

The Regulation of Psychedelic Drugs

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"It is precisely because the fruits of science can be as poisonous as they can be sweet that public understanding of their power is indispensable."

— Hans Selye, M.D.

Recently, controversy has arisen in both the popular¹ and scientific² press over the use of psychedelic drugs. The controversy has stemmed partly from the dismissal of two Harvard Psychology professors who used student volunteers in their drug experiments,³ and from the later activities of the same two professors and others as members of the International Federation for Internal Freedom, which advocated non-medical experimentation with psychedelic drugs.⁴ And undoubtedly the controversy has arisen partly because of rather sensational reports of some of the more bizarre effects of the drugs (example: for two days one person who had taken a psychedelic drug thought he was only six inches tall).⁵ As a result, investigators of psychedelic drugs have reason to consider their legal responsibilities in research, and proponents of the use of the drugs must determine the extent to which they may legally procure and use the drugs.

This paper therefore examines the legal limitations on the distribution and use (including experimental use) of psychedelic drugs, and the constitutionality of such limitations. Because the use of psychedelics is relatively novel and controversial, these drugs serve as excellent examples to illustrate the operation of the 1962 federal "new drug" legislation. Because the drugs have been used to promote religious experiences, they raise the unusual problem of the conflict between freedom of religion and legislative control of drugs. And in a broad sense, control of psychedelics reflects social and legal policy towards the novel, the unconventional and the potentially hazardous.

The paper does not discuss in detail the liability of manufacturers of psychedelic drugs to consumers injured as a result of ingesting the drugs. This problem does not seem to differ from that of liability for damage caused by drugs generally, which has been dealt with elsewhere.⁶ A recent leaning toward strict liability is indicated in the

holding that a drug manufacturer is liable to a consumer for any defect in his product, even in the absence of a contract between them,⁷ and even though the manufacturer was not negligent.⁸ However, a product which causes harmful effects is not defective for that reason only; a manufacturer will avoid liability for the harmful effects of a perfectly-made article if he gives adequate warning of the possible occurrence of such effects.⁹ If the article is a drug, it is sufficient for the manufacturer to warn that the drug should not be taken without a physician's prescription.¹⁰ But violation of food and drug legislation has been held to be *per se* negligence.¹¹

Because of the unfamiliarity of many laymen with psychedelic drugs, the following resumé of the scientific and social background relating to psychedelic drugs is included.

SCIENTIFIC AND SOCIAL BACKGROUND

What are psychedelic drugs?

Psychedelic drugs (also referred to as "psychotogenic", "hallucinogenic", "psychotomimetic", and "consciousness-expanding"¹²) have been defined by the originator of the term "psychedelic"¹³ as

. . . substances that produce changes in thought, perception, mood and, sometimes, in posture, occurring alone or in concert, without causing either major disturbances of the autonomic nervous system or addictive craving, and although, with overdosage, disorientation, memory disturbance, stupor, and even narcosis may occur, these reactions are not characteristic.¹⁴

Included among the psychedelic drugs are *d*-lysergic acid diethylamide (LSD), psilocybin, mescaline, and a number of lesser-known drugs.¹⁵ The group contains both synthetic and naturally-occurring substances; marijuana and hashish are sometimes included in the latter sub-group.¹⁶

Psychedelics constitute only one of several types of mind-affecting drugs. Hofmann, the discoverer of LSD,¹⁷ has listed five other classes, viz: (1) analgesics or euphorics (including opium derivatives); (2) sedatives or tranquilizers (such as reserpine); (3) hypnotics (including barbiturates); (4) inebriants (e.g. alcohol, ether); and (5) stimulants (such as caffeine).¹⁸ The psychedelics differ from drugs in the other classes,

. . . in that the latter for the most part modify only the mood; they either calm or stimulate it. In contrast with this, the so-called hallucinogens or psychotomimetics produce profound and acute changes

THE PSYCHEDELIC REVIEW

in the sphere of experience, in the perception of reality, changes even of space and time and in consciousness of self.¹⁹

Psychedelic substances exist naturally in certain species of mushroom and other flora.²² Mescaline is found in the cactus *Lophophora Williamsii*, commonly known as peyote (or "peyotl", "pellote"), which grows in the southern part of North America.²³ Psilocybin and psilocin are the active principles of hallucinogenic mushrooms found in Mexico.²⁴ It has recently been discovered that the seeds of some species of the common morning glory have psychedelic properties.²⁵

Indeed, it appears that many common substances have psychedelic effects when ingested — for example, nutmeg,²⁶ plastic cement,²⁷ paint and lacquer thinners,²⁸ and gasoline.²⁹ The fact that such substances are in common use implies that total prohibition of all psychedelic substances is impracticable.

Effects of Psychedelic Drugs

Psychedelic drugs may cause euphoria, depression, time disorientation, illusions and hallucinations, confusion, unresponsiveness, and loss of inhibitions. They have a direct biochemical effect, not completely understood, on the nervous system.³¹ Because the behavior of persons under the influence of the drugs is sometimes similar to that of psychotics, the drugs are often called "psychotomimetic".³² For example, subjects who ingested LSD were found to exhibit

. . . changes in perception, impaired concentration, inability to think abstractly, make associations, organize and interpret experiences.

They lost the sense of self-identity and frequently attributed their own feelings to other persons or physical objects.³³

In short, "retaining full consciousness, the subject experiences a kind of dream-world, which in many respects seems to be more real than the customary normal world."³⁴

Under the influence of LSD, subjects have shown impairment of memory, thought, and intellectual capabilities such as ability to think abstractly.³⁵ However, such impairment may be caused not by a failure in mental powers, but by preoccupation of the subject with his experience and by his attitude that cooperation with an interrogating investigator is not worth while.³⁶ "The very fact that someone should want to test [the subject] . . . may seem absurd and may arouse either hostility or amusement."³⁷

Effects of the psychedelics vary greatly with the mood of the subject and with the social and psychological context.³⁸ The sensory

The Regulation of Psychedelic Drugs

effects occur a short time after ingestion and typically last several hours, but in unusual cases have persisted for days or weeks.³⁹

Subjective reactions to psychedelic drugs have varied from very good to very bad.⁴⁰ The reaction of the discoverer of LSD to his first experience under the influence of the drug is typical :

Occasionally I felt as if I were out of my body. I thought I had died. My ego seemed suspended somewhere in space, from where I saw my dead body lying on the sofa.⁴¹

A variety of extraordinary reactions to psychedelic drugs have been reported.⁴² However, in four studies, a substantial majority of subjects found the psychedelic experience pleasant and of lasting benefit.⁴³ A significant number described the experience as religious or mystical.⁴⁴

Whether repeated ingestion of psychedelic drugs causes habituation is not yet clear. The drugs apparently are not addictive — i.e., they do not create physiological dependence as does heroin, for example.⁴⁵ Studies of consumption of peyote by Indians over several decades indicate that it does not cause habituation,⁴⁶ but an increasing number of informed scientists believe that habituation (meaning psychological rather than physiological dependence⁴⁷) to the drugs can and does occur.⁴⁸

Furthermore, there is considerable evidence that in a small minority of cases, ingestion of psychedelic drugs can cause lasting psychosis and persistent social and psychological maladjustment.⁴⁹ In rare instances, suicide or attempted suicide has followed ingestion of the drugs.⁵⁰ However, the reported cases of suicides or attempted suicide have involved psychiatric patients with histories of instability.⁵¹ It is arguable that such persons would have met disaster sooner or later anyway. It has also been suggested that unstable persons are more attracted than normal persons to the drugs.⁵² If this is so, the incidence of psychedelic casualties may be higher than would occur in the normal population.

On the whole, the drugs seem to be relatively safe. A study of some 25,000 ingestions of LSD revealed that psychotic reactions lasting more than 48 hours were observed in fewer than two-tenths of one per cent of the cases.⁵³ Rats have survived one thousand times the normal human dose of LSD without lasting harm.⁵⁴

Some observers have noted persistent harmful but not psychotic after-effects in previously normal persons who have taken doses of

psychedelic substances.⁵⁴ David C. McClelland, Chairman of the Harvard Center for Research in Personality, listed these after-effects as : (1) dissociation and detachment (a feeling of being above and beyond the normal world); (2) interpersonal insensitivity; (3) religious and philosophical naiveté — concern with oneself rather than humanity; and (4) impulsivity.⁵⁵ According to other scientists, "there is a tendency for those who ingest hallucinogens habitually to make the drug experience the center of all their activities."⁵⁶

There are conflicting reports on the stimulation of sexual desire by the psychedelics.⁵⁷ Some of the substances have been historically associated with orgiastic behavior;⁵⁸ others are said to diminish the sexual urge.⁵⁹ It has been further suggested that by themselves the drugs have no direct effect on sexual desire; they merely provide an unusual experience which the subject may or may not find appropriate for sexual activity.⁶⁰

Uses and Abuses of Psychedelic Drugs

Mental illness is one of the most prevalent and least understood diseases afflicting mankind,⁶¹ and the need for mental health research is pressing.⁶² In recent years, investigators have hypothesized an organic basis for schizophrenia, and some evidence has been adduced tending to substantiate the hypothesis.⁶³ If it is true that "behind every crooked thought there lies a crooked molecule,"⁶⁴ then any drug or chemical which induces psychotic symptoms in normal persons merits investigation as a possible clue to the cause of psychosis, and the psychedelics are such substances.⁶⁵ While there is yet no definite agreement as to the mode of biochemical action of psychedelic substances on the brain,⁶⁶ most investigators would agree that "in psychedelic drugs we have a remarkable opportunity for interesting research."⁶⁷

In addition to using psychedelics for research, psychiatrists have attempted to use the drugs as therapeutic agents, mostly in cases of neurosis.⁶⁸ Reports on the results of such therapy vary widely,⁶⁹ but there have been positive results in some cases.⁷⁰ The drugs have proven particularly valuable in the treatment of alcoholics,⁷¹ and preliminary experiments on convicts have indicated the possibility of improved recidivism rates following psychedelic drug therapy,⁷² as well as improved behaviour patterns among criminal psychopaths.⁷³ Some success has been obtained in using LSD as an analgesic for patients with severe and prolonged pain, such as occurs in advanced cancer cases.⁷⁴

The Regulation of Psychedelic Drugs

The ability of psychedelics to bring to light repressed childhood memories makes the drugs useful as psychoanalytic tools.⁷⁵ However, persons having non-psychotic schizoid personalities may become psychotic after ingestion of psychedelics.⁷⁶

If psychedelic drugs seem to be bizarre therapeutic agents, let it be remembered that many common psychotherapeutic measures are equally drastic — for example, electric shock treatment, and lobotomy.

