The Legal and Social Implications of Psychopharmacology

Thomas P. Dugan
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PSYCHOPHARMACOLOGY

One out of every four adults in the United States has taken a psychotropic agent in the last year; one out of every two has taken a psychotrope at some time in his life. Since their introduction in the 1950s, the new psychotherapeutic drugs have attained a position of importance in the armamentarium of the physician. Whether the increase in the use of these drugs is the result of "turbulent times," of promotional efforts, or of sloppy prescribing practices of clinicians is uncertain. There is, however, reason to believe that psychopharmacology will hold a unique position within drug liability in much the same way that the latter has been sui generis within products liability.

I. NATURE AND USE OF PSYCHOTROPIC DRUGS

A. What is a Psychotrope?

"Psychotropic agents are defined as those substances which have their main or principal effect on mood, thought processes, or behavior." There are six classes of psychotropic agents: major tranquilizers, minor tranquilizers, antidepressant agents, stimulants, sedatives, and hypnotics. Over the counter (OTC) psychotropes have been set aside for the bulk of this article. It is impor-

1. The terms "psychotropic", "psychotherapeutic" and "psychopharmacological" are used interchangeably throughout this article. For a definition, see text accompanying note 6, infra.
4. Hollister, Clinical Use of Psychotherapeutic Drugs II: Antidepressant and Antianxiety Drugs and Special Problems in the Use of Psychotherapeutic Drugs, 4 DRUGS 361, 386 (1972).
5. RESTATEMENT (SECOND) OF TORTS §402A, Comment k, at 353-54 (1965): There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. . . . Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous. See also, Rheingold, Products Liability—The Ethical Drug Manufacturer’s Liability, 18 RUTGERS L. REV. 947 (1964).
7. See Appendix I. The chart was taken from Parry, et al., supra note 3, at 772.
8. Over the counter psychotropes include stimulants (e.g., No-doz), tranquilizers (e.g., Cope and Compoz) and sleeping pills (e.g. Sominex and Sleep-Eze). See Appendix I.
tant to note that these "[p]sychotherapeutic agents act by un-
known mechanisms to reduce the level of symptomatology of pa-
tients but do not . . . directly affect the causative agent of the
illness in the same manner as antibiotic agents attack the mi-
crobes which cause infectious diseases." This is because the
etiology of psychiatric disorders is essentially unknown. Therefore,
most psychiatric disorders are hypothetical entities postu-
lated from psychological and physical symptoms manifested by
an individual.

The major tranquilizers were introduced into widespread use
in the mid-1950s. The phenothiazine-related compounds
compose the bulk of this class of drugs. They are primarily
thought of as agents effective in the treatment of one of the major
psychiatric disorders, psychosis, and thus, are often termed an-
tipsychotic drugs. The most common side effects of these com-
pounds include drowsiness and extrapyramidal symptoms such
as are seen in Parkinson’s disease; drug dependence of a
psychological or physiological nature does not occur. The minor
tranquilizers appeared about the same time as the major tran-
quilizers and are considered to be antianxiety agents. They may
produce a physiological dependence similar to that known to
occur with barbiturate drugs.

The antidepressant drugs came some years after the major
and minor tranquilizers. There are two principal categories: the
tricyclic series and the monoamine oxidase (MAO) inhibitors.
There is some evidence that concurrent consumption of a tricyclic
and a MAO inhibitor results in a toxic state; physiological de-
pendence, however, has not been established in this class of
drugs.

The stimulant class, of which amphetamines constitute the
bulk, are used to treat obesity and to some extent depression,

10. Id.
11. Id., at 4.
12. Id.
13. Id., at 5.
14. Id.
Res. 480 (1973).
16. Balter and Levine, supra note 2, at 5.
The sedatives, which are mostly barbiturates, have been available for a long period of time. Both psychological and physiological dependence exist with this class. The hypnotic class of drugs is effective in the treatment of sleep disturbances. When taken in large doses, marked intoxication results, and, over a period of time, severe psychological and physiological dependence can occur.

B. Societal Attitudes

Psychiatry is the only medical specialty in which generalizations about methods of treatment substitute for actual clinical experience. It is also the only specialty about which laymen have strong opinions for or against procedures in which they have either infinite faith or which they totally condemn.

There exist at least three views toward the use and development of psychotropic drugs. It seems that often these views are less predicated on profound convictions than on the popular view of such drugs.

Earlier popularized accounts of psychotherapeutic drugs as 'miracle drugs' appearing in the mass media—not infrequently in the same publications which have swung around to viewing the same drugs with alarm—have played their part in generating awareness of such drugs.

Nevertheless, there are those who perceive that decisions made in this field require assiduous scrutiny of a whole gamut of values—scientific, social, legal and ethical.

One view of these drugs is rooted in our history and has been termed "pharmacological Calvinism." This is a puritanical approach whose purpose is "abstinence from all chemical substances." Adherents view current phenomena in the drug field as being exemplary of general moral decadence. Struggle and pain are concomitants of human existence and thus, drug con-

17. Id.
18. Id.
20. Parry et al., supra note 3, at 770.
sumption resulting from an inability to cope with stress is considered a weakness of the highest order. Tension, anxiety, depression and despair "are all part of the normal repertoire of everyday life." By themselves, these moods and emotions are not considered pathological.

They are part of an individual's capacity to experience emotion as a part of his biological heritage, and they play an important adaptive role in facilitating man's adjustment to his environment.

This philosophy imparts the simple notion that "[i]f a drug makes you feel good, it must, somehow, be bad." The antithesis of this position "combines permissiveness . . . with the expectation that life could, and indeed should, be free from care and stress." Psychotherapeutic drugs become "simply adjuncts of comfort and utility." It is maintained that the dilemma with respect to mind-altering drugs is merely history repeating itself. When coffee and tobacco were introduced, they were the subject of as much debate as now surrounds marijuana.

As is the situation with most polarities, the truth lies somewhere in the middle. It is unfortunate, however, that doctors often find themselves in the position of adjudicating these philosophical and emotional conflicts. In fact, psychiatrists themselves eschew being characterized as drug therapists. The author believes that the most productive orientation is a moderate one, whereby we prescind from the enticing opportunity to indulge in moral indignation and instead examine the facts:

23. Id., at 119.
24. The opinions regarding drug intake for these "moods" should and probably do become less stringent as one begins to discuss the more serious "mental disorders" such as manic depression or schizophrenia.
26. Id., at 120.
27. Parry et al., supra note 3, at 770.
28. Id.
29. Klerman, supra note 22, at 120.
30. A survey of 360 psychiatrists' attitudes toward treatment disclosed a major professional inconsistency. Eighty percent of the psychiatrists rated themselves as being psychotherapists ("talk" therapy) even though most of them were not doing any psychotherapy. Only ten percent considered themselves somatic (drug) therapists even though the majority in public mental hospitals were prescribing large amounts of psychoactive drugs. See Pearlin and Klerman, Career Preferences of Psychiatric Residents, 29 PSYCHIATRY 56 (1966); Armor and Klerman, Psychiatric Treatment Orientations and Professional Ideology, 9 J. HEALTH AND SOCIAL BEHAVIOR 243 (1968).
There is such a thing as mental illness, and the major tranquilizers and anti-depressants perform a valuable role in its treatment. There are minor neurotic states and for these the various less-powerful psychotherapeutic drugs perform a useful temporary function.

Upon recognizing a legitimate need for psychotropic drugs, the problem which arises is how to ensure as much as possible that these drugs are effective and not unreasonably dangerous, and that the right drugs get to the right persons in the right amounts. This problem necessitates the kind of analysis commonly used in the products liability field: risk versus benefit. It also entails considerations beyond the legal sphere. As one doctor depicted the analysis:

There is no question but that drugs are one of the major tools our country's physicians have, both for preventing and treating disease, and as such, they constitute one of our most important resources for an effective health care system. At the same time, misuse and overuse of drugs, and wastage of drugs — in the sense that some products do not benefit the patient and have no rational use in therapy — pose some of the most important medical and social questions of the day.

