

PSYCHOPHARMACOTHERAPY IN SOUTH AUSTRALIA

There is a pleasure sure
In being mad, which none but madmen know.

Dryden, *The Spanish Friar*, II, i.

Since 1952, modes of treatment of mental health patients have changed radically. In that year, the new synthetic neuroleptic compound named chlorpromazine was first applied to a manic patient.¹ This marked the advent of a new era in curative techniques applicable to psychotic and schizophrenic patients, an era in which the more crude, primitive and directly physical psychotherapeutic methods would be phased out and in which psychiatric institutions would cease to resemble prisons and would assume the physical trappings of ordinary hospitals. Thenceforth, the majority of persons diagnosed as mentally ill would remain in the community receiving outpatient care in lieu of intensive institutional care, without hampering their rehabilitation and without putting their own safety or that of others in jeopardy. In addition, those detained in institutions became more amenable to the interpersonal psychotherapies.

The use of psychoactive drugs devised since 1952 has, however, generated a number of medico-legal problems which, it is hoped to show, are sufficiently serious to warrant intervention by the legislature with a view to a more precise regulation of the administration of certain psychoactive drugs to the mentally ill. As will be seen, the prescription for institutionalised mentally ill persons of psychopharmaceuticals lawfully marketed in the State is not directly regulated by State statute and is controllable unsatisfactorily by common law remedies.² This is explicable in historical terms; traditionally, statutory law has regulated the affairs of the mentally ill at two levels only: first, their admission into and discharge from institutions has been provided for; secondly, provision has been made for the vicarious management of the property of those of unsound mind. In recent times, statutory controls have become more thorough but have not, with the exception of two modes of treatment, extended so as to regulate the therapeutic discretion of psychiatrists.

In 1977, the Parliament enacted the Mental Health Act 1976-1977 (S.A.)³ which took effect on 1 October 1979. The Act repealed the Mental Health Act 1939-1974 with the exception of those parts dealing with "criminal mental defectives" (Part III) and with the administration of the estates of the mentally ill and the mentally handicapped, which underwent minor amendments. In many respects, the Act is a progressive measure. Crown servants charged with administering the Act are required to exercise their statutory responsibilities to ensure that patients receive the best possible treatment and are required to minimise restrictions upon the liberty of patients and interference with their rights, dignity and self-respect, so far as is consistent with the proper protection and care of the patients themselves and with protection of the public.⁴ The Act requires that, as soon as possible after admission, all involuntary patients

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1. R. Byck, "Drugs and the Treatment of Psychiatric Disorders," in L.S. Goodman and A. Gilman, *The Pharmacological Basis of Therapeutics* (5th ed., MacMillan, N.Y., 1975), 152, 153, 157.
2. The prescription of pharmaceuticals is indirectly controlled by the National Health Act 1953-1978 (Cth.) Part VII and by the National Health (Pharmaceutical Benefits) Regulations.
3. No. 24 of 1977, hereinafter called "the Act". An amending Act was passed in 1979 (no. 21).
4. S.9(a), (b).

be supplied with a statement of their legal rights.⁵ Detention orders are to be regularly reviewed.⁶ Legal representation must be made available to detained patients in proceedings before the Mental Health Tribunal and the Supreme Court unless declined by the patient.⁷ More significantly the Act restricts the use of psychosurgery and electro-convulsive therapy in relation to civilly detained patients⁸; in this respect, the Act is without precedent in Australia. Never before, in this country, have statutory restrictions been imposed on the therapeutic treatment of the mentally ill. Yet, among the more important shortcomings of the Act⁹ is its failure to regulate the use on mental patients of neuroleptic drugs. These pharmaceuticals are not as drastic in immediate effect as psychosurgery or ECT but many are both potentially dangerous and susceptible of abuse and their widespread use has provoked concern in many quarters.

It is proposed in this article to describe, albeit briefly, the classes of psychoactive chemicals used in South Australian mental institutions; special attention will be paid to those pharmaceuticals which are known or thought to induce grave side effects. There follows a discussion of the legal duties owed to mental health patients by psychiatrists and hospitals in relation to the prescription and administration of drugs and of the potential liability, civil and criminal, incurred by those who, innocently or otherwise, cause the administration of a deleterious drug to a patient. In conclusion, it will be submitted that civil remedies and criminal sanctions attaching to the administration of dangerous pharmaceuticals to the mentally ill are of little practical value to patients and that a system of *a priori* controls on the use of drugs in mental health institutions — a system which allows more participation and self determination by those patients not so irrational as to be incapable of enjoying it — is both practicable and necessary. Some preliminary observations on the subject of behaviour modification and techniques of drug therapy are necessary to put the matter in context.

Psychopharmacotherapy

Psychopharmacotherapy is the administration of a psychoactive pharmaceutical with a view to the modification of the behaviour of a mentally ill person either

- (a) directly (in cases where the mental illness is attributable to a specific biochemical imbalance in the central nervous system) by restoring that system to balance or
- (b) indirectly (in cases where the illness is exogenous or reactive) by creating conditions in which the patient may become responsive to a non-organic therapy such as psychoanalysis.

The psychoactive drugs can "cure" a mental illness (as opposed to suppressing its symptoms) only to the extent that it has an organic or chemical origin and manifests itself in behaviour. What orthodox psychiatric principles imply in the concept of "cure" is simply that the patient's behaviour, as opposed to his unexpressed or unactualised feelings about himself, is made more conso-

5. S.16(1)(a).

6. S.35(1).

7. S.39.

8. S.19. These two therapeutic techniques are now prohibited outright or subject to conditions in most jurisdictions in the United States of America: see R. Plotkin, "Limiting the Therapeutic Orgy," (1977) 72 *N.W. Univ. L. Rev.* 461, *Appendix*.

9. The Act is an incomplete and unsatisfactory measure in two other respects: it does not provide for a more constructive code of treatment for the criminally detained and it ignores the whole question of the treatment of mentally ill children.

nant with societal norms, with a consequent reduction in the stresses between the subject and his milieu. There is by no means unanimity among psychiatrists that mental illness of any kind can be cured by drugs, just as there is no consensus as to the nature of mental illness. There are at least six widely endorsed "models of madness" all of which may have some validity but none of which is universally accepted; of these models, only two acknowledge the utility of drug therapy¹⁰.

Techniques of behaviour modification are divisible into two classes, according as whether they do or do not produce a direct and deliberate alteration in the physical structure, dynamic functioning or chemical processes of the body. Those techniques which involve no organic modification of the patient — these include psychotherapy, hydrotherapy, milieu therapy, respondent-conditioning and operant conditioning — are relatively safe for the patient. On the other hand, those modes of behaviour modification which do involve physical interference with bodily processes are invariably attended by some risks to the subject; included here are carbon dioxide therapy, continuous sleep therapy, ECT, insulin therapy, electronic brain stimulation, psychosurgery and psychopharmacotherapy. Of these, it is claimed that neither carbon dioxide therapy nor insulin therapy is ever used in South Australian psychiatric institutions and that continuous sleep therapy is very rarely used here. Equally, there is no evidence that electronic brain stimulation has ever been used in a psychiatric institution in Australia. On the other hand, many lobotomies have been performed in Australia, mainly in New South Wales;¹¹ it is claimed that none has been performed in South Australia. As to ECT, it is believed that its use in this State is declining; it is however standard practice at psychiatric institutions in this State to subject all incoming patients diagnosed as suffering from suicidal depression and hypomania to shock therapy.

The standard mode of long-term treatment of mental illness in South Australian mental institutions is drug therapy, in conjunction with interpersonal programs and interview techniques. The extensive use of psychoactive pharmaceuticals here, as elsewhere, is attributable to a number of factors of which the following are the most significant:

- (i) drug therapy has contributed to a marked reduction in the numbers of persons institutionalised and the duration of institutionalisation¹²;
- (ii) drugs may be self-administered by patients, outside institutions;
- (iii) the vast numbers of drugs available encourage experimentation in the ordinary course of the practice of health care;
- (iv) some drugs (such as the sedatives and anxiolytics) are capable of providing immediate relief, inwardly or outwardly, and work very quickly in suppressing symptoms;
- (v) within institutions, drugs are more easily and cheaply used than other forms of behaviour modification and, by reducing demands

10. R. Slovenko, *Psychiatry and the Law* (Boston, Little Brown & Co., 1973), 409.

11. *Proceedings of the University of Sydney Institute of Criminology*, No. 34, *Rights of the Mentally Ill*, (1978), and No. 22, *Proposed Amendments to the Mental Health Act* (1975), 135.

12. It has been claimed that in the United States psychotic patients, treated as a single class, are now hospitalised for periods one third the duration of the average hospitalisation period obtaining in 1955: R.M. Julien, *A Primer of Drug Action* (Freeman, San Francisco, 1975) 124; S.H. Snyder, *Madness and the Brain* (McGraw Hill, N.Y., 1974), 19-20.

on personnel, serve institutional needs for orderly and efficient administration;

(vi) within limits, the effects of drug administration are predictable.¹³

For present purposes, a drug may be taken to mean any manufactured or synthesised article introduced into the human body, with the intention of being assimilated thereby, for the purpose of (1) affecting, correcting, restoring or modifying the operation or behaviour of the organs of the body or that part of its function called the mind, or (2) treating, mitigating, preventing or diagnosing a disease or its symptoms.¹⁴

The techniques of drug-therapy and the applications of the psychoactive drugs are too numerous to be listed in full; they vary from the most crude and simple, including the injection of urine into the blood streams of school children by school authorities,¹⁵ through the self-administration of anxiolytic, anti-depressant, sedative, amphetamine, psychedelic and hallucinogenic drugs, to the application of the antipsychotic drugs, the most powerful psychoactive agents. There are several different strategies of drug therapy. Psychopharmacotherapy, which has already been defined, means (in its strict sense) the use of drugs which directly alter the operation of the central nervous system and thereby the behaviour of the individual; but it encompasses unorthodox drug strategies such as aversive therapy and paralytic therapy, which will be alluded to later.

The Psychoactive Therapeutic Drugs

There are over 230 different pharmaceuticals presently available in North America and in Europe for the treatment of mental and emotional disorders; a slightly smaller number is marketed in Australia. For the purposes of discussion, the psychoactive drugs may be divided into five groups:

1. *The Anxiolytic Drugs:*

These are the minor tranquillisers; as a group, they are utilised to relieve depression, agitation, mild psychosis (manic or other), psychoneurosis and mild schizophrenia. They are the most frequently prescribed therapeutic agents.¹⁶ The anxiolytic drugs include meprobamate (sold under the labels Equanil and Mepron), chlordiazepoxide (librium), diazepam (ducene and valium), oxazepam (Adumbran and Serepax), hydroxyzine (atarax) and a newer drug called bromazepam which is claimed to effect an abatement of phobic syndromes. The diazepam group of drugs has a low acute toxicity and poses a low suicide risk but can cause delirium and confusion in older patients. Prolonged use of these drugs entails side effects: it is widely believed that meprobamate and valium are habituating and that librium induces slurred speech when used on a long-term basis.¹⁷ While valium and librium are exten-

13. I. Ladimer, "Rational Psychopharmacotherapy and Judicial Interpretation of the Right to Treatment," in F. Ayd, ed., *Rational Psychopharmacotherapy and the Right to Treatment* (Baltimore, Waverley Press, Inc., Ayd Medical Communications Ltd., 1975), 79.