Undoubtedly the most controversial use of psychedelic drugs is the creation of personality change in normal individuals.⁷⁷ A significant number of normal subjects who had taken psychedelics reported such lasting effects as "a greater understanding of the importance and meaning of human relationships", "a greater awareness of God, or a Higher Power, or an Ultimate Reality", "greater tolerance of others", "a set of new decisions and new directions for my life."⁷⁸ However, objective evidence of improvement in personality of normal persons seems to be lacking, perhaps because of an absence of objective criteria for assessing personality improvement in normal individuals. Proponents of personality change through the psychedelic experience nevertheless state categorically : "we know, yes we know, that science has produced methods for dramatically altering and expanding human awareness and potentialities,"⁷⁹ and "Make no mistake : the effect of consciousness-expanding drugs will be to transform our concepts of human nature, of human potentialities, of existence."⁸⁰ The company of persons who believe themselves to have benefited from the psychedelic experience has included such distinguished scholars as Aldous Huxley⁸¹ and Havelock Ellis.⁸²

Closely associated with the phenomenon of personality change is the mystical or religious nature of the psychedelic experience which is reported by many subjects. "There appear to be religious aspects of the drug experience that may bring about a change in behavior by causing a 'change of heart'.⁸³ The subject may experience a "rebirth", or a unity of himself with his environment that leads him to conclude that "all is one".⁸⁴ In a study of four hundred volunteers of whom less than ten per cent were orthodox believers or churchgoers, more than half the group reported religious aspects of the psychedelic experience.⁸⁵ The psychedelic experience has been seriously investigated by a number of active religious groups and leaders.⁸⁶

Furthermore, it is well-known that man has for centuries made use of naturally-occurring psychedelic substances for religious purposes.⁸⁷

THE PSYCHEDELIC REVIEW

The example closest to home is that of the Native American Church, whose Indian members have since the nineteenth century eaten peyote as part of their rites,⁸⁸ and whose forefathers did likewise in pagan and Christian rituals prior to the Church's establishment.⁸⁹ Adherents to the peyote religion believe that by eating peyote, they absorb God's Spirit and receive divine revelations.⁹⁰ Members of the sect observe other Christian doctrines, accept Christian ethics, and avoid alcohol.⁹¹

While one may be skeptical of drug-induced religion, material aids to spiritual improvement such as bread, wine and incense are common. Objectively, the psychedelic contribution to religion is hardly more unusual than that of trances, Yoga postures, or glossolalia.

Undoubtedly, the currently prevailing social appraisal of psychedelic experiences is one of suspicion and perhaps hostility.⁹² Bizarre drug experiences, misuse of the drugs by students and others for "kicks", and occasional casualties have all played a contributing part to social apprehension. But perhaps the main reason for society's outlook is its inertia, i.e. its reluctance to accept the utility or desirability of an uncommon practice. This should be especially true in American society of a practice which is introspective, following Oriental tradition. Perhaps most Occidentals would subscribe to these views of Harvard psychologist David C. McClelland:

It is probably no accident that the society which most consistently encouraged the use of these [psychedelic] substances, India, produced one of the sickest social orders ever created by mankind, in which thinking men spent their time lost in the Buddha position under the influence of drugs exploring consciousness, while poverty, disease, social discrimination, and superstition reached their highest and most organized form in all history.⁹³

Professor McClelland's remarks were directed against general use of psychedelics. However, informed medical opinion, while cautious, tends to favor the use of psychedelic drugs at least for mental research purposes, if proper safeguards and controls are enforced.⁹⁴

Proponents of the psychedelic experience can perhaps find hope in the fact that many valuable medical advances, when first discovered, were denounced by orthodox opinion. Included in the group were Jenner's smallpox vaccine, Lister's theory of antisepsis, sulfa drugs, and cod liver oil.⁹⁵ The chairman of the U.S. Army's Commission on Infectious Disease found early reports on the efficacy of penicillin to be incredible, and poured down the drain a sample delivered for clinical testing.⁹⁶ When coffee was first introduced into the commerce of the

The Regulation of Psychedelic Drugs

world, it was widely condemned as Devil's brew, and was prohibited, suppressed, and destroyed.⁹⁷ Accordingly, it would be premature to assert that the bulk of society will continue to reject psychedelic drugs as a means for personality improvement.

THE CONSTITUTIONAL BASIS FOR REGULATING PSYCHEDELIC DRUGS

In general, Congress may legislate with respect to drugs in interstate commerce under the Commerce clause of the Constitution,⁹⁸ and with respect to narcotics under its revenue powers.⁹⁹ The constitutional basis for State legislation lies in the police power of the States, which may be exercised to promote public health and safety.¹⁰⁰ This might be the end of the matter were it not for the arguments raised by proponents of psychedelic drugs. They have urged that any person who is mentally competent should have the right to explore the varieties of conscious experience if he can do so without harming himself or others.¹⁰¹ International Federation for Internal Freedom leaders Leary and Alpert insist that "the Fifth Freedom — the freedom to expand your own consciousness — cannot be denied without due cause."¹⁰²

If there is such a Fifth Freedom, it has yet to be specifically recognized by the courts. Freedom of thought is not constitutionally protected *per se*, but is indirectly protected through the more objective freedoms such as freedom of speech, of the press, and of religion. In any case, conventional notions of freedom of thought generally involve concepts such as the freedom to accept or reject a proposition without fear of official sanction. Such notions do not obviously extend to the freedom to experience a drug-induced para-normal state of consciousness. Accordingly, it is necessary to turn to the legally recognized freedoms.

It has been advanced as a basic legal principle that "every person has the right to protect his health as he deems best, as part of his fundamental personal liberties."¹⁰³ The existence of this principle has been argued in two cases. In *United States v. Olsen*,¹⁰⁴ the court held that such a right, if it exists, is subordinate to the right of Congress to regulate food and drugs.¹⁰⁵ And in *Jacobson v. Massachusetts*,¹⁰⁶ the court upheld the right of the State to enact "such reasonable regulations . . . as will protect the public health and the public safety,"¹⁰⁷ stating that any right of the defendant to care for his own body and

health as he saw fit might be restrained "for the common good".¹⁰⁸ On the strength of these two cases, it must be concluded that proponents of psychedelic drugs have the right to use them in "protecting their health" only to the extent permitted by legislation, unless some other constitutional principle dictates otherwise.

It is arguable that total prohibition of possession of psychedelic drugs in the hands of individuals would be unconstitutional as defying the basic right to have and use private property. A closely analogous case in which issue was argued is *Ex parte Francis*.¹⁰⁹ The Florida statute in issue in the *Francis* case sought to prohibit the possession or ownership of intoxicating liquor, even for personal consumption, in "dry" counties. In declaring the statutory provision unconstitutional, the court held that inasmuch as liquor is capable of private ownership (and so recognized in "wet" counties), the legislature might limit its sale, but could not entirely prohibit its private use and possession.¹¹⁰

In contrast to the *Francis* case, illegal possession of opium was in issue in *Luck v. Sears*,¹¹¹ but again the defendant challenged the constitutionality of a statute totally prohibiting its possession. In holding the legislation valid and not in violation of the "life, liberty or property" protection of the Constitution, the court distinguished the case at bar from cases involving possession of intoxicating liquor:

It is a matter of common knowledge that intoxicating liquors are produced principally for sale and consumption as a beverage, and so common has been their manufacture and use for this purpose that they are regarded by some courts as legitimate articles of property, the possession of which neither produces nor threatens any harm to the public. But the use of opium for any purpose other than as permitted in this act [i.e., for medicinal use] has no place in the common experience or habits of the people of this country, but is admitted by all to be an insidious and demoralizing vice, injurious alike to the health, morals, and welfare of the public.¹¹²

Psychedelic drugs cannot be arbitrarily placed in the same category as either opium or alcohol. The socially-accepted use of psychedelics, as of opium, probably does not extend, at present, beyond medicinal use. But it is impossible to state on the basis of present evidence that consumption of psychedelics is "an insidious and demoralizing vice", especially when there appears to be some religious value in the psychedelic experience. Like alcohol, psychedelic drugs have acknowledged legitimate uses, and are capable of ownership for at least some purposes. But their present use can hardly be regarded as

"common". And the injuries attributable to their use, while undoubtedly occurring less frequently than casualties attributable to alcohol, may be of sufficient seriousness to warrant a holding that the drugs do threaten harm to the public. Accordingly, it is hard to say with confidence what attitude a court would take toward a statute totally prohibiting private possession and use of psychedelic drugs. No doubt the decision, if and when it is made, will depend upon the developing social attitude towards the drugs, and upon the availability of objective evidence of the relative benefits and dangers of their use.

Of course, outright prohibition must be distinguished from regulation. Statutes which limit, rather than prohibit, possession, distribution or use of drugs have been repeatedly held to be constitutional.¹¹³

Freedom of Religion

Perhaps the most forceful attack which can be made upon the constitutionality of statutes limiting the availability and use of psychedelic drugs is that such statutes prevent persons from practising their religion — for, as discussed above, the drugs have been used to promote religious experiences.¹¹⁴ Proponents of the religious use of the drugs might well echo these words of a federal judge:

There is hardly a group of religious people to be found in the world who do not hold to beliefs and regard practices as important which seem utterly foolish and lacking in reason to others equally wise and religious; and for the courts to attempt to distinguish between religious beliefs or practices on the ground that they are reasonable or unreasonable would be for them to embark upon a hopeless undertaking and one which would inevitably result in the end of religious liberty.¹¹⁵

Notwithstanding comments such as the foregoing, it is not at all clear that psychedelic drug consumption for religious purposes would be given absolute constitutional protection by the courts. Indeed, at present there is more reason for reaching the opposite conclusion, as the following discussion attempts to indicate.

In the first place, the courts have tended to limit absolute constitutional protection of religion to freedom of belief, as opposed to freedom of action. While "the truth or falsity of a religious belief is beyond the scope of a judicial inquiry,"¹¹⁶ nevertheless "laws are made for the government of actions, and while they cannot interfere with mere religious beliefs and opinions, they may with practices."¹¹⁷ In other words, freedom of religion "embraces two concepts — freedom

to believe and freedom to act. The first is absolute but, in the nature of things, the second cannot be."¹¹⁸

But some acts are symbolic only. Oliver Cromwell is alleged to have said :

As to freedom of conscience, I meddle with no man's conscience, but if you mean by that, liberty to celebrate the mass, I would have you understand that in no place where the power of the Parliament of England prevails shall that be permitted.¹¹⁹

Cromwell apparently did not perceive that freedom of religion is eviscerated by the inability to perform those symbolic acts, especially sacramental acts, which are involved in the practice of the religion in question. American courts, however, have drawn the necessary distinction between those acts necessary to worship and those which are not. Thus, a New York court was able to assure defendants that "full and free enjoyment of religious profession and worship is guaranteed, but acts which are not worship are not."¹²⁰ The court decided that failure to provide medical care for the defendants' child was an act which could not be justified by freedom of religion (the parents believed in the healing power of prayer); such an act went beyond freedom of worship.¹²¹ In contrast, a State statute requiring schoolchildren to salute the flag was held by the Supreme Court to be in violation of the constitutional protection of religion.¹²² In this case the questioned act was of a symbolic nature, and thus invaded the sphere of freedom of conscience.

