic medication in chronic patients.

23. Published guidelines, scientific articles, presentations at professional meetings, and warnings in the Physicians' Desk Reference (a drug industry publication which repeats the information given in the package inserts) addressing one of the most troubling side effects called tardive dyskinesia (a potentially irreversible side effect characterized by rhythmical involuntary movements of the tongue, face, mouth, jaw, and extremities) appear to have had minimal effect on actual physician behavior in prescribing antipsychotic drugs. Gualterieri & Sprague, *supra* note 3, at 347. *See infra* notes 44-58 and accompanying text for a discussion of tardive dyskinesia. There has been no measurable decline in the number of antipsychotic prescriptions: 17 to 19 million in 1973, the same number in 1983. Gualterieri & Sprague, *supra* at 347. One can only speculate the underlying reasons for psychiatry's reluctance to depart from what had once been regarded as customary and uncontroversial treatment for major psychiatric disorders. Brooks, *supra* note 2, at 182. It has been suggested that the practice of psychiatry is intricately tied to the drug industry because of its prevailing influence on the practice of medicine. For example, medical journals are funded to a large extent by drug companies (one can pick up most any medical journal and see extensive advertising by the competing drug companies). Drug companies also sponsor seminars and research on aspects of psychiatric care and the use of drugs. PSYCHIATRIC DRUGS, *supra* note 1, at 28. *See* P. BREGGIN, *supra* note 2, at 256-59 for a further discussion of psychiatric dependence on drug companies. Psychiatrists may also be influenced by drug salespersons (detail men) who make periodic calls on physicians, pharmacists and hospital purchasing agents offering free samples to promote their firm's products. Dr. Dale Console, Medical Director for the E. R. Squibb pharmaceutical company testified during federal hearings that "[t]he primary purpose of the detail man is to make a sale even if it involves irrational prescribing and irrational combinations. During my time in the drug industry, I had a close ongoing relationship with detail men. It was from them that I learned the simple maxim, 'If you can't convince them, confuse them.'" PSYCHIATRIC DRUGS, *supra* at 28. It has also been suggested that with the advances in medicine and its growing technology, society has come to expect that medicine can put an end to all suffering. In psychiatry, psychiatric drugs in many cases stand as the sole vehicle of health delivery fitting into this fantasy. The psychiatrist, caught between priorities placed on rapid, effective treatment and his need to appear masterful, may be attempting to solve problems which go beyond the realm of medicine by prescribing only partially effective medication. *Id.* at 29.

treatment of the chronic mentally ill in the private sector of clinical practice are mandated.

This Comment will address the problems of antipsychotic drug usage in two areas in which the private practice of psychiatry is involved: nursing homes and board and care homes. Although each of these areas present an entirely different set of problems, and concern different age groups, they both serve functions which had traditionally been that of the state hospitals before deinstitutionalization — treating the chronic mentally ill. Before considering the use of antipsychotic medication in nursing homes and board and care homes,[24] the risk of side effects as a result of these drugs will be examined. It will be shown that negligent and even abusive use of these drugs occurs in the private practice of medicine, necessitating some type of medication regulation similar to that which is occurring in the public sector. The rights of doctors will also be addressed in conjunction with the state's authority to intervene in the private practice of medicine.

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24. The use of these drugs in these two areas, will specifically refer to practices in California, although similar practices are as likely to occur in nursing homes and board and care homes in other states as well. It is beyond the powers of the federal government to enact any regulations directly regulating the health, safety and welfare of the citizens within the borders of any given state. Any intervention pertaining to the administration of antipsychotic drugs would be left up to the discretion of state governments, and thus vary from state to state. California has not only taken the initiative to implement medication review in state facilities (*see supra* note 19) but also a medication monitoring system for all county operated and county contracted mental health facilities. The county quality assurance system provides for review of the appropriateness of the medications prescribed, the appropriateness of dosage levels, the effectiveness of the medication for the client, and the occurrence of any adverse reactions. CAL. HEALTH & SAFETY CODE § 5624(c) (West 1982). This statute is enforced by monitoring a 10% patient sample of each county physician, on the theory that if a physician is accustomed to prescribing medication irrationally it will be detected. Also the mere fact that a random 10% of a physician's caseload will be monitored is sufficient in deterring inappropriate medication administration for all patients. Telephone interview with Mike Writer, Pharmacy Coordinator, Community Mental Health Administration of San Francisco (October 17, 1984). Therefore, since California has regulated the use of antipsychotic drugs to such an extent in the public sector, the remaining issue to be addressed is the need for regulation in private practice as well. (The actual efficiency of California's attempt to curb negligent or abusive use of these drugs in state and county facilities is an entirely different issue beyond the scope of this Comment. What is important is that the problem has been recognized and steps are being taken to remedy the problem).

II. BACKGROUND

A. *The Effects of Antipsychotic Drugs*

The first important use of antipsychotic drugs was to reduce psychomotor excitement, severe agitation, or disturbed behavior by taking advantage of their sedative effects.[25] This clinical effect was utilized to manage those patients who became irritable with minimal provocation and became combative towards nursing staff and other patients in the hospital unit.[26] However, the main indication for antipsychotic drugs today is the treatment of acute schizophrenia.[27] Although these drugs only suppress the

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25. M. LADER, *supra* note 1, at 56. The drugs have symptomatic tranqualization effects on target symptoms, a term that emphasizes the drug effects on symptoms irrespective of diagnosis. For example, in patients with schizophrenia such drugs reduce restlessness, excitement, paranoid tension, panic, aggressive outbursts, stereotyped behavior (occurrence of repeated sequence of motor responses), and noisy destructive behavior. *Id.* *See id.* for target symptoms of other illnesses.

26. Patients diagnosed as psychotic or as having chronic organic brain syndrome (dementia) are the most likely to become assaultive or belligerent in moments of panic or hostility. M. LADER, *supra* note 1, at 56; Pirodsky, *supra* note 4, at 61. However, not all patients manifest symptoms of their illness in a hostile manner. Patients may exhibit marked symptoms of psychosis by becoming antisocial and withdrawn as well. L. SEIDEN & L. DYKSTRA, *supra* note 3, at 198. Although the use of these drugs in this manner may be viewed as a "chemical straitjacket," it has become a widely established practice. M. LADER, *supra*, at 56. Such medication is also helpful in decreasing hallucinations, emotional flattening (inappropriate effect), withdrawn behavior, sleep disturbance, as well as improving thought disorder. *Id.*; Pirodsky, *supra* note 4, at 60; Roth & Appelbaum, *What We Do and Do Not Know About Treatment Refusals in Mental Institutions*, in VALUES IN CONFLICT, *supra* note 9, at 182-83. There is also evidence that the earlier the drug treatment the more likely rehabilitation will persist up to five years after release. Roth & Appelbaum. *Id.* at 183. However, this lasting effect may be the result of shortening the patient's length of stay in the hospital, and thereby avoiding what has come to be known as institutionalism (syndrome characterized by lack of initiative, apathy, submissiveness to authority and extreme dependence on the institution), rather than a specific ongoing pharmalogical effect of the medication. *Id.*; Cole, *Patients' Rights v. Doctors' Rights: Which Should Take Precedence?* in VALUES IN CONFLICT, *supra* note 9, at 59; Lamb, *supra* note 6, at 900.

27. M. LADER, *supra* note 1, at 56. Schizophrenia refers to disorders in mood (marked by either the absence of emotional display or heightened emotional reactions termed inappropriate affect), behavior (manifestations include extreme withdrawal or bizarre activities such as remaining in one rigid position for hours at a time termed catatonic rigidity), and thought (fixed false beliefs called delusions, disturbed use of language, hallucinations, the most common being auditory, and attentional problems). L. SEIDEN & L. DYKSTRA, *supra* note 3, at 198; AMERICAN PSYCHIATRIC ASSOCIATION, DIAGNOSTIC & STATISTICAL MANUAL OF MENTAL DISORDERS, 181-84 (3rd ed. 1980). *See id.* at 181-93 for a complete clinical classification of this group of disorders and diagnostic categories.

symptoms of schizophrenia, they often prevent the progression of the condition both by cutting short the initial acute attack of thought disorder and subsequent relapses.[28] Evidence of the benefits of antipsychotic drugs for the chronic mentally ill, however, is not conclusive.[29] Thus, the necessity or effectiveness must be clearly established, and weighed against the risk of long-term side effects, before committing an individual to treatment with antipsychotics for more than a few months.[30]

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28. M. LADER, *supra* note 1, at 57. *See supra* note 12. The experimental literature has been summarized as revealing that 60%-70% of acute schizophrenics on no drugs are readmitted within one year, compared with 20%-30% who receive some form of drug therapy. G. Crane, *Clinical Psychopharmacology in Its 20th Year*, 181 SCI. 124, 125 (1973). *See* Dubose, *supra* note 1, at 1170-1202 for an extensive review of the experimental literature assessing the benefits of antipsychotic medication in the treatment of schizophrenia.

29. Brooks, *supra* note 2, at 183. There is a wide range of reported results in the literature on rehospitalization rates, comparing patients maintained either on drugs or on placebos. A review of 30 studies addressing the efficiency of continued antipsychotic medication in preventing psychotic relapse in chronic schizophrenia patients found nearly half of the chronic patients receiving a placebo did *not* deteriorate within a year. *Tardive Dsykinesia: Summary of Task Force Report of the American Psychiatric Association*, 137 AM. J. PSYCHIATRY 1163, 1167 (1980) [hereinafter cited as APA)]. Thus, for those patients who did not experience a relapse while receiving a placebo, it appears that there would not have been any clearcut benefit from having continued to take antipsychotic drugs. Another study making this comparison found reported differences in the rehospitalization rate between drug and placebo patients ranged from 12% to 59%. PSYCHIATRIC DRUGS, *supra* note 1, at 14. A review of 40 studies on patient deterioration after termination of the drugs reached the conclusion that no determination of the drug's effectiveness could be drawn because of methodological flaws in the studies they reviewed. *Id.* The fact that these studies focusing on chronic schizophrenia evaluate outcome at varying times may also explain this uncertainty. The longer the time after recovery or the more chronic the illness becomes, the harder it is to demonstrate that treatment with antipsychotic drugs makes any significant difference. Comment, *Madness and Medicine: The Forcible Administration of Psychotropic Drugs*, 1980 WIS. L. REV. 497, 540 n.188 (1980) [hereinafter cited as Comment, *Madness & Medicine*]. *See id.* at 539-40, nn.185-91 and Note, *A Common Law Remedy for Forcible Medication of the Institutionalized Mentally Ill*, 82 COLUM. L. REV. 1720, 1725, nn.52-57 (1982) for further studies offering conflicting conclusions.

30. APA, *supra* note 29, at 1167. Such a decision to continue treatment requires: (1) more than one acute psychotic episode without full return to prepsychotic status, (2) objective evidence of continuing psychosis, or (3) recovery but frequent recurrences that suggest the likelihood of future relapses, and (4) evidence of responsiveness to treatment. *Id.* It is essential that after a first acute psychotic episode of any type has cliinically remitted, the dosage should be gradually decreased and discontinued within several months because many acute episodes eventually prove to be episodes of manic-depressive illness, which has not been proven scientifically to benefit from continued antipsychotic treatment. *Id.* at 1168. It has been asserted that therapists may continue administration of those drugs without considering the possibility of naturally occurring remissions. Thus, the choice of drug regimen may be determined more by the severity of a previous episode, than by a patient's current status. Crane, *supra* note 28, at 125.

Many of the physical side effects which arise in conjunction with administration of these drugs are relatively "minor"[31] and are reversible if the medication is discontinued.[32] Such common adverse reactions include: drowsiness, nausea, constipation, uncontrollable restlessness, dizziness, faintness, blurred vision, dry mouth, significant weight gain, and altered eye and skin pigmentation.[33] In addition these medications often cause loss of sexual drive; males may even be unable to ejaculate, and in females swelling of the breast, spontaneous lactation, and menstrual irregularities due to blockage of ovulation may occur.[34] Other unwanted effects, perhaps even more disturbing for the patient, are frequently caused abnormalities in motor activity, called extrapyramidal effects.[35]

The earliest extrapyramidal effect to develop is acute dystonia characterized by spasmodic muscle contractions of the tongue, face, neck, and back.[36] This side effect can be quickly reversed by either the administration of an antiparkinsonian agent,[37] or diazepam (an anti-anxiety agent),[38] or by reduction or

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31. While these adverse reactions may be viewed as mild by clinical standards on the part of the psychiatrist, they are often extremely distressing to the patient. PSYCHIATRIC DRUGS, *supra* note 1, at 16. *See* Comment, *Madness & Medicine*, *supra* note 29, at 536 n.178 for a personal account of a former mental patient.

