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The Psychiatric Patient's Right to Effective Treatment: Implications of *Osheroff v. Chestnut Lodge*

Gerald L. Klerman, M.D.

Although Osheroff v. Chestnut Lodge *never reached final court adjudication, the case generated widespread discussion in psychiatric, legal, and lay circles. The author served as a consultant to Dr. Osheroff and testified that Chestnut Lodge failed to follow through with appropriate biological treatment for its own diagnosis of depression, focusing instead on Dr. Osheroff's presumed personality disorder diagnosis and treating him with intensive long-term individual psychotherapy. The author suggests that this case involves the proposed right of the patient to effective treatment and that treatments whose efficacy has been demonstrated have priority over treatments whose efficacy has not been established.*

(Am J Psychiatry 1990; 147:409–418)

In recent decades, the courts have played a growing role in setting standards for psychiatric treatment. Important court decisions have established the patient's right to treatment, the patient's right to refuse treatment, and the patient's right to the least restrictive environment. Most of these court decisions have concerned patients in public institutions, many of whom have been hospitalized involuntarily under civil commitment statutes. With regard to nongovernmental institutions and the private practice of psychiatry, the courts have mainly been involved in cases of negligence, many of which involved adverse consequences of biological treatments, such as drugs and convulsive therapy, or issues related to suicide (unpublished 1985 paper by K. Livingston).

Recently, the lawsuit of *Osheroff v. Chestnut Lodge* was settled out of court. The plaintiff claimed negligence because the institution failed to institute drug treatment and persisted in the use of individual psychotherapy as the sole treatment for his severe depression. This lawsuit is considered a landmark case dealing with a number of important issues confronting psychiatry—particularly the need for standards for psychiatric treatment and the ethical and legal consequences of the absence of such standards. The case has been widely discussed in legal journals (1), in the lay press (2), and in psychiatric circles (3–5); it was also discussed by Alan Stone in a paper given at the 1988 meeting of the American College of Psychiatrists.

The standards for psychiatric treatment include the safety, efficacy, and appropriateness of psychiatric treatment. These have long been subjects of controversy among the medical profession, psychiatry, and the public in general. The controversies have increased in recent years due to the introduction of new psychotropic drugs, new forms of psychotherapy and behavior therapy, increases in the types and numbers of mental health professionals, and the growing utilization of mental health services (6).

The lawsuit of *Osheroff v. Chestnut Lodge* raises a number of important clinical, scientific, public policy, and legal issues. The clinical issues have to do with the validity of psychiatric diagnoses and the criteria used in making treatment decisions. The scientific issues pertain to the nature of evidence for the safety and efficacy of psychiatric treatments. The public policy issues pertain to the respective roles and responsibilities of federal and state governments, the courts, and professional organizations in the protection of the welfare of patients with psychiatric conditions and the provision of careful, valid diagnoses and effective, hu-

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mane treatment and care. The legal issues have to do with the definition of standards of care in the criteria for malpractice and negligence.

I will summarize the salient clinical and legal developments in Dr. Osheroff's case, reviewing issues that have clinical, scientific, public policy, and legal implications. I will conclude with recommendations for clinical practitioners and for the profession.

THE CASE OF DR. OSHEROFF

Permission has been obtained from the patient to use his name and to report details of his history and treatment. Under usual circumstances, the patient's identity and that of the institutions where he was treated would not be given. However, since this case has already been discussed in the lay press (2) and in professional journals where the patient and the institutions have been frequently identified, further attempts at anonymity would be unjustified.

The patient, Dr. Rafael Osheroff, a 42-year-old, white male physician, was admitted to Chestnut Lodge in Maryland (in the Washington, D.C., metropolitan area) on Jan. 2, 1979. His history included brief periods of depressive and anxious symptoms as an adult; these had been treated on an outpatient basis. He had completed medical school and residency training, was certified as an internist, and became a subspecialist in nephrology. He was married and had three children—one with his current wife and two with his ex-wife.

Before his 1979 hospitalization, Dr. Osheroff had been suffering from anxious and depressive symptoms for approximately 2 years and had been treated as an outpatient with individual psychotherapy and tricyclic antidepressant medications. Dr. Nathan Kline, a prominent psychopharmacologist in New York, had initiated outpatient treatment with tricyclic medication, which, according to Dr. Kline's notes, produced moderate improvement. The patient, however, did not maintain the recommended dose, his clinical condition gradually worsened, and hospitalization was recommended.