It surely cannot be argued successfully that ingestion of a psychedelic drug is no more than a symbolic religious act. It is also an act which can have, in some instances, a harmful effect on the person taking the drug and possibly on other members of society.¹²³ This being the case, it falls within the category of acts which are given only qualified protection by the courts under the Constitution, subject to the right of the state to protect the public interest, and in particular, public health and safety.¹²⁴ Indeed, it has been frequently held that the state may undertake positive action infringing the religious beliefs of some citizens — for example, it may fluoridate the water supply,¹²⁵ quarantine its citizens,¹²⁶ and require compulsory vaccination.¹²⁷

While the Supreme Court has stated that there must be a "clear and present danger to a substantial interest of the State"¹²⁸ in order to justify restricting an act practiced for a religious cause, this principle appears to have been eroded in subsequent cases.¹²⁹ Furthermore, the

The Regulation of Psychedelic Drugs

hazards posed by psychedelics to the public health probably constitute a sufficient "clear and present danger" to warrant legislative control of the drugs. To permit freedom of religion to prevail over such legislation undoubtedly "would be to make the professed doctrines of religious belief superior to the law of the land, and in effect to permit every citizen to become a law unto himself."¹³⁰

In part, the probable rejection by courts of freedom of religion as a legally sufficient reason for ingestion of psychedelic drugs in defiance of controlling legislation would be because of the unconventionality of the practice.¹³¹ Such judicial suspicion of the unorthodox is not unusual. For example, in condemning the practice of polygamy in the *Mormon Church* case, the Supreme Court termed the practice an offense, "against the enlightened sentiment of mankind",¹³² and declared :

One pretence for this obstinate course is, that their belief in the practice of polygamy, or in the right to indulge in it, is a religious belief, and therefore, under the protection of the constitutional guaranty of religious freedom. This is altogether a sophistical plea. No doubt the Thugs of India imagined that their belief in the right of assassination was a religious belief, but their thinking so did not make it so.¹³³

And in another Mormon case, the Supreme Court posed this question :

Suppose one believed that human sacrifices were a necessary part of religious worship, would it be seriously contended that the civil government under which he lived could not interfere to prevent a sacrifice?¹³⁴

One observer, discussing cases holding that Jehovah's Witnesses must permit their children to accept blood transfusions, argued that

Society commonly accepts the religious opinions of larger groups who decline to accept certain medical treatment, but the same tolerance is not shown toward minorities. . .¹³⁵

On the basis of principle and tradition, then, it seems likely that courts would uphold as constitutional legislation limiting the use and distribution of psychedelic drugs. But there are a few cases directly on point, all involving Indian peyotists.¹³⁶ In one of the reported cases, the constitutional issue, although argued, was not decided.¹³⁷ In another case, the trial court held that an ordinance prohibiting the importation of peyote into a Navajo nation was a valid exercise of the police power,¹³⁸ but the affirming opinion of the Court of Appeal was based entirely on the holding that no constitutional protection of religion is guaranteed to Indian nations, in the absence of direct

THE PSYCHEDELIC REVIEW

Congressional action, because the Indian nations are distinct political entities not directly subject to either the First or Fourteenth Amendments of the United States Constitution.¹³⁹

In one reported case, however, the court did reach the religious issue and decided it. This was *State v. Big Sheep*,¹⁴⁰ a Montana case in which an Indian member of the Native American Church was charged with unlawful possession of peyote. The defendant offered to prove that peyote was used by members of the Church only for sacramental purposes, and pleaded freedom of religion as a defense to the charge. The court held, however, that the defense could not be upheld, and declared :

It was clearly within the power of the legislature to determine whether the practice of using peyote is inconsistent with the good order, peace and safety of the state. . . . While laws cannot interfere with mere religious belief and opinions, they may inhibit acts or practices which tend toward the subversion of the civil government, or which are made criminal by the law of the land.¹⁴¹

In an unreported decision,¹⁴² of which I have only secondary knowledge,¹⁴³ a Wisconsin Indian was apparently acquitted on a charge of illegally shipping peyote through the mails, on the defense that freedom of religion justified his action.

Finally in a recent unreported Arizona case,¹⁴⁴ a member of the Native American Church was charged with illegal possession of peyote. The defendant admitted possession, but challenged the statutory prohibition *inter alia* upon the ground of freedom of religion under the United States Constitution. McFate, J., agreed that the State, "under the police power, may regulate or prohibit the use or possession of substances, even though used in religious rites, if reasonably necessary to protect the public health or safety." However, he found on the evidence that peyote consumers are in possession of all "mental faculties", that "there are no harmful after-effects from the use of peyote," and that it "is not habit-forming". He further found that the only significant use of peyote is by the Native American Church members, and that "there is nothing debasing or morally reprehensible about the peyote ritual." The court therefore concluded that the Indians' use of peyote was consistent with the public health, morals and welfare, and that the statute outlawing its use was unconstitutional.

It is possible that the conflict of authority between the two unreported peyote cases and *State v. Big Sheep* results partly from the nature of the evidence before the courts involved. In the unreported

The Regulation of Psychedelic Drugs

Arizona case, McFate, J., nowhere alludes to the possibility of harm resulting from the ingestion of peyote. Had the court been presented with scientific evidence of the potential hazards of psychedelic substances, it is unlikely, in my view, that the court would have reached the conclusion it did. Furthermore, in the case of a conflict of scientific opinion, it is hard to resist the view of the Montana court in *State v. Big Sheep* that it is the duty and power of the legislature, not of the courts, to determine whether the good order, peace and safety of the state are in any way threatened by uncontrolled use of peyote.¹⁴⁵

Accordingly, unless proponents of the use of peyote (or any other psychedelic substance) can prove that it is so safe as to constitute no possible threat to the public health, order, morals, and safety, the judicial attitude will probably pattern itself on that of the court in *State v. Big Sheep*. And in the hypothetical case in which all available evidence is presented, it is hard to resist a finding of constitutionality of statutes regulating psychedelic substances.

FEDERAL REGULATION OF PSYCHEDELIC DRUGS

Federal Legislation Applicable to Psychedelics

Federal control of drugs is exercised largely through the Federal Trade Commission, the Bureau of Narcotics, and the Food and Drug Administration (FDA), and through the legislation and regulations discussed below.

The Federal Trade Commission is empowered to curb false advertising, by use of the mails or otherwise, which is intended or likely to induce the purchase of food, drugs, devices and cosmetics.¹⁴⁶ Because this area of control does not seem to present problems peculiar to psychedelic drugs, it will not be further discussed.

Federal narcotics legislation¹⁴⁷ is dependent for constitutional validity on the revenue powers of Congress.¹⁴⁸ Narcotic drugs are defined medically as those which produce "stupor, insensibility, or sound sleep",¹⁴⁹ and this definition applies to some psychedelic substances.¹⁵⁰ However, as used in federal narcotics legislation, the term "narcotic drug" is restricted to opium, morphine, coca leaves, codeine; and their preparations, derivatives, etc.¹⁵¹ The term "opiate" refers to any drug which, after due procedural formalities are observed, is proclaimed by the Secretary of the Treasury to have addiction-forming or addiction-sustaining liability similar to that of morphine or cocaine.¹⁵²

THE PSYCHEDELIC REVIEW

However, no psychedelic drug has been so proclaimed,¹⁵³ and it is unlikely that any psychedelics will be so proclaimed in view of present indications that psychedelics are not addictive.¹⁵⁴

The narcotic marijuana is given special legislative treatment.¹⁵⁵ While it has been included by some scientists in the category of psychedelic drugs,¹⁵⁶ its properties seem to be somewhat different from those of most other psychedelics,¹⁵⁷ and its social use is frequently associated with the misuse of addictive narcotics. Its exceptional status in American legal and social contexts renders it a major subject in its own right, and therefore inappropriate for detailed discussion here.¹⁵⁸

The Federal Food, Drug and Cosmetic Act¹⁵⁹ (hereinafter referred to as "the Act") includes most of the general federal legislation applicable to drugs. Because "practically all drugs are dangerous in some degree",¹⁶⁰ and because the Act touches "phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection",¹⁶¹ such legislation has been rightly described as "essential to the health and well-being of the American people."¹⁶²

In order for the Act to apply to psychedelics, they must fall within the definition of "drug" in Section 201(g) of the Act, the relevant parts of which read as follows:

The term "drug" means (1) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (3) articles (other than food) intended to affect the structure or any function of the body of man or other animals. . . .

In the three official pharmacopoeias named in the above definition, I was able to locate atropine and belladonna, both of which have psychedelic properties,¹⁶³ but none of the more common psychedelics such as LSD, mescaline or psilocybin was listed. However, the term "drug" is not confined to drugs so listed, as the statute clearly indicates and as has been held in court.¹⁶⁴ Insofar as psychedelic drugs are used for therapeutic purposes, they satisfy the requirements of sub-clause (2) above. Further, psychedelics are "intended to affect . . . (a) function of the body", and therefore satisfy subclause (3), even if not used therapeutically. The Food and Drug Administration agrees with this interpretation.¹⁶⁵ Although it might be argued that psychedelics are intended to affect the mind rather than the body, a more realistic

The Regulation of Psychedelic Drugs

view is that they affect the brain, a part of the body, through some biochemical process.¹⁶⁶

A more difficult problem is presented by those psychedelic substances, such as morning glory seeds, which have everyday uses independent of their psychedelic properties. Are such substances "drugs" within the meaning of the Act? The word "intended" in section 201(g) (3) of the Act implies that the answer depends upon the purpose for which the substances are used. Such has been held by a court construing this section:

It is the *intended use* of an article which determines whether it is a drug, regardless of its inherent properties or dictionary definition.¹⁶⁷

Therefore, if morning glory seeds are used for the purpose of growing morning glories, they are not drugs; but if used for their psychedelic effects, they are drugs within the meaning of the Act.

As drugs subject to the Act, psychedelics are within the purview of the statutory prohibitions against adulteration and misbranding, in common with other drugs.¹⁶⁸ Apart from the "new drug" section of the Act, discussed below, the only specific substantive provisions of particular interest in relation to psychedelics are sections 502(d) and 502(e) (1). The first of these requires that any drug containing any quantity of, *inter alia*, peyote, must be labeled "Warning — May be habit forming", in juxtaposition with a statement on the label of the quantity or proportion of peyote in the drug. (Incidentally, it is no defense to a violation of this provision that peyote has no habit-forming potential, for once so designated, it is considered to have such as a matter of law.¹⁶⁹) Section 502(e) (1) of the Act requires that any drug containing atropine or its derivatives include on its label the quantity or proportion of such substance.

Psychedelics are, of course, subject not only to the Act itself but to regulations promulgated under it by the FDA (nominally by the Secretary of Health, Education and Welfare).¹⁷⁰ The Secretary's power is "one of regulation only — and administrative power only — not a power to alter or add to the act."¹⁷¹ Nevertheless, this power has been called a "quasi legislative"¹⁷² power under which the Secretary is given a wide discretion and his judgment, if based on substantial evidence of record and within statutory and constitutional limitations, is controlling even though the reviewing court might on the same record have arrived at a different conclusion. The statute contemplates that he shall not arbitrarily exercise his power, but shall act only

THE PSYCHEDELIC REVIEW

upon a conscientious judgment derived from a consideration of the facts and conditions to which the regulation is to be applied.¹⁷³

Once the regulation is promulgated by the Secretary in conformance with the Act, it "has the force and effect of law to the same extent as though written into the statute."¹⁷⁴

It should be noted that the validity of the regulations promulgated by the Secretary cannot always be challenged by the defendant in a court proceeding brought by the FDA. Because the Act specifically provides a procedure under which many of the regulations may be challenged,¹⁷⁵ courts have held that such regulations may not be challenged collaterally as a defense to an action except on constitutional grounds¹⁷⁶ or on the ground that statutory procedural formalities have not been observed.¹⁷⁷ Because the statutory procedure for challenging many regulations under the Act must be initiated within thirty days after the Secretary publishes his proposed regulations,¹⁷⁸ it is important that persons likely to be affected by the regulations be faithful readers of the Federal Register or of a reliable food and drug news service.

