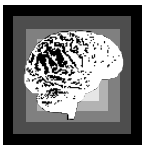

Article

History of Psychiatry
2016, Vol. 27(3) 290–306

DOI: 10.1177/0957154X16648822
hpy.sagepub.com
SAGE

Prohibited or regulated? LSD psychotherapy and the United States Food and Drug Administration

Matthew Oram
University of Calgary, Canada

Abstract
Over the 1950s and early 1960s, the use of the hallucinogenic drug lysergic acid diethylamide (LSD) to facilitate psychotherapy was a promising field of psychiatric research in the USA. However, during the 1960s, research began to decline, before coming to a complete halt in the mid-1970s. This has commonly been explained through the increase in prohibitive federal regulations during the 1960s that aimed to curb the growing recreational use of the drug. However, closely examining the Food and Drug Administration's regulation of LSD research in the 1960s will reveal that not only was LSD research never prohibited, but that the administration supported research to a greater degree than has been recognized. Instead, the decline in research reflected more complex changes in the regulation of pharmaceutical research and development.

Keywords
Drug Amendments of 1962, drug regulation, Food and Drug Administration, LSD psychotherapy, psychiatry

At a US congressional hearing in May 1966, Senator Robert F. Kennedy questioned Food and Drug Administration (FDA) commissioner James Goddard on the recent decline in the number of approved research programs exploring the medical potential of the hallucinogenic drug lysergic acid diethylamide (LSD). In April the drug's manufacturer, Sandoz Pharmaceuticals, had voluntarily withdrawn its sponsorship of LSD research, and subsequently the number of research programs had dropped from 70 down to nine. After ascertaining from Goddard that the FDA had considered all these programs worthwhile, Kennedy criticized the administration for doing too little to ensure their continuation: 'if they were worth while I would think you would let them continue … If it was

Corresponding author:
Matthew Oram, History of Medicine and Health Care Program, Department of Community Health Sciences, Cumming School of Medicine, University of Calgary, TRW Building 3rd Floor, 3280 Hospital Drive NW, Calgary AB T2N 4Z6, Canada.
Email: matthew.oram1@ucalgary.ca

helpful [research] 6 months ago, why is it not helpful now?' (Senate Subcommittee on Executive Reorganization, 1966: 59).

First synthesized in Switzerland in 1938, LSD had arrived in the USA in 1949, and had quickly become the object of widespread clinical research (Hofmann, 2009; Rinkel, 1957). Many psychiatric researchers had found the drug useful in facilitating various forms of psychotherapy, particularly in the treatment of neuroses and alcoholism. Indeed, research in the 1950s in Canada had reported an unprecedented 50% improvement rate with chronic, treatment-resistant alcoholics (Smith, 1958). However, during the 1960s growing public recreational use of LSD had made the drug the object of increasing public, medical and political concern. Indeed, Kennedy's hearings, entitled 'Organization and Coordination of Federal Drug Research and Regulatory Programs: LSD', were one of three sets that year to focus significant attention on the drug.[1]

Kennedy described the problem of fairly and effectively regulating LSD as a 'classic example' of the difficulties of balancing the interests of 'Government and science' (Senate Subcommittee on Executive Reorganization, 1966: 3). Historians and other commentators have primarily explained the decline in LSD psychotherapy research in the USA in the 1960s, towards its complete demise in the mid-1970s, as an outcome of the government backlash against the non-medical use of LSD: increasingly strict regulation of LSD either intentionally or unintentionally ended legitimate research (Doblin, 2000; Dyck, 2008; Hewitt, 2002; Lee and Shlain, 1985; Novak, 1997; Stevens, 1987). From this position, psychiatry lost a potentially significant treatment and research tool due to the US government's failure to regulate LSD in a way that rationally balanced the risks associated with its abuse with the potential benefits to public health that could result from its responsible medical use.

LSD research first came under government control in 1963, after the Kefauver-Harris Drug Amendments of 1962 amended the 1938 Federal Food, Drug, and Cosmetic Act,[2] significantly reforming the regulation of pharmaceutical research and development in the USA. Among other provisions, the amendments introduced FDA oversight over all pre-market clinical drug research. In the same year, the first major national controversy over LSD erupted, when Harvard psychologists Timothy Leary and Richard Alpert were fired from the university following concerns that their research with psychedelics had devolved into heavy informal use of the drugs among themselves, their colleagues, students and associates (Stevens, 1987). With the growth of an LSD-infused youth counterculture in the mid-1960s, the federal government began enacting strict regulatory controls designed to curb recreational use of the drug. The Drug Abuse Control Amendments of 1965 prohibited all but personal possession and government-approved research with LSD. In 1968 a further amendment was passed criminalizing personal possession, and in 1970 the Controlled Substances Act placed LSD in Schedule I – its most prohibitive regulatory category – along with heroin and marijuana.

As the scale of LSD psychotherapy research in the USA began to decline from 1963, and took a substantial dive in 1966, a causal link between the LSD controversy, increasing regulation, and the demise of LSD psychotherapy appears almost self-evident. Historian Steven Novak has clearly argued that the government deliberately shut down LSD research. He states that following the passage of the Drug Amendments of 1962, Congress began 'progressively tightening regulation of investigational drugs until research on LSD virtually ground to a halt' (Novak, 1998: 23), and in 1966 'Congress cut off nearly all LSD research' (Novak, 1997: 109). LSD researchers who had their FDA approval to use the drug revoked in the mid-1960s supported this perspective. Myron Stolaroff (1994: 29) recollected that in 1965 Commissioner Goddard 'brought a halt to all LSD research in the nation'. Harold Abramson described in 1967 how LSD research was being 'seriously hampered in the U.S. by the curtailment of Government approval'. Private-practice physicians were especially being prevented from conducting research, due to the government's inability to 'distinguish between the medical use of LSD and the sociological problems engendered by *all* drugs that influence the mind' (original emphasis).[3]

Although the decline in LSD research closely followed the drug's growing abuse and regulation, a detailed analysis of the provisions and implementation of the new regulations – through FDA files and congressional hearings – will reveal a much more complicated relationship between the rise in regulation and the decline in research than has previously been understood. Rather than a deliberate government initiative, the reduction in research reflected the formalization of pharmaceutical research and development engendered by the Drug Amendments of 1962, and was further influenced by the actions of Sandoz Pharmaceuticals. Prior to 1963, pre-market drug research had been only very loosely regulated, and was conducted almost completely at the discretion of a drug's manufacturer. After the 1962 amendments, new regulations required a research sponsor to file with the FDA a Notice of Claimed Investigational Exemption for a New Drug (IND), containing detailed information on the proposed research. If the FDA was not satisfied with the information provided, approval to use the drug in clinical research could be revoked (Larrick, 1963). In 1963 Sandoz and two independent research sponsors – Abramson, and Stolaroff's research foundation, the International Foundation for Advanced Study – submitted INDs for LSD psychotherapy research. Following the FDA's evaluation of these INDs will reveal that, although the INDs from Abramson and Stolaroff were terminated, there were objective reasons for this. Rather than thwarting LSD research, the FDA merely evaluated applications to conduct research according to the new criteria. Furthermore, in 1966, after LSD had been criminalized and Sandoz had withdrawn its IND, the FDA teamed up with the National Institute of Mental Health (NIMH) and the Veterans Administration to voluntarily save research from complete extinction – even Kennedy's criticism of the FDA was misplaced.