C. Use and Overuse of Psychotropic Drugs

The resounding question is whether psychotropic drugs are being overprescribed and overused in the United States. "Unfortunately, this issue is more easily raised than answered if conclusions are to be documented and factual rather than opinionated and judgemental." Statistical studies have been conducted in an attempt to ascertain usage trends for psychotropic drugs in the United States. It has been determined that "[i]n the year 1970, the last reported, some 214 million prescriptions were filled in American drugstores for . . . the main classes of psychotherapeutic drugs. These drugs in 1970 accounted for 17 percent of the total prescriptions of all kinds filled in drugstores in the United States (including refills)." Data collected for the year 1967 show that "there were 54.1 new prescriptions for psychotropic drugs filled for every 100 of adult population." The figures reflected an

33. Id.
34. See, e.g., id.; Parry et al., supra note 3.
35. Parry et al., supra note 3, at 770.
36. Balter and Levine, supra note 2, at 6. Of course, these drug acquisitions are not equally distributed per person.
increase of 65 percent in the number of new psychotropic drug prescriptions between 1958 and 1967, as opposed to a 35 percent increase for all other drugs in the same period. When trends for new psychotropic drug prescriptions are broken down by major drug class, it becomes apparent that the large overall increase . . . is mainly attributable to minor tranquilizers . . . .

Currently, chlordiazepoxide (Librium) and diazepam (Valium) are the most popular, accounting for almost 50 percent of retail sales of tranquilizers in the first half of 1970. Here, we are on the borderline between medical practice and social values. We are in debatable area because one, we are dealing with value questions, and two, we do not have good data.

An interesting aspect of the “minor tranquilizer phenomena” is that, although “. . . it can be seen that current prevalence rates for prescription psychotherapeutic drugs are twice as high for women as for men,” most of the statistical difference between sexes can be accounted for by a single broad class of drugs — the minor tranquilizer/sedative group. Perhaps one explanation of the high consumption level among women is that male drug prevalence rates with respect to “substitute” substances, specifically alcohol and marijuana, are substantially higher than female rates. Contrary to the image of the “pill-popping” middle class housewife, the data show that the lowest socioeconomic stratum is responsible for most of the high drug use. Drawing inferences from “high” drug use may be misleading in that a smaller percentage of low income users with a serious “high” level of consumption can outweigh a more pervasive, albeit more

37. Id., but note that part of the increase in new psychotropic drug prescriptions for 1966 is due to the passage of the Drug Abuse Control Amendments of 1965, 21 U.S.C. § 374 (1970), which set limits on the number of refills for sedative, stimulant and hypnotic drugs. Thus, a sharp increase in new prescriptions resulted.

38. Id.


41. Parry et al., supra note 3, at 774.

41.1. Id., at 774-75.

42. Id., at 775.

43. Id., at 779. This may indicate that middle class women are more moderate in their use; the fact that the lower socioeconomic levels are reporting greater prevalence rates for “high” drug use is thought to be a result of waiting “until symptoms are more serious and that consequently the drugs must be taken over longer periods of time.”; id.; see text accompanying note 68 infra for a discussion of manufacturer’s selling tactics with respect to housewives.
vidually moderate trend among middle class users. The author's personal, though limited, investigation reaffirms this: a suburban pharmacist gave sobering statistics on minor tranquilizer sales in an upper middle class area.\textsuperscript{44}

It was found that these drugs are most often prescribed by general practitioners and internists and usually on an "as needed" basis.\textsuperscript{45} Ironically, psychiatrists are not the big prescribers of psychotropic drugs:\textsuperscript{46}

Even in the case of antidepressants and major tranquilizers, primarily prescribed for mental disorders, psychiatrists and neurologists account for only about a third of the prescriptions written. Our own findings, approaching the issue from the direction of the patient, indicate that: 85\% of our respondents who had used prescription psychotherapeutic drugs in the year preceding our survey reported they had never seen a psychiatrist in their lives.

The fact that "... over 70 percent of all prescriptions for psychotropic agents are written by general practitioners, interns and surgeons"\textsuperscript{47} does not necessarily mean that they are usurping the psychiatric domain, for "new therapy with minor tranquilizers is just as likely to be directed to patients with a primary diagnosis of physical disorder as it is to persons with a primary diagnosis of mental disorder."\textsuperscript{48} However, the data indicate that the physician’s specific therapeutic intent at the time of prescribing is to alleviate symptoms of psychic or emotional distress regardless of the actual etiology.\textsuperscript{49} The fact that general practitioners are treating essentially psychic disorders causes difficulty with respect to those patients who do ultimately see a psychiatrist and one can only conjecture about the situation of those who fail to do so. One psychiatrist depicted the danger thusly: "[I]n our practical work we specialists hardly ever see depressed patients who did not

\textsuperscript{44} Interview with Louis Biundo, Greenvale Pharmacy, Greenvale, N.Y. He stated that monthly sales of Valium were 6,000, 3,000 and 1,500 for the 5 mg., 2 mg., and 10 mg. pills respectively or a total of 51,000 mg. per month. Librium sales average about half as much as those of Valium. Interestingly, he said that although the pharmacy's business could be roughly broken down to 75\% Roslyn (upper middle class to wealthy), and 25\% Greenvale (lower middle class), 97\% of minor tranquilizer sales were attributable to the Roslyn clientele.

\textsuperscript{45} Balter and Levine, supra note 2, at 12.

\textsuperscript{46} Parry et al., supra note 3, at 770.

\textsuperscript{47} Balter and Levine, supra note 2, at 10.

\textsuperscript{48} Parry et al., supra note 3, at 774.

\textsuperscript{49} Id.
already have some trial with antidepressant medication. The general practitioner is the first to prescribe these drugs, often in inadequate amounts.\footnote{Drug Safety Hearings, supra note 19, pt. 3, at 1222 (quoting article).} Dr. Nathan Kline, who heads the largest private practice in the country which specializes in psychopharmacology, has encountered similar problems.\footnote{Doctor Kline's office is located at 40 East 69th Street, New York City. He is also Director of Research at Rockland State Hospital.} He indicated that letters have arrived frequently from persons who have been receiving medication for various mental or emotional disorders from general practitioners.\footnote{Interview with Dr. Kline on December 12, 1973.} Often the medication is prescribed in inappropriate dosages for the patient's condition and at times the drug's action could serve only to enhance the symptoms.

D. Is there a "Cure" for Overuse?

Since general practitioners are "consistently overrepresented on use of all classes of psychotropic agents,"\footnote{See section II, infra.} and since the drugs are often the subject of conflicting opinion even among the specialists in the field,\footnote{Drug Safety Hearings, supra note 19, pt. 3, at 1216.} it would seem logical to give serious consideration to restricting prescribing by general practitioners at least until the nature of psychotropic drugs is better and more widely understood. For example, while FDA approval of Parnate (MAO inhibitor) was engendering controversy, the manufacturer "... itself [had] suggested the possibility of restricting use of the drug to hospitalized patients who were under the care of psychiatrists."\footnote{21 U.S.C. §355(i) (1970).} Prescinding from the difficulty of differentiating psychiatric from non-psychiatric use of psychotropes, a major outcry in response to a restriction of psychotropic prescriptions would be forthcoming from the medical profession, which has been traditionally allowed to prescribe any drugs approved by the FDA and some that are being investigated.\footnote{New York Times, Dec. 9, 1973, §4, at 6, col. 1.} The American Medical Association has often reflected doctors' "fears of losing their independence to government control ... .\footnote{Drug Safety Hearings, supra note 19, pt. 3, at 1216.} The physician's classical role in drug liability cases\footnote{"No court has yet held that a physician's departure from any portion of the approved labeling [or directions] conclusively establishes negligence."
Merrill, Compensation for Prescription Drug Injuries, 59 Va. L. Rev. 1, 53 (1973). In most jurisdictions a physician who follows the community standard of good medical practice is not negligent. E.g., Mallet v. Pirkey, 171 Colo. 271, 466 P.2d 466 (1970).} as an automatic

\footnote{Balter and Levine, supra note 2, at 10.}
"independent decision maker" is perhaps not consonant with the increase of specialization that modern technology has caused. The fact that doctors are inundated with information of varying degrees of importance and pertaining to fields with respect to which they may or may not be expert is virtually common knowledge. If so, does this not raise a question concerning the extent to which FDA can rely on the discretion of individual medical practitioners, in balancing the advantages and hazards of a drug? The broader question is one involving the scope of intervention on the part of the federal government. Should the individual proficiencies of physicians be subject only to license and regulation by the states? And, if so, does the responsibility of the FDA terminate once an approved drug is placed before persons who are licensed by the states to practice medicine? While licensing may be properly the province of the states, regulation of available drugs is a continual process. If the FDA concludes that misuse of a drug is widespread and that it should not regulate the practice of medicine, it has no choice but "to say this drug is in fact doing more harm than good, so we will take it off the market." In products liability it is the de facto use of a product which determines the unreasonableness of its danger, not the intended or proper use thereof.