14. See D.A. Kay, *The International Regulation of Pharmaceutical Drugs* (West, Washington, 1976), 77.

15. This occurred in Florida: see R. Martin, *Challenges to Behaviour Modification* (Res. Press, 1975), 37-38.

16. Byck, *supra*, n. 1, 187.

17. *Id.*, 191. See also *Mims Annual* (4th ed.) (1980), Aust. ed. (International Medical Statistics (A/Asia) Pty. Ltd., Sydney), 4.22-4.29. There are recent reports that even the diazepamoxides cause withdrawal symptoms.

sively used in Australia, the extent of the administration of meprobamate in South Australia is not known.¹⁸

2. Anti-Depressants:

These drugs are divisible into two classes, the *thymoleptics* (which elevate mood) and the *thymeretics* (also known as monoamine oxidase inhibitors, which disinhibit and energise). Drugs of the latter class are discussed more fully below. The thymoleptics include imipramine (tofranil), desipramine (norpromin), and trimepramine (surmontil); they are regarded as relatively safe for adults although they may be particularly toxic when taken by children. Short term adverse reactions in adults are claimed to be metallic taste in the mouth, perspiration, tremors, jerky leg movements (especially during sleep), inhibition of ejaculation, blurred vision, dizziness, insomnia and nausea.¹⁹

3. Sedatives and hypnotics:

Very large numbers of drugs are commonly described as sedatives and hypnotics. Drugs of this kind, which depress the perceptive centres and the cerebral cortex and thereby induce a feeling of tranquillity and sleep, are most usually barbiturates. Repeated and continuous use of barbiturates against insomnia may lead to habituation; sustained use at large dosages over a long period may result in impaired mental activity, restlessness, double vision, unsteady gait and rashes. In addition, these drugs are frequently used in suicide attempts. On withdrawal, convulsions may occur.²⁰ The use of barbiturates in psychiatric practice is declining.

4. Amphetamines:

These chemicals stimulate the cerebral cortex and are often self administered to relieve fatigue and to induce euphoria. Side effects of long-term consumption are claimed to include paranoid psychosis and necrotising angitis (that is to say, inflammation of blood vessels).²¹

5. Neuroleptic Drugs:

These are non-hypnotic sedatives claimed to be effective in curing psychosis and schizophrenia. As a group, they inhibit conditioned reflexes, reduce psychomotor activity and provoke emotional apathy and affective indifference, without diminishing consciousness. At the clinical level, the clear-cut pharmacological distinction between neuroleptics and tranquillizers does not hold good, although the two groups of drugs do stand apart insofar as the tranquillizers possess no anti-psychotic power and have no noticeable effect on schizophrenic thought disturbances, hallucinations and delusions.²² Func-

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18. Meprobamate has been phased out of use at Glenside Hospital because it was found to be ineffective but is believed still to be prescribed by private practitioners to non-institutionalised patients. By far, it is the most dangerous of the anxiolytic drugs; apart from its capacity to induce tolerance and physical and psychological dependence, it may precipitate convulsions, coma, psychotic behaviour and death on withdrawal; it has been claimed to cause defects to babies if administered to pregnant mothers in the first six weeks of pregnancy: Julien, *supra*, n. 12, 56-58; R.M. Patterson, ed., *Malpractice and Product Liability Actions Involving Drugs* (Smith, Allen, 1976), 172; *Mims Annual*, *supra*, n. 17, 4.24; L. Hollister, "Interactions of Psychotherapeutic Drugs," in M.A. Lipton & Ors., *Psychopharmacology: A Generation of Progress* (Raven Press, N.Y., 1978) 987, 991; Byck, *supra*, n. 1, 188-189.
 19. W. Poldinger, *Compendium of Psychopharmacotherapy* (Basle, La Roche, 1967), 116.
 20. Julien, *supra*, n. 12, 38 and Chapter Three. One widely used barbiturate is sodium pentobarbital, or carbromal; infrequently, this drug (which is said no longer to be administered at Glenside) induces anxiety neurosis and psychic dependence leading to compulsive self-administration and abuse. It should not, as a matter of prudence, be made available in large quantities to patients with suicidal tendencies. The drug was the subject of litigation in *Ruyon v. Reid* 510 P. 2d. 943 (1973).
 21. If untreated, this condition can cause death within five years of onset: W.W. Wells, "Drug Control of School Children," (1973) 46 *S.C.L. Rev.* 585, 596-597.
 22. Poldinger, *supra*, n. 19, 73.

tionally and chemically, the neuroleptic drugs may be divided into two main classes:

(A) *Anti-depressants*

(1) *Monoamine Oxidase Inhibitors*: these chemicals are claimed to operate to alleviate depression by increasing the electrical activity within the brain;²³ their efficacy, even in treating depression, has been limited since they became available for clinical use in 1957. Their usage in therapy has decreased because they are less effective clinically than the tricyclics, described below, and because they provoke graver side effects than other psychoactive drugs. These chemicals, marketed under the names Marsilid, Nardil, Niamid and Parnate may entail liver damage (including necrotizing hepatitis), dizziness, constipation, insomnia, fatigue, blurred vision and other adverse effects on the brain and cardiovascular system.²⁴ They create a risk of hypertensive crises which may be precipitated by ingestion of fermented foods containing tyramine and by interaction with drugs such as decongestants and amphetamines.²⁵ When taken in conjunction with the thymoleptic anti-depressants, the MAO-inhibitors have been claimed to provoke severe autonomic disturbances with tachycardia, hypertension or even severe collapse, bouts of sweating and nausea;²⁶ in conjunction with imipramine, the thymoretic anti-depressants have caused death.²⁷ At least two thymoretic anti-depressants or MAO-inhibiting drugs are used in South Australian psychiatric hospitals: phenelzine (Nardil) and tranylcypromine (Parnate). They share a capacity to provoke all the side effects previously referred to, but Parnate is probably the more dangerous.²⁸

(2) *Psychomotor Stimulants*: the commonest of these compounds in terms of usage are Methylphenidate (Ritalin) and Phenmetrazine (Preludin). The mechanisms of action of these compounds are not known and they have very limited value in the treatment of depressives because they produce short-term mood modification only but provoke psychic dependency and toxic states. Acknowledged side effects include tachycardia, hypertension, insomnia and agitation.²⁹

(3) *The Tricyclics*: known also as the thymoleptic anti-depressants, these pharmaceuticals include amitriptyline (Iaroxyl, elavil), nortriptyline (allegron, aventyl, sensival), protriptyline (concordin and vivactil), imipramine (imiprin, iramil and tofranil), desipramine (pertofran), trimipramine (surmontil),

23. Julien, *supra*, n. 12, 93; Byck, *supra*, n. 1, 181.

24. A. D. Brooks, *Law, Psychiatry and the Mental Health System* (Boston, Little Brown & Co., 1974), 881; G. L. Klerman "Psychotropic Drugs as Therapeutic Agents," 2 *Hast. Centre Studies*, January 1974, No. 1, 81, 86; Byck, *supra*, n. 1, 182; *Mims Annual*, *supra*, n. 17, 4.50-4.53.

25. D. S. Robinson & Ors., "Clinical Psychopharmacology of Phenelzine," in Lipton, *supra*, n. 18, 961; L. Lasagna, "Some Adverse Interactions with Other Drugs," in Lipton, *supra*, n. 18, 1005, 1007; Byck, *supra*, n. 1, 182-183.

26. Poldinger, *supra*, n. 19, 115; Julien, *supra*, n. 12, 93.

27. Poldinger, *supra*, n. 19, 115.

28. Within three years of the introduction of this drug into the U.S.A., approximately 400 cases of hypertensive reactions, including 50 cerebrovascular accidents and 16 deaths, were reported and statistics indicated that approximately 15% of patients likely to suffer adverse reactions would suffer stroke. The drug was withdrawn from sale in the U.S.A. for a short period in 1964 under direction from the U.S. Federal Drug Administration and its subsequent sale was authorised only after alterations in the warnings on the labelling: R. A. Merrill, "Compensation for Prescription Drug Injuries" (1973) 50 *Va. L. Rev.* 1, 12; Byck, *supra*, n. 1, 180; *Mims Annual*, 4.53. The use of Parnate in both Australia and the United States has declined in recent years.

29. It is believed that while neither Ritalin nor Preludin is used in South Australian psychiatric institutions, it is administered to small numbers of hyperkinetic children in child guidance clinics. In the United States, Ritalin has been administered to hyperactive school children despite that its initial effect is to increase pre-existing agitation: Julien, *supra*, n. 12, 76, 84-85; Wells, *supra*, n. 21, 596; Klerman, *supra*, n. 24, 86; *Mims Annual*, 4.62.

opipramol (insidon) and dibenzepine (noveril).³⁰ They are regarded as relatively safe and have a wide dose range; their side effects are generally mild and transient although uncomfortable. For these reasons, they are the most widely used anti-depressants. The tricyclics are not, however, absolutely safe; noted side effects include (at the mild level) dryness of the mouth, tachycardia, sweating, insomnia, tremor, hypotension and (at a more serious level) the aggravation of glaucoma and blurred vision in the elderly,³¹ grand mal seizures (infrequently)³² and there is some evidence that, when used in combination with the MAO inhibitors at excessive dosages, toxic effects can include death, vascular collapse, convulsions and hyperpyrexia.³³ Apart from these organic side effects, it has been claimed that long-term use of the tricyclics can induce an impairment of cognitive functioning in 13% of all patients and in 35% of all patients over the age of forty years. In practice, this impairment or deterioration in the patient either is attributed to exacerbations of the underlying disorder or goes undetected;³⁴ that is to say, the drugs may aggravate or reinforce the supposed mental illness whose cure they are hoped to work.

(B) *The Anti-Psychotic Drugs*

As a class, these are the most powerful psychoactive agents, although there is lingering doubt that they are capable of curing psychosis and schizophrenia.³⁵ At best, in the case of reactive or neurotic disorders, they suppress symptoms; in the case of those illnesses diagnosed as having an organic origin, they are prescribed in the belief that they can rectify the biochemical imbalance causing the disorder. Chemically, they fall into six groups, of which only three³⁶ are used in South Australia, namely:

(1) *the Phenothiazines*: these are the most widely used anti-psychotic drugs. Chlorpromazine, derived in 1952, is the prototypic drug of this class. Although the mechanism of action of the phenothiazines is not clear,³⁷ they are claimed to have significant beneficial effects in reducing thought distraction, social withdrawal, agitation, aggression, hallucinations and delusions. There are approximately twenty different phenothiazine derivatives, of which one half are used in treating psychosis.³⁸ The extent of consumption of the phenothiazines can only be guessed at.³⁹ Phenothiazines are not normally administered to children but some use on juveniles has been reported in at least two of the United States.⁴⁰ The phenothiazines used in psychiatric institutions

30. Julien, *supra*, n. 12, 93; Klerman, *supra*, n. 24, 86; Byck, *supra*, n. 1, 174-175. Two closely related tetracyclic compounds (mianserin and maprotiline) have recently been introduced into Australia.