This article will reveal, therefore, that the US government's response to the complex challenges that LSD posed in the 1960s was far less reactionary and repressive than has been depicted – at least in terms of its medical use. The case of LSD psychotherapy research, rather than demonstrating the government's inability to balance a drug's potential risks and benefits to public health or to see any potential benefit in altered states of consciousness, instead highlights the transformation of drug research and development of the 1960s, and the difficulties that this raised for independent researchers. The Drug Amendments of 1962 have frequently come to the attention of scholars due to their passage through Congress on the back of the thalidomide crisis, and their introduction of the requirement for proof of drug efficacy for a drug to be approved for sale by the FDA (Carpenter, 2010; Daemmrich, 2004; Hilts, 2003; Temin, 1980; Tobbell, 2012). However, the IND regulations have received far less attention.[4] This article therefore contributes to the history of drug research and development, as well as the history of psychiatry, as it demonstrates how these regulations altered the landscape of drug research in the USA, and how this impacted an unconventional but promising form of psychiatric research. Elsewhere, I have argued that the amendment's requirement that proof of efficacy be established through controlled clinical trials frustrated the progress of LSD psychotherapy research, as that method of research was ill-suited to evaluate the psychological rather than chemotherapeutic form of drug treatment (Oram, 2014). This article complements this work by further exploring the impact of the amendments on LSD psychotherapy research, and helping to build an alternative analysis of its demise, that sees it as a treatment lost in the changing contexts of pharmaceutical research and development of the 1950s and 1960s, rather than stamped out by blanket prohibition.[5]

The IND Regulations and Sandoz Pharmaceuticals

The IND regulations of the Drug Amendments of 1962 emerged as a result of FDA concerns that drug manufacturers were using the premarket phase of a drug's development for more than just research. Under the 1938 Federal Food, Drug, and Cosmetic Act, in order for the FDA to approve a drug for sale a sponsor (usually the manufacturer) was required to submit a New Drug Application

(NDA) containing proof of safety for the drug when used as directed. The nature and extent of pre-market clinical research was, however, largely at the discretion of the manufacturer. The manufacturer was free to distribute new drugs to qualified researchers so long as they were labelled for investigational use. The manufacturer simply had to obtain a written statement from the researcher that they had adequate facilities to perform research with the drug, and that all research would be under their direction.[6] From the mid-1950s, FDA officers had become increasingly aware that this form of regulation left them unable to prevent widespread distribution of investigational drugs to physicians for the ulterior purpose of establishing their place in the market prior to official release (Carpenter, 2010: 173–5). The danger of this practice became evident in the case of thalidomide, the teratogenic sedative that could cause phocomelia – a severe deformity characterized by a shortening of the limbs so that hands and feet appear to join straight to the body – when ingested during pregnancy. Although FDA medical officer Frances Kelsey had withheld approval of William S. Merrell Company's NDA for thalidomide in 1960 due to concerns over its safety, the firm had distributed the drug widely to physicians recommending its routine usage. As a result, an estimated 16,000 patients received thalidomide before its dangers became apparent (Daemmrich, 2004: 66).

In order to safeguard against dangerous and non-research investigational drug use, the Drug Amendments of 1962 granted the FDA oversight of drug research and development. The legislation provided that a drug manufacturer, or other investigative sponsor, would be granted an exception allowing them to use a drug without an approved NDA after providing the FDA with details of preclinical research which justified its use in humans (Title 1, part A, sec. 103 (b)). In order to enact these provisions, the FDA drew up new investigational drug regulations, which became effective on 7 February 1963 (Larrick, 1963). Earl Meyers, chief of the controls evaluation branch of the FDA's Division of New Drugs, described the intent of the regulations as ensuring that adequate preclinical research had been performed to justify clinical testing, that investigators were qualified to perform clinical research with the drug, and that a scientifically sound program of research would be followed.[7] To ensure this, the regulations created the IND form, officially entitled 'Form FD 1571' or 'Notice of Claimed Investigational Exemption for a New Drug', which required extensive data on the drug, preclinical research conducted, the investigators and the research plan. Before commencing clinical research with an investigational drug, the potential sponsor needed to submit this form to the FDA. Approval of the IND was not required; research could start immediately on submission. However, if the FDA was not satisfied with the contents of an IND, the sponsor's exemption could be terminated.[8]

For drugs that were already involved in human research, a deadline for the submission of IND forms was set for 7 June 1963.[9] Shortly before the deadline, Sandoz Pharmaceuticals submitted INDs for the clinical investigation of LSD and psilocybin, as the company had not submitted NDAs for the drugs. Sandoz had isolated the psychedelic psilocybin from hallucinogenic mushrooms in the late 1950s, and had subsequently synthesized it and made it available to researchers (Hofmann, 2009: 117–29). The INDs were very broad in their scope and light on details. The drugs were being investigated in the 'treatment of varied psychotic and psychoneurotic disorders' – including chronic alcoholism, and autism in children – as a facilitator of, and adjunct to, psychotherapy and as an analgesic for intractable pain. The INDs were more specific, however, on who would be able to research the drugs under Sandoz's sponsorship: access was restricted to those working under grants from, or the authority of, the NIMH, state agencies or the Veterans Administration, with all research to be conducted in a hospital setting.[10] The reason for this restriction is unclear, but it may have been in reaction to the growing controversy surrounding the use of psychedelics by psychologists Leary and Alpert, which had led to their dismissal from Harvard earlier that year.

The FDA's pharmacology department made its initial review of the Sandoz LSD and psilocybin INDs in August and September 1963. They found that the INDs lacked the required level of toxicity data, and therefore recommended that 'consideration be given to the termination of the clinical investigations'.[11] However, the FDA's Bureau of Medicine considered the fact that the LSD IND was supported by a bibliography of over 1000 scientific papers detailing a wide variety of research and conducted over more than 20 years, which had resulted in no deaths or serious side effects. As there was no 'serious doubt as to toxicity' and the literature attested to promising effectiveness, the Bureau of Medicine decided that clinical investigation could be continued, with a request for further data. Further review of the research confirmed that there existed sufficient data to allow research under the Sandoz IND (House Intergovernmental Relations Subcommittee, 1966: 2134–5).[12] Initially, Sandoz sponsored 17 LSD investigators; this number rose to approximately 70 by 1966 (Senate Subcommittee on Executive Reorganization, 1966: 62).

With Sandoz's decision to restrict its sponsorship of research to hospital-based government-endorsed studies, privately funded and non-institutional researchers who had been using LSD found themselves cut off. However, nowhere in the new regulations did it say that only a drug's manufacturer could act as a sponsor, so independent researchers were free to submit their own IND forms for clinical research with LSD. Examining the independent INDs that were submitted by Harold Abramson and the International Foundation for Advanced Study will reveal that the struggle to gain access to LSD in the years immediately following the Drug Amendments of 1962 was not due to any specific restrictions from the government, but instead the result of Sandoz's own efforts to limit research, and the general difficulty in meeting the IND requirements as an independent researcher. The IND rules supported a move away from a landscape of drug research characterized by numerous small independent research groups, each working in their own direction, towards a more formalized, larger-scale, manufacturer-directed, and institutionally-based research landscape.