32. However, for many chronic patients on maintenance antipsychotic therapy, these side effects are permanent in that they invariably accompany the continued intake of medication. Brooks, *supra* note 2, at 187.

33. M. LADER, *supra* note 1, at 59, 62; PSYCHIATRIC DRUGS, *supra* note 1, at 16; Brooks, *supra* note 2, at 184; Comment, *Madness & Medicine*, *supra* note 29, at 535 n.177. Pigmentary changes in the skin and eye is a long-term side effect, mainly with chlorpromazine (Thorazine), caused by the accumulation of drugs and their metabolites and pigments in the cornea, lens and skin. The skin becomes extremely sensitive to sunlight and exposure to the sun leads to a purple-gray discoloration. The eyes become opaque. This opacity may persist for as long as six months after termination of drug therapy. M. LADER, *supra* at 62; Dubose, *supra*, note 1, at 1204. *See* Blackwell, *supra* note 9, at 16 for an extensive list of unwanted effects of these drugs.

34. PSYCHIATRIC DRUGS, *supra* note 1, at 16; Brooks, *supra* note 2, at 184; Comment, *Madness & Medicine*, *supra* note 29, at 535. These effects are due to the antipsychotic medication suppressing activity of the hypothalamus, an area of the brain which regulates the secretion of hormones. *Id.*

35. M. LADER, *supra* note 1, at 59.

36. Callaway & Paull, *supra* note 7, at 788; M. LADER, *supra* note 1, at 59; APA, *supra* note 29, at 1164. A few doses or even a single dose of the antipsychotic drug may be sufficient to induce the condition, and has been found to most likely occur in males and in children. M. LADER, *supra*, at 59. These muscle spasms may mimic seizures. APA, *supra*, at 1164.

37. Unimpaired motor activity is the result of a delicate balance between two biogenic amines (neurotransmitters) in the basal ganglia of the brain: dopamine which acts

withdrawal from medication.[39] Another extrapyramidal effect is akathisia, an uncontrollable physical restlessness as well as a strong subjective sense of restlessness, characterized by the inability to sit still.[40] Although this side effect is most likely an indication that the drug dosage needs to be reduced, it may easily be mistaken for increasing psychotic tension, anxiety or agitation.[41] The most common extrapyramidal effect is akinesia, characterized by physical immobility and lack of spontaniety.[42]

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as a motor activity inhibitor and acetylcholine which acts as a motor activity facilitator. Comment, *Madness & Medicine, supra*, note 29, at 531 n.56. Antipsychotic drugs are believed to block the reception of dopamine, resulting in a decrease of dopamine which is responsible for producing the drugs' antipsychotic effect. (It is hypothesized that schizophrenia is "caused" by an excess of dopamine activity). M. LADER, *supra* note 1, at 59. However, by decreasing dopamine activity, an overbalance of acetylcholine occurs, producing the extrapyramidal effects. True parkinsonism is due to the naturally occurring lack of dopamine, and accordingly L-dopa, the metabolic precusor of dopamine, is used in treatment to increase dopamine levels to correct the overbalance of acetylcholine. L. SEIDEN & L. DYKSTRA, *supra* note 3, at 135. But since psychosis is thought to be the result of excessive dopamine, L-dopa would aggravate schizophrenia. *Id.* Antiparkinsonism drugs (anticholinergic drugs), instead of correcting the overbalance of acetycholine by increasing dopamine activity, decreases the activity of acetycholine to balance with the antipsychotic drug-induced lower levels of dopamine. *Madness & Medicine, supra*, at 531 n. 156. Anticholinergic drugs, however, produce their own side effects such as dry mouth, blurred vision, nausea, nervousness, and mental confusion. *Id.* Also, antiparkinsonism drugs are not effective in the prevention of extrapyramidal symptoms, but only in treatment once they occur. M. LADER, *supra*, at 60; Pirodsky, *supra* note 4, at 68-69.

38. M. LADER, *supra* note 1, at 59.

39. *Id.* at 60; Callaway & Paull, *supra* note 7, at 788; Pirodsky, *supra* note 4, at 68. Reduction or withdrawal of antipsychotic medication is preferable to avoid increasing susceptability to tardive dyskinesia. M. LADER, *supra*, at 60. *See infra* note 47 for an explanation of why the combination treatment of antiparkinsonian medication and antipsychotics should be avoided.

40. APA, *supra* note 29, at 1164; M. LADER, *supra* note 1, at 59. One study found that patient reluctance to take antipsychotic drugs was most notably associated with the patient's fear of akathisia or what has been referred to as the "syndrome of impatience." Patients often experience fright or terror at this compulsion to move. Van Putten, *Why Do Schizophrenic Patients Refuse to Take Their Drugs*, 31 ARCH. GEN. PSYCHIATRY 67, 71 (1974).

41. APA, *supra* note 29, at 1164; M. LADER, *supra* note 1, at 59. Due to the fact that the extrapyramidal manifestation is entirely subjective and in its milder form it may be almost impossible to distinguish from symptomatic anxiety of psychosis. Van Putten, *supra* note 40, at 71. Misdiagnosing akathisia as a psychotic symptom may lead to an increase in the dosage of medication prescribed. With akathisia, antiparkinsonian drugs are usually ineffective, but a benzodiazepine (an anti-anxiety drug) may help treat the restlessness. M. LADER, *supra*, at 59; APA, *supra*, at 1164.

42. Callaway & Paull, *supra* note 7, at 788; Brooks, *supra* note 2, at 184. Akinesia also effects fine-movement control manifested by small handwriting, a useful sign of this side effect. M. LADER, *supra* note 1, at 60. There are treatment-resistent cases of drug-induced parkinsonism in chronic drug-treated patients despite usual antiparkinsonian drug treatment. Gardos & Cole, *Overview: Public Health Issues in Tardive Dyskinesia*, 137 AM. J. PSYCHIATRY 776, 779 (1980).

This is caused by the drug weakening those muscles used in repetitive actions such as walking, and more severely affected patients show signs of drug-induced parkinsonism.[43]

The most serious extrapyramidal effect produced by antipsychotics is tardive dyskinesia, a potentially irreversible condition[44] characterized by involuntary muscle movements, particularly those of the face, mouth, and limbs.[45] In its most progressive state, the condition interferes with all motor activity, making speech incomprehensible and breathing and swallowing extremely difficult.[46] Unlike other neurologic side effects there is generally no effective treatment of tardive dyskinesia.[47]

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43. Signs of drug induced parkinsonism are a loss of associated movements: muscular rigidity, tremor, stooped posture, masked expression, shuffling gait, and excessive salivation and seborrhoea. M. LADER, *supra* note 1, at 60; APA, *supra* note 29, at 1163-64. Women, particularly the elderly, are the most commonly affected, and the incidence of parkinsonism is about 15%-25% among patients being treated with moderate doses of antipsychotics. M. LADER, *supra*, at 60.

44. M. LADER, *supra* note 1, at 61. In about half of the patients who already manifest tardive dyskinesia, the condition persisted even after withdrawal from the medication. *Id.* A review of 23 treatment studies in which antipsychotics were withdrawn for periods varying from several weeks to three years revealed that 36.5% had a remission of dyskinesia symptoms. These studies also indicated that presence of tardive dyskinesia three months after discontinuation of antipsychotic drugs may be a valid criteria for irreversible dyskinesia. Jeste & Wyatt, *Therapeutic Strategies Against Tardive Dyskinesia: Two Decades of Experience*, 39 ARCH. GEN. PSYCHIATRY 803, 812 (1982). It should be noted, however, that the low rates of reversibility in these discontinuation studies may be confounded by the rate of patient dropout due to psychiatric (usually schizophrenia) deterioration which can limit the follow-up time after discontinuation. Furthermore, these studies often involve patients who have histories of long antipsychotic drug exposure, so that the results may also be confounded by the duration of the tardive dyskinesia itself. Glazer, Moore, Schooler, Brenner & Morgenstern, *Tardive Dyskinesia: A Discontinuation Study*, 41 ARCH. GEN. PSYCHIATRY, 623, 625 (1984).

45. Roth & Appelbaum, *supra* note 12, at 185. An inability to keep the tongue extruded, and a quivering of the tongue on the floor of the mouth are some of the earliest signs of tardive dyskinesia. M. LADER, *supra* note 1, at 61. The patient may exhibit such involuntary movements as repeated sucking and smacking of the lips, darting of the tongue, blowing of the cheeks, and side to side movements of the jaw. PSYCHIATRIC DRUGS, *supra* note 1, at 16; Crane, *supra* note 28, at 127.

46. Crane, *supra* note 28, at 127; Callaway & Paull, *supra* note 7, at 788; Gardos & Cole, *supra* note 42, at 777.

47. Munetz, Roth & Cornes, *Tardive Dyskinesia and Informed Consent: Myths and Realities*, 10 BULL. AM. ACADEMY PSYCHIATRY L. 77 (1982); APA, *supra* note 29, at 1168. The treatment of tardive dyskinesia has been hindered by the fact that the specific cause of this side effect is unknown. Since it is believed that antipsychotic drugs block the reception of dopaminergic neurotransmitters, the prevailing explanation for tardive dyskinesia is the "dopamine supersensitivity" hypothesis. Antipsychotic drugs are not capable of selectively blocking all dopamine receptors, thus under this hypothesis, after continued administration of these drugs, those receptors which have not been blocked

Tardive dyskinesia is the center of much controversy in psychiatric treatment for several other reasons. First, there is no set duration of antipsychotic drug exposure before the dyskinesia occurs.[48] Although, as the name implies, it was originally thought only to appear late in patients who had been receiving long-term treatment,[49] it has been reported to occur after only a few months of treatment.[50] This unpredictability is further con-

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become hyperactive in an attempt to compensate for the receptors which are being blocked, resulting in excessive dopaminergic activity, causing the dyskinesic symptoms. Consequently, withdrawal makes the condition worse because even more receptors become active, adding to the already overabundance of dopaminergic activity, and if antipsychotic drugs are reinstated or the dose raised, this merely postpones the dyskinesia because eventually the supersensitivity of those receptors still remaining active increases, again causing dyskinesia. Antiparkinsonism medication worsens the condition because these drugs induce drug-metabolizing enzymes in the liver, which results in decreased plasma antipsychotic drug concentrations, leading to greater dopamine activity. Also, by decreasing the activity of acetylcholine (*see supra* note 37), the existing balance between acetylcholine and dopamine is overbalanced towards greater activity of dopamine. M. LADER, *supra* note 1, at 60-62. This finding has implicated routine administration of antiparkinsonism drugs as predisposing the patient to tardive dyskinesia. Yassa, Ananth, Cordozo, & Ally, *Tardive Dyskinesia in an Outpatient Population: Prevalence and Predisposing Factors*, 28 CAN. J. PSYCHIATRY 391, 394 (1983); *see generally* Jeste & Wyatt, *supra* note 44 for an extensive review of varying experimental treatment modes for tardive dyskinesia. Those studies which purport to have found an effective treatment for tardive dyskinesia should be interpreted cautiously. Statistically significant changes in improvement may not be synonymous with clinically meaningful improvement. For example, assume the mean amount of improvement resulting from a treatment when compared with a baseline is 25%-30%, yielding statistically significant results when a sufficient number of patients are studied. However, at the same time these patients showing improvement retain 70%-75% of their original dyskinesic symptoms. Also, the factor of dropouts are frequently ignored in data analysis. When patients who fail to complete a trial due to lack of improvement, side effects, or worsening of their primary psychiatric condition are excluded from the final analysis, the reported results are actually not as positive as they appear. *Id.* at 805.