The second outcry in response to an attempt to curb excessive prescribing practices among general practitioners would be from the manufacturers. The crucial question is: if, in fact, a drug is being overused, or if it is causing serious side effects, will any company in America be willing to lose a 5 to 10 million dollar market to correct it? Manufacturers, confronted as they are with the intersection of ethical and economic considerations, choose to

One example of the varied and often conflicting information received by doctors is the package inserts for Stelazine and Prolixin (major tranquilizers): "[the Stelazine package insert states 'In most cases (psuedo-Parkinsonism) symptoms are readily reversible when an anti-Parkinsonism agent is administered concomitantly.' The package insert for Prolixin... states 'A persistent psuedo-Parkinsonism syndromme [sic] may develop... (for which) anti-Parkinson agents are seldom of benefit.' What is a physician to do?... [H]e is under or misinformed." Turner, A Critical Assessment of Drug Marketing Practices, 1971 J. DRUG ISSUES 301, 304.

60. Drug Safety Hearings, supra note 19, pt. 1, at 180.

61. Id.

62. In Incollingo v. Ewing, 444 Pa. 263, 282 A.2d 206 (1971), the court found that despite adequate warnings on the drug label, the manufacturer could be liable for a de facto overuse among the medical profession where the manufacturer took no steps to minimize, and in fact encouraged, such use.

63. Turner, supra note 59, at 306.
enhance consumption through advertising,\textsuperscript{64} employment of
detail men,\textsuperscript{65} and other promotional avenues. "A series of congres-
sional investigations \ldots \ already revealed the industry to be a
high-profit group often not as vitally concerned with health as the
investigators might have expected it to be \ldots ."\textsuperscript{66} The industry
has been accused of lacking any ethical compulsions and of simply
"pushing" the product as it is done in any other industry. For
example, the detail manual for the introduction of Stelazine\textsuperscript{67}
places emphasis on the "\ldots calming effect \ldots and \ldots the
busy housewife whom most doctors agree is a 'natural' patient
type."\textsuperscript{68} The objective of the promotional campaign is "to remind
the M.D. that 'Stelazine' can calm without sedating—a feature of special value [to]
housewives and other active patients."\textsuperscript{69} Subsequent to the introduction of Stelazine, the FDA requested
the company to delete from the package insert the assertion that
the drug does not cause drowsiness.\textsuperscript{70} The detail manual even
gave exemplary conversations and starter packets contained with
the directive: "[t]ry them on your next three housewives \ldots ."\textsuperscript{71} Interestingly, Stelazine is a phenothiazine derivative
(major tranquilizer) and therefore an antipsychotic drug. "One
should bear in mind that to take antipsychotic drugs, one must
be crazy, either literally or figuratively."\textsuperscript{72} Instructions were also

\textsuperscript{64} Manufacturers spend $3,000 per year per physician. Merrill, supra note 58 at 25,
citing DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE, TASK FORCE REPORT ON PRESCRI-
PTION DRUGS, THE DRUG MAKERS AND THE DRUG DISTRIBUTORS 28 (1968), and SENATE COMM.
on the Judiciary, ADMINISTERED PRICES IN THE DRUG INDUSTRY, S. Rep. No. 448, 87th Cong.,

\textsuperscript{65} See Comment, The Ubiquitous Detailman: An Inquiry Into His Functions and
Activities and the Laws Relating to Them, 1 HOFSTRA L. REV. 183 (1973) for an excellent
analysis of the detailman's dual role.

\textsuperscript{66} Rheingold, The MER/29 Story—An Instance of Successful Mass Diaster
No. 1153, 89th Cong., 2d Sess. (1966); Kefauver Committee Report, S. Rep. No. 448, 87th
Cong., 1st Sess. (1961); Hearings Before the House Subcomm. on Government Operations,

\textsuperscript{67} Stelazine is a major tranquilizer of the phenothiazine group produced by Smith,
Kline and French of Phila., Pa.

\textsuperscript{68} Turner, supra note 59, at 307, quoting from the Stelazine detail manual used by
Smith, Kline and French.

\textsuperscript{69} Id.

\textsuperscript{70} Id. Turner cites a letter from Arthur Ruskin, M.D., Medical Officer, Division of
New Drugs, Bureau of Medicine to Smith, Kline and French Laboratories, Attn. Mr. T.
B. Wallace August 17, 1962. "[I]t should be pointed out that tranquilization [from
Stelazine] may be accompanied by drowsiness. \ldots ."

\textsuperscript{71} Id.

\textsuperscript{72} Hollister, Optimum Use of Antipsychotic Drugs, 12 CURR. PSYCH. THER. 81, 85
(1972).
given on how to handle specific questions so as to avoid answering them. As one commentator said, "[t]he idea is to put the doctor off, not to inform him . . . . This is particularly true when the doctor asking is a general practitioner and not a trained psychiatrist."73 [emphasis added]. Overall, due to the subjective nature of the drugs' effects74 it is easier to "play up" the efficacy of psychotropic drugs by words like "calming," or "feels good," than it is with drugs that have a more physiological action. "The use of sweeping superlatives . . . should be avoided . . . ,"75 and the FDA has the power to monitor misleading advertisements.76

To avoid the necessity of the FDA's removing drugs because of unbridled and perhaps indiscriminate use, and to avoid the exploitation by manufacturers of doctors whose knowledge has not kept pace with the swift developments in psychopharmacology, "serious efforts must be made in undergraduate and postgraduate training to insure the rational use of psychotropic agents."77 This alternative is clearly preferable to any further encroachment by government on the medical profession. It is perhaps glib to state that the majority of physicians need to be more informed about psychopharmaceuticals: if, however, change does not come voluntarily, other factors will force the improvement. "Unless physicians learn to use these drugs with restraint, political pressures stemming from the growing problem of drug abuse may lead to unwise constraints."78 And ultimately, "[i]f regulation by the FDA, Congress, the medical profession, and the industry itself does not result in improvement, then the private enterprise system of civil litigation will provide the solution."79

E. The Paternalism Issue

In a democratic society, one aspect of consideration in determining whether overuse of psychotropic drugs should be curbed, or whether, if in fact, there is "overuse" at all is consumer desire itself. At least some portion of both the manufacturer's and the physician's belief that over-consumption of psychotropic drugs

73. Turner, supra note 59, at 308.
74. See section II, infra.
77. Balter and Levine, supra note 2, at 10.
78. Hollister, supra note 4, at 397.
79. Rheingold, supra note 66, at 148.
Hofstra Law Review does not abound is attributable to self-interest. But, what of the individual who, not being a "pharmacological Calvinist," says he likes the drugs and wants them? "Three out of every four users felt the prescription psychotherapeutic drugs helped them 'a great deal' or 'quite a bit'. . . ." In what other field of medicine do we even ask the question? Is it that this class of drugs requires a decision making process that is more broad than the traditional one confined to the expertise of a physician? In some instances, the physician would not prescribe such drugs at all if it were not for the pressures of patients. Yet, the "... dilemma is compounded by the patient's conviction that his request, tacit or express, for psychotherapeutic drugs is legitimate and based on 'real' needs." Albeit difficult to document, the author doubts whether the situation occurs frequently in which the patient insists he has an infection and then proceeds to specify what he would like for it.

The course of events in the next several decades will directly affect concepts no less significant than our philosophy of individual freedom and government regulation. As George Larrick, former Commissioner of Food and Drugs, stated:

The judgements of society are not necessarily consistent with scientific facts. Neither are they always logical. They can be and sometimes are arbitrary. He astutely added, however, that:

Even so, neither the executive nor the legislative branches of government can long ignore them.

It is unwise to extrapolate from data indicatory that people like the drugs. Are they saying "yes" merely to a "good feeling" or are they giving the affirmative nod, after full disclosure from industry, government and the medical profession, to the creation of a drug-dependent society some thirty years hence? An answer

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80. See text accompanying note 21, supra.
81. Parry et al., supra note 3, at 773.
82. There is literature describing the dilemma caused by patients' requests for psychotherapeutic drugs where the doctor is not in agreement. See Mellinger et al., Patterns of Psychotherapeutic Drug Use Among Adults in San Francisco, 25 Arch. Gen. Psychiatry 385 (1971).
83. Parry et al., supra note 3, at 770.
84. Drug Safety Hearings, supra note 19, pt. 1, at 154.
84.1 Id.
85. See text accompanying note 81, supra.
to the second question could hardly be implied from an affirmative response to the first! As Dr. Kline indicated,

[I]t may be that tranquilization may just be another path to the extinction of the species. It may be that a certain amount of disruption, disharmony, instability is part of what gives us the thrust to keep moving, so I'm not sure that tranquility is really what one should aim for.86

That bulk of consumers which accounts for the excessive minor tranquilizer sales should be giving thought to long-range considerations rather than to the short-range benefits derived from the drugs.