The patient was hospitalized at Chestnut Lodge for approximately 7 months. During this time he was treated with individual psychotherapy four times a week. He lost 40 pounds, experienced severe insomnia, and had marked psychomotor agitation. His agitation, manifested by incessant pacing, was so extreme that his feet became swollen and blistered, requiring medical attention.

The patient's family became distressed by the length of the hospitalization and by his lack of improvement. They consulted a psychiatrist in the Washington, D.C., area, who spoke to the hospital leadership on the patient's behalf. In response, the staff at Chestnut Lodge held a clinical case conference to review the patient's treatment. They decided not to make any major changes—specifically, not to institute any medication regimen but to continue the intensive individual psychotherapy. Dr. Osheroff's clinical condition continued to worsen. At the end of 7 months, his family had him discharged from Chestnut Lodge and admitted to Silver Hill Foundation in Connecticut.

On admission to Silver Hill Foundation, Dr. Osheroff was diagnosed as having a psychotic depressive reaction. His treating physician began treatment with a combination of phenothiazines and tricyclic antidepressants. Dr. Osheroff showed improvement within 3 weeks and was discharged from Silver Hill Foundation within 3 months. His final diagnosis was manic-depressive illness, depressed type.

Although the patient's final diagnosis on discharge from Silver Hill was manic-depressive illness, depressed type, testimony of the treating physician at Silver Hill revealed that, of the two *DSM-II* diagnoses that would subsume a depressive illness as severe as Dr. Osheroff's (manic-depressive illness, depressed type, and psychotic depressive reaction), the diagnosis of manic-depressive illness, depressed type, was selected because of the potential future complications regarding child custody that could arise from a diagnostic label including the term "psychotic." The Silver Hill physician further testified that she did not find evidence of a narcissistic personality disorder in Dr. Osheroff and that the correct diagnosis according to *DSM-III* terminology would be major depressive episode with psychotic features.

Following his discharge from Silver Hill Foundation in the summer of 1979, the patient resumed his medical practice. He has been in outpatient treatment, receiving psychotherapy and medication. He has not been hospitalized and has not experienced any episodes of depressive symptoms severe enough to interfere with his professional or social functioning. He has resumed contact with his children and has also become active socially.

THE LEGAL ACTIONS

In 1982, Dr. Osheroff initiated a lawsuit against Chestnut Lodge. He claimed that as a result of the negligence of Chestnut Lodge in not administering drug treatment, which would have quickly returned him to normal functioning, in the course of a year he lost a lucrative medical practice, his standing in the medical community, and custody of two of his children.

When Dr. Osheroff's suit came before the Maryland Health Care Arbitration Panel it was marked, among other things, by the large number of expert witnesses for the plaintiff, including Drs. Donald Klein, Bernard Carroll, Frank Ayd, and myself. The Arbitration Panel found for the plaintiff and awarded him financial damages (7). This was not a majority decision, however, and the director of the Arbitration Panel sent the panel back for an amended decision, which reduced the award. Under Maryland statute, once an arbitration process is concluded, any party to the proceedings may reject the panel's arbitration and call for court review.

Both sides appealed. The claimant, Dr. Osheroff, requested a jury trial, which was to have taken place in October 1987. However, before any action was taken by the court, a settlement was agreed on by both parties.

CLINICAL AND SCIENTIFIC ISSUES

This case raises a number of clinical and scientific issues. The clinical issues have to do with the validity of the diagnosis and the process of decision making with regard to treatment. The scientific issues have to do with the nature of evidence for safety and efficacy of psychiatric treatments.

Divisions Within Psychiatry in the United States

Resolution of both the clinical and scientific issues is made difficult by the divisions within psychiatry in the United States, where psychiatry is divided theoretically and clinically into different schools—biological, psychoanalytic, and behavioral (7). This aspect of the sociology of psychiatry and other mental health professions and its effect on training and practice have been documented for a number of years (8–11). Various terms have been used to describe these divisions and splits—schools, movements, ideologies, and paradigms, for example (10, 12, 13). Whatever term is used, there is agreement that the differences in theory and practice involve controversies over the nature of mental illness, the appropriateness of different forms of treatment, and the nature of the evidence for the safety and efficacy of such treatments.