31. Hollister, *supra*, n. 18, 991.

32. R. Sovner and A. Di Mascio, "Extrapyramidal Syndromes and Other Neurological Side Effects of Psychotropic Drugs," in Lipton, *supra*, n. 18, 1021, 1029.

33. Lasagna, *supra*, n. 25, 1008; Byck, *supra*, n. 1, 176-179; *Mims Annual*, 4.45-52, 4.58.

34. Sovner and Di Mascio, *supra*, n. 32, 1029; Byck, *supra*, n. 1, 175-179.

35. Klerman, *supra*, n. 24, 86; Ayd, *supra*, n. 13, 17.

36. The three classes of anti-psychotic drugs not used for the treatment of psychosis in South Australia are the Thioxanthenes, the Rauwolfia compounds and the Benzoquinolines. As to these see *Mims Annual*, 2.10, 4.38; Klerman, *supra*, n. 24, 83; Julien, *supra*, n. 12, 132; Byck, *supra*, n. 1, 168.

37. Julien, *supra*, n. 12, 126. For a discussion of the possible effects of chlorpromazine on a schizophrenic, see E. Du Bose, "Involuntary Treatment," (1976) *60 Mimm. L. Rev.* 1149, 1170; E. Usdin, "Metabolic Pathways of Anti-Psychotic Drugs" in Lipton, *supra*, n. 18, 895, 900-902.

38. They are also said to be of utility in controlling nausea and vomiting, as analgesics and as anti-histamines: Byck, *supra*, n. 1, 157.

39. One American estimate is that between 1955 and 1965, some 150 million patients in the U.S.A. received compounds of this class: Brooks, *supra*, n. 24, 882. In all, some 250 million people had received neuroleptic drugs up to 1970: Byck, *supra*, n. 1, 157.

40. R. Plotkin and K. R. Gill, "Invisible Manacles: Drugging Mentally Retarded People" (1979) *31 Stan. L. Rev.* 637, 651.

in South Australia include chlorpromazine (protran, largactil and thorazine), prochlorperazine (compazine or stemetil), thioridazine (melleril), pericyazine (neulactil), trifluoperazine (stelazine), perphenazine (trilafon) and fluphenazine (serenol). These drugs are non-specific in their actions and affect a wide variety of body functions. Physicians often have difficulty in predicting an individual's response to a particular drug. They do not seem to develop tolerance or dependence and there are usually no withdrawal symptoms.⁴¹ Psychologically, the drugs improve mood and behaviour by producing an indifference to external stimuli and a reduction of psychic activity, initiative and anxiety. They block conditioned-avoidance behaviour but do not induce euphoria and generally they leave consciousness unimpaired.

Regrettably, the phenothiazines can provoke grave physiological and neurological side effects, including cholestatic hepatitis, jaundice and other liver damage,⁴² constipation, hypotension, interference with ejaculation, amenorrhea, lactation in women who are not pregnant, drowsiness, skin reactions, convulsions, iatrogenic parkinsonism,⁴³ dystonic abnormalities, akathisia,⁴⁴ diarrhea, more frequent epileptic episodes (by lowering the threshold of excitement needed to induce an epileptic fit), permanent extrapyramidal symptoms, blood dyscrasias (leucopenia and agranulocytosis),⁴⁵ altered pigmentation of the skin, pigment deposits in the eye, permanently impaired vision and hormonal changes. It has been found that chlorpromazine, if administered to pregnant women, can adversely affect offspring.⁴⁶ An important side effect of the long-term administration of phenothiazines is tardive dyskinesia⁴⁶. This iatrogenic disorder has been reported in 15% of institutionalised patients; in the case of elderly, long-term patients, the proportion of those affected is 20%. So serious are the extrapyramidal effects of the phenothiazines that it has been asserted that long-term neuroleptic therapy in the management of psychoneurosis, anxiety states, personality disorders, depression, mania or chronic pain syndromes should be discouraged and that particular care is called for in treating patients who have attained 50 years of age, especially in the presence of organic brain disease.⁴⁸ These effects create a significant clinical problem: patients, institutionalised or not, tend to evade or to refrain from taking their medication and so suffer a return of the symptoms for the suppression of which the drugs are prescribed.

While many of the phenothiazines are acknowledged to provoke significant side effects, there are four — prochlorperazine, promazine hydrochloride,

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41. Patterson, *supra*, n. 18, 65, 356; Julien, *supra*, note 12, 128-131; Du Bose, *supra*, n. 37, 1203-1206.
 42. Byck, *supra*, n. 1, 164.
 43. The Parkinson-like extra-pyramidal symptoms induced by the phenothiazines, namely expressionless face, shuffling gait and tremors, are thought to be provoked by a blocking of the dopamine receptors in the brain: see I. Creese and S. H. Snyder, "Behavioral and Biochemical Properties of the Dopamine Receptor," in Lipton, *supra*, n. 18, 377, 379, 381; Byck, *supra*, n. 1, 169. Parkinson-like symptoms occur in as many as 85 per cent of patients: Snyder, *supra*, n. 12, 35.
 44. Akathisia or, in the vernacular, the "jitters", is a subjective hyperkinetic state of motor restlessness ranging from a feeling of inner disquiet to inability to remain motionless: Byck, *supra*, n. 1, 169.
 45. Both these disorders manifest themselves in a deficiency of white blood corpuscles and elderly patients are particularly susceptible to them: see Byck, *supra*, n. 1, 164-165.
 46. G. R. Breese & Others, "Developmental Neuropsychopharmacology" in Lipton, *supra*, n. 18, 609, 611.
 47. R. J. Baldessarini and D. Tarsy, "Tardive Dyskinesia," in Lipton, *supra*, n. 18, 993, 995. Tardive dyskinesia is a complex syndrome of hyperkinetic involuntary movements characterised by involuntary motions of muscles of the mouth, limbs and trunk. The symptoms are frequently irreversible. Lowering the administered dosage of the drugs inducing the condition frequently worsens the symptoms, while increasing the dosage may alleviate the symptoms for a short period only. See Creese and Snyder, *supra*, n. 43, 382, 384.
 48. Baldessarini and Tarsy, *supra*, n. 47, 999; Byck, *supra*, n. 1, 169.

thioridazine and trifluoperazine — which are thought to involve abnormal risks for patients. The first of these, marketed as compazine and stemetil, is used in South Australia to control nausea and vomiting but is not used in the practice of psychiatry; it has been claimed to have caused the sudden death of a small number of patients in the United States, sometimes following asphyxia due to failure of the cough reflex.⁴⁹ Promazine hydrochloride (sparine), which is claimed no longer to be used in South Australian state institutions, has been found to cause gangrene when injected intramuscularly; warnings relative to gangrene, thrombophlebitis, vascular spasm and localised cellulitis (which may entail septicaemia and death) now appear in the package literature of the American distributor.⁵⁰ Thioridazine (melleril) is used in South Australian institutions, although its efficacy in treating neurotic disorders has not been definitively established; it is contraindicated in patients with severe depression or heart disease; large dosages may induce a counter-productive lethargy and it, too, has been associated with a "sudden death phenomenon".⁵¹ Trifluoperazine (calmazine, terfluzin and stelazine) is used here as elsewhere in the treatment of withdrawn and apathetic schizophrenics, chronic patients refractory to other therapies and patients suffering from delusions and hallucinatory dispositions. There are doubts that the drug is efficacious in abating neuroses. It is capable of inducing severe neurological disorders. Each of these four drugs can provoke severe side effects in ordinary patients; others may induce graver disorders in patients with abnormal sensitivities. Into the latter category falls fluphenazine (anatensol, modectate) which is very widely used as a controlling medication here; it has been claimed to induce convulsive spasms and haemorrhaging.⁵³

(2) *the Butyrophenones*: these drugs are of recent derivation. The only butyrophenones administered for psychotherapeutic purposes are haloperidol (serenace), which was first introduced for sale in North America in 1967, and droperidol (droleptan). Their pharmacological actions are similar to those of the phenothiazines.⁵⁴ While the serious toxicities induced by the phenothiazines do not normally accompany the prolonged administration of

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49. At least two actions for damages instituted in the United States for non-fatal injuries allegedly induced by this drug have been settled in favour of the respective plaintiffs, both young persons: Patterson, *supra*, n. 18, 292; *Vincent v. Smith Kline and French Laboratory & Ors.* (1973) (unreported) where an infant of tender years claimed damages for brain injuries alleged to have been caused by the drug from two physicians and the manufacturers; the case was settled before trial, as between the plaintiff and all defendants, for \$U.S. 160,000; *Tiells v. Smith Kline & French Laboratory & Ors.* (1973, unreported), where a 14 year old boy sued his physician and the manufacturer for damages for neuromuscular injury attributed to the drug; these proceedings were compromised for \$U.S. 409,500. See also *Smith v. United States* 394 F. 2d 482 (1968); D. M. Engelhardt & P. Polizos, "Adverse Effects of Pharmacotherapy in Childhood Psychosis," in Lipton, *supra*, n. 18, 1463; *Mims Annual*, 4.32, 4.81.
50. Verdicts for plaintiffs complaining of post-injection gangrene were entered in *Schrib v. Seidenburg* 458 P. 2d 825 (1969) and *Nolan v. Dillon* 276 A 2d. 36 (1971). See Patterson, *supra*, n. 18, 296.
51. Patterson, *supra*, n. 18, 349; *Carter v. Metropolitan Dade County* 253 So. 2d. 920, 921 (1971); *Mims Annual*, 4.36.
52. Patterson, *supra*, n. 18, 356-357; in *Lesser v. Farbe & Ors.* (1971, N.J. S.C., unreported) a patient to whom stelazine had been administered sued her physician and the manufacturer for damages for neurological disorders including parkinsonism. The plaintiff recovered \$U.S. 180,000.
53. *Naughton v. Bevilacqua* 458 F. Supp. 610 (1978); *Mims Annual*, 4.29, 4.37-38. Thorazine, too, has been the subject of litigation: *Montalto v. Smith Kline and French Laboratories Inc.* (1973, not reported), settled by a payment of \$U.S.9,000 in favour of the patient; Patterson, *supra*, n. 18, 65-66. The F.D.A. recently ordered alterations in the package inserts accompanying this compound so as to stipulate that special precautions including monitoring should be implemented when the drug is used on persons having difficulty in communicating adverse effects and to specify that the drug may impair cognitive capacity: see Plotkin & Gill, *supra*, n. 40, 653-654.
54. Byck, *supra*, n. 1, 166; *Mims Annual*, 4.34-4.35. Serenace is about 100 times as potent as chlorpromazine: Snyder, *supra*, n. 12, 240.