48. In a review of 56 tardive dyskinesia studies, out of the 21 studies exploring the length of drug treatment, 15 studies found no significant relationship between length of antipsychotic drug exposure and this condition. Six studies, on the other hand, found the length of treatment to be a significant factor; two of which involved patients who had been exposed to these drugs for brief periods. Kane & Smith, *Tardive Dyskinesia: Prevalence and Risk Factors, 1959 to 1979*, 39 ARCH. GEN. PSYCHIATRY 473, 476 (1982).

49. The dyskinesia typically takes several years to appear. A substantial percentage of patients who develop tardive dyskinesia manifest it within three years of drug exposure. However, since dating the emergence of tardive dyskinesia retrospectively is difficult, studies indicating the occurrence of symptoms to be within 18 months to three years may be conservative. *Id.*; M. LADER, *supra* note 1, at 61; Roth & Appelbaum, *supra* note 12, at 186.

50. A few cases have reported tardive dyskinesia occurs as a result of administering the drug for less than three months. Roth & Appelbaum, *supra* note 12, at 186; M. LADER, *supra* note 1, at 61. It has also been observed that the period of greatest risk for tardive dyskinesia to develop may be from six to eight years of exposure to antipsychotic medication, while the risk is not increased if the exposure is longer than eight years.

founded by the fact the symptoms may become apparent only after a reduction in dose or from a discontinuation of the drug,[51] because the antipsychotic drugs which produce dyskinesia can also mask its symptoms.[52] Secondly, the factors predisposing a patient to tardive dyskinesia are not completely known, making it difficult to predict who will be a victim. Advancing age and being female are the only risk factors consistently associated with an increased probability of developing this syndrome.[53] Fi-

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Branchey & Branchey, *Patterns of Psychotropic Drug Use and Tardive Dyskinesia*, 4 J. CLINICAL PSYCHOPHARMACOLOGY 41 (1984); Kane & Smith, *supra* note 48, at 476. If the maximum risk for the development of tardive dyskinesia does occur as a result of relatively short exposure to antipsychotic drugs, the statistical association between duration of exposure and this condition may become blurred when the patient population being studied consists of patients who have received antipsychotic treatment for prolonged periods. Branchey & Branchey, *supra*, at 44.

51. M. LADER, *supra* note 1, at 61. The term "covert dyskinesia" refers to this form of tardive dyskinesia. The prevalence of patients who develop dyskinesia upon discontinuation of the drug has been estimated to be 5%-40%. Many of these cases turn out to be "withdrawal dyskinesia," which is self-limited and usually disappears within 6 weeks. Similar to the prevailing view for the explanation of tardive dyskinesia, (*see supra* note 47), withdrawal dyskinesia is thought to be the result of temporary hyperactive dopamineric activity when the dopamine-blocking antipsychotic drugs are discontinued. When the dyskinesia persists beyond six weeks, it is a strong indication that tardive dyskinesia was previously suppressed by drugs ("covert dyskinesia"). Gardos, Cole & Tarsy, *Withdrawal Syndromes Associated with Antipsychotic Drugs*, 135 AM. J. PSYCHIATRY 1321, 1322 (1978); Gardos & Cole, *supra* note 42, at 788. Chronically institutionalized elderly patients with prolonged exposure to antipsychotic drugs are most likely to have developed irreversible covert dyskinesia, whereas those patients receiving drug treatment for a relatively shorter time are more likely to develop reversible covert dyskinesia. *Id.*

52. Munetz, Roth & Cornes, *supra* note 47, at 77; PSYCHIATRIC DRUGS, *supra* note 1, at 17. Consequently, the symptoms may be obscured until the course of tardive dyskinesia is far advanced. *Id.*

53. Callaway & Paull, *supra* note 7, at 791; Branchey & Branchey, *supra* note 50, at 44; APA, *supra* note 29, at 1164. Factors such as a decreased neuronal plasticity or age-related changes in drug metabolism, which leads to higher drug blood levels, may contribute to the existence of increased prevalence rates of tardive dsykinesia in older patients. Kane & Smith, *supra* note 48, at 476. Female patients particularly those over 50 years of age, have been found to be significantly more vulnerable than male patients to this side effect. Yassa, Ananth, Cordozo & Ally, *supra* note 47, at 393. It has been found that the greater the severity of tardive dyskinesia, the greater the ratio of female prevalence to male prevalence. Kane & Smith, *supra*, at 476. One possible explanation for this gender difference may be related to hormones. Seeman, *Interaction of Sex, Age, and Neuroleptic Dose*, 24 COMPREHENSIVE PSYCHIATRY 125, 127 (1983); Kane & Smith, *supra*, at 477. It has been suggested that estrogen induces a relative immunity to extrapyramidal side effects because estrogen, known to modulate the sensitivity of dopamine receptors, appears to inhibit dopamine activity. This is supported by the finding that women in their 20's and 30's appear to require lower doses of antipsychotics when estrogen levels are high, and higher doses in their 40's when estrogen levels begin to fall. Since antipsychotic medication decreases dopamine activity, lower doses are sufficient because high levels of estrogen already present in the body act to create a similar

nally, although the average prevalence[54] of this condition has been clearly established to be at least 20% in chronic drug treated patients,[55] the reported incidence rates, which are just becoming available, are widely variable.[56] Furthermore, research suggesting that the incidence is increasing has caused considerable debate.[57] However, despite these controversies and the psy-

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effect. Thus, increasing antipsychotic doses sufficiently to interfere with the pituitary-gonadal hormonal system which inhibits estrogen secretion, may be counterproductive in controlling psychotic symptoms in premenopausal women. Seeman, *supra*, at 127, 128. Estrogen also accomodates the dopamine-acetylcholine balance lessening the occurrence of supersensitivity of remaining dopamine causing tardive dyskinesia. *Id.* at 127. Therefore, womens' higher risk of developing tardive dyskinesia than men at an older age may be the result of increased supersensitivity due to postmenopausal estrogen withdrawal. *Id. See supra* note 47 regarding supersensitivity and the pharmacological basis for tardive dyskinesia.

54. Prevalence rates express the proportion of patients with tardive dyskinesia at a particular time in a treatment facility. Gardos & Cole, *supra* note 42, at 776.

55. *Id.* at 473; Branchey & Branchey, *supra* note 50, at 41; Seeman, *supra* note 53, at 125; Yassa, Ananth, Cordozo & Ally, *supra* note 47, at 393; Jeste and Wyatt, *supra* note 44, at 803. Although the reported prevalence of tardive dyskinesia has varied from .05% to more than 56%, this discrepancy in prevalence can be attributable to the following: arbitrary definitions of tardive dyskinesia, questionable reliability of rating scales, and scientifically inappropriate generalizability (study populations consisting of a large number of elderly hospitalized patients may confound the results by not being representative of the hospital patients receiving antipsychotics). Gardos & Cole, *supra* note 42, at 776. The average prevalence rate, however, should balance out these methodological problems, giving a valid percentage.

56. Brooks, *supra* note 2, at 186; Kane, Rifkin, Woerner, Reardon, Sarantakos, Schiebel & Ramos-Lorenzi, *Low-Dose Neuroleptic Treatment of Outpatient Schizophrenics*, 40 ARCH. GEN. PSYCHIATRY 893 (1983) [hereinafter cited as *Low-Dose*]. Incidence (as distinct from prevalence) refers to the number of new cases emerging in a well-defined population during a given time period. Gardos & Cole, *supra* note 42, at 776. It has been suggested there is a 12% incidence rate of tardive dyskinesia after four years of cummulative antipsychotic drug exposure. *Low Dose, supra*, at 893. Another study found the incidence rate to be approximately 4%-5% following one year of drug treatment. If the risk remains the same during each subsequent year, the incidence may be as high as 20%-25% over a five year period. Gardos & Cole, *supra*, at 776, 777. Other reported figures have ranged from 3% to more than 50%. M. LADER, *supra* note 1, at 61.

57. Comment, *Madness & Medicine, supra* note 29, at 533 n.163. The reported frequency of tardive dyskinesia depends on how carefully one looks for the complication, thus as researchers become more sophisticated in diagnosing tardive dyskinesia, they are able to detect it in an increasing number of patients. However, the American Psychiatric Association has asserted that the currently heightened awareness of tardive dyskinesia with increased sensitivity to minor degrees of abnormal movements may be leading to diagnosis based on abnormal movements unrelated to antipsychotic drug use. These abnormalities include minor movements that may be indistinguishable from habit spasms or other tics of unknown cause, psychotic mannerisms, or even normal movements associated with ill-fitting dentures. Furthermore, the geriatric population and schizophrenic population apparently have a greater incidence of naturally occuring movement abnormalities. APA, *supra* note 29, at 1164. To the contrary, see Munetz, Roth & Cornes, *supra* note 47, at 82 addressing this "myth," where only two of the 46 diagnoses of

chiatric research indicating that only a relatively small number of patients may actually experience tardive dyskinesia, for those that do, all of this seems irrelevant.[58] From a legal point of view, however, documented evidence of a high incidence of tardive dyskinesia is not necessary to warrant protective action. The possibility that a significant number of chronic mentally ill individuals may unnecessarily develop a permanent neurological disorder is sufficient.[59]

Other adverse reactions which have been associated with the use of antipsychotic drugs, are jaundice,[60] potentially fatal blood dyscrasias,[61] blindness,[62] and cardiac arrhythmias.[63] Ex-

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tardive dyskinesia studied were at all in question following a careful review of each case. Also the standard use of either the Abnormal Involuntary Movement Scale (AIMS) developed at the National Institute of Mental Health, or the Dyskinesia Rating Scale in most of the recent studies appears to undercut the APA's assertions. Jeste & Wyatt, *supra* note 44, at 804.

58. Furthermore, although not all those afflicted with tardive dyskinesia suffer the more severe abnormal muscular movements, even mild dyskinesia manifested by minor facial tics can be extremely distressful for the individual, and he or she consequently may become withdrawn. Likewise the facial movements can make a person highly unattractive and thus limit employment opportunities, as well as social adjustment. Gardos & Cole, *supra* note 42, at 777; PSYCHIATRIC DRUGS, *supra* note 1, at 16. It has been estimated that of the total 20% of patients with tardive dyskinesia (*see supra* note 55 and accompanying text) less than 10% have severe abnormal movements while 25%-35% show moderately severe movements. Munetz, Roth & Cornes, *supra* note 47, at 77. *See* APA, *supra* note 29 at 1164 (Table 2) for prevalence of tardive dyskinesia, in various degrees of severity, among chronic schizophrenic inpatients and outpatients treated with these drugs.

59. *See supra* note 29.

60. PSYCHIATRIC DRUGS, *supra* note 1, at 16. The incidence of jaundice is relatively uncommon and is the result of a hypersensitivity reaction, most likely to occur between the second and fourth weeks of therapy. Resembling infectious hepatitis, it is usually reversible on withdrawal from the medication, although instances of chronic jaundice have been reported. 38 PHYSICIANS DESK REFERENCE 1897 (1984) (package insert for Thorazine); M. LADER, *supra* note 1, at 62.

61. The most significant blood dyscrasia is agranulocytosis, a condition in which bone marrow production of white blood cells is reduced or stopped leading to an increased susceptibility to infection. This rare toxic effect occurs in one out of 3,000 patients treated with chlorpromazine (Thorazine) and 30% of these cases are fatal (one chance in 10,000 a patient will die from treatment). Dubose, *supra* note 29, at 537 n.180. *See id.* and package insert for Thorazine in 38 PHYSICIANS DESK REFERENCE 1897 (1984) for a discussion of other blood dyscrasias.

62. Retinitis, or retinal degeneration which may result in blindness, is caused by one drug, thioridazine (Mellaril) if dosages over the manufacturer's recommendation are being administered. PSYCHIATRIC DRUGS, *supra* note 1, at 16; M. LADER, *supra* note 1, at 62.