The choice is not between freedom and paternalism, for clearly we prefer the former; there are however, degrees of freedom, and choosing on the basis of limited knowledge implies less freedom. Jefferson felt that the appropriate aim of government was "to restrain men from injuring one another."87 Does restraining people from possibly harming themselves go "much beyond . . . [the aim of government so as] . . . to impose unjustifiable restrictions upon that paramount commodity — our personal freedom?"88 Before advocating encroachment upon this purported freedom of indulgence, we should consider launching a major campaign to inform the public. For example, few people would disagree that some serious thought should precede the taking of oral contraceptives. We have already seen the imposition of direct consumer warning requirements in oral contraception89 and one other area.90 For instance, the package insert for Librium states that one animal study indicated a marked decrease in fertilization rate, offspring viability, mating interest, and maternal nursing and care of the young associated with use of the drug. The public should be informed of any substance that can potentially

88. Id.
89. 21 C.F.R. § 130.45 (1973).
90. Davis v. Wyeth Laboratories, Inc., 399 F.2d 121 (9th Cir. 1968) (with respect to Sabin Oral polio vaccine). The Food Drug & Cosmetic Act even specifies publicity (press releases) as an enforcement mechanism, however, the legislature has limited its use to circumstances involving imminent danger to health or gross deception of the consumer. 21 U.S.C. § 375(b) (1970).
modify behavior that extensively. It is the author’s opinion that psychotropic theraphy is an area similar to that of the “pill” and the Sabin vaccine in that the decision to consume goes beyond the parameters of medical expertise.91

If we are “on the edge of a ‘choose your mood’ society,” 92 we should be certain that we are really “choosing” to go over that edge. One authority mentions no less than fifteen93 possible future alterations of life patterns through drugs, including but not limited to areas like the regulation of sexual responses,94 control of aggression,95 inducement or prevention of learning,96 and the relief or provocation of guilt97 feelings. The caveat added is that the uncertainty is not whether drugs will be capable of doing these things — they will — but “who should make the decisions as to when they should be used, on whom and by whom.”98 At this juncture, one would most likely conclude that more information should be given, first, by the manufacturers to the physicians and, second, by the industry, government and physicians to the public. Despite the desirability of having sufficiently informed patients and doctors, is there much that can be definitively said regarding the new field of psychopharmacology? There is little agreement as to what should be said and is it enough to say, “wait until we know more?”

II. Subjectivity: The Inherent Difficulty?

A. Animal Testing

“Every compound must have a beginning. It may be born on

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91. Many problems are involved with full disclosure to patients; disclosure may even lessen the benefits of the therapy. The difficulty is acute at the testing stage where doctor and patient bias may alter the results. See Rheingold, supra note 5, at 958. In light of this, the 1962 Kefauver-Harris amendments allow for the doctor’s discretion. Section 103(b), 76 Stat. 783 (1962), 21 U.S.C. §355(i) (1970), amending §505(i), 52 Stat. 1052 (1938).
92. Evans, Epilogue to Psychotropic Drugs in the Year 2000, supra note 86, at 158.
93. See Appendix II (taken from Psychotropic Drugs in the Year 2000, supra note 86, at 78).
94. One could “bank” or “stoke” the fires biochemically so that activity could match more closely the circumstances and thus allow man to devote more time to more exclusively human activities.
95. One is reminded of A Clockwork Orange, a film by Stanley Kubrik, from the book by Burgess, A Clockwork Orange (1962).
96. Greater efficiency in education can be achieved by biochemically enhancing the learning experience and thereby reducing the time required.
97. “How much simpler life would be if sufficient serve of guilt could be produced relevant to a particular type of situation to prevent its repetition. ‘Punishment’ would then be truly rehabilitative and practically instantaneous.” Psychotropic Drugs in the Year 200, supra note 86, at 82.
98. Id. at 77.
the scribbled scratch pad of an organic chemist. From the drugs inception, two policy considerations will be in constant conflict: safety versus the desire for swift development of new substances. An institutional system has been set up with the hope that as much as possible can be learned about a particular drug before it is administered to humans; if, and when, it is ready for human testing an attempt is made “to assure that clinical testing of persons in hospitals, prisons, research facilities, or other institutions is carefully supervised.” The obvious goal of this system is to minimize the risk that is inherent in the introduction of new drugs. The other consideration is as important. Since “[t]here is no such thing as absolute safety in drugs” and since “certain risks will have to be judged acceptable . . . [i]f major therapeutic breakthroughs are to be achieved. . . ,” we are, “[a]t the same time, . . . trying to speed up our actions so that drugs can be marketed and made available to the physician and the patient without unnecessary bureaucratic delays.”

This “tug of war” is present throughout the development of all kinds of drugs. When, however, one is dealing with a psychopharmaceutical, there are intrinsic difficulties which render the conflict more acute. For example, predicting drug effects across specie lines in the first place has always been problematic: “[d]uring the course of drug development, there are many instances where extrapolation of data from animals to man is difficult because the toxicologic and metabolic responses induced by drugs may be significantly different between the laboratory species.” The trouble is enhanced significantly, however, when the drug has potential therapeutic use in psychiatry, since all animals lack the mental faculties necessary to make such testing effective. The development of the imipramine type of anti-depressant is illustrative:

Although they act as stimulants in the pigeon and in depressed humans, anti-depressives of the imipramine type do not show a classical “anti-depressant” pattern of activity in rodents, the

103. Finkel and Zatman, supra note 100, at 31.
104. Smith, Poutsiaka and Schreiber, supra note 102, at 489.
105. Id. at 490.
animals generally used to screen psychotropic agents. The fact that the anti-depressive action of imipramine was discovered in human beings is, in itself, an interesting aspect of new-drug development. If the original purpose of the tests in animals conducted on this class of drugs had been primarily to detect anti-depressive activity per se, the compounds might never have been evaluated in man, because they appeared to be weak "tranquilizers".

B. Human Testing

The difficulties do not cease once the decision is made to go to human testing. With psychotropes, this is especially true with regard to testing for efficacy, which is required by the 1962 Kefauver-Harris Amendments to the Federal Food, Drug and Cosmetic Act. The inherently subjective nature of psychopharmaceuticals influences every stage of their development and use from pre-marketing testing to diagnosis and treatment. One doctor interviewed said, "There is no question that, generally speaking, by the nature of the illness you're dealing with, the testing of psychopharmaceuticals is more subjective; the diagnosis of emotional disease requires a subjective element, since you don't have something like a tumor in front of you." He quickly added that he was not describing a totally subjective situation, for there are numerous physical and objective indicia of the patient's reactions. He compared the testing of psychotropic drugs to the polygraph, in that both involve physical signs of what is essentially a subjective determination, specifically, truth and emotional states. Anxiety, then, can be defined in terms of either a subjectively perceived state or of objectively measured physiological parameters.

For the most part, information regarding mental disorders is derived from "some combination of the patient's and observer's
subjective data. Validity of [this] approach has long been based on ‘common sense’ and can rarely be verified.”\textsuperscript{112} [emphasis added]. Usually, “rating scales” are used to quantify psychiatric disease states,\textsuperscript{113} however, “[m]ood, essentially a private internal experience, can be reported with accuracy only by a responsive, cooperative subject. No rating scale is useful without a respondent’s cooperation.”\textsuperscript{114} Even if the patient is sincere, authorities have noted that non-drug factors, such as sex, age and intelligence, can affect the outcome of psychiatric drug therapy.\textsuperscript{115} One study attributed the variability of response to phenothiazines to differences in the personality structure of the drug recipient.\textsuperscript{116} Marked differences in response were found between those of the “extroverted athlete” class (low anxiety levels) and those of the “introverted intellectual” class (high anxiety level).