Psychedelics as "New Drugs"

Under the American system, unfortunately, it sometimes takes tragedy to supply the impetus for needed social and legislative reform. In 1937, more than one hundred persons died as a result of taking a new medicine which had been tested for appearance, fragrance, and flavor, but not for safety.¹⁷⁹ On June 25, 1938, President Roosevelt signed a new Food, Drug and Cosmetic Act.¹⁸⁰ Under this Act, which, as amended, is still in force, new drugs could not be legally marketed unless recognized by experts as safe.¹⁸¹ In the words of one commentator,

The idea that the safety of an article should be officially established before it is permitted to be marketed is certainly one of the important concepts of our times. . . . The quarter century since its [the Act's] enactment has seen a revolution in therapeutics. Over 14,000 New Drug Applications have been received and processed. Ninety per cent of the drugs in use today were unknown before 1938, most of them cleared through the New Drug procedure, yet with a remarkably small incidence of mishaps and mistakes.¹⁸²

But the 1938 Act was not perfect. In 1962, the thalidomide tragedy stimulated a previously reluctant Congress into passing the Drug Amendments Act of 1962.¹⁸³ Under the new legislation, the "new drug" provisions of the 1938 Act were tightened up;¹⁸⁴ for example,

The Regulation of Psychedelic Drugs

manufacturers of new drugs are now required to convince the FDA that the drugs are effective as well as safe, before the drugs may legally be marketed.¹⁸⁵

Opponents of the 1962 legislation expressed fears that further regulation and "red tape" might tend to prevent or delay useful new drugs from reaching the market,¹⁸⁶ that physicians and drug manufacturers would tend to rely not on their own trained judgment but on that of the FDA,¹⁸⁷ that adequate criteria for judging the effectiveness of new drugs are not set forth in the legislation,¹⁸⁸ and that history is replete with examples of rejection by orthodox opinion of new drugs and other medical advances.¹⁸⁹

Nevertheless, the evidence indicates that reforms were needed. Over a recent four-year period prior to the 1962 legislation, some 20 new drugs which had received FDA approval were removed from the market as having dangerous side effects (including carcinogenic effects, cataracts, hepatitis, liver damage, blood dyscrasias) some of which could lead to death.¹⁹⁰ And the manufacturers of new drugs have not always been cooperative with the FDA. For example, the manufacturer of thalidomide, in an effort to get the drug on the market, contacted the FDA fifty times, and some of its pressure tactics were vigorous.¹⁹¹ At one point, the company charged that a letter from the FDA's Dr. Kelsey (who was largely responsible for FDA refusal to clear thalidomide) was libelous.¹⁹² And it is not unknown for a drug manufacturer to be charged with falsification of new drug applications.¹⁹³

The FDA appears to be aware of the dangers of too strict new drug regulation.¹⁹⁴ One FDA official stated: "It is not our purpose to interfere with the development of useful new drugs but to promote a responsible approach utilizing the best available methodology."¹⁹⁵ And another representative expressed the view that officialdom should "keep its mind open to dissenting views and to the possibility, however remote, that an unorthodox opinion may contain the germ of truth."¹⁹⁶

It remains to be seen how psychedelic drugs are affected by the present "new drug" provisions. Under the Act as amended in 1962, a "new drug" is defined as

- (1) Any drug the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof, except that such a drug not so recognized shall not be deemed to be a "new drug" if at any

THE PSYCHEDELIC REVIEW

time prior to the enactment of this chapter it was subject to former sections 1-5 and 7-15 of this title, and if at such time its labeling contained the same representations concerning the conditions of its use; or

(2) Any drug the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.¹⁹⁷

A regulation under the Act further defines the "newness" of a drug as follows:

The newness of a drug may arise by reason (among other reasons) of:

(1) The newness for drug use of any substance which composes such drug, in whole or in part, whether it be an active substance or a menstruum, excipient, carrier, coating, or other component.

(2) The newness for drug use of a combination of two or more substances, none of which is a new drug.

(3) The newness for drug use of the proportion of a substance in a combination, even though such combination containing such substance in other proportion is not a new drug.

(4) The newness of use of such drug in diagnosing, curing, mitigating, treating, or preventing a disease, or to affect a structure or function of the body, even though such drug is not a new drug when used in another disease or to affect another structure or function of the body.

(5) The newness of a dosage, or method or duration of administration or application, or other condition of use prescribed, recommended, or suggested in the labeling of such drug, even though such drug when used in other dosage, or other method or duration of administration or application, or different condition, is not a new drug.¹⁹⁸

The only gloss put on the foregoing definitions by the case law is that if there is a genuine difference of opinion among experts as to the safety of a drug, it must be concluded that the drug is not generally recognized as safe for the use in question.¹⁹⁹

Probably all psychedelic drugs fall within the statutory definition of "new drugs", at least when used to cause a psychedelic experience, because of the general novelty of the use of drugs for this purpose, and because of the body of informed medical opinion which is yet to be convinced of the safety of the drugs.²⁰⁰ The FDA takes the view that at least some psychedelics are "new drugs".²⁰¹ It is true that some of the drugs, notably mescaline, have been known for decades, and thus might not be considered "new drugs" because of the clause in the statutory definition stating that a drug is not deemed to be a new drug if prior

The Regulation of Psychedelic Drugs

to the enactment of the Act (1938) the drug was subject to the 1906 Act, and its labeling contained the same representations concerning its conditions of use. This raises questions of law and of fact with respect to the older psychedelics. Was mescaline (say) as a matter of fact labeled, with respect to its psychedelic use, in substantially the same way in 1938 as it is today, for the same conditions of use? If not, it is as much a "new drug" as the recently-discovered psilocybin. Assuming that this hurdle is overcome, it remains to be seen whether, as a matter of law, the 1906 Act applied to mescaline. In my opinion it probably did. Although the 1906 statutory definition of "drug" did not include clause (3) of the present statutory definition,²⁰² and no section analogous to section 502(d), discussed above,²⁰³ appeared in the 1906 statute, there is evidence that, prior to 1938, peyote (which contains mescaline) was used in the cure, mitigation, or prevention of disease.^{204a} Thus its derivatives, including mescaline, probably qualify as "drugs" under the 1906 Act. However, it is improbable that it and other psychedelics were labeled prior to 1938 for research, personality change, and other psychedelic uses; therefore, for such uses, all psychedelics are "new drugs" under the present Act. I have no information that any new drugs have been cleared by the FDA for psychedelic uses, and at least some have not.^{205b}

The key words in the statutory definition of "new drug" are "safe" and "effective". They are also the key words in section 505 of the Act,²⁰⁴ which prohibits the introduction of any new drug into interstate commerce unless and until the FDA has approved an application showing that the drug is in fact safe and effective. The Commissioner of Food and Drugs has stated: "There are few drugs that are absolutely 100 per cent safe,"²⁰⁵ yet thousands of new drug applications have been approved.²⁰⁶ It is therefore apparent that the legal meaning of the words "safe" and "effective" requires elaboration.

Nearly all drugs are dangerous to some degree and are used despite their dangers.²⁰⁷ The Committee which guided the 1962 drug amendments through the House of Representatives explained:

[A] drug the use of which involves the risk of toxic side reactions is considered "safe" only if the drug is so valuable from the point of its efficacy as to overbalance this risk and if these side reactions are warned against in the proposed labeling of the drug.²⁰⁸

The medical profession also takes a relativistic view of safety. In an official statement to the aforementioned House Committee, the

American Medical Association's representative explained :

A prescription drug is, by definition, "unsafe" in the sense that its use in human beings can and does involve hazards. . . . Only the physician can add the "safety factor" through the knowledge at his command of all the consequences which may follow the administration of a specific dosage of a specific drug to a specific patient.²¹⁰

The approach of the FDA to the meaning of "safety" has been stated in simple terms by the Commissioner of Food and Drugs :

In determining whether or not a new drug is safe . . . we try to learn what the probable side effects and harm to be produced by the drug are.

We try to learn what good it will do.

Then we balance one against the other, and if the good outweighs the harm, we pass it.²¹¹

According to one expert, the FDA will approve a drug capable of inflicting considerable harm, even death, if it is capable of unusual therapeutic usefulness.²¹² Nor does the fact that a drug is habit-forming render it unsafe; it is merely one of the factors to be considered.²¹³

Although there are no reported cases directly on point, presumably the courts would, if the issue arose, accept the foregoing notions of relative safety in construing the "new drug" provisions of the Act. In a case involving a patent application on a new drug, the court stated :

With regard to . . . the nature of "safety" in the field of drugs and medicaments, we take judicial notice that many valued therapeutic substances or materials with desirable physiological properties, when administered to lower animals or humans, entail certain risks or may have undesirable side effects.²¹⁴

Like "safe", the word "effective" is also a relative term. The House Committee (who originally used the terms "efficacy" and "efficacious" rather than "effectiveness" and "effective" in their draft bill) explained :

The "efficacy" to which the bill refers is not efficacy in the abstract, but efficacy of the drug for use under the conditions prescribed, recommended, or suggested in its proposed labeling.²¹⁵

Language similar to the above appears in the statutory definition of a "new drug" and in section 505 of the Act dealing with new drugs.

Because the safety of a drug is assessed in the light of its therapeutic effectiveness, it might be argued that the addition of "effective" to the relevant statutory provisions is superfluous. The reason for the FDA's requested addition was to prevent manufacturers from making unproved claims for new drugs approved as safe for other purposes.²¹⁶ Although it is not at all clear that such practice by the manufacturers

The Regulation of Psychedelic Drugs

was permissible prior to the 1962 amendments, the addition of "effective" and "effectiveness" to the new drug provisions should remove any doubt.

But in other respects the inclusion of the "effectiveness" requirement raises new problems. Is a drug "effective" if it has therapeutic value for only half of the patients for whom it is prescribed? For only one per cent? What if some physicians find the drug effective, and others do not? An American Medical Association spokesman, in opposing the grant of authority to the FDA to judge efficacy of drugs, said :

A drug which is, on the average, less efficacious than another, must still be available to every physician since it may be completely efficacious in treating the medical problems of one of his patients. We do not practice medicine on the average — we seek to solve or alleviate the problems of each and every patient.²¹⁷

These A.M.A. fears should be alleviated if courts interpret the "new drug" legislation in the light of the Senate Report on the 1962 amendments. According to the Senate Committee :

When a drug has been adequately tested by qualified experts and has been found to have the effect claimed for it, this claim should be permitted even though there may be preponderant evidence to the contrary based upon equally reliable studies. . . . In such a delicate area of medicine, the committee wants to make sure that safe new drugs become available for use by the medical profession so long as they are supported as to effectiveness by a responsible body of opinion.²¹⁸

At first sight, psychedelic drugs seem to present somewhat unusual problems with respect to convincing the FDA of their safety and effectiveness. While a drug that helps psychotic patients to act normally is clearly valuable, what view should the FDA take of a drug which induces psychotic symptoms in normal people? By some standards, such a drug is inherently unsafe. And in what sense is a drug which causes personality changes "effective"? This sense of the word "effective", especially if the drug is "effective" in causing a mock psychosis, seems to be quite different from the therapeutic effectiveness implicit in the statutory language. Furthermore, if the only use of a psychedelic drug is as a research tool, a verbal paradox arises — research must be done to prove the drug safe and effective for research.

To escape at least some of these dilemmas, it is necessary to recall the relative manner in which the terms "safe" and "effective" are used. It might be argued that any drug which, in moderate doses, renders

a person unconscious and, in larger doses, causes death, is ineffective and unsafe. Yet anaesthetics act in this manner — but their effect is intended to be temporary only, and for an overriding beneficial purpose. A new anaesthetic is safe and effective if it can be used to achieve its intended purpose with minimal adverse side effects. Similarly, the psychotic symptoms caused by psychedelics are intended to be temporary only, and for an ultimately useful purpose, which may be an improvement in the mental health or personality of the persons taking the drugs, or a better understanding of the psyche by an investigator. Such drugs ought to be deemed "safe" if they can be used beneficially with relatively few casualties.

Nor is there any real contradiction or paradox in stating that limited research should be carried out to determine whether the drugs are safe enough to be used widely as research tools. The FDA is aware of the possibility that a drug may have no other use, and considers that new drug applications for such substances may ultimately be approved.²¹⁸

However, the problem of effectiveness is troublesome. As indicated above, there are conflicting reports as to the therapeutic value of psychedelic drugs.²¹⁹ Presumably the evidence supporting therapeutic value is sufficient, nevertheless, if the viewpoint of the Senate Committee, previously referred to, is adopted.²²⁰ With respect to research use of psychedelics, no criteria have been set forth defining "effectiveness" of drugs as research tools. And FDA approval of a new psychedelic drug application for therapeutic or research purposes would not make the drug available to normal persons who wish to ingest it to improve their personalities. Even if it is agreed that the term "effective" may be applied to personality improvement, it seems difficult to establish adequate criteria for judging whether or not a person's personality has in fact improved after ingestion of the drug. In short, the new drug legislation was obviously drafted without consideration of the specific problems relating to psychedelics. Presumably the FDA will settle these problems as they arise, on an *ad hoc* basis.