63. PSYCHIATRIC DRUGS, *supra* note 1, at 16. Persons treated with phenothiazines have been shown to have nonspecific abnormalities in their electrocardiograms, particularly those receiving thioridazine (Mellaril). Brown & Kocsis, *Sudden Death and Anti-*

tremely rare cases of sudden death have been reported from such arrhythmias.[64]

In addition to these purely physical side effects, the psychological effects can be extremely antitherapeutic, particularly in view of the purported benefit that antipsychotic drugs serve by allowing the chronic mentally ill to be integrated into society. Apart from the emotional distress arising from experiencing any of the physical side effects aforementioned, these drugs directly effect an individuals cognition, emotion, and motivation.[65] Research has indicated these drugs generate a "cognitive dampening," impairing a patient's ability to remember, reason, or function effectively in any complex learning situation, whether it be

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psychotic Drugs, 35 HOSP. & COMMUNITY PSYCHIATRY 486, 488 (1984). These abnormalities can be the forerunner of fatal cardiac tachyarrhythmias (excessively rapid heart beat). *Id.* at 487; Comment, *Madness & Medicine, supra* note 29, at 537 n.179.

64. Sudden death is a phenomenon which can occur in previously healthy persons. There is a substantial incidence of sudden death in the general population, more than 400,000 cases per year, representing one such death every minute. Although most victims are men who have coronary atherosclerosis, 25% have no recognizable cardiac disease. Brown & Kocsis, *supra* note 63, at 486, 487. Ventricular tachycardia or fibrillation (fine rapid uncoordinated twitching of individual muscular fibers, replacing the normal contraction of the ventricular muscle) accounts for more than 75% of such deaths. It is assumed that all persons who die suddenly from ventricular tachycardia have previously had arrhythmias, but not all patients with arrhythmias die of ventricular tachycardia. *Id.* at 487. Consequently, case reports of sudden death precipitated by antipsychotic induced arrhythamias are controversial, as well as inconclusive, in that this area is limited by retrospective data gathering, small sample size due to its rarity, and often sparse historical and laboratory data. *Id.* at 486. Furthermore, given the substantial incidence of sudden death in the general population, a certain proportion of medicated patients can be expected to coincidentally die suddenly even if no harmful effects are exerted by antipsychotics. However, on the basis of what is known about risk factors for ventricular tachycardia in the general population and the action of phenothiazines in producing arrhythmia, the psychiatric benefits must be weighed against cardiac risks in persons indicating any type of predisposing cardiovascular pathology. *Id.* at 490.

Phenothiazines have also been shown to depress the cough and the gag reflexes. Absence of the gag reflex has been reported in 40.3% of psychiatric patients. Zugibe, *Sudden Death Related to the Use of Psychotropic Drugs*, in LEGAL MEDICINE 1980 75, 76 (C. Wecht ed. 1980). This sudden death by asphyxia has been implicated when patients show sudden respiratory difficulty followed by collapse shortly after eating (autopsies finding food in the larynx or trachea). Brown & Kocsis, *supra*, at 488. However, a direct relationship to the drugs has not been established, attributed largely to the fact individuals receiving antipsychotics do not choke on food anymore frequently than do nonpsychiatric individuals. Zugibe, *supra*, at 78. *See generally* Brown & Kocsis, and Zugibe *supra* for further discussion of cardiovascular side effects and respiratory complications arising from the use of the drugs which have been associated with sudden death.

65. Comment, *Madness & Medicine, supra* note 29, at 534; Brooks, *supra* note 2, at 184.

social or interpersonal.[66] Thus, if a goal of rehabilitation is to replace chronic disability with self-sufficiency, antipsychotics have serious liabilities. Furthermore, these drugs produce listlessness and apathy, a characteristic "flattening" often described by mental patients by the term "zombiism."[67] Given this reduction in motivation, it is not surprising that it has been reported that a majority of chronic patients who live in the community continue to be unproductive and are often a burden to their families.[68] It has also been asserted that the "flattening" effect of antipsychotic medications may lead to the development of suicidal depression precipitated by feelings of emptiness, worthlessness, and loss of self.[69] Consequently, individuals who receive these drugs not only risk a wide variety of physical side effects, but must also relinquish any true sense of self-determination,

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66. PSYCHIATRIC DRUGS, *supra* note 1, at 21; Comment, *Madness & Medicine, supra* note 29, at 534. This raises the question of effectiveness of use of these drugs in conjunction with psychotherapy in that various kinds of interpersonal learning are involved; the patient is expected to learn from the therapist about how to view, react, or cope more effectively with his environment. PSYCHIATRIC DRUGS, *supra* note 1, at 21.

67. Brooks, *supra* note 2, at 184. This drug effect is the consequence of the suppression of dopamine activity in the limbic system which is involved in the regulation of emotion and motivation. It is this same effect which is responsible for the drugs' ability to reduce disordered thought and alleviation of psychotic anxiety. Comment, *Madness & Medicine, supra* note 29, at 534. The following account of this "zombiism" by a diagnosed schizophrenic illustrates the extent to which a patient may be overwhelmed by apathy and emptiness:

> What the drug is supposed to do is keep away hallucinations. What I think it does is just fog up your mind so badly you don't notice the hallucinations or much else.
>
> . . .
>
> On Thorazine everything's a bore. Not a bore, exactly. Boredom implies impatience. You can read comic books and "Reader's Digest" forever. You can tolerate talking to jerks forever. Babble, babble, babble. The weather is dull, the flowers are dull, nothing's very impressive. Muzak, Bach, Beatles, Lolly and the Yum-Yums, Rolling Stones. It doesn't make any difference.

M. VONNEGUT, THE EDEN EXPRESS 252-53 (1975) *reprinted in Psychiatric Drugs, supra* note 1, at 19, 20.

68. Crane, *supra* note 28, at 125.

69. Comment, *Madness & Medicine, supra* note 29, at 538. Depression may also be a secondary reaction to the physical side effects, particularly those of the akinetic type (*see supra* notes 42-43 and accompanying text). Brooks, *supra* note 2, at 185. However, drug induced suicidal depression is not without controversy by virtue that irrespective of medication, schizophrenic patients often have mood swings, and suicide is at least 50 times more common among schizophrenics than among the general population. M. LADER, *supra* note 1, at 62.

emotion, and enthusiasm for life.

B. *The Use Of Antipsychotic Drugs In The Private Sector*

It should be evident at this point that the use of antipsychotic drugs in the treatment of the chronic mentally ill poses many delicate and perplexing questions both for the patient and the physician. Even in the realm of sound clinical practice when a decision is made that continued medication is necessary, a patient must, nonetheless, be subjected to the inherent risks of debilitating side effects. Although the medical benefits of these drugs are disputable when viewing chronic patients as a whole,[70] the decision to continue drug therapy in an individual case may be one of valid professional medical judgment and in such instances, legal intrusions in the practice of medicine would be inappropriate.[71] Thus it is important to draw the distinction between the difficult question of the usefulness of antipsychotic drugs in the treatment of *chronic* disorders in general, and the prescription of these drugs to control unwanted behavior solely for the benefit of nursing staff or relatives, without substantial benefit to the patient. It seems clear that in the latter situation, chronic patients are exposed to the hazards of these drugs without justification.

This problem is not limited to the practice of psychiatry in the public sector.[72] Negligent and even abusive use of this medication in board and care homes and in nursing homes necessitates examination of the heretofore sacrosanct boundary between the public and private practice of medicine to afford all patients protection from such medication practices. Although the following two Sections will examine the use of antipsychotic drugs in these two specific areas, it is important to keep in mind

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70. *See supra* note 29.

71. The decision that long-term drug therapy is required is dictated by diagnosis, and as the U.S. Supreme Court has stated, "[t]he subtleties and nuances of psychiatric diagnosis render certainties virtually beyond reach . . . . Psychiatric diagnosis . . . is to a large extent based on medical 'impressions' drawn from subjective analysis and filtered through the experience of the diagnostician. This process often makes it very difficult for the expert physician to offer definite conclusions." Addington v. Texas, 441 U.S. 418, 430 (1979). Accordingly, legal intervention is limited to cases of medical negligence. *See infra* note 153 where the court has determined that long-term administration of these drugs amounted to malpractice.

72. *See supra* note 10.

that the potential for misuse of these drugs exists in all other areas of private medicine as well.

1. Nursing Homes

Approximately five percent of people age 65 and older in the United States are confined to nursing homes.[73] The potential for abuse of antipsychotic drugs is tremendous in the nursing home setting where long-term residents are often vulnerable, frail, alone and utterly dependent on those who care for them. In fact, it has been established that large numbers of elderly patients are kept in a drugged state to keep them manageable.[74]

The ramifications of antipsychotic drug use as a way to control behavior rather than for specific psychiatric treatment are extreme in this age population. Not only can these drugs accelerate the deterioration of general health in ambulatory patients by inducing muscular atrophy,[75] but their detrimental side effects are far more likely to occur in geriatric patients.[76] Furthermore,

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73. Dyer, Oles & Davis, *Geriatrics & Gerontology—The Role of the Pharmacist in a Geriatric Nursing Home: A Literature Review*, 18 DRUG INTELLIGENCE & CLINICAL PHARMACY 428 (P. Lamy ed. 1984). In California 1,170 nursing homes care for 105,000 people each day. *Task Force Blasts Abuse of Elderly in Nursing Homes*, L.A. Daily J., August 18, 1983, at 1 col. 4 [hereinafter cited as *Abuse of Elderly*].

74. J. ROBITSCHER, THE POWERS OF PSYCHIATRY 359 (1980). An investigation of nursing homes in Los Angeles and San Francisco revealed that patients were kept in drugged conditions as a way of lessening the burden of care on the staffs. *Abuse of Elderly, supra* at 1, col. 4. A study addressing antipsychotic drug use in 173 Tennessee nursing homes found epidemiologic evidence of abuse in that 43% of the patients were prescribed antipsychotic medication. Ray, Federspiel & Schaffner, *A Study of Antipsychotic Drug Use in Nursing Homes: Epidemiologic Evidence Suggesting Misuse*, 70 AM. J. PUBLIC HEALTH 485, 490 (1980). The Nader Task Force on Nursing Homes charged tranquilizers were given mostly for staff convenience. F. MOSS & V. HALAMANDARIS, TOO OLD TOO SICK TOO BAD: NURSING HOMES IN AMERICA 45 (1977). *See id.* at 45-48 for various testimonies from nursing home personnel before a U.S. Senate subcommittee on Long-term Care (1971) substantiating that in many instances the sole purpose of these drugs was that of quieting patients.

75. PSYCHIATRIC DRUGS, *supra* note 1, at 20.

76. With increasing age there is a decrease in the rate of drug metabolism, which may account for the relatively high evidence of adverse drug reactions in older patients. *Drug Interactions and Reactions Update* (P. D'Arcy ed.) 16 DRUG INTELLIGENCE & CLINICAL PHARMACY 925 (1982). The potentiation of drug effects with age are poorly understood. Although most elderly patients require dosage reductions of antipsychotic drugs due to the declining efficiency of the liver and kidneys, the effect of changes in drug protein binding in the blood, changes in the distribution and quantity of body water and fat with age, and changes at receptor sites in the brain are areas of speculation. Also the effects of nutritional deficiencies and diseased organ systems on pharmaco-

since geriatric patients frequently suffer from an array of physical conditions, the average nursing home resident receives four to seven prescriptions daily,[77] which increases the likelihood of adverse drug interactions.[78] As a result of this polypharmacy, many patients suffer from adverse and paradoxical drug reactions that are never diagnosed because the idiosyncratic behavior exhibited by the patient is seen as part of the aging or disease process, and thus is unrecognized as a drug side effect.[79]

The problem of inadequate control of antipsychotic drug use and overmedication is perpetuated by inadequate physician contact,[80] the overuse of prn (*pro re nata* which means as

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logic actions are yet to be ascertained. Dyer, Oles & Davis, *supra* note 73, at 430. *See supra* note 53 regarding the aging factor and tardive dyskinesia. Phenothiazine-induced Parkinsonism (akinesia) also occurs more frequently among the aged. M. LADER, *supra* note 1, at 65; F. Moss & V. HALAMANDARIS, *supra* note 74, at 182.

77. Certain patients even receive up to 18 or more daily medications. Dyer, Oles & Davis, *supra* note 73, at 428; J. ROBITSCHER, *supra* note 74, at 359.

78. The chances for serious drug interactions, adverse effects on disease states, and adverse drug reactions rise proportionately as the number of prescriptions increases. The incidence of adverse drug reactions also increases with the age of the patient. Dyer, Oles & Davis, *supra* note 73, at 429. It has been reported that greater than 50 percent of the people in nursing homes are receiving drugs which potentially interact and are consequently quite dangerous. F. Moss & V. HALAMANDARIS, *supra* note 74, at 52. *See* Salzman & Hoffman, *Clinical Interaction Between Psychotropic and Other Drugs*, 34 HOSPITAL & COMMUNITY PSYCHIATRY 897, 897-99 (1983) for a listing of drug interactions with antipsychotics, indicating those that are of clinical significance and may interfere with treatment or even be life-threatening.