Harold Abramson

New York psychiatrist Harold Abramson had been conducting research with LSD since 1951 (Abramson, 1960: 8). During the 1950s, he had become a leading developer of a form of LSD psychotherapy termed 'psycholytic therapy', in which multiple low- to medium-dose LSD sessions were used to facilitate psychoanalytically orientated psychotherapy. Researchers found that LSD could deepen and quicken the processes of psychotherapy, through its power to break down patients' defences, release repressed memories, produce powerful abreactions (an emotional re-living of past traumatic events), and deepen and cement psychological insight. Psycholytic therapy was primarily used to treat neurotic illnesses (Abramson, 1955, 1956). As well as this therapeutic research, with his colleagues at the Biological Laboratory, Cold Spring Harbor, New York, Abramson had conducted a wide variety of research exploring LSD's physiological and psychological effects, such as its effects on perception, motor performance, and concentration (Abramson, Jarvick and Hirsch, 1955; Abramson, Jarvick, Kaufman, Levine et al., 1955; Jarvik et al., 1955).

By 1963, Abramson was the director of research at the South Oaks Research Foundation, a division of the South Oaks Psychiatric Hospital, Amityville, New York (Abramson, 1967: xiii). Sandoz had initially listed Abramson as an LSD investigator in its IND, but he was quickly removed once the company decided to restrict its sponsorship to those working under the NIMH, state agencies and the Veterans Administration.[13] Abramson first contacted the FDA in May 1963, under the impression that he had been deemed unqualified to perform research under the new drug rules. Having used LSD for over 10 years, he wished to clarify his qualifications 'in order to eliminate

what at present is damaging to my position professionally'.[14] The FDA advised him to take up the issue with Sandoz, as it was a drug's sponsor, not the FDA, who initially determined the adequacy of researchers' qualifications. Subsequently, Abramson decided to become a sponsor for LSD research himself, and the FDA instructed him to submit an IND form.[15]

In November 1963, Abramson met with Frances Kelsey and Merle Gibson of the FDA's Investigational Drug Branch to discuss submitting an IND for LSD research. The FDA officers again emphasized that Sandoz's criteria for researching LSD under its IND had nothing to do with the new drug regulations. The decision was voluntary, and had come out of discussion between Sandoz and the NIMH. Clearly taking Sandoz's criteria personally, Abramson suggested that they might have denied him access to LSD because of his criticism of Sansert – another Sandoz drug that he had experimented with. He had argued that Sansert could produce effects similar to LSD, but with greater potential danger. Abramson also stated the he had been turned down for an NIMH grant due to the agency's disbelief of his work with Fighting Siamese Swordtails.[16] Abramson and Evans (1954) had published research reporting that the fish uncharacteristically swam nose up, tail down, when exposed to LSD. He had suggested that by exposing the fish to human urine, this phenomenon could be observed as a bioassay for the presence of LSD. Considering LSD to produce a model psychosis, he had also suggested that exposing the fish to schizophrenics' urine might help uncover a naturally occurring substance causing the illness. Abramson still had a stock of LSD that had previously been supplied by Sandoz. He wished to use this in research treating mental illness, particularly schizophrenia. He also believed that LSD psychotherapy was valuable in the treatment of alcoholism. Abramson presented a drafted IND form to Kelsey and Gibson, but they told him that it was lacking in chemical control data and that he should request this from Sandoz.[17]

Three days after the meeting, Abramson wrote to the US headquarters of Sandoz in New Jersey. He stated that he wished to become his own sponsor for LSD research, which he was able to do '*provided that Sandoz Pharmaceuticals will supply me with data covering items 1 to 6*'[18] of the IND form. These sections covered preclinical data such as the drug's chemical structure, composition and manufacturing controls, as well as details of animal and other research indicating that it was reasonably safe to conduct human research (Larrick, 1963). Only a drug's manufacturer could produce much of the chemical and manufacturing data, while the rest could theoretically be produced by any experienced scientist with supplies of the drug, but only at great expense and with difficulty. Abramson appealed to Sandoz to 'be kind enough to give me the required information since this can be obtained from no other source'.[19] Sandoz's Leonard Achor replied coolly, reiterating the company's criteria for LSD investigators, and stating,

> For the record, it is necessary to advise that Sandoz Pharmaceuticals will remain the sole sponsor of *LSD-25* in the United States as per Company policy. Accordingly, it will not be possible to supply you with the information contained in items one through six in the form #1571.[20]

Frustrated by this response, Abramson replied that Sandoz's statement directly contradicted advice he had received from the FDA's Bureau of Enforcement, that 'Anyone may become a sponsor for an investigational drug'. If 'for reasons which are obscure to me' Sandoz was unwilling to supply the data he requested, Abramson enquired whether the information was already filed with the FDA, and whether it was in the public domain. If this was the case he could use it to become his own sponsor, thus 'relieving Sandoz of any responsibility'.[21] In response, Achor again emphasized that Sandoz would remain the sole sponsor for LSD. He stated that the necessary data had been supplied to the FDA, but it was given in confidence and was 'not, I repeat not, in the public domain'.[22]

Reaching a dead-end with Sandoz, Abramson forwarded his correspondence with the company to Kelsey at the FDA. He complained that 'Sandoz refused to acknowledge the right to self-sponsorship' which the FDA had made clear to him. Unable to complete an IND, he asked how he could proceed. He pointed out that as he already had stocks of LSD, he did not need the company's cooperation to perform his proposed research.[23]

However, instead of the sympathetic support that Abramson was hoping to receive, the FDA began to view him with suspicion. Kelsey had heard that Abramson was 'rather an LSD enthusiast', and Sandoz had confirmed that he was no longer listed as one of their investigators. She therefore became concerned that Abramson was using the drug on humans without filing an IND, and decided to investigate. Kelsey decided to send an FDA inspector to visit Abramson. The inspector was to examine his stock of LSD, and investigate whether or not he was currently using the drug in human research. If there was any evidence of this, a sample of the drug was to be taken, on which seizure could be based.[24]

On 11 June 1964, New York FDA Inspector Irwin Schorr visited Abramson at the South Oaks Research Foundation. Abramson stated that he had not used the drug on humans since the new drug regulations. However, this was not because the FDA prohibited it, but due to his fear of malpractice suits, as his LSD was labelled for investigational use only. In fact, he felt that the government had no jurisdiction over his right as a doctor to 'administer any drug to his patients in the course of treatment'. Regarding his IND application, Abramson complained about the need to supply preclinical data that Sandoz had already filed with the FDA. Since he was using Sandoz LSD, he logically argued that requiring him to provide the data himself was unnecessary. However, Schorr told him that he needed Sandoz's written consent to refer to their data. Schorr was sympathetic to Abramson's situation, stressing that there were no doubts as to his qualifications and nothing personal in the delayed decision over his IND – 'it was just a matter of law'. Following the visit, Schorr reported to his superiors that he was satisfied that Abramson was not using his supplies of LSD on humans while his IND was under review. Although Abramson was 'extremely anxious' to have his IND approved, Schorr felt it 'doubtful that he would do anything to jeopardize his position as a prospective investigator/sponsor or doctor'. No sample for seizure was therefore taken.[25]

On 11 May 1965 FDA commissioner George Larrick sent Abramson the results of his IND review. The review concluded that Abramson's IND 'fails to contain sufficient data to support a conclusion that it is reasonably safe to initiate the intended clinical investigations with the drug'. This determination was based on the application's lack of information on both preclinical investigations and the 'methods, facilities, and controls used for manufacturing, processing and packing the investigational drug'. The letter acknowledged that Abramson had referenced Sandoz's data in regards to these sections of the IND, but it stated that the FDA could not refer to data already on file 'without written authorization' from the original submitter. Abramson was given 10 days to remedy the situation, otherwise his IND would be terminated.[26] On 23 July, Larrick sent notice to Abramson that his IND for LSD was terminated.[27] Abramson continued to pursue animal research with LSD, but he never resumed his clinical research with the drug.[28]