I do not propose to discuss in detail the procedure relating to the preparation and approval of new drug applications. Both the Act²²¹ and the regulations under it²²² contain provisions regarding the forms and particulars required for the applications, the investigations which must be made, and the records which must be kept. The FDA is

The Regulation of Psychedelic Drugs

required to keep confidential all information submitted in the applications,²²³ and is required to take action on each application within 180 days of its submission.²²⁴ There are specific provisions for appeal to a court if the FDA denies approval of an application.²²⁵ If new information reveals that approval should not be continued, the FDA may withdraw its approval.²²⁶

On the whole, the procedure seems to work smoothly; the Commissioner stated that there have been only two appeals from FDA objections to new drug applications in more than 20 years.²²⁷

Of current interest is the investigational use which may be made of psychedelic drugs prior to approval of new drug applications for them.²²⁸ Section 505(i) of the Act²²⁹ enables the FDA to promulgate regulations permitting "experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs" to use any unapproved new drug "intended solely for investigational use". Such use is conditioned upon FDA approval of an application by the sponsor of the investigation, setting forth the qualifications of the investigators, the nature of the investigation, the results of previous research, technical data concerning the composition and manufacture of the drug, and a host of other details.²³⁰ Additionally, each of the sponsor's investigators must submit a résumé of his qualifications and experience.²³¹ There are also obligations imposed on the sponsor regarding drug shipments, the maintenance of records, and the like.²³²

Nowhere in the Act or Regulations is there any requirement that an investigator be a physician or have any particular training — the Act simply requires that he be "qualified by scientific training and experience to investigate the safety and effectiveness of drugs". In the past, some psychedelic drug research has been carried out by psychologists with little or no medical or pharmacological training. Would such persons qualify as "experts" under the Act? No clear answer can be given, but one FDA official has stated :

We believe that at least in the early phases of clinical investigation of a novel drug it [the term "expert"] refers to physicians who have experience in drug investigation and are specialists in the field applicable to the specific drug. Furthermore, they should have adequate facilities for investigation with respect to patients, clinical laboratory services, and time to give attention to such studies. This usually does not apply to the busy general practitioner.²³³

Other authorities share the view that not every physician qualifies as

an expert,²³⁴ but the right of non-physicians to investigate new drugs remains uncertain. In view of the fact that both psychological and physiological hazards are presented by psychedelic research, it appears necessary to have at least one research-oriented psychiatrist in every psychedelic research project carried out under the Act. However, there seems to be no reason for prohibiting psychologists, chemists and others with no medical training from assisting in such projects, provided proper medical supervision is exercised.

One interesting statutory provision relating to the investigational use of drugs is that the experts must certify

that they will inform any human beings to whom such drugs, or any controls used in connection therewith, are being administered, or their representatives, that such drugs are being used for investigational purposes and will obtain the consent of such human beings or their representatives, except where they deem it not feasible or, in their professional judgment, contrary to the best interests of such human beings.²³⁵

This is probably merely a statutory confirmation of the common law duty of investigators, as will be discussed in greater detail below.²³⁶

Enforcement of Federal Legislation

Section 301 of the Act²³⁷ lists a series of prohibited acts, including adulteration, misbranding, and the following "new drug" offenses:

(d) The introduction or delivery for introduction into interstate commerce of any article in violation of section 505 of this title. . . .

. . . (1) The using, on the labeling of any drug or in any advertising relating to such drug, of any representation or suggestion that approval of an application with respect to such drug is in effect under section 505 of this title, or that such drug complies with the provisions of such section.

To enforce these prohibitions, the FDA (nominally, the Secretary of Health, Education and Welfare) has available a battery of remedies, including seizure of drugs introduced into interstate commerce in violation of the Act²³⁸ (which may be accomplished by an *in rem* proceeding against the drugs themselves rather than against any person²³⁹), injunction,²⁴⁰ and criminal proceedings which may result in a fine of \$10,000 or less and imprisonment of up to three years.²⁴¹ Even if the owner of the drugs is convinced of their safety, it is no answer to an FDA seizure action that the drugs are in no way dangerous to health, if the Act has in fact been violated.²⁴² Furthermore, one court has held that if an FDA official makes an error of fact or law in

The Regulation of Psychedelic Drugs

seizing the drugs, his action, if bona fide and not arbitrary or unreasonable, will be sustained.²⁴³ It has also been held that the fact that the Act imposes criminal sanctions does not mean that the FDA has to allege or prove guilty knowledge or intent.²⁴⁴

As indicated above,²⁴⁵ if a new drug has been approved by the FDA but is later found to be unsafe or ineffective for its recommended purpose, the FDA may withdraw its approval.²⁴⁶ Normally the applicant is given a hearing prior to withdrawal, but if the FDA finds that "there is an imminent hazard to the public health", it may suspend its approval without a hearing, thus rendering further introduction of the drug into interstate commerce illegal.²⁴⁷ In such an instance the applicant has the right to an expedited hearing.²⁴⁸ The FDA may also withdraw approval of a new drug application if the applicant has failed to maintain proper records or has denied access to them, or if the processing or labeling of the drug is deficient.²⁴⁹ The applicant has the right to appeal a withdrawal order on the same basis as an order denying initial approval of a new drug application.²⁵⁰

All of the foregoing offenses are limited to drugs which have been in interstate commerce, in accordance with the constitutional power of Congress under the commerce clause. Nevertheless, the Act has been given wide scope by the courts. As long as the drugs or their ingredients have been in interstate commerce at some time or other, an offense committed before, during or after their presence in interstate commerce is within the purview of the Act.²⁵¹ It does not matter how great a time lag occurs between the offense and the presence of the drugs in interstate commerce, nor how many interstate transactions intervene.²⁵²

But the chief thrust of the Act is not to punish violators. Rather, in the words of the Commissioner of Food and Drugs,

It has been the objective . . . from the very beginning to administer the statute in such a way as to prevent violations of the law rather than to punish violators after they occur.²⁵³

For minor violations, section 306 of the Act²⁵⁴ permits the FDA to issue a notice or warning rather than to prosecute. As a matter of policy, the FDA does not prosecute unless it is convinced that it has conclusive evidence that the law has been violated.²⁵⁵

In addition to the powers given to the FDA, the Secretary of the Treasury has the power to refuse admission into the United States of any imported drugs which are in violation of, *inter alia*, the adulteration, misbranding, and "new drug" provisions of the Act.²⁵⁶

THE PSYCHEDELIC REVIEW

REGULATION OF PSYCHEDELIC DRUGS BY THE STATES

As indicated previously, the constitutional power to regulate drugs is invested in the States through their police power.²⁶⁷ This power may not be exercised without limit—the State may not regulate interstate commerce,²⁶⁸ nor may its legislation impair the effectiveness of federal law.²⁶⁹ However, the courts have repeatedly upheld the validity of State drug legislation, stating that there has been no federal pre-emption of State statutes.²⁷⁰

It should be noted that neither federal nor State legislation entirely displaces the common law, which may in some cases impose greater liability than that set forth in the statutes.²⁷¹

The diversity in drug legislation of the several States precludes a detailed State-by-State analysis; I shall do no more than exemplify some of the important variations.²⁷² Fortunately, a number of States²⁷³ have enacted legislation patterned on the Model State Food, Drug and Cosmetic Act, which has been endorsed by the Executive Committee of the Association of Food and Drug Officials of the United States.²⁷⁴ Many portions of the Model Act are identical or similar to corresponding provisions of the Federal Act (for example, the definition of "drug"²⁷⁵), and it has been indicated that, in the absence of prior State decisions, State courts will follow federal decisions on the interpretation of such portions.²⁷⁶ Notwithstanding that criminal penalties may result from violations of State drug statutes, the statutes are "highly beneficial and remedial"²⁷⁷ and are not "to be subjected to such a hypercritical construction as would thwart the legislative design."²⁷⁸

As in the Federal Act, psychedelics are not treated as a special class in the State legislation. However, some of the psychedelics are individually subject to statutory provisions.

LSD is a derivative of ergot,²⁷⁹ and as such is classified variously as a "harmful drug"²⁸⁰, "poison"²⁸¹, or "dangerous drug"²⁸² and is thereby subjected to various labeling and dispensing requirements. Atropine and belladonna are also included among "poisons", and subjected to similar restrictions.²⁸³

Mescaline, in its naturally-occurring state in the peyote cactus, is the oldest of the important psychedelic drugs used in this country. It is not, therefore, surprising that of all psychedelic substances, peyote should be given the most prominent treatment in State statutes. Peyote has also been subjected to various labeling and distribution restrictions

The Regulation of Psychedelic Drugs

by reason of its classification as potentially "habit forming",²⁷⁴ "narcotic"²⁷⁵ (or subjected to the same restrictions as narcotics²⁷⁶), and sometimes as one of a list of "narcotic or hypnotic" substances.²⁷⁷ Peyote has been declared by the Colorado legislature to be "dangerous to the life, liberty, property, health, education, morals and safety of the citizens of this state, and is inconsistent with the good order, peace, and safety of the state."²⁷⁸ After this thorough indictment, one is not surprised to find, upon reading further, that the sale, use, possession, disposal, and importation of peyote are totally prohibited in Colorado.²⁷⁹

Montana and New Mexico, while prohibiting the possession and sale of peyote, have excepted from the prohibition peyote used "for religious sacramental purposes by any bona fide religious organization incorporated under the laws" of the State.²⁸⁰ Accordingly, any religious group contemplating the establishment of a new church which would employ psychedelics but would be independent of the Indian traditions of the Native American Church, would probably maximize its chances of avoiding legal difficulties by establishing the church in Montana or New Mexico and taking advantage of the permissive peyote legislation.

The future attitude of legislators towards peyote and other psychedelics is by no means easy to predict. In 1620, the Spanish Inquisitors against "heretical perversity and apostasy" ordered peyote condemned as an agent of the Devil,²⁸¹ and its users have had legal difficulties ever since. Congressional bills to prohibit its use have been introduced several times, but have never been passed.²⁸² The most recent of these was a proposal to apply the federal narcotics legislation to peyote.²⁸³ To the best of my knowledge, no action has been taken on the bill.

Of the State legislation applicable to drugs having certain specified pharmacological characteristics, only those provisions relating to "hypnotic" drugs appear to be relevant to psychedelics. For example, Massachusetts restricts the distribution of all "hypnotic" drugs, without specifically defining the term.²⁸⁴ In the absence of a statutory definition, the ordinary medical definition should apply; therefore this Massachusetts provision applies to such psychedelic drugs as have hypnotic (sleep-inducing) properties.

Psychedelics may also fall within State "new drug" provisions. In the Model Act, the definition of a "new drug" is patterned on that of the Federal Act except that the Model Act speaks only of a drug not generally recognized as "safe",²⁸⁵ whereas the federal statute uses the

words "safe and effective".²⁸⁸ Presumably the Model Act definition will be amended to correspond to the new federal definition; this amendment has already been made in California.²⁸⁹ Under the Model Act, a new drug subject to the Federal Act must be approved by the FDA before its sale or delivery is legal in the State.²⁹⁰ If the Federal Act does not apply to the new drug, the Model Act requires an application to be approved by State officials before the drug may be legally marketed.²⁹¹ It is interesting to note that almost half the States have no "new drug" laws.²⁹²

While State prohibitions against adulteration, misbranding, and misuse of new drugs tend to follow the federal pattern,²⁹³ much of the language used in State enactments is aimed at private local transactions, whereas federal legislation is necessarily restricted to drugs in interstate commerce. Thus state statutes may typically prohibit "the sale, delivery for sale, holding for sale, or offering for sale", of drugs in violation of the enactment.²⁹⁴ Occasionally, a State may prohibit possession of drugs, subject to certain exceptions.²⁹⁵ In general, violation of the various prohibitions gives rise to criminal or quasi-criminal sanctions.²⁹⁶

In their legislation to protect the public health, the States ordinarily include the regulation of the practice of medicine and of pharmacy.²⁹⁷ The administration of drugs to patients is ordinarily a medical procedure, and courts have so held.²⁹⁸ Thus, a psychologist who administers psychedelic drugs to persons risks prosecution for practicing medicine without a license. However, if the administration of a psychedelic drug to a person is clearly not a medical act, as in the case of religious use of psychedelics, the medical practice statutes would not apply.