C. Diagnostic Variability

The World Health Organization has reaffirmed the existence of great variability in psychiatric diagnosis in a recently published study of a major heuristic value.\textsuperscript{117} The divergence has been caused by a number of factors. Specifically, the report notes three categories of influence.\textsuperscript{118} The first involves the patients and “their attitudes to and experience of mental illness and the person who attempted to treat it, their ideas about the nature of the treatment, their social status, their desire for help, and the nature and course of their illness.”\textsuperscript{119} The characteristics of the clinician are considered in the second category: that is their training, skills and rules of classification.\textsuperscript{120} Finally, the nature of the situation is influential. This would include the circumstances (at home, in hospital, in public, under constraint), the prevalent societal attitudes, the reaction of relatives and the relationship between doctor and patient.\textsuperscript{121}

\textsuperscript{113} Id.
\textsuperscript{114} Salzman et al., \textit{Rating Scales for Psychotropic Drug Research with Geriatric Patients, II. Mood Ratings}, 20 \textit{J. AMER. GERIATRICS SOC.} 215, 220 (1972).
\textsuperscript{118} Id., at 30.
\textsuperscript{119} Id.
\textsuperscript{120} Id.
\textsuperscript{121} Id.
The report presented studies that are indicative of the degree of diagnostic agreement among psychiatrists. One of these showed that "there appeared to be good agreement on specific organic disorders such as general paresis (90%), epileptic psychosis (92%) and mental retardation (91%), a lesser degree of agreement on the functional psychoses (69%), and rather poor agreement on the neuroses (24%). At worst, there was barely any agreement at all." It was mentioned that in the 1940's there was similar disagreement among raters reading chest x-ray films. An interesting question thus arises: are the discrepancies among psychiatrists due to inherent subjectivity or is it rather a temporary phase in the state of the art, which is necessarily attendant to the evolution of a new field of endeavor? If the latter be true, it is a difficulty that is encountered in virtually every industry in the field of products liability. As the report suggests, standardization of classification rules and other interviewing data would minimize such inaccuracies. If the former hypothesis is representative, we have a problem that time will not solve.

The differences in diagnostic results are clearest between divergent cultural groups.

For example, a West Indian man who had recently arrived in England, who belonged to a religious sect that practiced some form of voodoo, and who had a poor command of English and perhaps a low intelligence would be likely, if he became excited or depressed, to present a clinical picture very different from that represented by a well-educated Englishman.

Obviously, such a variance in diagnosis would not appear if both the Englishman and the West Indian had infections. Bodily structure and function remain remarkably similar despite cultural differences. The same cannot be said of mental illness. The modus vivendi of a populace will produce its own signs or symptoms. We are not dealing with anatomy, but the way people live. This example is, of course, paradigmatic, but it is indicative of what occurs to a lesser extent within the same cultural group.

122. Id., at 32.
123. Id.
124. E.g., Greenman v. Yuba Power Products, Inc., 59 Cal. 2d 57, 377 P.2d 897, 27 Cal. Rptr. 697 (1962), in which evidence was submitted tending to prove that there were more positive ways of fastening the parts of the machine together.
125. REPORT OF THE INTERNATIONAL PILOT STUDY OF SCHIZOPHRENIA, supra note 117, at 37.
126. Id., at 34.
series of studies compared the diagnostic practices of England to those prevalent in the United States:\textsuperscript{127} 

The results of this exercise were fairly clear-cut. Hospital psychiatrists in New York did, as expected, diagnose schizophrenia more frequently and affective disorders less frequently, than hospital psychiatrists in London . . . . [these studies] indicate that the prevailing concept of schizophrenia is much broader in the United States than in Britain, embracing substantial parts of what British psychiatrists would regard as depressive illness, neurotic illness or personality disorder and almost the whole of what they would regard as mania . . . .

The difficulties in diagnosis are theoretical as well as practical.\textsuperscript{128} "In the first place, there is disagreement as to where to draw the line between psychotic and non-psychotic conditions. Indeed, there is even disagreement as to whether any line exists at all."\textsuperscript{129} Some believe that there is an endogenous or psychotic form of depression, while others maintain "that psychotic and neurotic forms of depression lie on the same continuum (or continua), one shading imperceptibly into the other."\textsuperscript{130} Complicating matters further is the fact that opinions with respect to therapy are often diametrically opposed; those doctors that abhor the use of drugs may prefer convulsive treatment, while many find the latter a barbaric practice.

Given all the conflicts, one encounters great difficulty in attempting to allocate responsibility. Ostensibly, the problem belongs to the medical profession, but recent trends in the products field\textsuperscript{131} have indicated that the word "product" does not connote a mere corporeal thing, \textit{i.e.}, the drug; it rather encompasses a whole rational context. If this context encompasses more than the independent decision maker, who is to undertake the Sisyphean labor of reconciling the competing interests?

III. THE FDA

The efficacy of the FDA depends primarily on its ability to

\textsuperscript{127} Id., at 36.

\textsuperscript{128} Besides cultural differences, which have been discussed, the report specifies several other "practical" considerations, namely, combinations of different forms of psychosis and previous clinical history influencing diagnosis of subsequent condition. Id., at 33.

\textsuperscript{129} Id., at 32.

\textsuperscript{130} Id., at 33.

collect data and consequently this area of its activities has been the source of much adverse comment. One psychiatrist related an incident wherein he called the FDA to inquire about the studies supporting a contraindication that was listed for one of the MAO inhibitors. To his dismay, the FDA admitted after several phone conversations that they had no data to support the directions. The FDA traced the decision to someone who had left the agency, but it could not account for the evidence or reasoning behind the contraindication.

Reporting of all side effects by the manufacturer is required even where the causal relationship is tenuous. Nevertheless, some physicians and manufacturers thwart the system by withholding information on various grounds, usually inconclusivity. Indeed, the causation question is formidable in light of the high incidence of polypharmacy (multi-drug therapy).

The problem of evaluating data obtained is more significant. Any comprehensive drug surveillance program, in addition to ascertaining whether an untoward effect is related to a particular drug, must be capable of estimating the type, magnitude and frequency of its risk and benefit. "Data is presently provided to the FDA in the form of spontaneous, voluntary reports . . . [and these] . . . do not constitute an adequate method of sur-

133. A contraindication is any symptom or circumstance indicating the inappropriateness of a form of treatment otherwise advisable.
134. The psychiatrist wishes to remain anonymous.
135. An FDA regulation, 21 C.F.R. §130.35(b)(7) (1973), requires the producer of a new drug to disclose "any information concerning any side-effect, injury, toxicity, or sensitivity reaction . . . which by kind, or incidence or severity is not fully disclosed in the labeling, whether or not determined to be attributable to the drug . . . ."
136. Merrill, supra note 58, at 6.
137. The flagrant withholding by Richardson-Merrell of data on MER/29 is familiar history. See Rheingold, supra note 66; Toole v. Richardson-Merrell, Inc., 251 Cal. App. 689, 60 Cal. Rptr. 398 (Dist. Ct. App. 1967).
138. "One frequently finds the following conglomeration of prescriptions for a schizophrenic patient: two phenothiazines (one high-dose and one low-dose); a tricyclic antidepressant (the patient is withdrawn); an antiparkinson drug (even if the patient has never shown any signs; this drug is completely superfluous in the presence of the anticholinergic tricyclic antidepressant); something for sleep; and something during the day to keep the patient awake. Such a choice of drugs is no choice at all and has many irrational aspects. Small wonder that some patients seem to improve after drugs are withdrawn! . . . [S]tudies . . . [show that no] . . . combination is superior for treating schizophrenics than a properly chosen single drug.” Hollister, supra note 72, at 85.
139. Side effects associated with tricyclics include: dizziness, fatigue, constipation, dryness of the mouth, gastrointestinal disturbances, liver damage, agitation, mania, tremors, paresthesias, memory impairment, seizures, headache, blurred vision, edema, body

http://scholarlycommons.law.hofstra.edu/hlr/vol2/iss2/18
Side effects due to psychotropic agents vary not only in degree, but in kind. This difference requires a qualitative analysis: should the dryness of the mouth that occurs persistently with the tricyclics be weighed equally with the occasional impotence and delayed ejaculation that occurs with said drug? Consider also the fact that the decreased sexual sensitivity returns to normal, "although this may take a number of months." [emphasis added]

The problematic nature of the FDA decisional process is only enhanced by the diversity of opinion within the psychiatric profession. The added difficulties are exemplified in the case of Parnate, an MAO inhibitor. Parnate was first marketed in February 1961. By February 1964 "approximately 400 cases of hypertensive reaction, including 50 cerebrovascular accidents with 16 deaths, had been reported." The FDA consulted eleven experts by phone and they opined that the "therapeutic value of the drug did not justify the number of serious adverse reactions which are occurring." Consequently, approval of Parnate was withdrawn. Letters from physicians and psychiatrists protesting the action were received and a reevaluation of the drug ensued.