The correspondence between Abramson, Sandoz and the FDA reveals three distinct attitudes regarding who was entitled to perform research with investigational new drugs. Sandoz felt that it had the right, as the drug's manufacturer, to control access to the drug. Abramson, by contrast, felt that his rights as a physician came first: as a qualified and experienced physician, he was entitled to use drugs in treatment and research as he saw fit. The FDA's position was theoretically neutral – anybody could sponsor clinical research with a drug as long as they could complete the necessary paperwork showing that it was reasonably safe to do so. However, as a drug's manufacturer was the only party practically able to produce much of the necessary data, and as the FDA held IND data in confidence – reading any subsequent applications with an artificial ignorance regarding the

safety of the drug – this seemingly simple, impartial requirement in fact put much control over research in the hands of the manufacturer. A manufacturer could not itself sponsor research without the FDA's approval, but it could prevent others from using stocks of their preparations for research that the FDA would otherwise approve. Sandoz used this power to limit LSD research to government-sponsored, hospital-based projects under its IND, while deliberately maintaining a monopoly over LSD sponsorship. Despite Abramson's claim that Sandoz's rejection of his requests was personal, there is little evidence to support this; Sandoz set up clear company policy for how it wished LSD research to proceed, and Abramson did not meet the criteria. Ultimately, Abramson's inability to gain approval to conduct clinical LSD research under the Drug Amendments of 1962 was not due to any effort by the FDA to restrict such research.

The International Foundation for Advanced Study

The International Foundation for Advanced Study, of Menlo Park, California, also submitted an independent IND to the FDA for human research with LSD in 1963. This IND also included psilocybin. The IND was eventually terminated in February 1965. Like Abramson, the researchers struggled to provide the preclinical data required for the IND form without the cooperation of Sandoz. Although this problem alone would have resulted in their IND's termination, the FDA review also cited another issue – the qualifications of the investigators. A non-profit organization founded to explore the potential of LSD, the Foundation was at the forefront of establishing the 'psychedelic therapy' method of LSD administration in the USA. This method, developed in the mid-1950s by Canadian researchers (Hoffer, 1967; MacLean et al., 1961) to treat chronic alcoholism, involved a single, high-dose LSD session enmeshed in a framework of brief, intensive psychotherapy. The aim was to produce a transcendental or mystical 'psychedelic' experience that could fundamentally alter a patient's outlook on life, personality and behaviour, leading to sobriety. Reflecting the unconventional nature of this form of drug research, the members of the Foundation came from a variety of backgrounds: experience was a more relevant qualification than medical credentials. Prior to 1962 this situation had not caused problems, but after the IND rules of the Drug Amendments of 1962 formalized access to investigational drugs, the Foundation's position became untenable.

The International Foundation for Advanced Study was founded in 1961 by electrical engineer Myron J. Stolaroff. He had been informally experimenting with LSD since psychedelic therapy pioneer and fellow engineer Alfred Hubbard introduced the drug to him in 1956 (Stolaroff, 1994: 18–26). Together with Hubbard, Stolaroff attracted a number of researchers to the Foundation, who came from a variety of backgrounds but had a common interest in psychedelic drugs. These researchers included psychiatrist Charles Savage, Stanford University Professor of Engineering Willis Harman, Stanford graduate student in psychology James Fadiman, and San Francisco State College Associate Professor of Psychology Robert Mogar.

Savage, who was hired as medical director, was the most qualified, experienced and esteemed member of the Foundation. He had begun research with psychedelics in 1949 at the Naval Medical Research Institute, Bethesda, Maryland, and continued research at a series of locations until his arrival at the Foundation: first at the NIMH in Maryland, and then in California at the Center for Advanced Studies in Behavioral Sciences, the Palo Alto Medical Research Foundation, the Napa State Hospital, and the Palo Alto Veterans Administration Hospital (House Intergovernmental Relations Subcommittee, 1966: 2212). Among the first in the country to use LSD, he had progressed during the 1950s from using it for psycholytic therapy (Savage, 1952) to exploring the Canadian psychedelic therapy method (Savage, 1962). As psychologists, Mogar and Fadiman were also qualified to perform LSD psychotherapy research, at least under medical supervision. However, Hubbard, Stolaroff, and Harman were, objectively, laymen.

The Foundation justified the use of lay researchers on the grounds that there were simply not enough therapists who had both training in psychiatry or clinical psychology, and experience with psychedelics. They considered psychedelic therapy 'an art which can be adequately learned only by personal participation in the therapeutic process', and that 'orthodox training may actually prove to operate as a handicap to learning'.[29] Savage indeed found value in Harman's background, even though it was not in psychiatry: he wrote that 'Harman brings to the project a background in scientific method, research design, communication and statistical theory, as well as an interest in the scientific basis of values and beliefs'.[30] They suggested that the situation was characteristic of revolutionary new treatments, comparing it to the early days of psychoanalysis, and that in the future those trained in psychedelic therapy would come from formal mental health backgrounds.[31]

By the time of the enactment of the Drug Amendments of 1962, research at the Foundation was well established. In 1962 the researchers published positive results in the *Journal of Neuropsychiatry* for their first study, which treated patients with a variety of psychiatric diagnoses and personal problems (Sherwood et al., 1962). From there the researchers drew up grant applications to the Department of Health, Education, and Welfare for three sophisticated controlled clinical trials with LSD that would significantly advance their understanding of the process by which psychedelic therapy benefited patients, and obtain objective data on its efficacy in the treatment of alcoholism.[32]

Exactly what came of these grant applications is unclear; however, the researchers did receive at least some funding from a Public Health Service Fellowship (Savage et al., 1966). The reason that the Foundation was denied any further federal funding appears not to have been due to any objection to funding LSD research in general, or to the Foundation's specific form of research. At 1966 congressional hearings entitled 'Drug Safety', Congressman Lawrence Fountain's Intergovernmental Relations Subcommittee questioned the FDA extensively on its regulation of LSD research. Subcommittee senior investigator W. Donald Gray asked why the International Foundation for Advanced Study was turned down for a grant, and if it was because the research was not 'bona fide' or because some of the investigators were unqualified. Kelsey replied that the National Institutes of Health, which administered the grants, 'think very highly and thought very highly of Dr. Savage'. She could not remember whether she had been told a specific reason why the grant had been turned down, but opined: 'There are usually a great deal more applications than there are funds for.' Gray added that the National Institutes of Health had informed him that the rejection 'wasn't necessarily on the basis of the proposed research, but largely the fact that there was some question about the reliability of some of the people there' (House Intergovernmental Relations Subcommittee, 1966: 2206). The grant proposals listed Harman as co-principal investigator, and knowledge that laymen Stolaroff and Hubbard directed the Foundation could have influenced suspicion of the personnel other than Savage.