Chestnut Lodge has played an important role in the modern history of psychiatry in the United States. For more than 40 years, Chestnut Lodge has been one of the major centers of theory and clinical practice in intensive individual psychotherapy based on psychoanalytic and interpersonal paradigms (14). Harry Stack Sullivan (15), who formulated the interpersonal theory of psychiatry, was a consultant to the institution. Many of his lectures and seminars at Chestnut Lodge have been published posthumously. Frieda Fromm-Reichmann was also on the staff at the same time. She had immigrated to the United States from Germany along with a large number of other leading psychoanalysts driven out of Europe by the Nazi regime. Fromm-Reichmann wrote a number of influential papers and books about the psychotherapeutic treatment of schizophrenia and manic-depressive illness (16, 17).

Several prominent U.S. psychiatrists were trained at Chestnut Lodge; many subsequently became leaders in clinical psychiatry. Alfred Stanton, who became psychiatrist-in-chief at McLean Hospital in Massachusetts, and Otto Will, who became medical director of the Austin Riggs Center in Massachusetts, are two notable examples. The writings of Sullivan (15), Fromm-Reichmann (16), Will (18), and others were influential in many psychiatric residency training programs from 1950 through the 1970s.

In the 1950s and 1960s, new psychopharmacological agents and the findings of neuroscientific research began to influence psychiatric teaching, practice, and research. New forms of psychotherapy based on approaches other than psychoanalytic were applied. Professional controversies increased, particularly over the comparison of the therapeutic efficacy of the different forms of psychotherapy (psychoanalytic, behavioral, family, group) and over the relative efficacy and safety of the psychotherapies, used either alone or in combination with psychopharmacological agents (19).

Diagnostic Issues in Dr. Osheroff's Hospitalization

At both Chestnut Lodge and Silver Hill Foundation there was agreement that Dr. Osheroff suffered from a severe depressive condition. There was disagreement, however, as to the diagnosis of narcissistic personality disorder. In a discussion of this case, Dr. Stone (3) described a "dispute" over the appropriate diagnosis: "The patient's psychiatric experts, in depositions that reflected their biological orientation, diagnosed him as having an obvious case of biological depression, emphasizing his vegetative disturbances. The private psychiatric hospital contended that the patient was properly diagnosed as having a narcissistic personality disorder."

It is to be noted that Dr. Osheroff's diagnoses at both Chestnut Lodge and Silver Hill Foundation were made in 1979 in accordance with *DSM-II,* APA's official nomenclature at the time of his hospitalization. *DSM-III,* which is the current diagnostic nomenclature for clinical psychiatric practice in the United States, did not come into use until 1980. *DSM-II* does not include a diagnostic category of narcissistic personality disorder, although that diagnostic category is included in *DSM-I* and in *DSM-III.*

DSM-II includes diagnostic categories of psychotic depressive reaction and manic-depressive illness, depressed type. Both refer to severe forms of depression. There is no evidence of clinical features of hypomania or mania in Dr. Osheroff's history or in the case records from either institution. The patient would not meet *DSM-III* criteria for bipolar disorder or *DSM-II* criteria for manic-depressive illness, manic or circular types.

The *DSM-II* diagnostic category of psychotic depressive reaction was replaced in *DSM-III* by major depressive episode with melancholia and/or major depressive episode with psychotic features. Melancholia is a term from the past denoting a particularly severe form of depression uniquely responsive to somatic drugs and/or ECT therapies. It is of note that the term "biological depression" does not appear in *DSM-II, DSM-III,* or *ICD-9.*

According to Chestnut Lodge records, there were differences in medical opinion as to the relative importance to be given to the patient's personality conflicts

and his depressive diagnosis as they influenced treatment decisions, not over the depressive diagnosis itself. As was the practice at that institution, the patient had two physicians, a psychiatrist-administrator and a psychotherapist (20). The hospital records suggest there may have been disagreement between these two physicians: the psychotherapist emphasized the need to treat the patient's personality problems as the major condition, and the administrator expressed concern over the continued severity of the patient's depressive symptoms and distressed behavior.

This aspect of the clinical process illustrates the tendency for many psychoanalytically oriented psychotherapists, both in institutional and in community practice, to focus treatment on a patient's personality conflict and character pathology rather than on symptoms. In *DSM-III* terms, there tends to be an emphasis on the axis II diagnosis and relatively less attention given to the axis I diagnosis. The axis I diagnosis, a severe depression in the case of Dr. Osheroff, is often missed, or, even if it is formulated, the personality disorder is chosen as the major target for treatment planning.