serenace, it does produce more pronounced involuntary movements (attributable to dyskinesia) than the phenothiazines, even in younger patients, and can also induce hypotension.⁵⁵ Serenace is used in psychiatric institutions in Australia as a standard neuroleptic for the long-term maintenance and control of schizophrenic and severely agitated patients. Paradoxically, the side effects which it provokes often disappear at abnormally high dosage levels;⁵⁶ these effects include leucopenia and less frequently agranulocytosis⁵⁷ both of which may result in sudden death; when used in conjunction with lithium, serenace may cause dementia and tardive dyskinesia.⁵⁸

(3) *Lithium*: this drug is an alkali metal which is claimed to be effective in the treatment of mania and to exhibit few effects on the central nervous system apart from its specific action on mania. The mechanism through which it operates is still speculative.⁵⁹ Lithium may, it is reported, cause abnormalities in babies if administered to pregnant women⁶⁰ and provoke grand mal seizures and confusional episodes in small numbers of adult patients.⁶¹

Civil Liability for the Benevolent Prescription of a Deleterious Psychoactive Drug:

"To protect us against doctors there is no law against ignorance, no example of capital punishment. Doctors learn at our risk, they experiment and kill with sovereign impunity, in fact the doctor is the only one who may kill. They go further and make the patient responsible; they blame him who has succumbed."

Plinius Secundus, *Naturalis Historia*, 29.19

No pharmaceutical is free of toxic side effects.⁶² From the material rather cursorily presented in the preceding paragraphs, it will have been gathered that many of the drugs currently used for psychotherapeutic purposes have or are claimed to have undesirable and unpleasant side effects which vary in intensity and duration. Some of the more serious side effects have given rise, in the United States, to claims for damages in tort against doctors and psychiatric institutions.⁶³ It is likely that, in the next few years, there will be even more litigation in the United States with a view to the recovery of damages for injuries sustained in consequence of the administration of toxic pharmaceuticals and that the American experience will be a catalyst for the institution of similar claims in Australia as it has been in other areas of tort and contract law.

It is proposed in this part of the article to summarise the rules developed by the common law by reference to which any claim for damages for personal injuries arising out of the prescription or administration within South Australia of a deleterious pharmaceutical would be adjudicated. The principles of law applicable to claims against medical practitioners and health institutions are, for the most part, clear and unquestioned at the theoretical level. The application of those principles to particular claims in this context is rendered abnormally complex by a number of factors: knowledge is lacking of the exact mechanisms of action of many pharmaceuticals; conflicting data about many drugs is emerging rapidly; individual patients may have idiosyncrasies and

55. Poldinger, *supra*, n. 19, 48; Byck, *supra*, n. 1, 167; Julien, *supra*, n. 12, 131-132; Klerman, *supra*, n. 24, 84;

56. Creese and Snyder, *supra*, n. 43, 382.

57. Byck, *supra*, n. 1, 167.

58. Lasagna, *supra*, n. 25, 1007.

59. Julien, *supra*, n. 12, 132-133.

60. Hollister, *supra*, n. 18, 991; *Mims Annual*, 4.36.

61. Sovner and Di Mascio, *supra*, n. 32, 1029, 1030; Byck, *supra*, n. 1, 185; *Mims Annual*, 4.32.

62. Julien, *supra*, n. 12, 33. See also Kay, *supra*, n. 14, 47-48.

63. See above nn. 20, 49-53.

peculiar sensitivities which may not be known to or discoverable by the diagnosing physician; many mental health patients will not be sufficiently rational or articulate to give their physicians "feedback" about positive or adverse effects of a course of drug therapy; side effects may mistakenly be diagnosed as an exacerbation of the mental illness for which no drug is responsible; and the assessment of damages will be not only extremely difficult but will always be disputed in cases of a relevant, pre-existing disorder, that is to say in the overwhelming majority of cases.

The discussion which follows will be directed predominantly to the issue of the liability to patients of the prescribing physician and of mental health institutions rather than to that of drug manufacturers, and it will be confined to the width and components of the professional duty of care; the more particular problems of causation and quantification of damages, while they pose more acute difficulties for aggrieved patients seeking compensation for iatrogenic injuries and for their legal advisers, do not admit of generalised discussion. In this domain, proof of causation will depend on material drawn from the biochemical sciences with respect to the relevant drug or combination of drugs, the specific course of therapy followed and the peculiarities of the individual patient's reaction to the drug. Equally, proof of damages in particular cases will raise singular problems and will depend very much on the individual's diagnosis and state of health at the outset of therapy and on his prognosis at the date of the trial.

At common law, a mental health patient's remedy in respect of iatrogenic injuries will depend in the final analysis on whether he did or did not consent to the therapy or treatment which gave rise to the injuries, whether he was a voluntary patient or a detained patient.

A. *Where a Drug is Administered Non-Consensually*: at common law, the administration of any medication to an adult, being an ordinary patient in control of his faculties, without his consent and without other lawful authority, would *prima facie* be a battery and therefore actionable without proof that the medication was harmful or caused physical or mental injury.⁶⁴ The onus of proof of consent is borne by the defendant,⁶⁵ and honest belief in consent is no defence⁶⁶. Such a non-consensual administration might also constitute a criminal assault.⁶⁷

If no actual injuries flowed from the use of the drug, nominal damages only would be recoverable. If actual loss or injury flowed directly from the forcible administration, then substantial damages would be recoverable, other conditions being satisfied. If the drug was dangerous to the knowledge of the person administering it, or if it was supplied for an improper purpose, then the plaintiff might be entitled to recover aggravated or exemplary damages.⁶⁸

64. J. G. Fleming, *The Law of Torts* (5th ed., Law Book Co. Ltd., Sydney, 1977), 23; Halsbury, *The Laws of England* (2nd ed.), vol. 26, 18; S. R. Speller, *Law of Doctor & Patient* (H. K. Lewis & Co. Ltd., London, 1973), 16; J. Jacob, ed., *Speller's Law Relating to Hospitals* (6th ed., H. K. Lewis & Co. Ltd., London, 1978), 179.

65. *Reibl v. Hughes* (1977) 78 D.L.R. (3d.) 35, 41.

66. Speller, *supra*, n. 64, 16.

67. Criminal Law Consolidation Act (S.A.) 1935-1978, ss. 39-47.

68. Aggravated damages are a species of compensatory damages which may be awarded where the conduct of the defendant, which results in the infliction on the plaintiff of a non-pecuniary injury, excites the natural indignation of the court and demands a more generous solatium. Exemplary damages are intended to punish a wilful tortfeasor and are not calculated exclusively by reference to the plaintiff's injuries: see *Cassell & Co. Ltd. v. Broome*, [1972] 1 All E.R. 801, 825-826, 873. In Australia, exemplary damages may be awarded only in cases of conscious wrongdoing in contumelious disregard of the plaintiff's rights: see *Australian Consolidated Press Ltd. v. Uren*, (1967) 117 C.L.R. 221.

The proper defendant in an action in battery would nearly always be the person who administered the drug and those who assisted him, for battery, being a trespassory action, lies only in respect of acts directly involving an infringement of a legal right. Thus, if the non-consensual administration was perpetrated by the patient's own physician, the latter would be the proper defendant. Normally, though, drugs are administered either by the patient himself after prescription and dispensation by a pharmacist or, where the patient is institutionalised, by a member of the nursing staff. In the former situation, there will be no battery; in the latter, the nurse concerned will be liable, to the exclusion of the prescribing physician and the hospital administration. Mere prescription of a drug is too remote from its administration to render the prescribing physician liable. The nurse's employer would be liable in battery only if he or his authorised agent had expressly or by necessary implication commanded the nurse to administer the drug despite the lack of consent or, in other words, did direct and assent to the battery complained of.⁶⁹ Thus, the hospital would not be liable in battery if the nurse administered a drug pursuant to the direction of the patient's own physician. *A fortiori*, in the present state of the authorities it is most unlikely that a person not related to the nurse as employer (e.g., an external consulting physician) could be liable in trespass on the basis alone of directing or inciting the nurse to commit a battery.⁷⁰

These principles apply to a voluntarily institutionalised patient. Are they equally applicable to a person detained lawfully but without his affirmative consent in a psychiatric institution? This single question gives rise to two further distinct questions. First, is a detained patient capable, as a matter of law, of consenting to treatment? Secondly, does the law authorise those having the care of an involuntarily committed patient to treat him either without his consent or over his objection?

There is no English or Australian authority on either of these questions. As to the first question, the Mental Health Act itself implies that a detained mental patient can, as a matter of law, participate effectively in the regulation of his own treatment, for it is provided that a detained patient who has sufficient command of his mental faculties to make a rational judgment on the matter may grant or withhold consent to psychosurgery or E.C.T.⁷¹ That is, capacity to consent raises questions of fact rather than questions of law. The preponderance of opinion in the United States favours this approach; there, detained patients are regarded as capable, as a matter of law, of retaining their freedom to regulate their own treatment and it is settled that a detention order does not even raise a factual presumption of incapacity.⁷² However, while accepting that patients do have the power to consent to treatment, American courts have held that, in the circumstances prevailing in mental institutions, consents to extraordinary measures such as psychosurgery and E.C.T. should not be accepted at face value and may be invalid because uninformed or not

69. See *Sharrod v. The London and North Western Railway Co.*, (1849) 4 Ex. D. 580, 585-586; *McCorquodale v. The Shell Oil Co. of Aust. Ltd.*, (1932) 33 S.R. (N.S.W.) 151, 154; *Rutherford v. Hawke's Bay Hospital Board* [1949] N.Z.L.R. 400; *Teakle v. Tom the Cheap (S.A.) P/L*, (1971) 2 S.A.S.R. 258, 260-261; Fleming, *supra*, n. 64, 370-371; *Deatons Pty. Ltd. v. Flew*, (1949) 79 C.L.R. 370; *Darling Island Stevedoring and Lighthouse Co. Ltd. v. Long*, (1956-7) 97 C.L.R. 36, 64-65, 69-70.

70. There is American authority in favour of holding the prescribing physician liable in battery: see *Stowers v. Wolodzko* 191 N.W. 2d. 355, 365 (1971).

71. S.19(1).

72. See, for example, *N.Y. City Health & Hospitals Corp. v. Stein* 335 N.Y.S. 2d 461 (1972); *Dale v. Hahn* 440 F.2d. 633 (1971); *Rogers v. Okin* 478 F. Supp. 1342 (1979); *Winters v. Miller* 446 F. 2d. 65 (1971); Plotkin, *supra*, n. 8, 488-490; B. J. Ennis & R. D. Emery, *The Rights of Mental Patients* (N.Y., Avon Books, 1978), 132.

truly voluntary.⁷³ The requirements of a valid consent to treatment are discussed below.