Furthermore, a physician who administers psychedelic drugs unlawfully is in danger of losing his license to practice.²⁹⁹ And if a psychologist or some other person without medical training were deemed to be practicing medicine in administering psychedelics, a physician who aided and abetted the illegal practice would be in violation of State legislation forbidding such aiding and abetting, and accordingly in danger of losing his license.³⁰⁰

The Regulation of Psychedelic Drugs

LEGAL LIMITATIONS ON EXPERIMENTATION WITH PSYCHEDELIC DRUGS

As has been shown, ingestion of psychedelic drugs can cause injury.³⁰¹ Because these drugs have been and are likely to be used extensively in research work, an examination is in order of the extent to which investigators may make use of the drugs without legal liability to subjects who are injured in some way as a result of their participation in a psychedelic experiment. I do not propose to deal here with the difficult problem of the extent to which mental trauma unaccompanied by physical injury is actionable;³⁰² I shall proceed on the assumption that at least some of the possible injuries to research subjects may give rise to a cause of action.

Because there is a dearth of authority on the legal responsibility of investigators to their research subjects, it is necessary to derive many of the principles likely to be applied by courts from cases dealing with the closely analogous relationship of physician and patient.

Legal Liability for Experimental Injuries

From a reading of many of the reported cases, a layman might conclude that an investigator conducting medical research does so at his peril, and that he will be liable for any injury caused to a subject.³⁰³ However, such a conclusion would not be justified. In the cases cited, the courts developed the unfortunate habit of labelling as "experiments" departures from recognized medical treatment sufficient to constitute malpractice. This usage has been justly criticized³⁰⁴ as a failure by these courts to distinguish between (1) unauthorized and unaccepted medical procedures which would not be practiced by responsible physicians, and (2) organized scientific research. Because the cases in question have not dealt with properly conducted research, they cannot be deemed authoritative concerning liability for research mishaps. Furthermore, there is no indication, in any of the cases cited, that the patient gave consent to an "experiment" in any sense of the word; an entirely different case is presented where there is consent by a subject to a properly conducted experiment.

In two circumstances it seems reasonably clear that no liability should attach to the investigator for an experimental mishap. The first of these is the situation in which the "experiment" is being conducted for the therapeutic benefit of the patient and is only incidentally of

THE PSYCHEDELIC REVIEW

research value. Thus, a psychiatrist using psychedelic drugs in the treatment of neurotic patients may incidentally report the results of such treatment in scientific manner; the treatment, if justifiable according to accepted medical practice, surely does not become actionable merely because it is also the subject of research. It has been pointed out that "every medical procedure, no matter how simple or accepted, is an experiment since it is applied in a new context each time."⁸⁰³

Secondly, a normal volunteer may be paid for his participation in a research project. In such a case, the volunteer is in a contractual situation vis-à-vis the investigator. If the volunteer assumes certain specified risks under the contract, knowing their probability, he ought not to have a cause of action if these risks materialize, assuming that he has been correctly informed and the experiment has been properly carried out. It is arguable, however, that a person cannot consent to assume the risk that the experiment will not be properly conducted,⁸⁰⁴ on the rationale that a person may not unreasonably consent to an assault on his body.

If there is no contract and no possibility of therapeutic benefit to the subject, the investigator still may, in some circumstances, have legal immunity against liability for experimental injuries. The basis for such immunity has been set forth as follows :

If a legal action is brought against the scientific experimenter, its result will depend upon the existence of a privilege conferred on the experimenter by society, determined by balancing the risk of possible harm to the subject against the potential returns to society, and upon the legal efficacy of the subject's consent.⁸⁰⁵

Although the existence of such a "privilege conferred by society" has not yet been expressly conceded by the courts, one court has acknowledged the need for medical research and has hinted at the possibility of a limited immunity for investigators :

We recognize the fact that if the general practice of medicine and surgery is to progress, there must be a certain amount of experimentation carried on; but such experiments must be done with the knowledge and consent of the patient or those responsible for him and must not vary too radically from the accepted method of procedure.⁸⁰⁶

Although the use of the term "patient" by the court might limit its dictum to cases in which the experiment is possibly of therapeutic value to the subject, this choice of terminology may be explained by the assumption that the court was not directing its attention to other

The Regulation of Psychedelic Drugs

situations. In view of the overwhelming social need for medical research using normal, healthy volunteers as well as ill persons, it seems likely that the law will not impose strict liability on investigators when normal volunteers are involved.

Conceding the existence of some legal immunity for investigators, one must ascertain its bounds. The Nürnberg Military Tribunal in the *Medical Case*⁸⁰⁷ undertook perhaps the most extensive legal study of medical experimentation ever made, and listed several criteria by which to judge the legality of particular experiments.⁸⁰⁸ Because these criteria were held applicable to a criminal prosecution, it is likely that criteria no less stringent would be applied to civil actions involving liability for experimental injuries.

With respect to the question of whether an experiment is justified at all, the tribunal stated :

The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.⁸⁰⁹

But not all experiments which might yield fruitful results are justifiable :

No experiment should be conducted where there is an *a priori* reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects.⁸¹⁰

Even where the risk of injury is comparatively small,

the degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.⁸¹¹

Presumably the risks to be considered should include the possibility of emotional or mental injury as well as physical injury. In the opinion of the American Psychological Association,

Only when a problem is significant and can be investigated in no other way is the psychologist justified in exposing research subjects to emotional stress.⁸¹²

On the whole, properly conducted psychedelic experimentation appears to offend none of the foregoing criteria. Although psychedelics can cause mental injury, they are relatively safe;⁸¹³ in most cases the risk of injury is small, and the potential benefits to society in improved mental health are enormous.

Assuming that the experiment in question is justified, the subject's consent must be obtained, and the experiment must be properly conducted. These requirements obviously apply not only to cases in which

a healthy volunteer is used without compensation, but also to cases in which a patient or a paid volunteer is the experimental subject. The two requirements will therefore be discussed in detail.

(1) Consent

A physician must obtain consent, express or implied, before he can treat a patient.³¹⁴ Without consent, the physician is liable for trespass against the person.³¹⁵ Furthermore, the consent must be an informed consent directed to the treatment in question — consent to treatment of one ailment does not ordinarily extend to collateral or additional treatment, especially where surgical operations are involved.³¹⁶

A fortiori, it seems reasonable to require that an investigator obtain specific and informed consent from the subject of an experiment in order to avoid liability for trespass against the subject.³¹⁷ In the *Medical Case*, the Nürnberg Military Tribunal listed first among the principles which must be observed in medical experimentation, the duty to obtain consent :

The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.³¹⁸

Although these general principles should apply to psychedelic research, there are several problems peculiar to this type of research which merit discussion.

Firstly, the experimenter may not know what results to expect from the experiment; the literature is replete with reports of bizarre behavior resulting from the ingestion of psychedelic drugs.³¹⁹ If he cannot predict or foresee the possible consequences of the experiment on the subject, how can he adequately inform the subject of the risks? The sound course of action is probably the most obvious, viz. to tell the subject that the risks are not completely known.

The Regulation of Psychedelic Drugs

Secondly, subjects under the influence of psychedelic drugs are responsive not only to suggestions made while the drug is taking effect but also to suggestions made beforehand.³²⁰ This fact has two undesirable consequences : (1) it impairs the value of the experiment, which should be free from the personal influence of the experimenter; and (2) because the subject has been informed of the hazards, his resulting anxiety is a factor increasing the probability of their occurrence.³²¹

As a practical matter, it is probable that a warning of the hazards involved can be made without undue suggestive effect. For example, one mental research institution used the following language in its consent form for psychedelic research :

I give this authorization with the understanding that the administration of such drugs and such examination [of their effects] involve new techniques and procedures which may produce new and unusual physiological and psychological effects.³²²

The question remains whether a warning such as the foregoing is sufficiently explicit. In my opinion, it is. In physician-patient cases, courts have recognized that there are situations in which less than full disclosure of the hazards of treatment to the patients is justifiable.³²³ These cases apparently rely on the principle that the physician must consider the patient's welfare above all else and should not unduly alarm the patient.³²⁴ A warning by a psychiatrist to a subject that "these drugs may make you permanently insane" would probably maximize the chances of persistent psychosis; accordingly, particularly in view of the relatively infrequent occurrence of injury,³²⁵ a general warning of the risk of "new and unusual physiological and psychological effects" ought to be sufficient.

A final consent problem presented in psychedelic research is that subjects may be psychiatric patients in mental hospitals and legally incompetent to give consent to experiments. If the experiment is intended to be of therapeutic benefit to the patient, consent given by his legal guardian is sufficient.³²⁶ However, if the purpose of the experiment is to advance scientific knowledge, without possibility of direct therapeutic benefit, it is not at all clear that the guardian can give valid consent to the procedure. The guardian is supposed to act for the benefit of the patient — it is hard to find a principle which would justify the guardian's exposing his ward to risk of harm with no countervailing possibility of benefit, and bind the patient to take no action if he later recovered.³²⁷

The same word of warning applies to subjects who are children

not of legal age. Although older juveniles have been held legally competent to give consent to necessary medical treatment³²⁸ and to treatment not of a serious nature,³²⁹ the general rule is that the parents' consent must be obtained.³³⁰ One case has suggested that if the child has reached the age of understanding, the consent of both parent and child must be obtained.³³¹ It is again difficult to find a principle upon which a parent can justifiably expose a child to risk of harm when there is no possibility of therapeutic benefit to the child, and at the same time bind the child not to take legal action if injury occurs.³³² On the other hand, if the child has reached the age of understanding and both he and his parents have given consent, it would seem a miscarriage of justice to permit the child to withdraw the consent later.

It must be emphasized that if the subject is legally competent, he must in *every* case give his consent. For example, in one case³³³ the physician in charge of an emotionally-disturbed patient did not inform the patient of the risks of shock treatment, but instead informed the patient's wife and obtained her consent to the treatment. When the patient was injured as a result of the shock treatment, it was held that the physician's failure to obtain an informed consent from him rendered the physician liable for the injury.

It should be understood that consent is given on the implied condition that the experiment will be properly conducted,³³⁴ and as has been mentioned, it is arguable that this condition cannot be waived.³³⁵

(2) Standard of Care

In a sense, due care is required of the investigator before the experiment begins, because his preparations for the experiment must be carefully carried out. In the first place, the investigator must himself have acquired the necessary training and experience to qualify himself for research.³³⁶ This requirement has been discussed with respect to the "new drug" provisions of the Federal Food, Drug and Cosmetic Act.³³⁷

Secondly, the experiment on humans must be preceded by preliminary tests on animals, to minimize the risk of harm to human subjects.³³⁸ In the case of psychedelic research, animal experimentation may be of limited value, because the investigator is likely to be primarily interested in the mental effects of psychedelics. However, the physiological effects of the drugs may be investigated in animals.