Despite receiving some funds from the Public Health Service, Sandoz excluded the Foundation from its IND, probably due to its research taking place in an outpatient clinic rather than a hospital. Subsequently, the Foundation submitted its own IND for LSD and psilocybin on 5 June 1963. On 7 October, FDA Division of Pharmacology reviewer William D'Aguanno wrote to Kelsey recommending termination of the IND, as 'the animal data [supplied] are insufficient to support clinical studies'. The IND had referred to Sandoz's IND for animal data, but, like Abramson, they had not provided authorization from Sandoz to use this confidentially filed data.[33]

Despite this immediate recommendation, the Foundation's IND was not terminated until February 1965. At the 1966 'Drug Safety' congressional hearings, Chairman Fountain questioned the FDA as to the reasons for this delay. He drew attention to numerous recommendations for termination from several different FDA officers, due primarily to the lack of preclinical and

manufacturing control data, which had been given between the initial October 1963 review and the final termination. Kelsey explained that they respected Savage as a 'distinguished scientist' with great experience with LSD, and had wished to avoid unnecessarily terminating potentially useful research. They therefore gave the Foundation a chance to provide the necessary data. The researchers promised to do this, and offered to suspend their clinical work while their IND was under review. However they were unable to obtain the data (House Intergovernmental Relations Subcommittee, 1966: 2202–3).

Ultimately, the final nail in the coffin of the Foundation's IND came with Savage's departure: by September 1964, he had accepted a new job at Spring Grove State Hospital, Maryland, where he would continue his psychedelic research from February 1965.[34] For Kelsey, with the requested data not supplied, Savage's departure was the deciding factor in termination. Additionally, by 1964 the FDA was growing suspicious that the Foundation was using LSD outside its legitimate research. In November an undercover agent was sent to the Foundation to try to obtain LSD treatment. He was unable even to obtain a promise of treatment, but 'the inference seemed to be that possibly it could be arranged' (House Intergovernmental Relations Subcommittee, 1966: 2203–4). At the December meeting of the FDA's Advisory Committee on Investigational Drugs, Kelsey gave a scathing report of the Foundation's IND, criticizing Hubbard's qualifications, the lack of a 'reasonable investigation plan', and the absence of controls. In response, committee member Sidney Merlis stated, 'the sponsor should not be dignified by a site visit – it should be terminated'.[35] The Foundation researchers had attempted to bring credibility back to their application by appointing a new psychiatrist as medical director, but his location in New Jersey suggested this was a token position (House Intergovernmental Relations Subcommittee, 1966: 2137).

Finally, on 6 January 1965 the FDA sent the International Foundation for Advanced Study a notice of the deficiencies in its IND application. If corrections were not provided within 10 days, the IND would be terminated. As well as listing deficiencies in the preclinical and manufacturing data provided, the FDA also judged the investigators and their plans to be inadequate:

> In our opinion, the proposed co-investigators, Willis W. Harman, Alfred M. Hubbard and Myron J. Stolaroff, do not possess the necessary qualifications for undertaking the proposed clinical investigations; in addition, the data submitted do not support the use of psychotomimetic compounds in such syndromes or diseases such as asthma, colitis, psoriasis, etc. Furthermore, the supervision of the project in California by the principal investigator in New Jersey, is unsatisfactory.[36]

The inclusion of asthma and other physical ailments in the Foundation's investigative plans suggests that the researchers had proposed branching into psycholytic therapy: while not a common indication of psychedelic therapy, many psychoanalysts researched and treated asthma, believing it to be psychosomatic (Hale, 1995: 257–63). On 2 February the IND was terminated (House Intergovernmental Relations Subcommittee, 1966: 2202).

From its inception in 1961, the Foundation had led the field of psychedelic therapy research in the United States. Not only had the researchers been among the first to adopt the Canadian method, but they had attempted to advance the field by designing controlled clinical trials. While some of their plans were not realized, they accrued great experience with psychedelics, administering them to approximately 350 subjects (Stolaroff, 1994: 26), and published their findings in mainstream journals such as the *International Journal of Neuropsychiatry* (Savage et al., 1966). Whilst several of the core researchers of the Foundation had no formal training in medicine or psychology, they were not merely making excuses when emphasizing the importance of experience over medical credentials. LSD administration was known to cause few medical complications; its effects, contraindications, and dangers were all related to psychological factors. Additionally, medical training

did not prepare a therapist for handling the powerful and variable effects of the drug, as carefully manipulating set and setting were not normal aspects of medical drug administration. Indeed the experience and innovation of Hubbard was highly regarded by many psychiatrists researching LSD with whom he had collaborated, such as Ross MacLean, Humphry Osmond, and Abram Hoffer in Canada (Hoffer, 1967; MacLean et al., 1961). However, with the formalization of drug research through the Drug Amendments of 1962, this was not a perspective that the FDA could support. Ultimately, without a medically qualified lead investigator such as Savage, the foundation would have been denied an IND for clinical research with any drug, let alone LSD.

Research in the era of prohibition

The first legislation to control LSD specifically was signed into law in July 1965. The Drug Abuse Control Amendments of 1965 (Sec. 3) amended the Federal Food, Drug and Cosmetic Act to prohibit the manufacture, sale, distribution, and possession (except for personal use) of depressant, stimulant, and hallucinogenic drugs outside legitimate channels of commerce and research. This increased control of hallucinogens reflected growing public and political concern over their non-medical use. Although the amendments contained no provisions that directly affected LSD researchers working under an IND, the increasing controversy over LSD abuse had a negative impact on this research: in April 1966, two months after the amendments became effective, Sandoz cited the controversy when withdrawing its IND for LSD research. As Sandoz had maintained itself as the drug's sole sponsor, this meant that all research was in jeopardy. The scale of LSD research in the USA dropped significantly as a result. However, a joint initiative of the FDA, the NIMH, and the Veterans Administration prevented it from ending entirely.

By late 1965, the FDA and NIMH were already aware that Sandoz was planning to withdraw its sponsorship of LSD, as its patent for the drug had expired. At that time, the NIMH was supplying grants to approximately 20 investigations using LSD. Therefore Jonathan Cole, chief of the NIMH's Psychopharmacology Service Center, called a conference between representatives of Sandoz, the NIMH, and the FDA to discuss the future of LSD research. The conference was held on 7 December 1965. Cole considered that there was 'some evidence of benefit' with LSD therapy in the treatment of alcoholism, treatment resistant neuroses, and 'hardcore sociopathic personalities'. He therefore wished to ensure that Sandoz's withdrawal would not prevent NIMH grantees, and other legitimate investigators, from having access to the drug.[37]

The Sandoz representatives suggested that they could hand over their remaining supplies of LSD to the NIMH, which could act as the sponsor itself. The NIMH was, however, unable to take on this role. Three other possibilities were discussed. First, the NIMH could find a new source of LSD, and supply investigators who individually submitted their own INDs. Second, the FDA could give LSD an effective New Drug Application 'under very restrictive labeling'. Seeming to support this possibility, Kelsey pointed out that research 'could not go on indefinitely without some attempt at obtaining an approved NDA'. Indeed, the IND regulations stipulated that a drug's sponsor 'shall not unduly prolong distribution of the drug for investigational use', but should submit an NDA 'with reasonable promptness' after establishing its safety and efficacy (Larrick, 1963: 180). However, Sandoz, although open to being a bulk supplier of LSD, was 'not considering submitting an NDA'. Cole made the third suggestion: if some individual or organization, possibly Sandoz, would take on sponsorship, the NIMH could cover all costs involved. The conference ended with all parties agreeing that this last scenario was a possibility.[38]

Three months later, on 8 April 1966, Sandoz contacted the FDA to inform them that it intended to withdraw its sponsorship of LSD and psilocybin without delay. Sandoz had not planned to take any measures to ensure continued legitimate research with the drugs. The company's American

medical director, Craig Burrell, explained that the withdrawal was a result of the increased misuse of the drugs outside medicine. Although Burrell was convinced that 'no Sandoz produced LSD and Psilocybin reached black market channels', the increased publicity around the drugs, and increasing black market production, created a situation where 'we can no longer bear the responsibility for the allocation and distribution of these substances'. Sandoz's cessation of LSD and psilocybin distribution was worldwide (Senate Subcommittee on Executive Reorganization, 1966: 80–1). The earlier plan of sharing the burdens of sponsorship between Sandoz and the NIMH was now off the table. Concerned by this prospect, officials from the FDA, the NIMH, and the Veterans Administration discussed the matter with Sandoz. Together they decided that, while most of the approximately 70 Sandoz-sponsored investigators would have their stocks of LSD recalled, 12 would be allowed to continue using the drug while they wrote up and submitted their own INDs. On 11 April Sandoz sent official notices to all LSD researchers, except these 12, informing them of the cancellation of their sponsorship and recalling any stocks of the drug. Sandoz then topped up the 12 remaining investigators' supplies of LSD and delivered the rest of their stock to the NIMH, who would now take over the role of distributor (House Intergovernmental Relations Subcommittee, 1966: 2135–6).