The Disputed Diagnosis of Personality Disorder

An important clinical consideration at issue in *Osheroff* is whether the patient suffered from a personality disorder as well as from depression and whether the presence of the narcissistic personality disorder militated against the use of medication for the depression. Long-term psychoanalytically oriented psychotherapy is often justified by the theory that some states of clinical depression derive from unresolved personality conflicts whose origins lie in developmental problems related to childhood intrafamilial psychopathology (17, 21). This theory of etiology and pathogenesis of depression is the subject of scientific research and professional discussion (22). Expert witnesses testified on this issue at the *Osheroff* hearings.

It should be noted that the psychiatric experts who testified in this case did not agree on the validity of the diagnosis of narcissistic personality disorder for the patient. One expert, a trained psychoanalyst who is currently responsible for Dr. Osheroff's treatment and who had treated him when the patient was 29 years old and at the time of his divorce (when he was 34 years old), did not accept the diagnosis of narcissistic personality disorder and testified to this effect at the court hearing. He noted the patient's successful life achievements before the onset of the illness episode that led to hospitalization at Chestnut Lodge, including his professional success as a nephrologist, his ability to sustain a high income, and his loving, empathic, and sensitive relationship with his children.

The admitting psychiatrist at Silver Hill Foundation did not make the diagnosis of any personality disorder. An expert witness called by Chestnut Lodge to testify at the court hearing also did not think that the patient had a narcissistic personality disorder. In contrast to the near unanimity of expert opinion as to the patient's severe depressive condition, disagreement existed as to whether the patient met any criteria for narcissistic personality disorder.

Scientific Evidence for Evaluating Psychiatric Treatment

With regard to all kinds of therapeutics—pharmacotherapy, surgery, radiation, psychotherapy—the most scientifically valid evidence as to the safety and efficacy of a treatment comes from randomized controlled trials when these are available. Although there may be other methods of generating evidence, such as naturalistic and follow-up studies, the most convincing evidence comes from randomized controlled trials.

There have been many controlled clinical trials of psychiatric treatments; most have been conducted to evaluate psychopharmacological agents. These trials were initiated in the 1950s and 1960s in response to the controversy that followed the introduction of chlorpromazine, reserpine, and the other "tranquilizers." The application of controlled trials in psychopharmacology expanded after the passage in 1962 of the Kefauver-Harris Amendments to the Food, Drug, and Cosmetic Act, which mandated evidence of efficacy before a pharmaceutical compound could be approved by the Food and Drug Administration and marketed.

Research on the efficacy of psychotherapy has lagged behind that of psychopharmacology but has, nevertheless, been extensive. Smith et al. (23) analyzed more than 400 reports of psychotherapy research. Specific reviews of the evidence have appeared with regard to psychotherapy of neurosis (24), schizophrenia (25), depression (26), and obsessive-compulsive disorders (27).

In view of these developments, a review of the state of evidence regarding the treatments of the two psychiatric conditions diagnosed for Dr. Osheroff at the time of his hospitalization is in order.

With regard to the treatment of the patient's diagnosis of narcissistic personality disorder, there were no reports of controlled trials of any pharmacological or psychotherapeutic treatment for this condition at the time of his hospitalization (28). The doctors at Chestnut Lodge decided to treat Dr. Osheroff's personality disorder with intensive individual psychotherapy based on psychodynamic theory.

With regard to the treatment of the patient's *DSM-II* diagnosis of psychotic depressive reaction, there was very good evidence at the time of his hospitalization for the efficacy of two biological treatments—ECT and the combination of phenothiazines and tricyclic antidepressants. The combination pharmacotherapy was the treatment later prescribed at Silver Hill Foundation.

There are no reports of controlled trials supporting the claims for efficacy of psychoanalytically oriented intensive individual psychotherapy of the type advocated and practiced at Chestnut Lodge and administered to Dr. Osheroff. The closest approximation to a

controlled clinical trial of this form of intensive individual psychotherapy has been reported with hospitalized schizophrenic patients at two institutions in the Boston area (30). Contrary to the expectations of the investigators, one of whom was Dr. Alfred Stanton who had held a senior position at Chestnut Lodge and was one of the authors of *The Mental Hospital* [20], which describes the Chestnut Lodge institution), the results indicated that intensive individual psychotherapy offered no advantage over standard treatment (hospitalization, medication, and supportive psychotherapy) for these patients.