79. Delineating what behavior is actually a manifestation of the aging process or the progression of a physical illness and what is the result of a drug side effect poses a very real obstacle in determining the extent the medication regimen is harmful to the patient. The use of multiple drugs often stems from the fact that complaints of elderly patients are difficult to diagnose and certain diagnostic tests may not be readily available in a nursing home. Also, physicians may be hesitant to order such tests that may expose older patients to physical risks and increase the cost of care. Consequently, physicians frequently prescribe medications which reduce the pain or intensity of the symptoms instead of determining its underlying source. These medications may accumulate in the body so that it is difficult to differentiate which are beneficial and which are contributing to the patients problem. Dyer, Oles & Davis, *supra* note 73, at 428-29.

80. *Id.* at 429. The underlying reasons why private physicians all too frequently maintain only minimal contact with nursing home patients leading to an apparent abdication of their responsibilities in caring for such patients may involve a variety of difficult factors. One possible factor may be what one United States Senator has labeled the "Marcus Welby Syndrome." F. Moss & V. HALAMANDARIS, *supra* note 74, at 178. This syndrome is perpetuated because the primary emphasis of medical education in the United States is acute illness. Therefore, many physicians have not received any specialized training in the area of geriatric medicine, making the acute hospital the focus of the medical profession. Besides this insufficient training and understanding in geriatrics, physicians may have a personal aversion to having to deal with large numbers of chroni-

needed) prescriptions,[81] and rapid staff turnover particularly common in the nursing home industry.[82] Infrequent physician contact results in patient care being delegated to nursing staff,[83] which may in turn lead to a continuation of medications beyond their clinical usefulness,[84] confusion about dosage levels, and telephone communication errors.[85] Because nursing staff turnover is higher, patients may repeatedly be exposed to undesirable

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cally ill patients, growing out of ego, pride and the desire to "cure" patients. As with any individual, the physician must maintain self-esteem if he/she is to live and work effectively. Thus, where the physician's self-evaluation is grounded in being capable of eliminating pain and restoring health, self-esteem can easily suffer when no clear improvement in the patient can be seen as a result of his/her efforts. No matter how false this rationalization, with its resulting neglect of the patient, many physicians avoid nursing home patients because they feel they are unable to heal them. *Id.* at 177, 178. Other disincentives range from inconvenience from traveling to nursing homes isolated from hospitals, inadequate compensation and uncertainty of payments in the administration of Medicare and Medicaid, to their own frustration at the lack of back-up support available as a result of untrained nursing home personnel. Physicians may also unconsciously wish to avoid the depressing and unpleasant atmosphere in a nursing home, particularly when physicians themselves are approaching nursing home age. *See id.* at 172-78.

81. The extensive drug use among elderly patients is complicated by the number of drugs prescribed on a prn basis. *See supra* note 10. It has been estimated that prn medication use ranges from 3.2 orders to 4.1 orders per patient. Dyer, Oles & Davis, *supra* note 73, at 430. Antipsychotic drugs often are given on a prn basis. One study revealed that 53% of all psychoactive drugs were prescribed on a prn basis. Thus arises the ability of nursing staff to control patients who are inconvenient for the staff. *Id.*

82. Staff turnover is the unavoidable consequence of a high degree of job dissatisfaction. For any number of nursing home staff, working in a setting in which one is routinely both witness and party to a lack of attention to the patient's human needs can become extremely unsettling over a prolonged period of time. Undesirable working conditions as well as unattractive economic compensation often makes labor-force stability under these conditions an impossibility. Rango, *Sounding Boards: Nursing Home Care in The United States*, 307 NEW ENG. J. MED. 883, 887 (1982).

83. This problem is exacerbated by financial constraints which can limit staff levels to the minimum legal requirement. Thus the trained professional staff (i.e., registered nurses and consulting pharmacists) become heavily burdened with administrative duties. Consequently, the least trained personnel may become responsible for patient care. Furthermore, the effect of rapid staff turnover implicates that many of these lower level nursing staff personnel are relatively new in their jobs and to a lesser extent able to handle medication problems. Dyer, Oles & Davis, *supra* note 73, at 429.

84. *Id.* at 430. This can often be attributed to the fact that prn drugs are not used routinely in many cases, so that these orders may continue unnoticed indefinitely. *Id.* Even when antipsychotic drugs have been prescribed for legitimate purposes (i.e., schizophrenia) the lack of review of patient medication needs because of such prn orders may result in overdosage. Since the schizophrenic process is not static, a patient may be functioning at a level which requires less medication. PSYCHIATRIC DRUGS, *supra* note 1, at 25.

85. The opportunity for such an occurrence cannot be underestimated when most medications are prescribed over the telephone. One nursing home administrator testified before the United States Senate Subcommittee on Long-term Care that if it weren't for Alexander Graham Bell, there would be no medicine practiced in the United States long term homes. F. Moss & V. HALAMANDARIS, *supra* note 74, at 182.

side effects.[86]

The Federal government has attempted for almost twenty years to address some of these problems.[87] Concern over drug interactions and medication errors instigated the Department of Health, Education and Welfare (DHEW) to allocate large sums of money toward training programs for pharmacists who could perform clinically-oriented services such as drug therapy monitoring.[88] In 1974, when DHEW promulgated regulations implementing the Social Security Act of 1972, the pharmacist's position in skilled nursing facilities changed from one of an administrator of drug distribution systems to the individual primarily responsible for promoting the rational clinical use of drugs.[89] Although the states retain the right to expand the role of the consultant pharmacist, most have not.[90] Furthermore, in all cases, the physician retains the privilege to reject the pharmacist's recommendations,[91] since the pharmacist has no authority to alter a patient's drug regimen.[92] Apparently, however, given the continuing abuse of drugs, particularly antipsychot-

86. Again this can often be attributed to the widespread use of prn medications contributing to problems of drug reactions and interactions (e.g., when a previously prescribed prn medication produces an undersirable interaction with a recently prescribed drug). Dyer, Oles & Davis, *supra* note 73, at 430.

87. *Id.* at 429.

88. *Id.*

89. In addition to the pharmacist's traditional responsibilities of drug procurement, distribution, and control, the regulations require the pharmacist to monitor each patient's drug therapy at least monthly. *Id.*

90. *Id.* One state that has extended beyond the federal requirement that a pharmacist review drug therapy of all patients monthly is North Carolina. Regulations for the licensure of nursing homes in that state specify that all new orders should be reviewed against existing ones to prevent drug interactions. The pharmacist's monthly check must also involve an examination of the patient's medical record, including physicians' orders and progress notes as well as any nurses notes, results of laboratory procedures, discharge summaries, medical histories, and physical examination reports. *Id.* While such a drug monitoring system is admirable, the fact that North Carolina's standards are built-in to state licensing requirements presents problems associated with enforcement. Attempts at quality assurance by way of licensing has not proved to be an effective tool, because such standards aggravate local problems of access by making needed services even scarcer in a given area. Rango, *supra* note 82, at 887; California Assembly Permanent Subcommittee on Mental Health and Developmental Disabilities, *Improving California's Mental Health System: Policy Findings and Recommendations* 46, 47 (1978) [hereinafter cited as *Policy Findings*].

91. Dyer, Oles & Davis, *supra* note 73, at 429. Studies addressing physician acceptance of pharmacist's recommendations have found at least a 60 percent acceptance. *Id.* at 432.

92. *Id.*

ics,[93] this expanded role of the pharmacist as consultant has not proven sufficient.

In addition to the large number of patients who may be receiving antipsychotic drugs solely for management purposes, the chronic mentally ill may be subjected to negligent or excessive use of this medication simply because nursing homes have traditionally been ill-prepared to handle such patients.[94] Nonetheless, nursing homes suddenly became new depositories for the chronic patient as a result of deinstitutionalization. California is a perfect example of a state's ambitious program to empty state hospitals and place patients in nursing homes and other small community based programs. There were 12,000 aged in California state hospitals in 1959 and by 1974 only 578 remained institutionalized.[95] An unfortunate consequence of moving elderly patients from state hospitals, is that staff at nursing homes merely provide housing and supervision rather than focusing on rehabilitation.[96] In such an environment, there is a substantial likelihood that the sole form of treatment would be drug therapy. The serious psychological problems, with serious interpersonal relationship problems may very well be far more than most untrained nursing staff personnel can manage, especially when they are expected to concurrently manage severe physical disabilities in the same patients. Thus, antipsychotic medication may be negligently administered in excessive amounts as a way for the staff to handle these patients to the best of their ability given their lack of psychiatric training.

Because these wide variety of factors contributing to abusive or negligent use of antipsychotics in nursing homes are interwoven, many of them could be controlled by the physician. If there were more physician contact with patients, the need for such an abundance of prn prescribing should diminish and lessen the potential for overdosing and drug interactions. How-

93. *See supra* note 74.

94. F. Moss & V. HALAMANDARIS, *supra* note 74, at 104.

95. *Id. See id.* at 105 (Table 6-1) demonstrating this national trend in each individual state. A major impetus for the massive transfer from state hospital into the community was the desire to preserve state dollars and replace them with federal dollars. *See supra* note 6.

96. F. Moss & V. HALAMANDARIS, *supra* note 74, at 113. Any individual showing some degree of mental impairment may quickly receive the label of "senility" which may connote to staff that the patient is "hopeless" and can be ignored. *Id.*

ever, too many private physicians treating nursing home patients continue to avoid the nursing homes, making greater physician contact for many patients an impracticality. The monitoring of prescriptions via legislatively imposed regulations would serve to alleviate this misuse of antipsychotic drugs consequent to insufficient physician contact.

2. Board And Care Homes

A large number of persons receiving antipsychotic drugs in board and care homes[97] are also in the private sector.[98] Many of these facilities house large numbers of psychiatric patients including both the deinstitutionalized and new generations of chronically mentally ill.[99] Unlike some nursing homes, board and care homes are for the most part adequate in the sense there is no life-threatening neglect or other gross abuses.[100] Accordingly, any inappropriate use of antipsychotic drugs in this environment most likely has its origin in failing to carefully monitor the individual for adverse reactions or the continuing necessity of

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97. In California, the term "board and care homes" is used to describe a variety of unlocked facilities providing a shared room, three meals a day, dispensing of medication, and minimal staff supervision for residents ranging from one to more than one hundred in number. Lamb, *supra* note 6, at 903.

98. It is important to distinguish, for purposes of this discussion, those residents who are under a private physician's care as opposed to receiving outpatient services from state or county facilities. Outpatient services provide short-term or sustained therapeutic intervention for individuals experiencing acute or ongoing psychiatric distress. Relevant to this discussion, it is mandatory that antipsychotic medication prescribed and dispensed through state hospital outpatient services must also be accompanied by evaluation of side effects and results of medication. CAL. ADMIN. CODE tit. 9, R. 543 (1984). Residents receiving care through outpatient services from county physicians are afforded some form of protection by virtue of the medication monitoring system. *See supra* note 24. Thus this discussion of board and care homes is focused on the potential problems of antipsychotic drug usage in relation to residents under the supervision of private physicians. Board and care homes are required by state law to provide a physician, while county regulations may require an additional psychiatrist, or a physician who is also a psychiatrist (e.g., San Francisco County). Telephone interview with John Riggs, Director of Board and Care Residences, San Francisco (Nov. 14, 1984).

99. Lamb, *supra* note 6, at 903.

100. *Id.* While many enter in the nursing home industry for profit, operators of board and care facilities are most likely operating such a facility out of genuine concern for their residents. Those housing the mentally ill only receive a flat rate of $476.00 per month for each resident, a clear indication that operators, many who have opened their own homes to these individuals, are not managing a board and care home for the money. *Id.* Since there is a great deal of variability in these facilities, any attempts to generalize would clearly be erroneous. Rather this discussion is merely bringing to attention the possibility for negligent use of these drugs given the circumstances.

drug therapy.[101]

By the very nature of a board and care home setting, in that it is only a 24-hour a day nonmedical care and supervision shelter, medications may not be adequately supervised and operators of board and care homes may lack training in observing an individual's response to antipsychotic medication.[102] Often the patient either has to become a behavior problem or develop a very serious, obvious side effect before the board and care operator can detect that the medication needs to be altered.[103] Thus, the prescribing physican's attentiveness is the only reliable means for the monitoring of medication.