When Kennedy criticized the FDA at his 1966 congressional hearing for the reduction in LSD research following Sandoz's withdrawal of its IND, he therefore failed to appreciate the nature of the IND regulations, and to give the agencies fair credit for ensuring that research survived at all. Defending their role, Goddard, with NIMH director Stanley Yolles, explained to Kennedy that the regulations required that all investigators worked under an IND. Therefore, with Sandoz's withdrawal, investigators had to submit individual INDs if they wished to continue using LSD. The reason for some projects not being cut off was that those researchers used the drug on a daily basis, so any disruption caused by the approval process would have had a major detrimental effect on their work. These researchers still had to submit INDs, but were allowed to continue using LSD in the interim. Goddard further explained that the reduction was also partly because some of the research projects had been concluding at the time. Ultimately, while he invited the submission of INDs, Goddard explained that it was not the FDA's responsibility to stimulate research, but simply to assess the adequacy of research proposals: 'We certainly do not want to be in the position of thwarting research that is needed … However, the responsibility for initiation does lie with the individual scientist' (Senate Subcommittee on Executive Reorganization, 1966: 57). Yolles stressed that the NIMH had accepted Sandoz's supplies of LSD precisely to ensure that valuable research continued. The NIMH had been under no obligation to become LSD's distributor, and could easily have had the stocks destroyed. Yolles also confirmed that if they found research that needed to be performed but had not attracted scientists, the NIMH was willing to stimulate the research and carry it out (pp. 55–7, 73, 77).

LSD research became subject to further new regulations under the Controlled Substances Act of 1970. Also designed to tackle drug abuse, this Act had a greater potential to discourage or even disable psychedelic research, as gaining approval to conduct research became more complex. The Act reformed the complex set of federal laws that controlled drugs of abuse to bring all such drugs under a single regulatory framework, administered and enforced by the Department of Justice (Spillane, 2004). The Act created five schedules for drugs, each denoting a different level of regulation. LSD, along with other psychedelics such as mescaline and psilocybin, was listed in the most prohibitive schedule, Schedule I. The criteria for inclusion in Schedule I were:

(A) The drug or other substance has a high potential for abuse.
(B) The drug or other substance has no currently accepted medical use in treatment in the United States.
(C) There is a lack of accepted safety for use of the drug or other substance under medical supervision. (Controlled Substances Act, 1970: sec. 202 (b), (1))

The last criterion can seem to contradict scientific experience with LSD, as the safety record for all forms of LSD psychotherapy had been exemplary when performed under medical supervision (Cohen, 1960). However, from congressional hearings on the legislation, it is clear that officials in the Department of Justice's Bureau of Narcotics and Dangerous Drugs considered that determining whether or not a drug was safe, or had a medical use, did not require lengthy deliberation, but simply a checking of the drug's official status with health authorities (House Subcommittee on Public Health and Welfare, 1970: 165–7, 343). A drug's medical use and safety under medical supervision were established officially in the USA through the FDA's approval of an NDA. The criteria for Schedule I therefore simply meant that a drug had a high potential for abuse and did not have an approved NDA. In fact, as Schedule I was the only schedule for drugs without an accepted medical use, any drug with an abuse potential but without an approved NDA would be placed in that schedule. LSD clearly met these criteria.

The regulation of Schedule I drugs equated to their total prohibition. However, as with the previous law, there was an exemption for legitimate scientific research: medical practitioners could use a Schedule I drug in research after obtaining registration to do so from the Attorney General. This was in addition to the standard FDA approval process to conduct research with an investigational drug. While this provision appears to have put the ultimate control of research in the hands of the Department of Justice, the Attorney General's powers to deny registration were in fact very limited. On receiving an application for registration, the Attorney General was required to refer it to the Secretary of Health, Education, and Welfare, who judged the adequacy of the researcher's qualifications and the merits of their research proposal. If the Secretary then recommended registration, the Attorney General was only permitted to deny it if he or she found that the applicant had falsified information in their application, had been convicted of a felony related to a controlled substance, or had had their licence to practise medicine revoked (Controlled Substances Act, 1970: Sec. 303, (f); Sec. 304 (a)).

Whether or not the registration requirements of the Controlled Substances Act had any impact on LSD psychotherapy research is not easy to determine. The NIMH did not cease funding psychedelic research until 1974 (Asher, 1975), and research did not come to a complete close in the USA until 1976 (Yensen and Dryer, 1993–1994). However, from the start of the 1970s, research was clearly in decline and had faded away to almost nothing before its eventual demise (Doblin, 2000: 53–4). Difficulties in gaining and maintaining approval for research could have influenced this. A 1972 survey of *Behavior Today* readers who were interested in psychedelics found that 81% of respondents rated governmental red tape as a 'large' obstacle for research with the drugs (Clark et al., 1975: 8). FDA officials responded to claims of prohibitive regulations by arguing that they received few applications for psychedelic research, which they put down to disillusionment with the drugs. They also argued that widespread research with marijuana suggested that registration requirements did not prevent access to Schedule I drugs (Asher, 1975). Ultimately, although the increased regulation may have had some impact, the decline in LSD research in the 1970s can be more convincingly explained through other processes. As I have argued elsewhere (Oram, 2014), difficulties in evaluating psychedelic therapy through controlled trial methodologies – as required under the efficacy provisions of the Drug Amendments of 1962 – left researchers in the late 1960s and early 1970s with negative or underwhelming results. This led many researchers, regulators, and funders to conclude that LSD therapy was ineffective. With little subsequent encouragement from the scientific community and funding bodies, research dwindled.

Conclusion

During the 1960s, LSD psychotherapy research transformed rather than died. Instead of the government prohibiting research due to concerns over its non-medical use, the FDA evaluated

applications to conduct research according to rules put in place under the Drug Amendments of 1962. When Sandoz's IND withdrawal threatened to bring research to a complete halt, the FDA, NIMH, and Veteran's Administration voluntarily stepped in to ensure it survived. Through the new regulatory systems, the field of psychedelic research was transformed from one that had progressed in a disorderly fashion, with a large and diverse population of researchers all conducting their own small and varied studies, into fewer formal clinical trials. While the smaller number of researchers using LSD can give the impression that research was in decline, the studies that remained were significantly more methodologically sophisticated than previous studies. They therefore had the best chance of producing convincing proof of treatment efficacy, as needed to potentially turn the drug into an approved pharmaceutical. Ultimately, however, achieving this would prove more difficult than gaining approval to conduct the research.