McGlashan and Dingman (30, 31) have reported results from follow-up studies of groups of patients treated at Chestnut Lodge. The findings from this naturalistic study do not support the efficacy of long-term psychotherapy and hospitalization for severely depressed patients such as Dr. Osheroff.

It should not be concluded there is no evidence for the value of any psychotherapy in the treatment of depressive states. Depressive states are heterogeneous, and there are many forms of psychotherapy. There is very good evidence from controlled clinical trials for the value of a number of brief psychotherapies for nonpsychotic and nonbipolar forms of depression in ambulatory patients (26). The psychotherapies for which there is evidence include cognitive-behavioral therapy (32), interpersonal psychotherapy (14), and behavioral therapy (33). However, no clinical trials have been reported that support the claims for efficacy of psychoanalysis or intensive individual psychotherapy based on psychoanalytic theory for any form of depression.

Personality Disorder and Depressed Patients' Response to Pharmacotherapy

An important clinical issue raised by *Osheroff* has to do with the possible influence of a patient's diagnosis of personality disorder on the decision to use medication and on the expected response to medication of depressed patients treated either with medication alone or with medication in conjunction with psychotherapy.

Even if we assume that the personality disorder was correctly diagnosed in Dr. Osheroff's case, there is no evidence to support the premise that the presence of a narcissistic personality disorder militates against the use of antidepressant medication. Patients with a personality disorder in addition to depressive illness may be relatively less responsive to medication than those without an associated personality disorder (34). However, the presence of a personality disorder by itself does not contraindicate the prescription of appropriate medication or predict complete failure to respond.

A related therapeutic issue raised by the case has to do with the possible negative interactions between psychotherapy and pharmacotherapy for depression. Many psychoanalytically oriented psychotherapists have argued against the use of medication in patients receiving psychotherapy because of the possible adverse effects of the pharmacotherapy on the conduct of the psychotherapy (35), although there is evidence that the combination of drugs and psychotherapy does not interfere with the psychotherapy of depression (36). Moreover, findings from controlled trials suggest that the combination of drugs and psychotherapy may have beneficial additive effects in the treatment of depression (37).

Decision Making in Psychiatry

Given this state of evidence, it is difficult to justify the rationale used by the Chestnut Lodge staff in forming their treatment plan and in making specific decisions. On the one hand, there was a body of scientific evidence from controlled trials attesting to the value of medication and/or ECT for the type of severe depression that the institution diagnosed this patient as having. On the other hand, there was no scientific evidence for the value of psychodynamically oriented intensive individual psychotherapy for either the patient's depressive condition or his diagnosis of personality disorder. Nevertheless, the patient was treated only with intensive psychotherapy.

It might have been reasonable to have undertaken a period of psychotherapy, particularly in view of the tendency of many depressive states to remit spontaneously. However, several clinical studies (38, 39) have concluded that, in the absence of intervention with somatic treatments, severe health impairment and greater mortality are associated with deep depressions.

The hospital continued its treatment plan for many months in the face of continued worsening of the patient's clinical state. Meanwhile, the prolonged hospitalization was having adverse effects on the patient's medical practice, financial resources, and marital and family relations.

PUBLIC POLICY ISSUES

In addition to clinical and scientific issues regarding diagnosis and treatment, this case raises some important issues regarding public policy. The policy issues have to do with the locus of responsibility for the protection and welfare of psychiatric patients and the activities of the government, the courts, and professional groups in establishing criteria for diagnosis and treatment.

The Roles of the Federal and State Governments

There is a federal agency, the Food and Drug Administration, that has statutory authority to review the evidence for the efficacy and safety of pharmacological treatments. Because of the Kefauver-Harris Amendments, a pharmaceutical firm that makes promotional claims for the efficacy of a drug is expected to present evidence from controlled trials in support of its assertions.

Consider, however, the situation with regard to psychotherapy. There are no statutory constraints on claims made for psychotherapy. No government body is authorized to review the evidence for psychotherapy or comment on its status. In the late 1970s, the Senate considered the creation of a National Commission on Mental Health Treatments, but the proposal was opposed by the mental health professions and was not enacted into law (40).