In June 1964 remarketing was permitted with a drastically revised label. Several of the developments that influenced the remarketing decision have been discussed elsewhere. The usual analytical problems were noted: a highly causal relationship between drug and reaction could only be established in about fifteen percent of the reported cases; there was concomitant drug consumption in a high percentage of the cases. A survey of academic psychiatrists showed thirteen favored marketing, four had no comment and sixteen thought the drug was dispensable. A survey of twenty-one clinical investigators, however, unanimously suggested that the drug, albeit potentially dangerous, "was relatively safe under proper precautions." This survey indicated

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weight change, appetite change, skin sensitivity, hyperhidrosis (sweating), dysuria, sexual disturbances and insomnia. The list is meaningless without a discussion of how often they appear, to what extent and for how long. See KLINE, DEPRESSION: ITS DIAGNOSIS AND TREATMENT/LITHIUM: THE HISTORY OF ITS USE IN PSYCHIATRY 45-57 (3 MODERN PROBLEMS OF PHARMACOPSYCHIATRY 1969).

140. Anello and Hanson, supra note 132, at 9.
141. KLINE, supra note 139, at 49-55.
142. Id. at 55.
143. Drug Safety Hearings, supra note 19, pt. 3, at 1208.
144. Id.
145. Merrill, supra note 58, at 13.
146. Drug Safety Hearings, supra note 19, pt. 3, at 1210.
147. Id.
that the more experience a physician had with Parnate, the more favorably he viewed it. This evidence demonstrates the validity of the suggestion that the drug should be confined to those who use it frequently and can give the careful observational followup that such a drug demands, i.e., the specialists.

The FDA has been criticized for its decision to remarket Parnate. The reasons include failing to evaluate alternative therapies, especially electro-convulsive treatment, and failure to discover whether any patients were "Parnate specific", that is, unresponsive to any other therapy. The presupposition inherent in this criticism is that if a drug's beneficial properties are merely cumulative vis-a-vis other available remedies, while its risk is significantly higher, it should not be approved. In light of the divergence of opinion among psychiatrists with respect to electro-convulsive and drug therapies, such a determination of substitutability is impossible. Who can say authoritatively that Parnate is superfluous in the presence of electroconvulsive treatment? Do not those, both physician and patient, who abhor the use of the latter method of treatment have a therapeutic right to have what they consider a preferable therapy available to them? Assuming the warnings are brutally honest, can we deny a person a drug that may avoid severe depression and perhaps suicide—a possibility that always exists with the depressed patient? After the decision to require drastic re-labeling, use of Parnate fell to thirty percent of its former level. Perhaps this is the appropriate level: if a drug has substantial therapeutic use, even if among a few, and if the relevant data are honestly conveyed to the user, such a drug should be available to those who freely chose it.

The author believes that the lesson to be derived from the Parnate decision does not involve the specific points that were or were not considered by the FDA, but rather the overall decisional process. Dr. Joseph Sandusk was ultimately responsible for the remarketing decision. He had become Director of the FDA's Bureau of Medicine on April 1, 1964 during the period between

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148. Id. at 1182 et seq.
149. See text accompanying note 130, supra.
151. As to whether the user should be construed as the patient or physician for purposes of information dissemination see section I.E, supra.
the initial decision to withdraw and the later decision to remarket. Was the decision to remarket merely the result of a change of personnel, or of new insight?

These decisions . . . are made by the Medical Director based on what he considers to be a consensus of opinion among his staff. In other words, we do not hold a formal meeting in which a vote pro and con is taken. At the time of decision, only one psychiatrist was in the FDA’s Bureau of Medicine and he was opposed to recommending reapproval of Parnate. It is difficult to ascertain to what extent the various factors contributed to Dr. Sadusk’s decision. What can be gleaned from Dr. Sadusk’s testimony before the Senate Subcommittee is that the ultimate decision was highly discretionary. It is the author’s opinion that approval of psychotropic substances is particularly susceptible to the hazards that traditionally inhere in discretionary judgment. Dr. Sandusk subsequently left the Bureau of Medicine to accept an executive position with Parke-Davis & Company.

Many are concerned that FDA pronouncements are not “institutional”. There are two considerations in making judgments regarding drugs. The FDA which makes national decisions must consider all types of patients “with a multitude of disease processes”, and doctors with varying degrees of skill. The average practicing physician is “not necessarily qualified to make the broader decisions about permitting nationwide marketing of a drug.”

On the other hand, the safety and efficacy of a drug is not an a priori determination. The drug’s safety and efficacy is determined by its use and its use is a function of the attending physician. The physician can discuss the various side effects with the patient; he can best discern the individual propensities of the patient; he can aptly monitor the therapeutic response, and perhaps prevent a particular reaction by changing the dosage or, if necessary, the drug. This individualized responsibility is borne

154. Id. at 1232.
155. Id. at 1233.
156. Merrill, supra note 58, at 13, n.47.
158. Id., pt. 1, at 153.
159. Id.
160. The physician should do on a microcosmic scale what the FDA does, that is, weigh benefit against risk, except he can personalize and modify the data to some extent for he knows who the patient will be. The FDA can only consider the “collective” patient.
by the physician and is only enhanced in the context of psychotropic drugs, which are inherently "individual."

The national decision precedes the individual one, however, and

[the] agency has a responsibility to protect the American people, not the drug companies, not the doctors, but the American people. The consuming public, the people who take these drugs, may live or die, depending upon how safe and efficacious they are.161

Some of those citizens concerned about having an institutional and impartial data collecting and evaluating body have formed a non-profit corporation called Medicine in the Public Interest (MIPI).162 Expressing "concern over the lack of concerted non-public, non-lobbying activity by the private sector in the health care and scientific fields,"163 the organizers hope to develop a "non-biased group or foundation"164 whose function will be to keep "policymakers and the public . . . better informed . . . ."165

The present board of directors is composed of four doctors, but ultimately there will be nine or ten members, including members "from other disciplines, such as economics, law and sociology . . . ."166 By conducting "pharmacologic, medical, behavioral and other scientific research and related legal research,"167 MIPI will obtain analytical data which will be made " . . . available for the benefit of the public, through educational presentations and information dissemination via various media . . . ."168 If its intentions are realized, MIPI may alleviate some of the problems that exist in our current system, particularly, lack of both an informed populace and an adequate regulatory procedure.

IV. COMPENSATING INJURIES

A. The Manufacturers

Since complete prohibition of the sale of a particular product is a drastic decision in a free enterprise system, most "design" defect cases focus on the adequacy of the product's warning. Drug

162. MIPI was incorporated in Washington, D.C. on April 3, 1973 and is supported principally by private contributions.
163. Statement of intent, called "The Need for Medicine in the Public Interest."
164. Id.
165. Id.
166. Id.
167. Articles of Incorporation of Medicine in the Public Interest, Inc.
168. Id.
manufacturers who, in the past, have been hesitant, obfuscatory or even deliberately evasive in their warnings are finding that short range gains from such practices are outweighed by potential liability. As mentioned earlier, the psychopharmaceuticals are apt to be overpromoted because of the somewhat nebulous nature of the drugs' action and the lack of proficiency in their use among general practitioners. By honest labeling and promotion, a drug manufacturer can avoid liability and undoubtedly increase long range profits.

For purposes of strict liability, many drugs have been termed "unavoidably unsafe products" and as a result the manufacturers of such products have been afforded special consideration. Comment j of section 402A of the Restatement (Second) of Torts defines an adequate warning as one that specifies side effects that are foreseeable in a "substantial number" of users. The effect of this qualification of that comment is to render causes of action based on theories of negligence, breach of implied warranty and strict liability "functionally interchangeable in most drug injury cases." In fact, "... there is not one case in a hundred in which strict liability would result in recovery where negligence would not." The duty, then, of a manufacturer to warn is fulfilled if he keeps up with the relevant scientific findings, and conveys such information to the physician. Within the context of present law, we might ask two questions regarding psychotropic drugs. First, should the manufacturer be able to terminate his liability merely by giving warning information to the physician, as has traditionally been the case? This decision embraces a duty question involving broad policy considerations: who do we want to know what? The desirability of direct consumer warning has been discussed. The second question one might ask concerns the obliga-

169. During the 1960's, several drug manufacturers underwent litigious examination of their warnings. E.g., MER/29 (Richardson-Merrell), Aralen (Sterling Drug Co.) and Chloromycetin (Parke-Davis); see Merrill, supra note 58, at 40-49.
170. See text accompanying note 73, supra.
171. RESTATMENT (SECOND) OF TORTS §402A, Comment k, at 353-54 (1965).
172. Id., Comment j, at 353.
173. Id., Comment k, at 353-4.
174. Merrill, supra note 58, at 31.
175. Prosser, The Assault Upon the Citadel (Strict Liability to the Consumer), 69 YALE L.J. 1099, 1114 (1960).
178. See text accompanying notes 90-91, supra.
tion of the drug manufacturers to initiate or enhance research so as to be better able to identify the allergic user. Nowhere is such research more important than in psychopharmacology, where the good as well as detrimental effects of drugs are idiosyncratic.