Nor is there a clear answer to the second question. No authority to treat detained patients without their consent is conferred by the Act. Now while, in South Australia, consents to treatment are sought from voluntary patients as a condition of treatment by drugs, it has always been assumed by those charged with the administration of mental health institutions here and elsewhere in the common law countries that non-statutory law conferred sufficient authority to warrant the unconsented administration of medication to detained patients; that is, that the common law permitted those having the care of the civilly and criminally committed to administer such drugs or other therapy as was thought reasonably necessary for the cure of the patient's illness and the preservation of his health.⁷⁴ This assumption is made and acted upon in public psychiatric institutions throughout Australia. It is submitted, however, that this assumption is erroneous. There are no reported decisions of English, Australian or Commonwealth courts on this point. There are American decisions to the effect that, except in an emergency, the administration of medication to a civilly or criminally detained mental health patient without the consent of the patient is tortious and actionable as a battery.⁷⁵ The American decisions will not necessarily be followed in Australia but they are, it is submitted, sound in principle and should be applied here, to the extent that they are based on the common law, as opposed to constitutional rights peculiar to American citizens. The converse result would effectively deprive mental patients of a valued civil right. There is no warrant, either in the Act or in the principles of the common law, for the proposition that the mere making of a detention order pursuant to Part III of the Act suspends or terminates the right of the patient to refuse medication. No doubt, medication may lawfully be administered without the consent of the patient pursuant to an order made by the statutory Guardianship Board after the Board has received the patient into its guardianship⁷⁶ or where another lawful guardian of the patient consents to the treatment. In addition, the common law would probably authorise the administration of drugs to a patient without the consent of the patient or his guardian

- (i) where the patient appeared likely to injure himself or another or to damage the property of another and where the only reasonably practicable mode of restraint was sedating medication;⁷⁷ or

73. *Kaimowitz & Doe v. Dept. of Mental Health* (1973) 42 U.S.L.W. 2063. The decision is reviewed by J. A. Gold, "Comment," (1974) 4 *N.Y.U. Rev. L. & S.C.*, 207; Y. D. Koskoff, "The Kaimowitz Case" (1975) 13 *Duquesne L. Rev.*, 879; J. M. Spoonhour, "Psychosurgery & Informed Consent," (1974) 26 *U. Fla. L. Rev.* 432; see also Brooks, *supra*, n. 24, 902-921.

74. J. Jacob, "The Right of the Mental Patient to his Psychosis" (1976) 39 *M. L. Rev.* 17, 19. G. H. Morris, "Institutionalising the Rights of Mental Patients" (1974) 62 *Cal. L. Rev.* 957, 990; Jacob, *supra*, n. 64, 204-206; *Barsy v. Govt. of Manitoba* (1966) 57 *W.W.R.* 169, 171-172; P. R. Friedman, "Legal Regulation of Applied Behaviour Analysis in Mental Institutions and Prisons" (1975) 17 *Ariz. L. Rev.* 39, 41; *O'Donoghue v. Riggs* 440 P. 2d. 823, 828 (1968) and *Marshall v. Watson* (1972) 124 C.L.R. 640. In South Australia, civilly detained patients are committed neither into the custody of the Crown nor into the custody of the supervisor of the hospital in which they are detained. For that reason, they cannot be equated with persons under arrest or serving imprisonment who may be unable to sue in respect of certain kinds of "benevolent batteries" such as forced feeding and medical attention: see *Leigh v. Gladstone* (1909) 26 T.L.R. 139 and compare Part IV, Div. 2 of the Act.

75. *Stowers v. Wolodzko* *supra*, n. 70; *Scott v. Plante* 532 F. 2d. 939, 946 (1976); *Rogers v. Okin*, *supra*, n. 72, 1365-1367, 1383-1384.

76. S.27(:)(d).

77. See Fleming, *supra*, n. 64, 81, 92-94; Jacob, *supra*, n. 74, 33-34.

- (ii) where the drug was necessary to preserve the patient's life or health from permanent or serious injury or to prevent grave pain and suffering.⁷⁸

In these last two classes of case, authority would probably be implied even where the patient expressly withheld consent under the influence of temporary irrationality or unreasonableness or where the guardian of an incompetent patient unreasonably withheld consent.⁷⁹ Where a guardian, unreasonably objecting to treatment, is expressing his own wishes, they may be disregarded in an emergency; but it is not clear whether consent can lawfully be dispensed with where the guardian is acting on the patient's known wishes in withholding consent.⁸⁰

A great deal of doubt envelops these two questions and action by the legislature to clarify the law would be of benefit both to patients and their professional aides.

B. *Where a Drug is Administered Consensually:*

A patient who has effectively consented to the administration of a deleterious drug, either by way of giving his physician or hospital staff general leave and licence to carry out such therapy as might reasonably be considered necessary to effect his cure or by assenting to the use of a specific pharmaceutical, has no cause of action in battery; his only cause of action against the prescribing doctor and the hospital is based on negligence⁸¹ in the prescription or administration of the drug. This latter proposition is true whether there was or was not a contract between the patient and the doctor or the hospital;⁸² whether the patient relies on contract or tort, the gist of his action is negligence, that is the breach by the defendant of a duty of care owed to the patient. If that duty is breached, the patient is entitled to recover compensatory damages⁸³ for injuries caused by the conduct constituting the breach to the extent that they were reasonably foreseeable at the time of the breach of duty; the purpose of the award of damages is to put the plaintiff in the position he would have occupied but for the defendant's negligence.

At common law, a hospital owes myriad duties to its patients; a mental hospital has several super-added duties arising from the special need of its patients for supervision and physical surveillance.⁸⁴ One duty owed by a hospital organisation to every patient is the responsibility of taking due care in carrying on the hospital and, in particular, in rendering medical services.⁸⁵ A hospital may be answerable for the negligent acts of employed doctors⁸⁶, nurses⁸⁷, and para-professional staff committed in the course of the discharge of their pro-

78. *Marshall v. Curry* [1933] 3 D.L.R. 260, 275; *Murray v. McMurchy* [1949] 2 D.L.R. 442. See generally, P.D.G. Skegg, "A Justification for Medical Procedures Performed Without Consent" (1974) 90 L.Q.R. 512.

79. Skegg, *supra*, n. 78, 522-528; Jacob, *supra*, n. 64, 191.

80. Speller, *supra*, n. 64, 27-28.

81. See *Halsbury, supra*, n. 64, 17-19; *Gold v. Essex C.C.* [1942] 2 K.B. 293, 301-303. The patient may also have a cause of action in negligence against the manufacturer of the drug (*Thompson v. Distillers Co. (Biochemicals) Ltd.* [1971] A.C. 458; see Fleming, *supra*, n. 64, chapter 23) and against those statutory authorities which control the flow of drugs into commerce: see, by analogy, *Dutton v. Bognor Regis U.D.C.* [1972] 1 Q.B. 373. See also R. A. Merrill, *supra*, n. 28.

82. *Roe v. M.O.H.* [1954] 2 Q.B. 66; *Samios v. Repatriation Commission* [1960] W.A.R. 219.

83. Exemplary damages are not recoverable for unintentional torts: *Cassell & Co. Ltd. v. Broome, supra* n. 68, 828.

84. See H. D. S. Venables, *A Guide to the Law Affecting Mental Patients*, (Butterworths, London, 1975), 78-81.

85. *Halsbury, supra*, n. 64, para. 27.

86. *Collins v. Herts C.C.* [1947] K.B. 598, 618-620; compare *Albrighton v. Royal Prince Alfred Hospital* [1979] 2 N.S.W.L.R. 165, 168-169.

87. *Henon v. Perth Hospital* (1939) 41 W.A.L.R. 15; *Gold's case, supra*, n. 81, 313.

essional skills as it is for negligent conduct perpetrated by clerical or administrative or ancillary servants in the performance of their duties.⁸⁸ In addition, a hospital may be held responsible for the negligent acts of an external specialist or visiting consulting doctor where the doctor's services are rendered as part of the treatment provided by the hospital,⁸⁹ that is, for the negligence of all doctors save those employed by the patient himself and for the negligence of all members of staff save those working under the immediate direction and control of the patient's own doctor.⁹⁰ The hospital's liability for a doctor's negligence is not conditional on the nexus of a contract of service between the hospital and the doctor. In other words, the hospital can be held liable for losses caused by the careless administration of a drug to a patient by hospital staff and for the negligent prescription of a drug by any physician save one selected and employed by the patient himself.

The duty of every medical practitioner to his patient is to bring to the discharge of his tasks that degree of skill and competence which a reasonably competent doctor in the physician's position would possess.⁹¹ A doctor does not impliedly warrant either the efficacy or the safety of medical procedures which he undertakes⁹² and does not impliedly undertake to achieve a cure.

In the present context, the physician's sole role in the medication of patients is normally the mere prescription of an approved pharmaceutical, and ordinarily the doctor will not assume responsibility for the actual administration of drugs: whether he does so or not depends on the relationship between doctor and patient on the one hand and doctor and hospital staff on the other.⁹³

A prescribing physician may breach his duty of care in one of several ways.

(i) *Obtaining an informed consent*: as has been stated, unconsented medical treatment involving the intentional touching of the patient's body is, in general, a battery. A doctor who proposes to treat a patient by way of a procedure which entails touching the patient must have the patient's informed consent thereto. No consent is informed which is obtained from a person incapable of reaching a rational conclusion on material put to him or of assimilating or assessing information conveyed to him; for example, a consent allegedly forthcoming from a person labouring under delusions of paranoia or from a person under sedating drugs would be suspect. Equally, the consent must be voluntary.⁹⁴ It has been held that where an apparent consent is vitiated because not voluntary or because uninformed, subsequent medical treatment is a battery and the failure to seek an effective, informed consent may be negligence.⁹⁵ From this it follows that failure by a physician (one who is employed or selected by a mental hospital) to obtain the patient's consent to the administration of a drug before prescribing it and directing its use on the patient may be an act of negligence for which both the doctor and the hospital would be answerable. On the other hand, the mere prescribing of a drug by a physician employed by the patient himself would probably not be actionable

88. See Fleming, *supra*, n. 64, 361, and the cases there cited, and in particular *Collins' case*, *supra*, n. 86, 620.

89. *Samiou v. Repatriation Commission*, *supra*, n. 82; *Ramsay v. Larsen* [1964] A.L.R. 1121, 1129. But see *Albrighton's case*, *supra*, n. 86, 168-169, and *Collins' case*, *supra*, n. 86, 620.

90. *Crits v. Sylvester* (1956) 1 D.L.R. (2d) 502; *Johnston v. Wellesley Hospital* (1970) 17 D.L.R. (3d) 139, 152-153; *Roe v. M.O.H.*, *supra*, n. 82; *Jacob*, *supra*, n. 64, 242-244.