The extent to which this responsibility is carried out by private physicians has not been established. Testimony before the California Assembly Subcommittee on Mental Health and Developmental Disabilities revealed that it was common practice for medication to be reviewed only once a month in board and

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101. However, these drugs may also be prescribed to solve management problems within the board and care homes. These drugs can often take on such a function as a result of physicians, family members, and board and care staff fearing potential acts of violence, while failing to distinguish between manifestations of illness and the individual's reaction to frustrations arising from the deprivation of the environment in which he is forced to live (for many, the only alternative would be homelessness) or frustrations from unpleasant and uncontrollable side effects (see *supra* notes 31-69 and accompanying text). Crane, *supra* note 28, at 125; Lamb, *supra* note 6, at 903.

102. PSYCHIATRIC DRUGS, *supra* note 1, at 18. Although this speculation is one directly related to the quality of staff, the chronic mentally ill in board and care homes may be experiencing a drain in resources and personnel as a result of the significantly higher funding available for similar resources for the developmentally disabled. In California, the 1984 rate paid to operators of homes for the developmentally disabled varied from a minimum of $525/month for easily manageable residents to $840/month for "intensive treatment." Since there is only one flat rate of $476/month for the mentally ill, regardless of the severity of the problem and the need for intensive supervision and care, many of the better board and care operators have stopped serving the mentally ill so that they may take advantage of the higher rates for the developmentally disabled. Lamb, *supra* note 6, at 903.

103. *Policy Findings*, *supra* note 90, at 54. Thus, if a person is exhibiting symptoms of akathisia (*see supra* notes 40-41 and accompanying test) which can easily be mistaken as anxiety or agitation, a board and care operator might not think it necessary to notify the home's physician. The emergence of fine abnormal movements associated with tardive dyskinesia (*see supra* notes 44-47 and accompanying text) can also go unnoticed. This may be extremely important because tardive dyskinesia has a better prognosis if recognized early in the onset of the syndrome. Gardos & Cole, *supra* note 42, at 779; Glazer, Moore, Schooler, Brenner, & Morgenstern, *supra* note 44, at 626; Munetz, Roth & Cornes, *supra* note 47, at 77.

care homes.[104] Although it is arguable whether this is sufficient physician contact in cases where the patient has stabilized and the physician is certain that the drug regimen is the most appropriate,[105] newer patients need to be monitored at least bi-weekly, or even weekly, for adverse reactions.[106] Furthermore, the extent to which this medication review entails assessing whether dosages can successfully be lowered or discontinued so as to minimize side effects[107] and ensure against overmedication appears questionable.[108] Consequently, although it would be unfair to generalize about the actual prescribing practices of these physicians, the chronically mentally ill may, nonetheless, be put in the precarious position of enduring unnecessary side effects, with increasing risk of irreversible tardive dyskinesia, if, in fact, physicians fail to continuously monitor and evaluate the appropriateness of treatment.

Assuming that there are chronically mentally ill who do not need antipsychotics or for whom these drugs are harmful rather than helpful, the use of long-acting injectable tranquilizers deserves special attention. Injectable fluphenazine, marketed under the brandname Prolixin Deconoate, provides for maximum control of the patient and psychotic symptoms with minimum contact by the physician.[109] A single injection may be ef-

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104. *Policy Findings, supra* note 90, at 54.

105. This amount of contact may be viewed as insufficient from the standpoint of monitoring patient compliance when these drugs are in fact necessary. It has been estimated that approximately one half of all oral medications prescribed are somehow discarded. J. ROBITSCHER, *supra* note 74, at 360. Likewise, studies have revealed that approximately 50% of those given prescriptions for antipsychotic drugs stop taking them for one or more of the following reasons: 1) side effects, particularly sedation, 2) complexity of regimen, 3) lack of social supervision, and 4) severity of illness (default rates have been shown to be highest in those schizophrenics who are most ill at time of discharge). It has also be reported that there are a small group of patients, most of whom have grandiose delusions, who prefer their psychotic state to drug-induced version of reality. PSYCHIATRIC DRUGS, *supra* note 1, at 18.

106. *Policy Finding, supra* note 90, at 54.

107. Low dosages of antipsychotic medication appears to have a significant advantage in producing fewer early signs of tardive dyskinesia (*see supra* notes 44-57 and accompanying text). *Low-Dose, supra* note 56, at 896; Seeman, *supra* note 44, at 125; Pirodsky, *supra* note 4, at 59. Lower doses also may help alleviate akathisia (*see supra* notes 40-41 and accompanying text). APA, *supra* note 29, at 1164.

108. A study of a representative sample of all board and care residents in California found 39% of the patients were on dosages higher than recommended for outpatient treatment by noted psychopharmacologist Leo Hollister. PSYCHIATRIC DRUGS, *supra* note 1, at 20.

109. Squibb Pharmaceutical Company which markets Prolixin, emphasizes in its ad-

fective in controlling schizophrenic symptoms up to four weeks or longer, and in some patients the response has been found to last as long as six weeks.[110] Thus, this drug serves as the ultimate approach in impersonal treatment, having the potential to deemphasize any psychiatric approach that is based on a long, slow development of a therapist-patient relationship.

The use of Prolixin has been advocated as a method of circumventing dependence on untrained board and care operators to supervise patient compliance.[111] However, it has the tremendous disadvantage of being used to indiscriminately treat patients without emphasis on the patient as an individual. Furthermore, if the patient has a strong adverse reaction to the injection, the patient has to suffer for several weeks because it takes that long to metabolize the medication.[112] The most apparent danger of the Prolixin approach, however, is that because it is cheap and impersonal, and does not require much investment of professional skills, a physician having such limited contact with a patient may maintain that patient on Prolixin long after the need for medication is over.[113]

Antipsychotic medication plays an extremely important role in community based facilities such as board and care homes, for it may be the only form of treatment available.[114] This, however, does not justify its continued use, without attempting to taper

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vertising campaign that the use of Prolixin saves "times, money, and people." J. ROBITSCHER, *supra* note 74, at 362.

110. 38 PHYSICIANS' DESK REFERENCE 1934, 1935 (1984) (package insert for Prolixin Decanoate).

111. J. ROBITSCHER, *supra* note 74, at 360. *See supra* note 105 for a discussion of patient compliance.

112. Whereas other antipsychotic medication only has a 24 hour half-life, a strong reaction can be remedied either by a reduction in dose or discontinuation of the drug. Telephone interview with Dr. Steve Schone, Deputy Director of Clinical Services, Cal. Dept. of Mental Health (Nov. 6, 1984). The side effects of depot (long-acting) fluphenazines may also be more severe than other antipsychotic medication. One study of outpatients on depot injections showed that 45% had signs of Parkinsonism (although they were also receiving antiparkinsonism drugs), 8% had tardive dyskinesia, and 21% suffered from motor restlessness (akathisia). J. ROBITSCHER, *supra* note 74, at 361.

113. J. ROBITSCHER, *supra* note 74, at 362.

114. Community based treatment is effectively contradicted by Medicaid and Medicare provisions which only pay for hospitalization and medications. Thus, for the many board and care residents who are welfare recipients, if no community treatment programs are readily available, the only form of treatment which they can afford is drug therapy, covered by Medicaid (MediCal). Goleman, *'Snakepits,' Jails Are No Answer, and Lawyers Push Alternatives*, L.A. Daily J., April 30, 1984, at 4, col. 3.

medication, when there is even a remote possibility an individual could function without it. Thus, it is important that the physician not only maintain sufficient contact to monitor patients for even the slightest side effects, but approach each individual from the prospective that the lowest possible dosage should be achieved once the patient has stabilized, while periodically attempting to discontinue the medication altogether thereafter. Medication regulation should be able to foster this goal through quality of care monitoring.

Board and care homes and nursing homes are only two isolated environments illustrating that negligent and sometimes abusive use of antipsychotic drugs can occur in the private practice of medicine. However, given the apparent inevitability of these drugs to produce side effects, and their great potential to be inappropriately prescribed, legislative action designed to minimize their misuse in all areas of private medicine is essential.[115] Legislatively imposed regulations concerning the use of antipsychotic drugs would help insure a responsible level of medical and staff practice in administration of these drugs, as well as protect individuals receiving these drugs from needlessly assuming the risk of their side effects. The following analysis will address the propriety of state intervention in the prescribing of antipsychotic drugs, and propose one possible form of legislative action to help remedy the problem of their misuse.

III. ANALYSIS

Regulating the use of antipsychotic drugs in the area of private practice of medicine, will surely trigger an uproar among psychiatrists and other physicians working in the mental health profession, in view of the medical profession's general aversion toward legal intervention in the practice of medicine.[116] Thus, it

115. The inability to ascertain the actual extent these drugs are inappropriately prescribed should not be a barrier to legislative action. The court addressing the reasonableness of externally imposed regulation implemented to deter the misuse of dangerous drugs (i.e., drugs which are addictive) relied on an earlier Supreme Court decision which stated: "[f]rom the beginning of civilized societies, legislators and judges have acted on various unprovable assumptions . . . . Nothing in the Constitution prohibits a state from reaching . . . a conclusion and acting on it legislatively simply because there is no conclusive evidence or empirical data." Whalen v. Roe, 429 U.S. 590, 597, 598, n.21 (1977) (quoting Paris Adult Theatre T. v. Slaton, 413 U.S. 49, 61, 63 (1973)).

116. Although opposition to restrictions would also arise among other individuals

is necessary to evaluate any proposed regulation with respect to the physician's right to practice medicine free from unwarranted state interference.

The state has a profound interest in seeing that medical procedures are performed under circumstances insuring maximum safety for the patient.[117] Regulations of all professions concerned with health is an acknowledged, legitimate function of the state's police power.[118] Thus, the issuance of a state license to practice medicine is not an absolute right to practice medicine free of reasonable restrictions.[119]

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working with the mentally ill, this discussion will be limited to licensed physicians, because they are the persons authorized to write or issue prescriptions. *See* CAL. HEALTH & SAFETY CODE § 11150 (West 1975); CAL. BUS. & PROF. CODE § 4036 (West 1985). If the controversy which is continuing over recognizing that involuntary mental patients have a right to refuse is any indication, unwelcome legal intrusions on the private practice of medicine will be attacked. The American Psychiatric Association, through its council on Psychiatry and Law, recently issued a statement reflecting "serious misgivings" about the *Jamison* standards (*see supra* note 11) stating:

> We believe that a proper approach to the basic question of the right to refuse medication should begin with the recognition that antipsychotic medication has proven to be a highly effective, and often essential treatment for patients who require involuntary psychiatric hospitalization. The proposed guidelines by contrast, reflect a harsh view of the appropriateness of this form of treatment, relegating it instead to 'last resort' status . . . . To approach the question of medication as though it were only a threat to individual liberty seems to us unjustified and misguided.

APA Decries Jamison Standards, 8 MENTAL & PHYSICAL DISABILITY L. REP. 496, 496 (1984). *See generally*, Feldman, *The Legal Restraints on Psychiatric Care*, in LEGAL MEDICINE 1980 221-27 (C. Wecht ed. 1980) and Brooks, *supra* note 2, at 179, 212 for further examples of disapproval of legal intervention in the practice of psychiatry.

117. Roe v. Wade, 410 U.S. 113, 150 (1973); Aden v. Younger, 57 Cal. App. 3d 662, 679, 129 Cal. Rptr. 535, 545 (1976).

118. Barsky v. Bd. of Regents, 347 U.S. 442, 449 (1954). Police power has been defined as the "power inherent in a government to enact laws within Constitutional limits to protect the order, safety, health, morals and general welfare of society." Blinder v. State Dept. of Justice, Div. of Narc. Enforce., 25 Cal. App. 3d 174, 179, 101 Cal. Rptr. 635, 638 (1972) (quoting *In re* Rameriz, 193 Cal. 633, 649-50, 226 P. 914, 921 (1924)). This interest in the public health, safety and welfare has justified the licensing of physicians (CAL. BUS. & PROF. CODE § 2000 et seq.), regulations of conditions within medical treatment facilities (CAL. HEALTH & SAFETY CODE § 1400 et seq., CAL. WELF. & INST. CODE § 11000 et seq.), and regulation of pharmaceuticals (CAL. HEALTH & SAFETY CODE § 1100 et seq.). Aden v. Younger, 57 Cal. App. 3d 662, 674, 129 Cal. Rptr. 535, 542 (1976) (citing these codes as examples of the proper exercise of police power).