Since adverse reactions have become an increasingly frequent problem and since "... adverse reactions from psychotherapeutic drugs are far from completely known or explained," it is imperative that manufacturers allocate resources to research which will help physicians identify the allergic users, whether or not their numbers are "substantial." Manufacturers, for example, could be instrumental in standardizing some of the diagnostic tools, such as rating charts, and perhaps in further defining the appropriate use of drugs in broad areas of symptomatology, such as the "depressed patient." Although our regulatory system has been criticized for placing inordinate financial demands on our drug industry, there is contrary evidence. Therefore, it would seem manufacturers are probably able to sustain the increased financial burden that such an obligation would impose. Even assuming that manufacturers' research has increased the foreseeability of injuries and that the results of their research have been transmitted to the physician or patient, some drug injuries will still be inevitable. "There is no such thing as absolute safety in drugs."

179. It has been estimated that the incidence of complications in drug therapy is 10 percent and that 5 percent of the patients admitted in general hospitals are receiving treatment because of serious drug reactions. See Edwards, *Rational Drug Therapeutics*, FDA Papers, Feb., 1971, at 4.


181. See text accompanying note 113, supra.

182. The problem of picking the correct drug for a specific kind or degree of depressed patient is awesome, and primarily rests with the physician. The manufacturer, however, could aid the practitioner by including in its labeling data on a wide range of patients. At present, it is unlikely that manufacturers would have the incentive to restrict the use of their product.

183. At an interview with Dr. Kline, supra note 52, he stated that "due to financial considerations, the amount of new drugs being produced in the United States had been radically reduced and it really is driving a substantial part of the industry out of the United States." Also, Dr. Leslie Baer, during an interview on Dec. 12, 1973 stated that he has used drugs for hypertension which are not so indicated. The reason that hypertension was not a primary indication is that the company did not want to incur the expense necessary to have the FDA permit the additional indication. Dr. Norris of Pfizer Pharmaceuticals, Inc., supra note 110, stated, to the contrary, that manufacturers are most anxious to test for as many indications as possible so as to enhance the prospective market.

184. The drug manufacturers spend $3,000 per year per physician on advertising; see note 64, supra, and see text accompanying note 66, supra.

If we have decided to explore mental and emotional illness and its possible correction through drugs, should the isolated victims bear the cost themselves? As one commentator described the realities of the situation,

Most reactions are the by-product of what amounts to government-approved medical experimentation, conducted ostensibly to advance society's interest in having available a broad range of prescription medications.\(^{166}\)

Such questions have been advanced under various theories that can be conveniently labeled “risk distribution.”\(^{167}\) Calabresi has been a prolific writer in this area\(^ {188}\).

Analysis of drug risk distribution has shown that there are at least two different classes of drugs to consider.\(^ {189}\) If the drug is taken in the treatment of a highly contagious disease (e.g., smallpox) the benefit derived from its success inures to society as a whole, that is those who have been saved from contamination. But, if the patient suffers from an allergic reaction, the classic “free rider” situation arises wherein the multitude receives the benefit of the treatment, whereas the individual bears the injury alone. The second class of drugs appears to benefit the user alone as the disease treated is not contagious (e.g., Parkinsonism). Theoretically, this risk should not be distributed when society gains no benefit.

Whether one advocates risk distribution through taxation\(^ {190}\) or manufacturers’ liability, it will be necessary to classify mental and emotional afflictions. Mental illness is not considered to be contagious and the primary benefit from drug consumption accrues to the patient. Yet, there is considerable benefit to be derived by society in having those, who would otherwise be incapacitated, leading functional and productive lives. Just the decrease in hospital expenditures is significant.\(^ {191}\) Logically, then, the cost of adverse reactions from psychotherapeutic drugs should be apportioned between user and society. The allocation would depend

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166. Merrill, supra note 58, at 87-88.
167. Id., at 87-99.
169. Merrill, supra note 58, at 99-102.
190. Id., at 103.
191. See Hollister, Clinical Use of Psychotherapeutic Drugs I: Antipsychotic and Antimanic Drugs, 4 Drugs 321, 323 (1972).
on the degree of incapacitation (society gains more from the rehabilitation of a hospitalized psychotic patient than from the relief of one's minor stress or depression).

Implementing a system of risk distribution, whereby the manufacturer compensates the consumer for unforeseeable drug injuries, would encourage the industry to spend more on the kind of research mentioned above. Under such a system, an unforeseeable reaction would render the manufacturer liable. But, if the manufacturer helped bring the state of the art to the point where the potential plaintiff could be identified before use, liability would be avoided. In the latter case, the manufacturer's responsibility would cease and the physician might be liable for prescribing after being adequately warned.

If courts are reluctant to accept a general risk distribution theory, they might take a first step in that direction by redefining the concept of implied warranty. Several attempts have been made, although unsuccessfully. In *Davis v. Wyeth Laboratories, Inc.* the appellant contended the warranty should have been construed to cover individuals rather than the public as a whole. The latter interpretation would require only "that the vaccine . . . have been reasonably fit and reasonably safe for use by the public as a whole." A similar argument was proffered in *Green v. American Tobacco Co.* Judge Cameron, dissenting, felt that the implied warranty applied to the plaintiff, individually. Such a theory would render every allergic reaction a breach of implied warranty provided there was no misuse (e.g., not following dosage directions).

Should the law develop, as suggested, to a point where all or most adverse reactions are compensated by the manufacturer or the physician, the only remaining hurdle would be proving causation. As the causes of mental and emotional illness are discovered and as the mechanisms of psychotropic agents are revealed, proving causation will prove less formidable. As a consequence, numerous possibilities may unfold for legal action in psychopharmacology. Suppose a depressed patient visited a physician and an appropriate psychotropic drug was prescribed. If the patient subsequently were to experience a severely increased depression, there would be several possible explanations. The drug may have

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192. See text accompanying notes 180-1, *supra.*
193. 399 F.2d 121 (9th Cir. 1969).
194. Id. at 126 n.5.
195. 304 F.2d 70 (5th Cir. 1962).
been effective and minimized what might have been a more severe episode. The drug may have had no effect at all and the disease syndrome continued as it would have without the medication. Finally, the drug may have caused the depressive progression. In the second illustration, the manufacturer might incur liability and in the third he definitely would.

Such a hypothetical involves weighty causation problems and courts anticipating them would probably find that the defendant owed the plaintiff no duty. For example, courts have hesitated to find a duty on the part of the defendants to minimize the risk of second collision injuries. As better evidence on second collision causation became available, some courts began to establish this duty. We may see the same process in psychopharmacology. The irony is that now when psychopharmacology is in its infancy and the dangers are numerous, such a cause of action would be overly speculative. As the state of the art in psychiatry improves, the dangers will lessen, but the increased insight will afford an appropriate basis for a products liability suit.

B. The Prescribing Physician

If liability follows responsibility, the physician may emerge as the primary target in future drug injury cases. If the FDA’s requirements are satisfied and if the manufacturer reports all it knows to the physician, the buck stops there. “The next deep pocket behind that of the manufacturer is the physician’s,” and there are several new and developing ways to get to it.

The package insert, for instance, has dual implications. As it affords the manufacturer more and more protection from liability, the same instrument is rendering the practitioner more vulnerable to a malpractice suit. Although the FDA regulates its contents, to some extent, the package insert “is, in essence, a promotional item.” The FDA decides what drugs are on the market, not how they are to be used and thus, has no jurisdiction

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197. E.g., “It is a matter of common knowledge that state and federal authorities, non-governmental agencies, and legal and medical groups, as well as automotive producers, are currently engaged in research, discussion and hearings . . . .” Evans v. General Motors Corp., 359 F.2d 822 (7th Cir. 1966) (Kiley, J., dissenting).
198. E.g., Larsen v. General Motors Corp., 391 F.2d 495 (8th Cir. 1968).
to compel adherence to the brochure’s directives. “A well-informed physician . . . possesses greater knowledge both in depth and in breadth than that outlined in a package insert.”

Yet, deviation is often difficult to defend. Recent trends indicate that “an erosion of the community standard rules in malpractice litigation involving prescription drugs” is taking place. The Minnesota Supreme Court, for example, has said that:

[A] doctor’s deviation from such recommendation [in the package insert] is prima facie evidence of negligence if there is competent medical testimony that his patient’s injury or death resulted from the doctor’s failure to adhere to to the recommendations.