91. *Mahon v. Osborne* [1939] 2 K.B. 14; Fleming, *supra*, n. 64, 109-110; *Albrighton's case*, *supra*, n. 86, 172-173.

92. Halsbury, *supra*, n. 64, para. 26.

93. Halsbury, *supra*, n. 81, para. 23.

94. See Plotkin, *supra*, n. 8, 486-488; L. E. Rozovsky, "Consent to Treatment" (1973) 11 *Osgoode Hall L.J.* 102, 111.

95. *Kelly v. Hazlett* (1976) 75 D.L.R. (3d.) 536, 555-556.

because not the effective cause of any injuries sustained in consequence of consumption of the drug, where the only carelessness attributable to the doctor is failure to obtain an informed consent.

In seeking an informed consent, the doctor should fully, honestly and accurately summarise the facts, probabilities and known opinions as to the risks and potential benefits of treatment.⁹⁶ If the doctor's advice is inaccurate through carelessness, he may be liable in negligence;⁹⁷ equally, failure on the part of the doctor to warn the patient of a risk of injury inherent in the therapy of which the physician knew or ought to have known is *prima facie* actionable where the patient would not have consented to the treatment if the risk had been disclosed to him.⁹⁸ A doctor need not, however, allude to risks which an ordinary man would know to be inherent in the pertinent medical procedure.⁹⁹ In addition, in seeking the patient's consent, the physician is entitled to withhold information which, in the reasonable opinion of the doctor, would merely alarm a patient who is already apprehensive and who may, if warned, refuse to undertake treatment in which there is a negligible risk of injury or where disclosure may result in actually increasing the risk by reason of the psychological results of the apprehension itself.¹⁰⁰ Finally, the doctor may properly abstain from offering an explanation in an emergency.

When the doctor obtains the informed consent of the patient (or, in appropriate circumstances, of his guardian) it is said for the purposes of the law of negligence that the patient has (as against the doctor) voluntarily assumed the legal risk of treatment; thereby, the doctor is relieved of any liability which might otherwise have accrued upon actualisation of the risks accepted by the patient.¹⁰¹ For the purposes of the law of trespass, the patient is said to have consented to what would otherwise be a battery and can maintain no action in trespass in respect of those risks which were part and parcel of the treatment to which he assented, provided that those risks were disclosed to him and were within the ambit of his consent. Nor can the patient maintain an action in battery in relation to injuries the risk of which was merely collateral to the treatment to which he assented; but there may be an action in negligence in respect of such injuries where failure to disclose the risk was careless and not justified by any therapeutic privilege.¹⁰² The burden of proving an informed consent and a voluntary assumption of risk is borne by the defendant.¹⁰³

(ii) *Negligence in treatment and prescription*: if a doctor prescribes a deleterious drug for a patient after obtaining a sufficient consent, he may nevertheless be liable in negligence. For example, it has been held that a doctor is negligent in an actionable way if he carelessly omits to carry out a sensitivity test to ascertain whether the patient has an abnormal sensitivity to the drug or, in the case of a drug known to be fatal to a certain class of persons, he fails to take a patient history to test for allergy.¹⁰⁴ From this it follows that a doctor might be negligent if he imprudently omitted to monitor the effects of the

96. *Halushka v. Univ. of Saskatchewan* (1976) 53 D.L.R. (2d.) 436; *Kelly v. Hazlett*, *supra*, n. 95, 565; *Natanson v. Kline* 350 P. 2d. 1093; *Speller*, *supra*, n. 64, 19-21; *Jacob* *supra*, n. 64, 182-187.

97. *Smith v. Auckland Hospital Board* [1965] N.Z.L.R. 191.

98. *Halsbury*, *supra*, n. 81, 18; *Fleming*, *supra*, n. 64, 79; *Woods v. Brumlop* 377 P. 2d. 520, 524 (1962); *Friedman*, *supra*, n. 74, 52-56; *Reibl v. Hughes*, *supra*, n. 65, 44; *Speller*, *supra*, n. 64, 20; *Smith v. A.H.B.*, *supra*, n. 97.

99. *Kelly v. Hazlett*, *supra*, n. 95, 558.

100. *Woods v. Brumlop*, *supra*, n. 98, 525; *Natanson v. Kline*, *supra*, n. 96, 1103; *Kenny v. Lockwood* [1932] 1 D.L.R. 507, 525.

101. See *Fleming*, *supra*, n. 64, 283, 287.

102. *Kelly v. Hazlett*, *supra*, n. 93, 558.

103. *Fleming*, *supra*, n. 64, 74, 283.

104. *Chin Keow v. Govt. of Malaysia* [1967] 1 W.L.R. 813; *Naughton v. Bevilacqua*, *supra*, n. 53, 614.

prescribed drug on his patient before prescribing further applications; it has, in addition, been held that a doctor may be liable if he fails to inform a patient of harmful side effects of treatment which are detected by the doctor but not by the patient.¹⁰⁵ In short, it can be stated that a prescribing physician may be guilty of negligence if he authorises use of a drug which a practitioner of ordinary competence, in the then existing state of medical knowledge, would not deem it prudent to prescribe for the plaintiff. If a drug is new and one whose effects have not been previously observed by the prescribing doctor, he should apply it with caution and may be guilty of negligence if he advises a patient that it is safe.¹⁰⁶

A defendant physician will not necessarily rebut a *prima facie* case of negligence merely by showing that he followed the manufacturer's use and dosage recommendations or that the drug has been approved by the Department of Health. The medical practitioner must, in prescribing a drug, exercise his own professional judgment, taking into account the manufacturer's recommendations, warnings and contraindication remarks, the terms of approval of the drug by the Department of Health, pertinent material contained in the pharmacopoeia, the doctor's own knowledge, if any, of the operation of the drug and any sensitivities of the patient. The role of approved labelling in malpractice litigation remains uncertain. There are cases in the United States where physicians have escaped liability despite deviation from the manufacturer's instructions and no court has yet held that a physician's departure from any portion of the approved labelling conclusively establishes negligence.¹⁰⁷ Where the physician's use of the drug is consistent with the manufacturer's directions, there would usually be no liability unless a competent practitioner in the defendant's position would have been aware from other sources, such as official or professional literature or previous experience, that the use of the drug complained of would probably injure the plaintiff.¹⁰⁸ The orthodox administration of those drugs specifically dealt with in preceding pages, whose use is approved by the Department of Health, consistently with the manufacturer's labelling could rarely be negligent. However, use in accordance with labelling would be negligent if incompatible with idiosyncrasies or sensitivities in the patient of which the physician knew or ought to have known.

One problem confronting both physicians and patients is the uncertainty of effect of many of the drugs used in the ordinary course of psychiatric therapy. As has been seen, the mechanisms of action of many psychoactive drugs are still unknown and, despite the fact that the most potent psychoactive drugs began to be used almost thirty years ago, research into the effects of these drugs on the body and mind has not moved beyond infancy. To some extent, physicians and consumers of the psychoactive drugs are engaging in disguised experimentation, sometimes with serious consequences.¹⁰⁹ Nevertheless, wholesale prescription and consumption of the psychoactive drugs continues, sometimes in quite irrational patterns.¹¹⁰ So far, it appears that, in

105. *Gerber v. Pines* (1934) 79 Sol. J. 13.

106. *Halushka v. Univ. of Saskatchewan*, *supra*, n. 96, 444.

107. See Merrill, *supra*, n. 28, 52-54.

108. A medical practitioner has a limited duty to inform himself of new clinical developments: see Speller, *supra*, n. 64, 64-66; Jacob, *supra*, n. 64, 223.

109. For statistics on drug-induced deaths in hospitals, see Patterson, *supra*, n. 18, ix; Merrill, *supra*, n. 28, 4-6.

110. For estimates of the quantities of prescriptions written for psychiatric purposes, see H. J. Parry & Ors., "National Patterns of Psychotherapeutic Drug Use" (1973) 28 *Arch. Gen. Psych.* 769; Patterson, *supra*, n. 18, iv. Drug consumption has been said to have reached high levels in the United States because of frequent resort to combined drug programs for ulterior motives and to serve "frankly commercial goals": L. Hollister, in Ayd, *supra*, n. 13, 19-20.

the context of the civil liability of the prescribing physician and the administrator of a drug, this uncertainty has tended to benefit the psychiatric profession.¹¹¹ It has been concluded that the problem of drug-induced injuries is certainly not substantial for the medical profession,¹¹² indeed the problem has been described as "minuscule".¹¹³

It is far from clear that the problem is minuscule for mental health patients. The paucity of claims may be attributable to a lack of serious, actionable drug-induced injuries or it may be attributable to the difficulties faced by an injured patient in establishing liability on the part of those who prescribed and administered the drug to him. In negligence litigation, the plaintiff bears the burden of proof on all issues, throughout the trial. In professional negligence actions, the burden of proof is exceedingly difficult to discharge. The first ingredient of the plaintiff's claim is, of course, that a duty of care was owed to him by the defendant; as has been stated, this duty is implied on proof of the doctor-patient relationship. The plaintiff must then prove that the defendant physician did not discharge that duty of care, that is, departed from the standard of ordinary professional competence. As part of his case, the plaintiff must adduce evidence from doctors as to the standards of average professional skill and practice and as to the state of average knowledge within the profession at the relevant time. It is notoriously difficult to persuade one medical practitioner to testify against another and this second ingredient is a formidable practical obstacle to success. The next element of the plaintiff's case is that the negligence complained of caused compensable injury. On the issue of causation, the plaintiff must also adduce expert evidence; but he may be able to elicit sufficient evidence from pharmacologists and research chemists without having to call practising psychiatrists. The fourth issue on which the plaintiff bears a burden of proof is that the injuries which he sustained were of a kind which the defendant ought to have foreseen when the drug was prescribed; in the course of proof on this issue, there would have to be a review of current professional literature, the terms of the manufacturer's labels and the doctor's personal knowledge, if any, of the effects of the relevant drug.

The final burden borne by a plaintiff in a negligence suit is that of proving his damages, in monetary terms. This task is never easy to discharge. While awards for purely physical injuries tend to become standardised by reason of the huge volumes of claims determined by courts and assessed by insurance companies, damages for proven psychological injury, pain and suffering, loss of amenity and mental anguish are much more difficult to quantify. Where the plaintiff is shown to have suffered from a mental illness, his damages will be discounted, insofar as they would otherwise compensate for his loss of enjoyment of life, because it will be taken as given that his enjoyment of life would, apart from the injuries, have been less than that of a plaintiff without a relevant, pre-existing incapacity. Pecuniary damages are in any event inherently incapable of providing full compensation for personal injuries, physical or psychological.