Acknowledgements

Special thanks go to Alison Bashford for her advice in preparing this article. Thanks also to Stephen Robertson for his guidance of my doctoral work from which this originates, as well as Stephanie Schmitz and staff at Purdue University Archives and Special Collections for their great assistance in facilitating access to their collections.

Funding

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

Notes

1. See also US House of Representatives Intergovernmental Relations Subcommittee of the Committee on Government Operation (1966) and US Senate Special Subcommittee of the Committee on the Judiciary (1966).
2. Relevant details of the legislation mentioned in this paragraph are given in the References under *(a) US Legislation*.
3. Harold A. Abramson (January 1967), 'Will the Legal Supply of LSD to the Private Medical Practitioner be Stopped Indefinitely?' *Mademoiselle* file National Institute of Mental Health, box 10, Peter G. Stafford Papers, Rare Book and Manuscript Library, Columbia University Libraries, New York.
4. Of these works, only Carpenter's focuses significant attention on the IND regulations.
5. Langlitz (2013: 29–30, 37–8) has also recognized that the initial decline in LSD research in the 1960s was due to a restructuring of the regulation of pharmaceutical research, and that the eventual demise of research was the result of a number of complex factors – including lack of funding and professional discouragement – rather than simple prohibition. This article adds significant narrative detail and evidence to advance this perspective.
6. Frances O. Kelsey, 'Symposium on Investigational Drugs – The Government', paper delivered to the American College of Apothecaries and American Society of Hospital Pharmacists, Miami Beach, Florida, 15 May 1963, in FDA (comp. 1979), *Speeches and Papers, 1963. Part 1*, Rockville, MD: Food and Drug Administration. FDA Biosciences Library, Silver Spring, Maryland.
7. Earl L. Meyers, 'The Food and Drug Administration's View of Investigational Drugs', paper delivered at the annual pharmacy congress of St. John's University, Jamaica, New York, 18 April 1963, p. 3, file 505.51 April–May, box 3572, General Subject Files 1938–1974, Division of General Services, RG 88 Records of the Food and Drug Administration, National Archives at College Park, MD (hereafter RG 88).
8. Bureau of Enforcement to Directors of Bureaus and Divisions, and Directors of Districts, memo, 7 May 1963, file 505.51 April–May, box 3572, RG 88.
9. Meyers, 'Investigational Drugs'; see Note 7.
10. J.F. Reilly to Kelsey, memo, 15 Aug. 1963, file 505.51 August, box 3570, RG 88; William D'Aguanno to Kelsey, memo, 19 Sep. 1963, file 505.51 Sep., box 3570, RG 88.

11. Reilly to Kelsey, memo, 15 Aug. 1963; D'Aguanno to Kelsey, memo, 19 Sep. 1963.
12. The psilocybin IND was also approved, presumably after similar deliberation.
13. Craig Burrell to Frances Kelsey, 5 Mar. 1964, file 521.6-525.091, box 3758, RG 88.
14. Harold A. Abramson to FDA, 9 May 1963, box 3750, RG 88.
15. C.E. Beisel to Harold A. Abramson, 13 June, 22 Aug. 1963, box 3750, RG 88.
16. Francis O. Kelsey, 'Memorandum of Interview', 8 Nov. 1963, file 521.6-525.091, box 3758, RG 88.
17. Francis O. Kelsey, 'Memorandum of Interview', 8 Nov. 1963, file 521.6-525.091, box 3758, RG 88.
18. Harold A. Abramson to Rudolph Bircher, 11 Nov. 1963, file 521.6-525.091, box 3758, RG 88 [original emphasis by underlining].
19. Harold A. Abramson to Rudolph Bircher, 11 Nov. 1963, file 521.6-525.091, box 3758, RG 88.
20. Leonard B. Achor to Harold A. Abramson, 18 Nov. 1963, file 521.6-525.091, box 3758, RG 88 [original emphasis by underlining].
21. Harold A. Abramson to Leonard B. Achor, 21 Nov. 1963, file 521.6-525.091, box 3758, RG 88.
22. Leonard B. Achor to Harold A. Abramson, 12 Dec. 1963, file 521.6-525.091, box 3758, RG 88.
23. Harold A. Abramson to Frances O. Kelsey, 2 Jan. 1964, file 521.6-525.091, box 3758, RG 88.
24. C.J. Karadimos to Director, New York District Division of Field Operations, memo, 15 Apr. 1964, file 521.6-525.091, box 3758, RG 88.
25. Irwin Schorr to Director, New York District, memo, 29 June 1964, file 521.6-525.091, box 3758, RG 88.
26. Geo. P. Larrick to Harold A. Abramson, 11 May 1965, box 3750, RG 88.
27. Geo. P. Larrick to Harold A. Abramson, 23 July 1965, box 3750, RG 88.
28. Merle L. Gibson to Harold A. Abramson, 18 June 1969, file 505.51 June, box 4247, RG 88.
29. 'Research Program of the International Foundation for Advanced Study', undated, p. 3, file 'Foundation Grants and Papers', box 1, MSP 70 Charles Savage Papers, Archives and Special Collections, Purdue University Libraries, IN (hereafter Savage Papers).
30. Charles Savage and Willis Harman, 'LSD-25: Value Changes in the Psychedelic Experience', application for research grant to the U.S. Department of Health, Education, and Welfare, received 2 July 1962, p. 11, file 'Foundation Grants and Papers', box 1, Savage Papers.
31. 'Research Program of the International Foundation for Advanced Study', p. 3; see Note 29.
32. See Savage and Harman, 'LSD-25'; Charles Savage and Willis Harman, 'A Controlled Study of LSD-25 and Alcoholism', draft application for research grant to the US Department of Health, Education, and Welfare, 27 Dec. 1962, file 'LSD as Used by Various Therapists', box Addition 1, Savage Papers; Charles Savage and Willis Harman, 'A Controlled Investigation of the Psychedelic (LSD-25) Approach to Alcoholism', undated draft proposal, file 40, box Addition 2, Savage Papers.
33. William D'Aguanno to Kelsey, memo, 7 Oct. 1963, file 505.51 October, box 3570, RG 88.
34. Albert A. Kurland to Charles Savage, 28 Sep. 1964, file 'Clippings, Correspondence, Reprints, Manuscripts', box Addition 1, Savage Papers. The exact date Savage stopped working with the Foundation is not clear.
35. Food and Drug Administration, Summary of Proceedings, Thirteenth Meeting, Advisory Committee on Investigational Drugs, 3 Dec. 1964, Washington, DC, p. 5, file 1, box 13, Frances Oldham Kelsey Papers, Manuscript Division, Library of Congress, Washington, DC.
36. John L. Harvey to Myron J. Stolaroff, 6 Jan. 1965, box 3750, RG 88.
37. Merle L. Gibson, 'Memorandum of Conference', 7 Dec. 1965, file 521.6-525.091, box 3758, RG 88.
38. Merle L. Gibson, 'Memorandum of Conference', 7 Dec. 1965, file 521.6-525.091, box 3758, RG 88.

References

(a) US Legislation (in date order)

Drug Amendments of 1962, 87 P.L. 781; 76 Stat. 780, 10 October 1962.
Drug Abuse Control Amendments of 1965, 89 P.L. 74; 79 Stat. 226, 19 July 1965.
Amendment, 90 P.L. 639; 82 Stat. 1361, 24 October 1968.
Controlled Substances Act, 91 P.L. 513; 84 Stat. 1242, 27 October 1970.