The National Institutes of Health (NIH) conduct consensus development conferences to review the evidence about specific procedures relevant to health and medicine, including the efficacy of treatments. An NIH consensus development conference was held on long-term drug treatments of affective disorders in 1984 (41), and a conference on electroconvulsive therapies was held in June 1985. However, the efficacy of psychotherapies has not been addressed by NIH.

It might be expected that two other federal government agencies concerned with health financing and disability—the Health Care Financing Administration and the Social Security Administration—would be involved in judgments as to the appropriateness of treatment, inasmuch as they are involved in the disbursement of large amounts of funds. The Health Care Financing Administration provides reimbursement under both Medicare and Medicaid, and the Social Security Administration determines the disability status of individuals with psychiatric illness. However, only limited efforts have been undertaken by these agencies to establish criteria for the safety and efficacy of treatments for which reimbursement will be provided. In this respect it is of note that the legislation establishing Medicaid and Medicare did not include criteria of safety or efficacy but, rather, discussed the criteria of reasonable and medical necessities. These criteria have not been explicated in specific regulations or procedures.

Although the federal government has no direct regulatory role with regard to psychotherapy, as it does with regard to drugs, it has a major role in supporting scientific research on mental illnesses and their treatment. The current imbalance in available evidence for efficacy of psychotherapy in relation to psychopharmacology has many sources; one is the social and economic structure of treatment research. In the case of pharmacological agents, the pharmaceutical industry is organized into large corporate bodies with considerable resources and incentives for research on the efficacy and safety of their products. In contrast, the psychotherapy "industry" is made up of many small firms and practitioners whose resources are less extensive and who are less capable of concerted action. It might be expected that the institutes of the Alcohol, Drug Abuse, and Mental Health Administration, particularly the National Institute of Mental Health (NIMH), would devote leadership and resources to treatment research, but here again, for complex reasons, NIMH's record on funding psychotherapy research is inadequate in total grants and not reflective of clinical practice or professional judgment. Efforts to correct this imbalance require greater cooperation between officials of the Alcohol, Drug Abuse, and Mental Health Administration and the professional leadership than has been achieved to date.

State governments have an important potential role with respect to these issues because licensure and certification of health professionals are the responsibility of state governments, as is the licensing of hospitals and clinics. Almost all state governments have established standards for professional licensing of physicians. An increasing number of state governments have established criteria for licensing and/or certification of psychotherapists, particularly psychologists and social workers. Similarly, almost all hospitals, including private psychiatric hospitals such as Chestnut Lodge and Silver Hill Foundation, require licensing in their respective states. However, no state has attempted to establish guidelines for the selection of treatments based on efficacy as part of licensing or certification requirements.

The Role of the Psychiatric Profession

In the absence of a government body similar to the Food and Drug Administration, patients and the public might expect that professional associations such as APA, the American Psychological Association, or the National Association of Social Workers would undertake to provide this service to the public. No guidelines for treatment have emerged, however, although peer review criteria have been established. APA issued a report on the status of ECT in 1978 (42). The Royal Australian and New Zealand College of Physicians has contracted with the Australian Ministry of Social Security to undertake a quality assurance program, which has issued a series of reports reviewing the state of scientific evidence for selected diagnoses, including depression (43).

As of the late 1970s, when Dr. Osheroff was hospitalized, APA had published a manual for peer review of hospital utilization (44). With regard to the *DSM-II* diagnosis of psychotic depressive reaction, this manual recommended the use of drugs or ECT. It did not recommend individual psychotherapy. Furthermore, this manual recommended that if hospitalization has continued beyond 1 or 2 months, the case should be reviewed and the use of ECT or drug treatments considered. Therefore, although there were no government bodies offering legal guidelines, APA had established peer review criteria for the hospital treatment of psychotic depressive reaction (44).

APA is currently completing a project on psychiatric treatments under the leadership of T. Byram Karasu (45). Preliminary reports from this project have been published (46).

The Role of the Courts

Given that there are no government bodies judging the efficacy of claims for psychotherapy, and given the limited efforts undertaken by professional associations, it is understandable that individual patients use the courts to seek redress for their grievances.