111. Malpractice cases for maladministration by psychiatrists of injurious drugs are relatively few, even in the USA; there, insurance company statistics have been interpreted to show that, as a class of action, psychiatric malpractice claims occur at the rate of 1.5 claims per 100 psychiatrists per annum whereas claims made against other kinds of medical practitioners occur once in respect of each practitioner every fourth year. No tabulation of successful psychiatric malpractice suits has been prepared and it is not known how many psychiatric malpractice suits per annum relate to drug induced injuries. Most claims relate to shock therapy, improper involuntary confinement, faulty diagnosis, breach of confidentiality, improper sexual relations and patient suicides: Slovenko, *supra*, n. 10, 399; D. J. Dawidoff, *The Malpractice of Psychiatrists*, (C. C. Thomas, Springfield, 1973), viii.

112. Slovenko, *supra*, n. 10, 398.

113. J. T. Gibson, *Medication Law and Behaviour* (Wiley, 1976), 356-358, 385-386.

A mentally ill person, or a plaintiff with a history of mental illness, labours under peculiar disadvantages in the litigious context. In the very nature of things, he will rarely be able satisfactorily to supervise the conduct of litigation by his advisers. "Litigation neurosis" will tax him severely. He will have problems in funding an action; few persons have sufficient financial resources to undertake a professional negligence action, certain as it is to be defended strenuously; those patients who are impecunious may find themselves without legal aid because legal aid managers are understandably reluctant to support actions where the prospects of success cannot be shown to be good. In the very worst cases of drug-induced injuries, a course of deleterious therapy will totally deprive a patient of his capacity to provide workable instructions to his legal advisers and to give evidence, and will hinder him in establishing his condition and prognosis before the side effects of the therapy manifested themselves. For these reasons, one is drawn irresistibly to the conclusion that the civil remedies available to an injured patient are, in the existing order of things, inadequate alone to control the use of potentially harmful psychoactive drugs. Detained patients in particular require additional rights and safeguards for their more adequate protection. The extent to which the criminal law furnishes protection to mental health patients will now be considered.

Criminal Liability for Malevolent Administration of Psychoactive Drugs:

There are two principal criminal law sanctions on the improper treatment of the mentally ill by drugs. In the first place, any unauthorised, intentional touching of the body of the patient would be an assault.¹¹⁴ In the second place, the Mental Health Act provides that

"Any person having the oversight, care or control of a person who is suffering from a mental illness or mental handicap who ill-treats or wilfully neglects that person, shall be guilty of an indictable offence."¹¹⁵

Clearly, psychiatrists and institutional staff are within the class of persons "having the oversight, care or control" of such of their patients as are resident in hospitals, voluntarily or otherwise.¹¹⁶ Given the present context, the offence of wilful neglect may be ignored, and attention will be focussed on the legal consequences of injuries resulting from an active programme of drug therapy, that is from positive treatment. When can such treatment be said to be "ill-treatment"? So far as is known, there are no reported English or Australian cases on the applicability of provisions such as section 44 to drug abuse. Clearly, the Act requires more than the mere administration of a deleterious drug; the use of a toxic drug appears to be a necessary but insufficient condition of liability. In accordance with the general principles of the criminal law, a proven intention to ill-treat or culpable recklessness is probably a condition of responsibility.¹¹⁷ Arguably, the Act prohibits several unprofessional and unorthodox techniques of drug therapy. First, it would catch the unconsented administration of a toxic drug which was purely experimental or punitive where the foreseeable detriment to the patient outweighed any therapeutic advan-

114. See above n. 67, and Skegg, *supra*, n. 78, 530; as to whether consent can be a defence to an assault perpetrated by a medical practitioner, see P. D. G. Skegg, "Medical Procedures and the Crime of Battery" [1974] *Crim. L. Rev.* 693; Jacob, *supra*, n. 64, 226-228; G. Parker, "Two Views on Consent in the Criminal Law" (1963) 26 *M.L. Rev.* 233.

115. S.44(1); sec. 49 prescribes a maximum penalty of \$2000 and a term of imprisonment not exceeding one year for offences under s.44.

116. See *R. v. Holmes* [1979] *Crim. L. Rev.* 52; Halsbury, *supra*, n. 64, vol. 29, para. 912; see also, *Rosey v. Lipson* [1958] S.A.S.R. 41 and s.27(1)(b) of the Act.

117. See C. Howard, *Criminal Law*, (3rd ed., Law Book Co. Ltd., Sydney, 1977), 358-359; S. Mitchell, ed., *Archbold: Pleading, Evidence & Practice in Criminal Cases* (40th ed., London, Sweet & Maxwell, 1979), 938-945.

tage. Secondly, it might prohibit the dispensation of a toxic drug to a patient for an ulterior motive, such as the convenience of staff or the mere control of patients. Thirdly, it would cover non-consensual aversion therapy and punitive therapy accompanied by real pain and distress in the patient.

Some comment is called for in relation to this last mentioned type of conduct. Aversion therapy can be a legitimate and valuable curative technique; it is the basis of many voluntary programmes for the cure of alcoholism and other addictive disorders. It is submitted, however, that non-consensual aversion therapy programmes ought not to be permitted, especially where the patients are mentally disturbed and especially where the programme involves the use of major tranquillizers. Whatever may be the utility of the major tranquillizers in the benevolent treatment of mental illness, it appears that the psychological effects of these drugs are seldom pleasant and may indeed be dysphoric in the case of non-psychotic patients. As a result, these drugs are not subject to self abuse.¹¹⁸ Some of the neuroleptic drugs do lend themselves to aversive and punitive therapy; at least three have been used for these purposes in the United States. The phenothiazine Thorazine is suspected of having been widely used for the control and punishment of inmates in both penal and civil psychiatric institutions and of use in a punitive and vindictive manner by way of the administration by institutional staff of larger doses than necessary.¹¹⁹ Anectine (succinylcholine) is legitimately used in South Australia as an accompaniment to ECT: it induces total muscular paralysis with a view to preventing physical injuries during convulsions; by virtue of its action as a neuro-muscular blocking agent, the drug is capable of paralysing the neuro-muscular system within five minutes. Respiratory collapse follows but consciousness is unimpaired. The patient may sustain a loss of respiratory capacity for several hours, during which time he is, to his knowledge, incapable of supporting his own life and utterly dependent on an external oxygen source. In the United States, the drug has been used to horrify and torture criminally detained mental health patients in a way which would outrage any right thinking observer.¹²⁰ The third drug is apomorphine, which is believed not to be used in psychiatric institutions in South Australia. It has been used in the United States as an emetic, for punitive purposes, notwithstanding that it can worsen tardive dyskinesia; its improper use in that country has been enjoined by federal courts.¹²¹ Clearly, the use of these three pharmaceuticals in South Australia for the purposes to which they have been applied abroad would be prohibited by section 44.

The adverse psychic potency of the major tranquillizers and their capacity to be abused are additional reasons for stricter controls on their availability and

118. See Julien, *supra*, n. 12, 130.

119. Brooks, *supra*, n. 24, 878; R. G. Spece, "Prisoners and Mental Patients", (1972) 45 S.C.L. Rev. 616, 617; Plotkin & Gill, *supra*, n. 40, 649. In *Nelson v. Heyne*, 491 F. 2d. 352, 357 (1974), cert. den. 417 U.S. 976 (1974) the court found that thorazine and sparine had been administered to juveniles in a penal reform school for non-therapeutic purposes. It was held that this amounted to cruel and unusual punishment. The court accepted evidence that these drugs, when administered to juveniles, could cause cardio-vascular collapse, asphyxiation through closing of the throat and could exert a depressant effect on the production of bone marrow and induce jaundice and other haematological disorders. See also *Veals v. Ciccone* 281 F. Supp. 1017 (1968); *Peek v. Ciccone* 288 F. Supp. 329 (1968); *Morgan v. State of New York* 319 N.Y.S. 2d. 151 (1970); *Cox v. Hecker* 218 F. Supp. 749 (1963); *Kosberg v. Washington Hospital Center Inc.* 394 F. 2d. 947 (1968); and the cases cited in n. 53, *supra*.

120. For a discussion of the punitive use of the drug, see Spece, *supra*, n. 119; Brooks, *supra*, n. 24, 887; and see *Mackey v. Proconier* 477 F. 2d. 877, 878 (1973); *Chapman v. Argonaut-Southwest Ins. Co.* 290 So. 2d. 779, 782 (1974); *Patterson, supra*, n. 18, 334.

121. *Knecht v. Gillman* 488 F. 2d. 1136, 1140 (1973). For a discussion of this drug, see *Baldessarini & Tarsy, supra*, n. 47, 1001.

on their use than are provided for by the existing law. It is now proposed to consider the question whether techniques of control over drugs other than those provided for by the law at present are feasible.

The Patient's Right to Control his Therapy:

As has been seen, the law at present provides for several indirect controls on the administration of pharmaceuticals to mental health patients. In the first place, the National Health (Pharmaceutical Benefits) Regulations and the Schedule of Benefits for Medical Practitioners impose various restrictions on the prescription, initial and repeated, of several of the drugs referred to in this article. Secondly, the criminal law offences of assault and of wilful neglect and ill-treatment render illegal the deliberate, non-therapeutic application of deleterious drugs to mental health patients and certain kinds of unorthodox drug therapy. Thirdly, the civil law provides for *a posteriori* remedies against the unconsented or careless use of toxic drugs. Even in combination, these controls do not involve adequate safeguards, before the event, against the supply of potentially dangerous pharmaceuticals to mental health patients. The mentally ill have special claims to abnormally strict protective measures because they are in many senses wards of the society, because they are least able to assert their rights and because, due to their incapacities, they may be unable to assess or articulate side effects of therapy. Two additional modes of control over drug therapy are available: the Mental Health Act might, directly or by regulation, restrict the use of those drugs which are potentially very harmful; or patients might be given the right to regulate their own therapy, to the extent to which they are capable of doing so.

Statutory controls on drugs might take one of several forms. Section 9 of the Act, which prescribes the objectives to be pursued by those administering the Act, might be made more specific so as to confer on each patient an enforceable right to be given individual care and treatment adapted to his needs which is skilfully, safely and humanely administered with full respect for his dignity and personal integrity and which is the least painful, disruptive and traumatic treatment practicable in the circumstances. Section 19 of the Act, which at present imposes restrictions on psychosurgery and ECT, in the case of detained patients, might be broadened, or regulations might be proclaimed under sub-section (3), so as specifically to prohibit improper uses of drugs, such as the administration of medication for the convenience of institutional staff, the use of drugs as a substitute for a therapeutic program or in quantities that are excessive, or the use of pharmaceuticals for experimental, aversive or punitive purposes. In addition, that provision or regulations under it might identify drugs which are considered to be so toxic that their hazards outweigh their potential benefit to patients, and might according to their toxicities prohibit their use either absolutely or subject to the affirmative consent of the patient or a guardian. Consideration might also be given to making "drug holidays" mandatory for all patients after, say, 2 or 3 months¹²² of treatment, for a period sufficiently long to enable an assessment to be made of beneficial and harmful effects of drug therapy on each individual patient.