119. Blinder v. State, Dept. of Justice, Div. of Narc. Enforce., 25 Cal. App. 3d 174, 182, 101 Cal. Rptr. 635, 640 (1972); *see* Barsky v. Bd. of Regents, 347 U.S. 442, 451 (1954).

Although physicians are granted certain privileges respecting the administration of drugs,[120] this privilege is limited where harm from their use or misuse is readily forseeable.[121] Accordingly, a state's broad police power extends to regulating the administration of such drugs by health professionals.[122]

A state's police power to enact legislation in the areas of health and safety, is not without constitutional limitations.[123] Regulations limiting certain fundamental rights may be justified only by a compelling state interest.[124] Although the right of privacy, founded in the fourteenth amendment's concept of personal liberty and restriction upon state action, has been declared a fundamental right,[125] a physician's right to privacy in his/her practice of medicine is not implicated under this constitutional protection.[126] Therefore, unless legislative regulation infringes

120. Blinder v. State, Dept. of Justice, Div. of Narc. Enforce., 25 Cal. App. 3d 174, 182, 101 Cal. Rptr. 635, 640 (1972).

121. *See* Minnesota *ex rel* Whipple v. Martinson, 256 U.S. 41, 45 (1921) where the court upheld a California statute regulating morphine on the basis that there was no question of authority of the state in the exercise of its police power to regulate the administration, sale, prescription and use of dangerous and habit-forming drugs; Whalen v. Roe, 429 U.S. 589, 603 n.30 (1977) where the court upheld a New York statute regulating dangerous, legitimate drugs (drugs which have both lawful and unlawful market) such as opium and opium derivatives, cocaine, methadone, and amphetamines, requiring all prescriptions for these drugs be made out in triplicate and one copy be forwarded to the state; Blinder v. State, Dept. of Justice, Div. of Narc. Enforce., 25 Cal. App. 3d 174, 181, 101 Cal. Rptr. 635, 639 (1972) where the court upheld California statutes providing for treatment of narcotic addicts as a proper exercise of police power; People v. Privitera, 23 Cal. 3d 679, 709, 591 P.2d 919, 926, Sup., 153 Cal. Rptr. 431, 438 (1979) where the court upheld a California statute making the sale, prescribing or administering of any unapproved drug intended for the alleviation or cure for cancer (e.g., laetrile) a misdemeanor.

122. *See, e.g.,* Minnesota *ex rel* Whipple Martinson, 256 U.S. 41, 45 (1921); Blinder v. State, Dept. of Justice, Div. of Narc. Enforce., 25 Cal. App. 3d 174, 181, 101 Cal. Rptr. 635, 639 (1972); People v. Privitera, 23 Cal. 3d 697, 705, 591 P.2d 919, 923, Sup., 153 Cal. Rptr. 431, 435 (1979).

123. Blinder v. State, Dept. of Justice, Div. of Narc. Enforce., 25 Cal. App. 3d 174, 180, 101 Cal. Rptr. 635, 638 (1972).

124. Roe v. Wade, 410 U.S. 113, 155 (1973).

125. *Id.* at 152-55.

126. Cases which may be characterized as protesting "privacy" have involved two different kinds of interest: 1) an individual interest in avoiding disclosure of personal matters, and 2) an interest in making certain kinds of important decisions. Whalen v. Roe, 429 U.S. 589, 599-600 (1977). An asserted privacy interest involving professional judgment, such as the case in prescribing antipsychotics, is more akin to the second interest. However, the kinds of "important decisions" recognized by the court as falling within this category of right to privacy involve "matters relating to marriage, procreation, contraception, family relationships, and child rearing and education." *Id.* at 600 n.26 (quoting Paul v. Davis, 424 U.S. 693, 713 (1976)). Thus, decisions involving medical treatment are not covered in these kinds of right to privacy cases. People v. Privitera, 23

upon a fundamental right belonging to the patient, the state's justification in interposing its authority on behalf of the public is viewed under the rational basis standard.[127] Furthermore, when danger to health exists, state regulations encroaching upon a patient's right to privacy are also tested under the rational basis standard.[128] In that the state may properly assert a legitimate interest in safeguarding health by maintianing medical standards which insure maximum safety for the patient, the privacy right of the patient cannot be said to be absolute.[129]

Since there is no recognized fundamental right involved in the practice of medicine, and no absolute right to privacy belonging to the patient because of the danger to health antipsychotic drugs present, state regulations on the prescribing of antipsychotic drugs will be considered under a rational basis standard. The patient's right to privacy, however, will also be addressed to determine the extent such regulations may properly be asserted by the state in conflict with this right.

In applying the rational basis test, the courts have inquired (1) whether the interests of the public require such interference; and (2) whether the means used would be reasonably necessary for the accomplishment of that purpose, taking into consideration whether these means are unduly oppressive upon individuals.[130]

The state has a legitimate interest in maintaining medical standards so as to reduce negligent and abusive use of antipsy-

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Cal. 3d 697, 702, 591 P.2d 919, 922, Sup., 153 Cal. Rptr. 431, 434 (1979). Furthermore, any right to privacy physicians have in the doctor-patient relationship is derivative from, and therefore no stronger than, the patient's. Whalen, 429 U.S. at 604. *See infra* notes 128, 129 and accompanying text for a discussion of the patient's right to privacy.

127. People v. Privitera, 24 Cal. 3d 697, 703, 592 P.2d 919, 922, Sup., 153 Cal. Rptr. 431, 434 (1979).

128. Roe v. Wade, 410 U.S. 113, 163 (1973); People v. Privitera, 23 Cal. 3d 697, 703, 591 P.2d 919, 922, Sup., 153 Cal. Rptr. 431, 434 (1979).

129. Roe v. Wade, 410 U.S. 113, 153-54 (1973). Although the court held the decision to have an abortion falls within the right to privacy, the court also acknowledged state regulations in areas protected by that right were appropriate. Accordingly, a woman's decision whether to terminate her pregnancy were limited by State regulations requiring abortions be performed at licensed institutions, and by licensed physicians. *Id.* at 163-65. The State's legitimate interest in the health of the mother also limited her right to terminate her pregnancy only to the end of the first trimester of the pregnancy. *Id.* at 163.

130. Blinder v. State, Dept. of Justice, Div. of Narc. Enforce., 25 Cal. App. 3d 174, 179, 101 Cal. Rptr. 635, 638-39 (quoting Lawson v. Steel, 152 U.S. 133, 137 (1894)).

chotic medication and to minimize the number of patients exposed to the inherent risks of these drugs,[131] regardless of whether such practices are occurring in the public or private sector of medicine. Consequently, the interests of the public require that the state exercise its police power to protect the health and safety of its citizens.[132] Implementing some form of prescription regulations to establish medication guidelines, would undoubtedly have a reasonable relationship to the achievement of this state interest, because such regulations could reasonably be expected to have a deterrent effect upon inappropriate medication practices. However, before assessing the oppressiveness of state regulation and the nature of the patient's privacy right involved, it is necessary to first propose a working model of a legislatively imposed system regulating prescriptions at antipsychotic drugs.

One possible way for the state to attempt some form of regulation regarding the prescribing of antipsychotics is to develop regional computerized drug ordering systems which establishes and maintains drug records for each patient prescribed antipsychotic drugs. Under this system, the physician would be required to send a copy of a standarized prescription form to the state for every prescription of antipsychotic drugs. Thus, the state would have access to the necessary data to determine and regulate the use of these drugs. Several authors[133] have proposed such a computerized drug ordering system in which active and historic drug information, including drug name, dosage per administration, frequency, physician name, and cancellation information could be stored in each patient's computer record. Built into this drug ordering system would be a core drug formulary of clinical guidelines for antipsychotic drug prescriptions, so that when each new drug order for a patient is entered into the computer, it is automatically reviewed against these guidelines scanning all other active drug orders and relevant information about the patient (which would be required by the physicians to provide either on the initial prescription form at the onset of drug treatment or on continuing prescription forms). Thus, the medication review system could check for inappropriate combinations of drugs, and inappropriate dose levels (doses generally above or

131. For a discussion of inherent risks *see supra* notes 33-64 and accompanying text.
132. *See supra* note 118 and accompanying text.
133. Laska, Siegel & Simpson, *supra* note 19.

below a clinically acceptable range, and dose ranges for specific patient subgroups [e.g., children, adults, or elderly patients]). Those orders that are considered exceptions to guidelines, would generate exception reports. These exception reports, created by the computer, would then be sent back to the prescribing physician, indicating a justification report is necessary before prescriptions will be continued to be filled as originally prescribed (the physician's justification could accompany the original prescription form to avoid this step). These justifications may then be added to the patient's computer record. Once such a system appears workable, other areas of drug prescribing could be added to the system (i.e., extended drug exposure without an indication that attempts have been made to reduce dosage, and evaluation of side effects).[134]

Although such a system would in no way guarantee against continuing misuse of these drugs,[135] it does alert the physician to possibly inappropriate drug regimens. Assuming that most physicians overprescribe these drugs without any bad intentions, such a computerized drug-review system would be invaluable as a clinical tool enabling periodic review of a patient's complete drug history. Also the mere fact that a physician knows he must account for his prescriptions by way of reply to exception reports, will help reduce inappropriate drug practices.[136]

The implementation of such a computerized drug review system as a form of regulation does not appear to be unduly oppressive to physicians.[137] In so far as regulations serve only to

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134. *See id.* for further detail on how such an automated review system is organized and procedurally utilized.

135. As with any type of external regulation, the possiblity always exists there will be those physicians and psychiatrists who may attempt to circumvent the regulation. One sociologist has observed: "Most rules are easily subverted in practice; when regulations are imposed, efforts are often devoted to meeting their bureaucratic requirements without major impact on behavior; and the proliferation of regulation itself adversely affects morale and practice." Brooks, *supra* note 2, at 213.

136. *See supra* note 24 indicating that the California county quality assurance system which monitors a random 10% of the physician's caseload has proven sufficient in deterring inappropriate medication because the physician knows he/she is being monitored.

137. However, from the viewpoint of staff who have strongly relied on these drugs in managing large numbers of patients in understaffed facilities, regulations limiting their ability to overmedicate patients may be unduly oppressive. However, staff convenience is beyond the legitimate use of these drugs, and thus such an argument is without merit.

prescribe excessive or other inappropriate prescribing, a physician's ability to practice medicine in accord with professional standards would not be impaired.[138] Furthermore, regulatory schema would necessarily be designed to allow for justifiable exceptions.[139] Therefore, at most, such regulations should entail no more than administrative paperwork which would not be considered unduly burdensome.[140] Consequently, regulating the prescription of antipsychotics would be a justifiable restriction on the right to practice medicine, given the rational basis test enumerated above has been satisfied.

Regulations requiring physicians to disclose certain information to the state about patients receiving antipsychotic drugs does not automatically entail an impermissible violation of the individual patient's right to privacy. Although these disclosures may reflect unfavorably on the character of the patient,[141] such disclosures of private medical information would be indistinguishable from existing "invasions" of privacy associated with

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138. However, it can be argued that the passive, timid, and unsure physician may blindly conform to all guidelines, so as to avoid any entanglements with the authorities. Thus, such a drug ordering system may promote practicing medicine by the rules, rather than appropriately individualizing treatment to best meet the patient's needs. Laska, Siegel & Simpson, *supra* note 19, at 827. Although this may be a possible problem, the physician is free, nonetheless, to act in accordance with his/her professional experience and training, by virtue deviations from imposed guidelines only has to be justified. *See infra* note 148 and accompanying text concerning justifiable exceptions.