(b) US Hearings

House of Representatives Intergovernmental Relations Subcommittee of the Committee on Government Operations (1966) *Drug Safety (Part 5, Appendixes, and Index)*. 89th Congress, 2nd Session. Washington: US Government Printing Office.

House of Representatives Subcommittee on Public Health and Welfare of the Committee on Interstate and Foreign Commerce (1970) *Part One, Drug Abuse Control Amendments – 1970*. 91st Congress, 2nd Session. Washington: US Government Printing Office.

Senate Subcommittee on Executive Reorganization of the Committee on Government Operations (1966) *Organization and Coordination of Federal Drug Research and Regulatory Programs: LSD*. 89th Congress, 2nd Session. Washington: US Government Printing Office.

Senate Special Subcommittee of the Committee on the Judiciary (1966) *The Narcotic Rehabilitation Act of 1966*. 89th Congress, 2nd Session. Washington: US Government Printing Office.

(c) Publications and theses

Abramson HA (1955) Lysergic acid diethylamide (LSD-25): III. As an adjunct to psychotherapy with elimination of fear of homosexuality. *Journal of Psychology* 39: 127–155.

Abramson HA (1956) Lysergic acid diethylamide (LSD-25): XIX. As an adjunct to brief psychotherapy, with special reference to ego enhancement. *Journal of Psychology* 41: 199–230.

Abramson HA (1960) *The Use of LSD in Psychotherapy*. New York: Josiah Macy, Jr. Foundation.

Abramson HA (1967) *The Use of LSD in Psychotherapy and Alcoholism*. Indianapolis, IN: The Bobbs-Merrill Company, Inc.

Abramson HA and Evans LT (1954) Lysergic acid diethylamide (LSD 25): II. Psychobiological effects on the Siamese fighting fish. *Science* 120: 990–991.

Abramson HA, Jarvick ME and Hirsch MW (1955) Lysergic acid diethylamide (LSD-25): VII. Effect upon two measures of motor performance. *Journal of Psychology* 39: 455–464.

Abramson HA, Jarvick ME, Kaufman MR, Levine A, Kornetsky C and Wagner M (1955) Lysergic acid diethylamide (LSD-25): I. Physiological and perceptual responses. *Journal of Psychology* 39: 3–60.

Asher J (1975) Whatever happened to psychedelic research? *APA Monitor*: 4–5.

Carpenter D (2010) *Reputation and Power: Organizational Image and Pharmaceutical Regulation at the FDA*. Princeton, NJ: Princeton University Press.

Clark W, Lieff J, Lieff C and Sussman R (1975) Psychedelic research: obstacles and values. *Journal of Humanistic Psychology* 15: 5–17.

Cohen S (1960) Lysergic acid diethylamide: side effects and complications. *Journal of Nervous and Mental Disease* 130: 30–40.

Daemmrich AA (2004) *Pharmacopolitics: Drug Regulation in the United States and Germany*. Chapel Hill, NC: The University of North Carolina Press.

Doblin RE (2000) Regulation of the medical use of psychedelics and marijuana. Unpublished PhD dissertation, Harvard University.

Dyck E (2008) *Psychedelic Psychiatry: LSD from Clinic to Campus*. Baltimore, MD: The Johns Hopkins University Press.

Hale NG, Jr (1995) *The Rise and Crisis of Psychoanalysis in the United States: Freud and the Americans, 1917–1985*. New York: Oxford University Press.

Hewitt KA (2002) Psychedelics and psychosis: LSD and changing ideas of mental illness, 1943–1966. Unpublished PhD dissertation, University of Texas.

Hilts PJ (2003) *Protecting America's Health: The FDA, Business, and One Hundred Years of Regulation*. New York: Alfred A. Knopf.

Hoffer A (1967) A program for the treatment of alcoholism: LSD, malvaria and nicotinic acid. In: Abramson HA (ed.) *The Use of LSD in Psychotherapy and Alcoholism*. Indianapolis, IN: The Bobbs-Merrill Company, Inc., 343–406.

Hofmann A (2009) *LSD: My Problem Child. Reflections of Sacred Drugs, Mysticism and Science*, trans. J Ott. Santa Cruz, CA: The Multidisciplinary Association for Psychedelic Studies; originally published in 1979 as *LSD: Mein Sorgenkind*.

Jarvik ME, Abramson HA and Hirsch MW (1955) Lysergic acid diethylamide (LSD-25): IV. Effect on attention and concentration. *Journal of Psychology* 39: 373–384.

Langlitz N (2013) *Neuropsychedelia: The Revival of Hallucinogen Research since the Decade of the Brain*. Berkeley and Los Angeles: University of California Press.

Larrick GP (8 January 1963) Procedural and Interpretative Regulations; Investigational Use. *Federal Register* 28(5): 179–182.

Lee MA and Shlain B (1985) *Acid Dreams. The Complete Social History of LSD: The CIA, the Sixties, and Beyond*. New York: Grove Press.

MacLean JR, MacDonald DC, Byrne UP and Hubbard AM (1961) The use of LSD-25 in the treatment of alcoholism and other psychiatric problems. *Quarterly Journal of Studies on Alcohol* 22: 34–45.

Novak SJ (1997) LSD before Leary: Sidney Cohen's critique of 1950s psychedelic research. *Isis* 88: 87–110.

Novak SJ (1998) Second thoughts on psychedelic drugs. *Endeavour* 22: 21–23.

Oram M (2014) Efficacy and enlightenment: LSD psychotherapy and the Drug Amendments of 1962. *Journal of the History of Medicine and Allied Sciences* 69: 221–250.

Rinkel M (1957) Pharmacodynamics of LSD and mescaline. *Journal of Nervous and Mental Disease* 125: 424–427.

Savage C (1952) Lysergic acid diethylamide (LSD-25): a clinical-psychological study. *American Journal of Psychiatry* 108: 896–900.

Savage C (1962) LSD, alcoholism and transcendence. *Journal of Nervous and Mental Disease* 135: 429–435.

Savage C, Fadiman J, Mogar R and Allen MH (1966) The effects of psychedelic (LSD) therapy on values, personality, and behavior. *International Journal of Neuropsychiatry* 2: 241–254.

Sherwood JN, Stolaroff MJ and Harman WW (1962) The psychedelic experience – a new concept in psychotherapy. *Journal of Neuropsychiatry* 4: 69–80.

Smith CM (1958) A new adjunct to the treatment of alcoholism: the hallucinogenic drugs. *Quarterly Journal of Studies on Alcohol* 19: 406–417.

Spillane JF (2004) Debating the Controlled Substances Act. *Drug and Alcohol Dependence* 76: 17–29.

Stevens J (1987) *Storming Heaven: LSD and the American Dream*. London: Heinemann.

Stolaroff MJ (1994) *Thanatos to Eros: Thirty-five Years of Psychedelic Exploration*. Berlin: VWB – Verlag für Wissenschaft und Bildung.

Temin P (1980) *Taking Your Medicine: Drug Regulation in the United States*. Cambridge, MA: Harvard University Press.

Tobbell DA (2012) *Pills, Power, and Policy: The Struggle for Drug Reform in Cold War America and its Consequence*. Berkeley and Los Angeles: University of California Press.

Yensen R and Dryer D (1993–1994) Thirty years of psychedelic research: the Spring Grove experiment and its sequels. *Jahrbuch des Europäischen Collegiums für Bewußtseinsstudien / Yearbook of the European College for the Study of Consciousness*: 73–102.