In another case involving Promazine, a phenothiazine derivative (major tranquilizer), the package circular stated that eighteen instances of agranulocytosis had occurred among three and a half million patients and further provided directions for observational followup. The court said that the package insert would absolve “the manufacturer from any liability in warranty.” The record did, however, warrant an inference of negligence on the part of the prescribing physician “who failed to follow directions emanating from the manufacturer . . . .” The package insert, in the area of psychopharmacology, may have a desirable disciplinary effect on general practitioners, but may just as easily inhibit sound medical judgment among psychiatrists. Dr. Kline, who has actively practiced psychiatry for twenty-five years, stated that one cannot properly have anything that approximates “absolute” directions in psychopharmacology. As Dr. Kline said, “It would be like saying the proper manner in which to approach a tort case is this and only this one because we have statistical proof that sixty percent of the cases are won that way.”

Physicians are also subject to an increasing number of malpractice suits on the basis of lack of “informed consent”. This is occurring in cases that involve nonsurgical aspects of medical

201. Id.
202. Merrill, supra note 58, at 62.
205. Id., at , 29 Cal. Rptr. at 327.
206. Interview with Dr. Kline, supra note 52.
207. Id.
care, such as insulin shock therapy, treatment with radioactive cobalt following a mastectomy, or the use of a spinal anesthetic.

Insulin-shock therapy is used to treat a psychiatric patient who is unresponsive to other therapies. In a Missouri case, involving fractures resulting from convulsions induced by insulin therapy, the court said that “. . . the doctors owed their patient in possession of his faculties the duty to inform him generally of the possible serious collateral hazards. . . .” The same court qualified this holding in a subsequent insulin therapy case by saying that the question of what disclosure of risks should be made in a given situation is a medical judgment determined by the normal practices of the reasonable practitioner in the particular community. Both these cases involved a drug-related injury and the issue was how extensive the warning must be in order for the consent obtained to qualify as an informed consent. The law of the immediate future will most likely specify to what degree the manufacturer’s warnings must be passed on to the user. A physician prescribing psychopharmaceuticals will, however, face unique considerations in making this choice.

It is, of course, not desirable to have disclosure of possible risks where such disclosure “may have such an adverse effect on the patient as to jeopardize success of the proposed therapy. . . .” Conveying to an extremely anxious patient the possible adverse reactions could understandably diminish the efficacy of an antianxiety agent. The extent of disclosure, then, is a matter of professional discretion, but patients will have to be let in on some of “the mysteries of drug use” which have heretofore been “solely the province of the physicians and drug companies.” Special importance should be attached to informing the patient of possible behavioral reactions to psychotropic drugs. A

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208. Mitchell v. Robinson, 334 S.W.2d 11 (Mo. 1960); Aiken v. Clary, 396 S.W.2d 668 (Mo. 1965).
212. Aiken v. Clary, 396 S.W.2d 668 (Mo. 1965).
213. Id. at 674.
214. Turner, supra note 59, at 301.
patient may prefer a restlessness engendering drug to one that impairs sexual capacity and for this reason, “[the] importance of various side effects to the patient should be a guide in choosing his specific treatment.”\textsuperscript{216} This is all part of the more individualized concept of benefit versus risk, called the “art of psychopharmacology”,\textsuperscript{217} and responsibility for an accurate balancing of interests rests primarily with the physician.

CONCLUSION

Statistics show that psychopharmaceutical consumption trends in the United States are not atypical of Western industrialized nations.\textsuperscript{218} The United States can, however, be a forerunner in devising and implementing effective policies in this field. We must ask ourselves if it is prudent to proceed the same way with a drug that affects our minds as we do with one that can harm us physically. We must also consider that we are dealing with a new generic class of drugs such that the undesirable effects may not emerge for several generations.

More fundamental than a need for more knowledge is the necessity of deciding how to use what we already know. “In a sense, we are in the same ethical and moral dilemma as the physicists in the days prior to the Manhattan Project.”\textsuperscript{219} One psychiatrist said that if there is a Mount Everest there, we will climb it. The issue, however, is not the ascent, but determining which route will be the safest.

\textit{Thomas P. Dugan}

\textsuperscript{216} Hollister, supra note 72, at 84.
\textsuperscript{217} Shader, supra note 39, at 83.
\textsuperscript{218} Parry et al., supra note 3, at 769.
\textsuperscript{219} Evans, \textit{Introduction to Psychotropic Drugs in the Year 2000}, supra note 86, at xx.
\textsuperscript{220} Interview with Dr. Kline, supra note 52.
## APPENDIX I

### Table 1.—Classification of Psychotherapeutic Drugs

<table>
<thead>
<tr>
<th>Prescription (Rx)</th>
<th>Examples: Generic Names</th>
<th>Examples: Tradenames</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Major Tranquilizers</strong></td>
<td>Phenothiazine derivatives</td>
<td>Chlorpromazine, thioridazine</td>
</tr>
<tr>
<td>Butyrophenones</td>
<td>Haloperidol</td>
<td>Haldol</td>
</tr>
<tr>
<td>Thioxanthenes</td>
<td>Thiothixene, chlorprothixene</td>
<td>Navane, Taractan</td>
</tr>
<tr>
<td><strong>Major Tranquilizers</strong></td>
<td>Substituted diols</td>
<td>Meprobamate, tybamate</td>
</tr>
<tr>
<td>Benzodiazepines</td>
<td>Chlordiazepoxide, diazepam, oxazepam</td>
<td>Librium, Valium, Serax</td>
</tr>
<tr>
<td><strong>Miscellaneous</strong></td>
<td>Hydroxyzine, buclizine</td>
<td>Atarax, Softran</td>
</tr>
<tr>
<td><strong>Antidepressants</strong></td>
<td>Tricyclics</td>
<td>Imipramine, amitriptyline</td>
</tr>
<tr>
<td>MAO inhibitors</td>
<td>Isocarboxazid, phenelzine</td>
<td>Marplan, Nardil</td>
</tr>
<tr>
<td><strong>Other</strong></td>
<td>Methylphenidate, combination of amitriptyline &amp; perphenazine</td>
<td>Ritalin, Triavil, Etrafon</td>
</tr>
<tr>
<td><strong>Stimulants</strong></td>
<td>Amphetamines</td>
<td>Dextroamphetamine (&amp; combinations), methamphetamine</td>
</tr>
<tr>
<td>Others</td>
<td>Deanol, pentylenetetrazol &amp; combinations</td>
<td>Deenar, Metrazol</td>
</tr>
<tr>
<td><strong>Sedatives</strong></td>
<td>Barbiturates (long-acting &amp; intermediate-acting)</td>
<td>Phenobarbital, butabarbital</td>
</tr>
<tr>
<td>Others</td>
<td>Bromovalum</td>
<td>Bromural</td>
</tr>
<tr>
<td><strong>Hypnotics</strong></td>
<td>Barbiturates (short-acting)</td>
<td>Secobarbital, pentobarbital</td>
</tr>
<tr>
<td>Others</td>
<td>Glutethimide, ethchlorvynol</td>
<td>Doriden, Placidyl</td>
</tr>
<tr>
<td><strong>Over the Counter</strong></td>
<td>Caffeine</td>
<td>No-doz, Vivarin, No-nod</td>
</tr>
<tr>
<td>Tranquilizers</td>
<td>Scopolamine and/or methapyrilene</td>
<td>Cope, Compoz</td>
</tr>
<tr>
<td>Sleeping pills</td>
<td>Scopolamine and/or methapyrilene</td>
<td>Sleep-Eze, Mr. Sleep, Sominex, Nytol</td>
</tr>
</tbody>
</table>

APPENDIX II

PROBABLE FUTURE ALTERATIONS OF LIFE PATTERNS BY DRUGS

1. Prolong Childhood and (Shorten?) Adolescence
2. Reduce Need for Sleep
3. Provide Safe, Short-acting Intoxicants
4. Regulate Sexual Responses
5. Control Affect and Aggression
6. Mediate Nutrition, Metabolism and Physical Growth
7. Increase or Decrease Reactivity (Alertness, Relaxation)
8. Prolong or Shorten Memory
9. Induce or Prevent Learning
   a. Experience without reinforcement
   b. Vicariously with reinforcement
10. Produce or Discontinue Transference
11. Provoke or Relieve Guilt
12. Foster or Terminate Mothering Behavior
13. Shorten or Extend Experienced Time
14. Create Conditions of 'jamais vu' (Novelty) or 'deja vu' (Familiarity)
15. Deepen our Awareness of Beauty and our Sense of Awe