The Regulation of Psychedelic Drugs

Finally, risks to human life and health should be minimized by preventive measures,³³⁹ and if there is doubt concerning the safety of the experiment, it has been rightly suggested that the investigator subject himself to the experiment before risking injury to others.³⁴⁰

During the experiment, all effort should be made to minimize risk of suffering and injury,³⁴¹ and the investigator should be prepared to terminate the experiment at any stage if circumstances warrant this.³⁴² Administration of certain tranquilizing drugs is known to halt the traumatic mental effects of ingestion of psychedelics.³⁴³ Also, if the subject himself does not want the experiment to continue, he should be at liberty to bring it to a halt.³⁴⁴

Extra-Legal Limitations on Experimentation

In addition to the restrictions imposed by law, limitations on experimentation include

the ethics of the biological-medical professional community; the standards, codified or grounded in practice, of reputable medical and health institutions; . . . and perhaps least explicit, but of commanding influence, the social climate and opinion of the public.³⁴⁵

Unfortunately, social needs do not always coincide with legal duties; for example, research on mentally ill patients may fulfil a pressing social need, but it may be impossible in some cases to obtain legally sufficient consent to such research.³⁴⁶ Commenting on psychedelic drug research, one observer argued that because of the pressure of politicians, mass media, and vested-interest groups, "the simple division of legal versus illegal is not always a reliable guide to the scholar as to the pursuits by which society will best be served."³⁴⁷ To some extent, misunderstanding between the legal and medical professions can be cleared up by apt choice of terminology. It would undoubtedly have been better for courts not to have used the term "experiment" in straightforward examples of malpractice, for example. In other areas where there is genuine conflict between medical and legal standards, one can only hope for an exchange of views between the two professions and an expression of such views to legislative bodies.

CONCLUDING NOTE

The use of psychedelic drugs for many purposes, and particularly for religious use and personality change, must be considered to be in its

THE PSYCHEDELIC REVIEW

infancy. In general, the law follows rather than precedes social change; the law relating to psychedelic drugs is no exception. The oldest of the most important psychedelics used in America, peyote, has been the subject of many statutory provisions. It is to be expected that as more becomes known about other psychedelics, specific legislation will be enacted to control their use. If, over the years, the drugs become accepted as having a genuine medical, religious or social value, the law will undoubtedly become less restrictive than it is now. Until such time, the law will continue to reflect the present American social climate which, despite the unparalleled innovations of the twentieth century, remains rather suspicious of radical changes.

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The Regulation of Psychedelic Drugs

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The Regulation of Psychedelic Drugs

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THE PSYCHEDELIC REVIEW

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The Regulation of Psychedelic Drugs

136. *Infra*, notes 137, 138, 140, 142, 144.
137. *Oliver v. Udall*, 306 F. 2d 819 (D.C. Cir. 1962), *cert. denied* 372 U.S. 908.
138. *Native American Church v. Navajo Tribal Council*, 272 F. 2d 131, 133 (10th Cir., 1959).
139. *Id.* at 134.
140. 75 Mont. 219, 243 Pac. 1067 (1926).
141. *Id.* at 239, 240; 243 Pac. at 1073.
142. *United States v. Mitchell Neck, alias Nah-qua-tah-tuck* (Wis. 1914).
143. See Slotkin, *The Peyote Religion* 181 (1956); De Ropp, *Drugs and the Mind* 31 (1957); Taylor, *Narcotics: Nature's Dangerous Gifts* 139 (1963).
144. *State v. Attakai*, No. 4098, Super. Ct. of Coconino County, Arizona, July 26, 1960. All quotations are from a copy of the transcript of the decision of Yale McFate J.
145. *Supra*, note 141.
146. 15 U.S.C. §§45, 52 (1958) (as amended Supp. IV, 1963).
147. For a general discussion of the history and operation of Federal narcotics statutes, see Ellis, *A General Outline of Federal Narcotics Statutes*, 18 Food Drug Cosm. L.J. 372 (1963).
148. See authorities cited *supra*, note 99.
149. Stedman, *Medical Dictionary* (20th ed., 1961).
150. Schultes, *Botanical Sources of the New World Narcotics*, 1 *Psychedelic Rev.* 145 (1963).
151. 26 U.S.C. §4731(a) (Supp. IV, 1963). See also 21 U.S.C. §171(a) (1958).
152. 26 U.S.C. §4731(g) (Supp. IV, 1963).
153. A list of drugs so proclaimed follows 26 U.S.C.A. §4731, to date.
154. See text accompanying note 44a, *supra*.
155. See 21 U.S.C. §176a (1958); 26 U.S.C. §§4741 ff. (1958).
156. Metzner, *The Pharmacology of Psychedelic Drugs*, 1 *Psychedelic Rev* 69, 70 (1963).
157. *Ibid.*
158. For a thorough sociological, psychological, medical and pharmacological study of marijuana, see *The Marihuana Problem in the City of New York*, (Mayor's Committee on Marihuana, 1944).
159. 21 U.S.C. §301 ff. (1958), as amended to date.
160. Willcox, *Public Protection, Private Choices and Scientific Freedom: Food, Drugs and Environmental Hazards*, 18 Food Drug Cosm. L.J. 321, 326 (1963).
161. *United States v. Dotterweich*, 320 U.S. 277, 280 (1943).
162. Willcox, *supra* note 160 at 322.
163. Henry, *The Plant Alkaloids* 84, 105, 106 (4th ed. 1949); De Ropp, *Drugs and the Mind* 272 ff. (1957).
164. *United States v. 48 Dozen Packages, More or Less, of Gauze Bandage Labeled in Part Sterilized*, 94 F.2d 641, 642 (2d Cir., 1938).
165. Kelsey, CCH Food Drug Cosm. L. Rep. para. 80024, p. 80098 (Apr. 25, 1963).
166. See note 31, *supra*.

THE PSYCHEDELIC REVIEW

167. United States v. 3 Cartons, More or Less, "No. 26 Formula GM", 132 F. Supp. 569, 573 (S.D. Calif. 1952).
168. 21 U.S.C. §331 (1958), as amended to date.
169. See . . . Archambault v. United States, 224 F. 2d 925, 928 (10th Cir. 1955).
170. 21 U.S.C. §§371(a); 355(i) (1958; Supp. IV, 1963).
171. United States v. Antikamnia Chemical Co., 231 U.S. 654,666 (1913).
172. Byrd v. United States, 154 F. 2d 62, 63 (5th Cir., 1946).
173. *Ibid.*
174. Archambault v. United States, *supra* note 169 at 928.
175. See, e.g., 21 U.S.C. §371(e)(2), (f) (1958; Supp. IV, 1963).
176. Byrd v. United States, *supra* note 172 at 64.
177. United States v. Bodine Produce Co., CCH Food Drug Cosm. L. Rep. para. 40056, p. 40157 (D. Ariz. 1962).
178. 21 U.S.C. §371(e)(2).
179. Young, *The 1938 Food, Drug, and Cosmetic Act*, presented at the 77th Annual Meeting of the American Historical Association, Chicago, Dec. 30, 1962.
180. *Ibid.*
181. 52 Stat. 1040, 1052 (1938).
182. Janssen, *FDA Since 1938*, presented at the 77th Annual Meeting of the American Historical Association, Chicago, Dec. 30, 1962.
183. 76 Stat. 780 (1962). For an excellent account of the events leading to the enactment of this statute, see Harris, *Annals of Legislation* (pts. 1-3), *The New Yorker*, Mar. 14, p. 48, Mar. 21 p. 75, Mar. 28 p. 46 (1964).
184. See generally Kleinfeld, *New Drug Applications and Suspension Procedures*, 18 Food Drug Cosm. L.J. 632 (1963).
185. 21 U.S.C. §355 (Supp. IV, 1963).
186. Jurow, *The Legislative Picture for the Drug Industry*, 18 Food Drug Cosm. L.J. 97, 102, 103 (1963); *Hearings Before the House Committee on Interstate and Foreign Commerce*, 87th Cong., 2d Sess., on H.R. 11581, 11582 (the Drug Industry Act of 1962), at 234-235 (1962) (remarks of T. G. Klumpp, M.D.).
187. Remarks of Klumpp, *supra* note 186, at 239.
188. *Id.* at 231.
189. *Id.* at 232.
190. Sen. Rep. No. 1744, 87th Cong., 2d Sess., p. 43 (1962).
191. *Id.* at 41-42.
192. *Ibid.*
193. See CCH Food Drug Cosm. L. Rep. para. 40093, p. 40237 (1964).
194. Willcox, *Public Protection, Private Choices and Scientific Freedom: Food, Drugs and Environmental Hazards*, 18 Food Drug Cosm. L.J. 321, *passim* (1963).
195. Meyers, *The Food and Drug Administration's View of Investigational Drugs*, 18 Food Drug Cosm. L.J. 391, 402 (1963).
196. Willcox, *supra* note 194, at 395.
197. 21 U.S.C. §321(p) (Supp. IV, 1963).

The Regulation of Psychedelic Drugs

198. 28 Fed. Reg. 6377 (1963), replacing 21 C.F.R. §130.1 (h).
199. Merritt Corp. v. Folsom, 165 F. Supp. 418, 421 (D.D.C. 1958); United States v. 354 Bulk Cartons Trim Reducing-Aid Cigarettes, 178 F. Supp. 847, 853 (D.N.J. 1959).
200. See text accompanying notes 47-56, *supra*.
201. CCH Food Drug Cosm. L. Rep. paras. 40028, 80024 (1963).
202. 34 Stat. 769.
203. See text following note 168, *supra*.
- 203a. Schultes, *The Appeal of Peyote (*Lophophora Williamsii*) as a Medicine*, 40 Am. Anthropologist 698 (1938).
- 203b. *Supra*, note 201.
204. 21 U.S.C. §355 (Supp. IV, 1963).
205. *Hearings Before the House Committee on Interstate and Foreign Commerce on the Drug Industry Act of 1962* (H.R. 11581, 11582), 87th Cong., 2d Sess., p. 80 (1962).
206. Janssen, *supra* note 182.
207. Willcox, *supra* note 194, at 326.
208. Note 205, *supra*, at 23.
209. *Id.* at 593.
210. *Id.* at 80.
211. Herrick, *New Drugs* 77 (1946).
212. *Id.* at 78.
213. Application of Hartop, 311 F. 2d 249, 255 (C.C.P.A. 1962).
214. *Hearings Before the House Committee on Interstate and Foreign Commerce*, *supra* note 205, at 24.
215. *Id.* at 573.
216. *Id.* at 594-595.
217. Sen. Rep. No. 1744, 87th Cong., 2d Sess., p. 16 (1962).
218. CCH Food Drug Cosm. L. Rep. para. 80024 (Apr. 25, 1963).
219. See note 69, *supra*.
220. See text accompanying note 217, *supra*.
221. 21 U.S.C. §355 (Supp. IV, 1963).
222. 21 C.F.R. §§130.1-130.34 (as amended in 28 Fed. Reg. 179-183, 6377-6384 (1963)) See also the proposed new regulations in 29 Fed. Reg. 2790-2791 (1964).
223. §130.32, 28 Fed. Reg. 6384 (1963).
224. 21 U.S.C. §355(c) (Supp. IV, 1963).
225. 21 U.S.C. §355(h) (Supp. IV, 1963).
226. 21 U.S.C. §355(e) (Supp. IV, 1963). See *infra* text accompanying notes 245 ff.
227. *Hearings Before the House Committee on Interstate and Foreign Commerce, on the Drug Industry Act of 1962* (H. R. 11581, 11582), 87th Cong., 2d Sess., p. 82 (1962).
228. See generally Meyers, *The Food and Drug Administration's View of Investigational Drugs*, 18 Food Drug Cosm. L.J. 391 (1963).
229. 21 U.S.C. §355(i) (Supp. IV, 1963).
230. §130.3, 28 Fed. Reg. 179-182 (1963)