An expert consultative committee might be established to review the general use of hazardous drugs. In relation to particular patients declared by it or by the Guardianship Board to have insufficient capacity to give informed consent to treatment and to participate effectively in treatment decisions, the Commit-

122. This period is suggested because a lag time of three to four weeks is required for any positive effects of drugs to manifest themselves; on one view, if no positive effects become apparent after four weeks, treatment should be discontinued and the diagnosis reviewed: Byck, *supra*, note 1, 173, 175, 187.

tee might be vested with the power to approve the long-term application of drugs in relation to which caution is required. In exercising its powers, the committee should be required to consider the capacity of the relevant drug therapy to effect a non-transient improvement in the patient's condition, the character and probabilities of any such improvement, the dangers to the patient of non-administration of the drug, the risks and likely duration of adverse side effects and whether these can be mitigated, the age and sex of the patient, the patient's wishes so far as they are ascertainable, whether the therapy is experimental or orthodox, and whether the patient's disorder is sufficiently serious to warrant application of very potent drugs or whether less potent and less toxic drugs might not be equally effective in treating the disorder. Such a committee should, to be effective, be independent of the hospital treating the patient concerned and should operate other than as a peer review group.

A different regime of control might be created in relation to those patients who are determined by the Guardianship Board to have the capacity to participate in their own treatment decisions. The law should explicitly declare that, except in emergencies (that is, situations where the use of drugs whose effects are not irreversible is necessary to save life or to prevent dangerous or violent behaviour or to prevent the imminent deterioration of the patient's condition or to alleviate severe pain or distress) the administration of drugs without the consent of the patient is wrongful. In addition, it should become a principle of institutional health administration that patients able and willing to do so should have a right of self determination in formulating their treatment programs. Initially, this right might be limited to the negative one of refusal of treatment except in emergencies, whether the patient be voluntary or detained.

A valuable source of law reform material in this area is the United States, where much pioneer work has been done in improving the lot of the institutionalised mentally ill. At the legislative level, the Congress has enacted the Developmentally Disabled Assistance and Bill of Rights Act.¹²³ This legislation benefits the "mentally retarded" rather than the "mentally ill", but it may be a precursor of similar legislation for the benefit of the mentally ill. Relevantly, the legislation provides that both the Federal and State governments "have an obligation to assure that public funds are not provided to any institutional ... program for persons with developmental disabilities" that does not prohibit "the excessive use of chemical restraints on such persons and the use of such restraints as punishment or as a substitute for a rehabilitation program or in quantities that interfere with services, treatment or habilitation for such persons"¹²⁴ At the State level, the legislatures in a majority of States have enacted restrictions on psychosurgery and ECT. Only about twenty have granted institutionalised patients an absolute or qualified right to refuse psychoactive drugs.¹²⁵

American courts, too, have been active in recognizing two complementary rights in institutionalised patients, that is, a right to receive proper and adequate treatment and a right to refuse treatment. So far, the cases on a right of refusal have been decided on constitutional grounds, so that the reasoning employed in them is inapplicable in Australia. The decisions do not go beyond laying down rules against the unconsented use of psychosurgery and ECT and

123. 42 U.S.C. 6001 (1975).

124. S.6010(3)(iv).

125. Plotkin, *supra*, n. 8, *Appendix*.

against aversive conditioning, excessive and unnecessary medication and experimental, unusual and hazardous treatments.¹²⁶

The reforms that have been suggested here are based on the presupposition that the long-term administration of several neuroleptic drugs involves grave risks of serious harm to significant percentages of patients which may outweigh the probably benefits of therapy and that many of these drugs should not incautiously be administered to the mentally ill; *a fortiori*, they should not be forced on the involuntarily detained. If these risks are to be borne at all by patients, they should be assumed as a last resort when other available and less hazardous therapy has been exhausted and then only where the physician has obtained the informed consent of the patient (if he be sufficiently rational) or his guardian in other cases. It is acknowledged that the decision as to whether any particular patient has sufficient command of his faculties to approve or disapprove a long term course of neuroleptic therapy is one of the most difficult problems of mental health administration. For this reason, it has been suggested that the final power to make this decision be vested in an expert committee, detached from the specific institution accommodating the patient.¹²⁷ The treatment decision of a civil patient declared to be rational should be inviolable.

There are clinical objections to the use of drugs, even when benevolently prescribed; a decision to prescribe drugs may be a response to behaviour which is merely upsetting to others or deviant to the point of being labelled a symptom of mental illness; when this is the case, the drug serves mainly to mask the problem and to make it easier for others to cope with the drugged individual. Drugs do not alter the conditions out of which a mental problem developed and may in fact serve to perpetuate the existence of positively harmful social arrangements by concealing the need for a long-term alternative solution. Concededly, the administration of drugs during psychotic episodes may, when the episode has organic origins, be an effective short-term method of bridging an immediate crisis to enable long-term therapy to take place; it is otherwise when effected to enable patients to cope with indefinite structural problems in their lives.¹²⁸ There is no unanimity among psychiatrists that the disorders against which the neuroleptic drugs are directed are such as will respond to organic therapy and that the drugs are of real benefit to patients; disorders of the "mind" having dynamic or environmental origins rather than a source in deranged cerebral chemistry cannot be defeated by drugs. Specifically, it has

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126. As to psychosurgery and ECT, see *Price v. Sheppard* 239 N.W. 2d. 905 (1976) and *Wyatt v. Stickney* 344 F. Supp. 373, 387 (1972); 325 F. Supp. 781 (1971); 503 F. 2d. 1305 (1974). In *Winters v. Miller*, *supra*, n. 72, the court held that an involuntary patient who objected on religious grounds to taking certain drugs had a constitutional right to resist medication which the institution was seeking to force her to accept. Conversely, it has been held first, that a person involuntarily committed to a state mental hospital has a constitutional right (derived from the Fourteenth Amendment) to receive such individual treatment as will give him a reasonable opportunity to be cured or at least to improve his mental condition and secondly, that a detained patient whose condition poses no dangers for himself and others and who is capable of surviving outside the institution must be constructively treated or released: *Donaldson v. O'Connor* 493 F. 2d. 507; 422 U.S. 563, 576, 577 n. 12 (1975). Burger, C.J. dissented on the question whether there was a constitutional right to treatment. See also *Whitree v. State of New York* 290 N.Y.S. 2d. 486 (1968); B. Ennis, *Prisoners of Psychiatry*, (N.Y., Harcourt Brace Jovanovich, 1972), Chapter 5; Note, (1974) 87 *Harv. L. Rev.* 1190, 1316-1365.
127. See Note, "A Model Statute to Regulate the Administration of Therapy within Mental Health Facilities" (1977) 61 *Minn. L. Rev.* 841, 851, 865. The Committee would be similar in constitution and function to the Consultative Committee which supervises psychosurgery in N.S.W.; see *Proceedings of the Institute of Criminology, University of Sydney*, No. 22: *Proposed Amendments to the N.S.W. Mental Health Act, 1975*, 82 ff., 135-136.
128. E. M. Bates, *Models of Madness*, (University of Queensland Press, Brisbane, 1977), 99-100.

been asserted that large drug studies reveal that at most only one half of schizophrenics have derived benefit from drug treatment and that many of those who do improve in consequence of drug therapy "do not show anything approaching a recovery from the disease or restoration of full social effectiveness."¹²⁹ In other words, the benefits to be gained from drug therapy are, in many cases, speculative at best and may not be outweighed by the potential adverse somatic consequences of long-term neuroleptic drug therapy. In addition, as has been noted in relation to the tricyclic anti-depressants, certain drugs can actually exacerbate the symptoms for whose abatement they are applied. In this state of things, can we conscientiously tolerate the enforced or incautious administration of potentially deleterious chemicals on the unwilling or the uninformed? If it is agreed that we cannot, what should be done? No reform should be executed in such haste as to jeopardise the orderly administration of psychiatric institutions or the welfare of patients and no reform should unreasonably restrict the discretion of the diagnosing psychiatrist.

The proposals for reform outlined above would, it is submitted, prove to be neither unworkable for institutional staff nor an intolerable restraint on the therapeutic discretion of psychiatrists, yet they would provide substantial improvement in the legal safeguards protecting the mentally ill.

Conclusion

The article has sought to show that the time has arrived for a more thorough regulation of psychopharmacotherapy. This proposition is true, with particular emphasis, in relation to the neuroleptic drugs whose marketing and use has been authorised by Commonwealth and State health authorities but whose practical applications are virtually uncontrolled in advance. No doubt, many drugs administered in the ordinary course of psychopharmacotherapy are very useful to many patients, their benefits outweighing any unintended side effects, and there is no basis for suggesting a total prohibition of drug therapy even when applied involuntarily. However, the efficacy and safety of many widely used neuroleptic drugs has been called in question and drugs of this category ought not to be administered involuntarily to any person other than as an exceptional measure.

So far, the law has not served well the interests of psychiatric patients. Generally, in respect of civilly committed patients, it is true to say that the law intervenes in their aid in relation to drug therapies only in two ways: first, by regulating the flow of drugs into commerce; and secondly, by sanctioning the careless manufacture and the negligent or unconsented administration of drugs in circumstances where the case is one falling within the limits of the torts of battery or negligence or the crime of assault. Neither of these modes of intervention has been effective to ensure the invariably safe and effective use of the psychoactive drugs and it cannot be denied that in the result large numbers of patients have been injured.

One premise on which the future growth of the law should be based is that except in emergencies no patient should be subjected to drug therapy unless it is clear that no less intrusive therapy will serve the interests of the patient in the relief of his disorder. There is yet no irrefragable evidence that any single psychoactive drug is capable of curing any particular mental illness (as opposed to suppressing its symptoms) or that, long term, the psychoactive drugs as a class are more effective therapeutic agents than non-intrusive techniques such

129. F. Sulser and S. E. Robinson, "Anti-Psychotic Drugs: Modes of Action," in Lipton, *supra*, n. 18, 943, 952; cf. Byck, *supra*, n. 1, 152, 156, 172, 173, 176.

as psychotherapy. A second premise is that the routine administration of psychoactive drugs should be controlled in advance rather than being regulated by criminal penalties or by awards of damages after a legally actionable injury has been inflicted. In the present regimes of compensation for the maladministration of injurious drugs, it is very difficult in practice for an injured party to gain compensation; indirectly, these practical difficulties tend to leave the administration of legal but injurious drugs unregulated. Control by an independent committee or if practicable by the patient himself, in the manner proposed in the preceding pages, will strike a more equitable adjustment between the competing interests of society (in suppressing anti-social behaviour and in having all its members capable and functioning) and of the patient (in being free and inviolable) than is struck by the present rules of law.

Law reform in these directions, which became desirable shortly after the introduction of chlorpromazine in 1952, is now imperative.