Not only does each individual's physiology determine the specific pharmacological effects on antipsychotic drugs, but numerous "non specific" factors also play an important role in their therapeutic effects. These include the race, age, and sex of the patient; the intellectual, emotional, and psychodynamic aspects of the patient's personality; the patient's attitudes and expectations about treatmnt, as well as the treating staff or physician, and the therapeutic setting. Cole, *supra* note 26, at 57. Thus, taking into consideration these differing physiological and "non specific" factors, justifiable exceptions to the guidelines are inevitable, and are to be expected.

139. *See supra* note 133 and accompanying text.

140. *See* Blinder v. State, Dept. of Justice, Div. of Narc. Enforce., 25 Cal. App. 3d 174, 180-81, 101 Cal. Rptr. 635, 639-40 where the court held that statutes regulating the treatment of narcotic addicts were not unduly oppressive although they restricted the amount of methadone which may be given and limited locations where treatment could be administered.

141. A previous or existing diagnosis of "mental illness" unquestionably has a stigmatizing effect making an individual who has received, or is receiving antipsychotic drugs, extremely vulnerable in our society. Such an individual may be reproached and treated with caution, unnecessary concern, or avoidance by many employers or other people in interpersonal situations. *See generally*, J. ROBITSCHER, *supra* note 74, at 230-42 for a discussion of the stigmatization and discrimination as the result of being diagnosed "mentally ill."

many facets of health care.[142]

As mentioned above, when there exists a danger to health, the state's legitimate interest in the health and safety of its citizens "supercedes" the privacy right of the individual patient.[143] Therefore, state regulations enacted to protect the safety, health and welfare of society are only required to bear a reasonable relationship to the accomplishment of that purpose.

Nonetheless, legislative enactments and administrative procedures implementing a drug monitoring system could safeguard against unwarranted public disclosures.[144] Such protective measures would help insure that information disclosed by physicians is available only to a small number of public health officials with a legitimate interest in the information for protection of the community from apparent abuse and negligent misuse of antipsychotic drugs.[145]

Opponents to regulating the prescribing of antipsychotic drugs may assert that patients in the private realm of medicine have voluntarily given their informed consent to such treat-

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142. Disclosure of private information to other doctors, hospital personnel, insurance companies, and to public health agencies is a common occurrence in modern medical practice. Whalen v. Roe, 429 U.S. 589, 602 (1977). Examples of existing statutory reporting requirements are those relating to venereal disease, child abuse, injuries caused by deadly weapons, certifications of fetal death, and treatment of narcotic addicts. *Id.* at n.29. *See* CAL. HEALTH & SAFETY CODE §§ 11215-11221 (West 1975 & Supp. 1984) for statutory requirements concerning treatment for addiction.

143. *See supra* note 29 and accompanying text.

144. Public disclosure of any patient information could be prohibited by a statute with accompanying penalties for violations sufficient to deter any health department employee from failing, either deliberately or negligently, to maintain proper security. The legislature could also consider the need to enumerate the extent of physician-patient evidentiary privileges to protect stored data from being offered into evidence in any judicial proceedings involving a patient or a doctor. *See* Whalen v. Roe, 429 U.S. 589, 600-02 (1977) for further discussion on preventing public disclosure of patient information.

145. Arguably, there will always exist a threat to privacy implicit in the accumulation of personal information in computerized data banks or other government files. The collection of taxes, distribution of welfare and social security benefits, supervision of public health, and information kept by the Armed Forces are just a few examples of personal information in computerized data banks which is potentially embarassing or harmful if disclosed. *Id.* at 605. However, proper security measures in the utilization of such computerized systems have been held to be sufficient in guarding against an invasion of the constitutionally protected right to privacy, provided that a legitimate state interest exists to justify the disclosure of private medical information. *Id.* at 606. Aden v. Younger, 57 Cal. App. 3d 662, 683, 129 Cal. Rptr. 535, 549 (1976).

ment,[146] and thus if medication is being inappropriately prescribed, the professional tort doctrine of malpractice is available. This conclusion, however, is based on erroneous assumptions. The first being the extent to which this consent is in fact voluntary.

Individuals with psychosis (e.g., schizophrenia) often exhibit psychotic behavior periodically, rather than continuously.[147] Patients who may fear "going crazy" or who are experiencing delusions, hallucinations, overbearing irrational fears, or who are obsessed with the idea that they are about to decompensate and do some injury, are greatful for anything that can relieve these frightening symptoms. It is under these circumstances a patient consents, arguably unable to contemplate which is worse, the illness itself or the side effects of the medication.[148] Furthermore, patients who do not want these medications may be pressured into taking medications for fear of having to return to the hospital.[149] In the case of board and care residents, admission into these facilities is often contingent upon continuing the residents' drug regimens.[150] Elderly nursing home patients are often so institutionalized,[151] that they are even less apt to refuse their medication.[152] Thus, to consider the consent "voluntary" is somewhat misleading.

A second erroneous assumption is the availability of a suc-

146. For purposes of this discussion it will be assumed that the patient has been fully informed of all potential side effects.

147. L. SEIDEN & L. DYKSTRA, *supra* note 3, at 198.

148. Brooks, *supra* note 2, at 191.

149. Some patients are discharged from the hospital or are treated initially as outpatients on the contingency that they will continue their medication. Failure to show up for medication (i.e., fluphenazine injection) on the appointed day, can result in being returned to the hospital. Therefore, the threat of rehospitalization can pressure a person into taking his medication. J. ROBITSCHER, *supra* note 74, at 91.

150. Telephone interview with Mal Branstein, Chairman of Residential Services Committee of Northern California Psych. Society (Nov. 16, 1984). Although board and care operators are not allowed to evict a person for refusing to take his or her medication, they do interview prospective boarders, having complete discretion to turn away any individual they fear may not comply with their medication regimen. *Id.*

151. *See supra* note 26 for discussion of the syndrome of institutionalism.

152. It is also important to consider that the emotion and cognitive dampening, and apathy induced by these drugs (see *supra* notes 65-68 and accompanying text) may limit *any* chronic patient's ability to later determine on one's own to discontinue drug therapy, choosing to go against a psychiatrist's or physician's judgment, particularly when that individual has grown to respect and trust the physician.

cessful malpractice suit. Malpractice may be difficult to prove except in grossly negligent situations[153] due to problems of causation[154] and the fact that side effects occur even if medication is responsibly and competently prescribed.[155] Most importantly, however, malpractice recovery is only a remedy, offering no preventive protection[156] and entirely incapable of making the afflicted plaintiff truly "whole."

One final and important consideration in support of legislatively imposed regulations, is the distinguishing ability of antipsychotic drugs to alter the thinking process, personality, and behavior patterns of the patient, as opposed to other prescription drugs having adverse side effects if misprescribed. Therefore, conceivably surpassing the degree of the state's interest in limiting the number of individuals risking irreverisble neurological injury, which can occur without warning and without regard to length of drug exposure,[157] is the state's interest in protecting patients from unwarranted intrusions into their mental processess.[158] Unlike other areas of medical treatment utilizing medications which may inadvertently alter or reduce the function of one organ or another to improve its effectiveness,[159] the therapeutic aim of antipsychotic drugs is to alter brain function, proportionately reducing the individual's capacity to function as a person by blunting emotions, deadening memory and the ability

153. *See* Clites v. State of Iowa, 322 N.W.2d 917 (Ct. App., Iowa 1982) and Faigenbaum v. Oakland Medical Center, No. 79-904-736 (Wayne County Cir. Ct. N.M., July 27, 1982). In both cases there was a failure to diagnose the plaintiff's severe tardive dyskinesia, and antipsychotic treatment was continued without the patient's or family's consent. *See* Wettstein & Appelbaum, *Legal Liability for Tardive Dyskinesia*, 35 HOSPITAL & COMMUNITY PSYCHIATRY, 992-93 (1984) for a discussion of these two cases.

154. *E.g.*, since the typical development of tardive dyskinesia occurs after treatment with antipsychotic medication over an extended period of time, oftentimes a patient in the community has been treated by several different physicians in different facilities, making it difficult to hold any specific physician responsible. Wettstein & Applebaum, *supra* note 153, at 993. *See also supra* note 71 concerning the difficulty of the expert physician to offer definite conclusions.

155. *See supra* note 13.

156. Although litigation, in theory, should provide an incentive to physicians to comply with sound clinical practices, the fact that the irreversible damage of tardive dyskinesia typically occurs over an extended period of time during which the patient has been prescribed these drugs by perhaps several physicians, dissipates such an incentive. *Id.*.

157. *See supra* notes 13 and 48-50.

158. Aden v. Younger, 57 Cal. App. 3d 662, 678, 129 Cal. Rptr. 435, 545-46 (1976).

159. *E.g.*, some cardiac medications weaken the heart muscle so as to prevent arrhythmias. P. BREGGIN, *supra* note 2, at 159.

to reason, and diminishing motivation.[160] The individual becomes less able to think and feel, deprived of the power to control one's mind. In this respect, antipsychotic drugs lack a meaningful distinction from psychosurgery and electroconvulsive therapy (ECT).[161] California has acknowledged that the constitutionally protected right to privacy clearly includes privacy of the mind, as well as the essential right to be free in the exercise of one's own thoughts.[162] Accordingly, California has regulated conditions under which psychosurgery and shock treatment can be performed, requiring that all other treatments must be exhausted and that such treatment is critically needed.[163] Although these forms of treatment are administered less frequently and considered more controversial than antipsychotic drugs,[164] the fundamental rights of patients do not cease to exist because drug therapy has become such an established mode of treatment within the field of psychiatry. Neither do these rights cease the moment a patient "voluntarily" consents.[165] Any patient needlessly receiving these drugs, whether it be the consequence of a physician's failure to monitor the continuing necessity of treatment or abusive administration for management purposes, is divested of perhaps the most sacred privileges in our society-freedom of thought and expression of individuality.

IV. CONCLUSIONS

The state has a profound interest in preventing unnecessary

160. *See supra* notes 65-68 and accompanying text.

161. Whereas the danger of psychosurgery, and to some extent ECT, revolves around such treatment's irreversible alteration of the brain, similar chemically induced effects of antipsychotic drugs remain only as long as treatment is continued. However, the chronic individual maintained on antipsychotic drugs beyond their clinical usefulness is in reality experiencing the same deprivation of self-awareness and self-determination. *See* Aden v. Younger, 57 Cal. App. 3d 662, 671-72, 129 Cal. Rptr. 535, 541 for a discussion of the hazards of psychosurgery and ECT.

162. *Id.* at 679, 129 Cal. Rptr. at 546.

163. *See* CAL. WELF. & INST. CODE §§ 5000-5404.1 (West 1975). Although the court held that the terminology "critically needed" was an unconstitutionally vague criterion, the probable legislative intent was interpreted as requiring a "compelling need for these forms of treatment beyond the mere existence of a behavioral or mental disorder." Aden v. Younger, 57 Cal. App. 3d 662, 678, 129 Cal. Rptr. 535, 545 (1976).

164. Aden v. Younger, 57 Cal. App. 3d 662, 680, 129 Cal. Rptr. 535, 547 (1976).

165. *See id.* at 683, 129 Cal. Rptr. at 548-49 where the court addressed the intrusive and hazardous nature of psychosurgery, holding that substantive review of the treating physician was constitutional although the patient had voluntarily consented to the surgery.

administration of hazardous and intrusive treatment.[166] Antipsychotic drugs, clearly both hazardous[167] and intrusive,[168] are frequently prescribed for other than their legitimate medical use, or without clinical necessity. Although only nursing homes and board and care homes have specifically been addressed, there is reason to suspect this is a health concern in private hospitals and institutions as well, given widespread use of these drugs within the medical profession.[169] Properly drafted legislative regulation of the prescription of antipsychotic drugs enforcing compliance with clinically approved guidelines would allow the continued use of this treatment when appropriate, while curbing their negligent misuse and abuse.

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166. Aden v. Younger, 57 Cal. App. 3d 662, 680-81, 129 Cal. Rptr. 535, 547 (1976).

167. *See supra* notes 44-64 and accompanying text.

168. *See supra* notes 65-69 and accompanying text. These drugs are intrusive in that they can change thinking processes, personality, and behavior patterns whether the patient given these drugs likes it or not.

169. *See supra* notes 3, 20 and 23.

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