THE PSYCHEDELIC REVIEW

231. §130.3 (12), (13). 28 Fed. Reg. 180, 181 (1963).
232. §130.3, 28 Fed. Reg. 179-182 (1963).
233. Meyers, *supra* note 228, at 396.
234. Herrick, *New Drugs* 81 (1946); Harvey, Deputy Commissioner of Food and Drugs, quoted in 108 Cong. Rec. 16126 (1962).
235. 21 U.S.C. §355(i) (Supp. IV, 1963).
236. See text accompanying notes 314-335, *infra*.
237. 21 U.S.C. §331 (1958, Supp. IV, 1963).
238. 21 U.S.C. §334 (1958).
239. 21 U.S.C. §334(b) (1958).
240. 21 U.S.C. §332 (1958, Supp. IV, 1963).
241. 21 U.S.C. §333 (1958, Supp. IV, 1963).
242. Ewing v. Mytinger & Casselberry, Inc., 339 U.S. 594, 601 (1940).
243. Merritt Corp. v. Folsom, 165 F. Supp. 418, 421 (D.D.C. 1958).
244. United States v. Hohensee, 243 F. 2d 367 (3d Cir. 1957), *cert. denied* 353 U.S. 976, *rehearing denied* 354 U.S. 927.
245. See text accompanying note 226, *supra*.
246. 21 U.S.C. §355(e) (Supp. IV, 1963).
247. *Ibid.*
248. *Ibid.*
249. *Ibid.*
250. 21 U.S.C. §355(h) (Supp. IV, 1963).
251. United States v. 40 Cases, More or Less, of Pinocchio Brand 75% Corn, Peanut Oil and Soya Bean Oil Blended with 25% Pure Olive Oil, 289 F. 2d 343 (2d Cir. 1961) *cert. denied* 368 U.S. 831; United States v. 4 Devices, Labeled in Part "Color-therm", 176 F. 2d 652, 654 (10th Cir. 1949); Arner Co. v. United States, 142 F. 2d 730, 733 (1st Cir. 1944), *cert. denied* 323 U.S. 730.
252. United States v. Sullivan, 332 U.S. 689, 696 (1947).
253. Lerrick, *Administering New Food and Drug Laws*, 18 Food Drug Cosm. L.J. 133-134 (1963).
254. 21 U.S.C. §336 (1958).
255. Harvey, *Administration of the Food, Drug, and Cosmetic Act*, 10 Food Drug Cosm. L.J. 441, 443 (1955).
256. 21 U.S.C. §381 (1958, Supp. IV 1963).
257. *supra*, note 100.
258. Savage v. Jones, 225 U.S. 501, 524 (1912).
259. *Id.* at 529; McDermott v. Wisconsin, 228 U.S. 115, 133-134 (1913).
260. *E.g.*, Whitehall Laboratories v. Wilbar, 397 Pa. 223, 154 A. 2d 596 (1959); And see cases cited 21 U.S.C.A. §301, note 7, p. 262.
261. Martin v. Bengue, Inc. 25 N.J. 359 at 376, 136 A.2d 626, 635 (1957).
262. A State-by-State summary of drug legislation appears in the CCH Food Drug Cosm. L. Rep., para. 1100ff.
263. A list of 22 such states appears in 108 Cong. Rec. 17396 (1962).
264. CCH Food Drug Cosm. L. Rep. para. 10100, p. 10101 (gives text of the Model Act).
265. Model Act, §2(d), CCH Food Drug Cosm. L. Rep. para. 10100, p. 10101.

The Regulation of Psychedelic Drugs

266. Merck & Co. v. Kidd, 242 F.2d 592 (6th Cir. 1957), *cert. denied* 355 U.S. 814.
267. Commonwealth v. Sweeney, 61 Pa. Super. 367-370 (1915).
268. *Ibid.*
269. Metzner, *The Pharmacology of Psychedelic Drugs*, 1 Psychedelic Rev. 69, 72 (1963)
270. *E.g.*, Mass. Gen. Laws ch. 94, §187A (1963 Supp.).
271. *E.g.*, Cal. Bus. & Prof. Code §4160(p).
272. *E.g.*, Wis. Stat. §151.07(1) (1964 Supp.).
273. *E.g.*, N.Y. Educ. Law, §6813.
274. *E.g.*, Ark. Stat. §82-1115(d) (1960 Supp.).
275. *E.g.*, Cal. Health & Safety Code, §11001(l).
276. S.Dak. Code §22.1324 (1939).
277. *E.g.*, Mass. Gen. Laws ch. 94, §187 (1963 Supp.)
278. Colo. Rev. Stat. §48-5-1 (1953).
279. Colo. Rev. Stat. §48-5-2 (1953).
280. Rev. Codes Mont., Crimes & Crim. Proc., §94-35-123 (1963 Supp.); N. Mex. Stat. §54-5-16 (1962 Supp.).
281. Stewart, *Peyote and Colorado's Inquisition Law*, 5 The Colo. Quarterly 79 (Summer, 1956).
282. *Id.* at 86.
283. 109 Cong. Rec. 23394 (1963) (daily ed'n).
284. Mass. Gen. Laws, ch. 94, §187A (1963 Supp.).
285. §2(n), CCH Food Drug Cosm. L. Rep. para. 10102.
286. 21 U.S.C. §321(p) (Supp. IV, 1963).
287. Cal. Health & Safety Code, §26211.
288. §16(a), CCH Food Drug Cosm. L. Rep. para. 10116.
289. *Ibid.*
290. For a list of such States, see 108 Cong. Rec. 17396 (1962).
291. *E.g.*, Rev. Code Wash. §69.04.040 (1962).
292. N.Y. Educ. Law, §6821.
293. *E.g.*, Fla. Stat. ch. 500, §500.151 (1961).
294. *E.g.*, Mass. Gen. Laws, ch. 94, §187A (1963 Supp.).
295. *E.g.*, N.Y. Educ. Law, §§6502, 6802ff.
296. Gouy Shong v. Chew Shee, 254 Mass. 366 at 369, 150 N.E. 225, 227 (1926); Order of United Commercial Travelers v. Shane, 64 F. 2d 55 (8th Cir. 1933).
297. Cf. Du Vall v. Bd. of Medical Examiners, 66 P. 2d 1026 (Sup. Ct. Ariz. 1937).
298. *E.g.*, Conn. Gen. Stat. §20-45 (1959). See generally 70 C.J.S. Physicians and Surgeons §17(7).
299. See text accompanying notes 47-56, *supra*.
300. On this subject, see for example Smith, *Relation of Emotions to Injury and Disease : Legal Liability for Psychic Stimuli*, 30 Va. L. Rev. 193 (1944); Cantor, *Psychosomatic Injury, Traumatic Psychoneurosis, and Law*, 6 Clev.-Mar. L. Rev. 428 (1957).
301. Slater v. Baker, 2 Wils. K.B. 359, 95 Eng. Rep. 860 (1767); Carpenter

THE PSYCHEDELIC REVIEW

- v. Blake, 60 Barb. 488 (N.Y. Sup. Ct. 1871), *rev'd on other grounds* 50 N.Y. 696; Jackson v. Burnham, 20 Colo. 532, 39 Pac. 577 (1895); Owens v. McCleary, 313 Mo. 213, 281 S.W. 682 (1926); Allan v. Voje, 114 Wia. 1, 89 N.W. 924 (1902).
302. Ladimer, *Ethical and Legal Aspects of Medical Research on Human Beings*, 3 J. Pub. L. 467, 480 (1954).
303. *Id.* at 482.
304. Markel, *Legal Considerations in Experimental Design in Testing New Drugs on Humans*, 18 Food Drug Cosm. L.J. 219, 223 (1963).
305. *Legal Implications of Psychological Research with Human Subjects*, [1960] Duke L.J. 265, 267.
306. Fortner v. Koch, 272 Mich. 273 at 282, 261 N.W. 762, 765 (1935).
307. United States v. Brandt, 2 Trials of War Criminals Before the Nürnberg Military Tribunals (1949).
308. *Id.* at 181-182.
309. *Id.* at 182.
310. *Ibid.*
311. *Ibid.*
312. Ladimer, *supra* note 302, at 492.
313. Note 52, *supra*.
314. See generally, Oppenheim, *Informed Consent to Medical Treatment*, 11 Clev.-Mar. L. Rev. 249 (1962); McCoid, *A Reappraisal of Liability for Unauthorized Medical Treatment*, 41 Minn. L. Rev. 381 (1957). For an illustrative case, see Dietze v. King, 184 F. Supp. 944 (E.D.Va. 1960).
315. E.g., Franklyn v. Peabody, 249 Mich. 363, 228 N.W. 681 (1930).
316. Salgo v. Leland Stanford Jr. University Bd. of Trustees, 154 Cal. App. 2nd 560, 317 P. 2d 170 (1957); Natanson v. Kline, 187 Kan. 186, 354 P. 2d 670 (1960); Pratt v. Davis, 224 Ill. 300, 79 N.E. 562 (1906), *aff'd* 118 Ill. App. 161.
317. Cf. quotation accompanying note 306, *supra*.
318. United States v. Brandt, *supra* note 307, at 181-182.
319. Authorities cited notes 1, 2, 42, 68, *supra*.
320. Sherwood *et al.*, *The Psychedelic Experience — A New Concept in Psychotherapy*, 4 J. Neuropsychiatry No. 2, p. 69 at 72-73 (Dec. 1962); Unger, *Mescaline, LSD, Psilocybin, and Personality Change*, 26 Psychiatry 111, 118 (1963).
321. Unger, *supra* note 320 at 118.
322. Pharmacotherapy Project, Mass. Mental Health Center.
323. Natanson v. Kline, *supra* note 316; Dietze v. King, *supra* note 314, at 949.
324. Salgo v. Bd. of Trustees, *supra* note 316 at 578, 317 P. 2d at 181.
325. See text accompanying note 52, *supra*.
326. See *Faber v. Olkon*, 40 Cal. 2d 503, 254 P. 2d 520 (1953). See generally 44 C.J.S. Insane Persons §85(c)(1). Cf. 70 C.J.S. Physicians & Surgeons §48(g).
327. This problem is dealt with by Bowker, *Legal Liability to Volunteers in*

The Regulation of Psychedelic Drugs

- Testing New Drugs*, 88 Can. Med. Ass'n J. 745, 748 (1963).
328. Bishop v. Shurly, 237 Mich. 76, 211 N.W. 75 (1926).
329. Lacey v. Laird, 166 Ohio St. 12, 139 N.E. 2d 25 (1956).
330. Zoski v. Gaines, 271 Mich. 1, 260 N.W. 99 (1935). See generally 70 C.J.S. Physicians & Surgeons §48(g).
331. Bonner v. Moran, 126 F. 2d 121, 122-123 (D.C.Cir. 1941), *seembe*.
332. This is discussed by Bowker, *supra* note 327, at 748.
333. Mitchell v. Robinson, 334 S.W. 2d 11 (Sup. Ct. Mo. 1960).
334. See State v. Gile, 8 Wash. 12, 35 Pac. 417 (1894); See generally Ladimer, *May Physicians Experiment?* 172 Int'l Rec. Med. 586, 596 (1959).
335. Markel, *supra* note 304.
336. United States v. Brandt, *supra* note 307, at 182.
337. See text accompanying notes 233, 234, *supra*.
338. United States v. Brandt, *supra* note 307, at 182.
339. *Ibid.*
340. Ladimer, *supra* note 302, at 491.
341. United States v. Brandt, *supra* note 307, at 182.
342. *Ibid.*
343. Sherwood *et al.*, *supra* note 320, at 74.
344. United States v. Brandt, *supra* note 307, at 182.
345. Ladimer, *supra* note 334, at 586.
346. Cf. text accompanying note 327, *supra*.
347. Maher, *Drugs and Academic Freedom*, 7 Mass. Psychol. Ass'n Newsletter No. 3, p. 3 (Oct. 1963).

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