Governmental and professional bodies have been urged to issue judgments recommending treatments so that these criteria could be used by reimbursement agencies. In response, the Senate considered possible legislation to establish a National Commission on Mental Health Treatments in the late 1970s and, more recently, APA established the Commission on Psychiatric Therapies, led by Dr. Karasu. Some have advocated that the profession not make such recommendations in regard to treatment, assuming that if the profession did not take such actions the courts would ignore the issue or not take a position. The opposite seems to be the case. In the absence of professional criteria for standards of care, the courts are increasingly becoming the arena in which these disputes are adjudicated. Thus, case law and individual precedents may become the criteria for adequacy of diagnosis and treatment.

Biological Versus Psychodynamic Psychiatry

Dr. Stone (3) raised the possibility that patients who have not improved after prolonged psychotherapeutic treatment may have found a way around their frustrations—a way provided by "biological psychiatrists." Dr. Stone noted that biological psychiatry appears to be on the scientific ascendancy over psychodynamic psychiatry due to the prestige of the neurosciences and the evidence for efficacy of biological treatments.

My conclusion, however, is that the issue is not psychotherapy versus biological therapy but, rather, opinion versus evidence. The efficacy of drugs and other biological treatments is supported by a large body of controlled clinical trials. This body of evidence is all the more relevant to public policy in view of the paucity of studies indicating efficacy for individual psychotherapy.

It is regrettable that psychoanalysts and psychodynamic psychotherapists have not developed evidence in support of their claims for therapeutic efficacy. Twenty years ago, psychodynamic psychotherapy was the dominant paradigm of psychiatry in the United States, particularly in academic centers. A number of European psychiatrists, mostly psychoanalysts, contributed intellectual leadership and imaginative ideas to psychiatry here. Currently, however, psychoanalysis is on the scientific and professional defensive. This situation is, in part, a consequence of the failure of psychoanalysis to provide evidence for the efficacy of psychoanalysis and psychodynamic treatments for psychiatric disorders (47, 48).

In the period between World War I and World War II, biological psychiatry was in poor repute. Numerous treatments, often of a heroic nature, were advocated: colonic resection, adrenalectomy, excision of teeth, lobotomy. These interventions were based on biological laboratory research of dubious quality and without any systematic studies of safety and efficacy. The situation changed after World War II, with evidence for the value of ECT for depression and insulin coma therapy for schizophrenia and, later, with the introduction of chlorpromazine and other drugs.

The Respectable Minority Doctrine

The case of *Osheroff v. Chestnut Lodge* prompts a reevaluation of the doctrine of the respectable minority. Until recently, this doctrine held that if a minority of respected and qualified practitioners maintained a standard of care, this was an adequate defense against malpractice. I propose that this doctrine no longer holds if there is a body of evidence supporting the efficacy of a particular treatment and if there is agreement within the profession that this is the proper treatment of a given condition. Moreover, the respectable minority have a duty to inform the patient of the alternative treatments. In an unpublished 1985 paper discussing *Osheroff v. Chestnut Lodge*, K. Livingston wrote,

> Under this view, the respectable minority view would still constitute a defense to a malpractice action where even 10% of practitioners would adhere to the treatment in question. However, the shield of the respectable minority rule would not be available unless the patient had been given informed consent after a disclosure of risk/benefits and alternatives to the therapy.

How Do We Proceed in the Absence of Consensus?

When there is consensus in the profession as to the appropriate treatment for a given condition (in the case of *Osheroff*, the essential nature of biological treatment for severe depression), then a standard of care can be agreed on and can provide the basis for malpractice action.

However, how are we to evaluate claims for the efficacy of treatments for clinical conditions about which there is no consensus? What are the standards to be applied in diagnostic and clinical situations where there is no consensus within the field with regard to the treatment of the particular disorder? This is a serious policy question that, in the future, may become a legal question. In my opinion, there are three aspects to this issue: 1) What constitutes evidence for efficacy? 2) Who is responsible for generating the evidence? and 3) Who is to make the appropriate evaluation of treatments?

What constitutes evidence of treatment? In my view, the best available evidence as to efficacy comes from controlled trials. I am not taking the position that the only source of evidence for efficacy comes from such trials. Clinical experience, naturalistic studies, and fol-

low-up studies are also sources of relevant evidence. However, when results from controlled clinical trials are available, they should be given priority in any discussion of scientific evidence.

Who should be responsible for generating the evidence? What should be society's policy in regard to treatments for which there is no positive or negative evidence? This issue has not reached resolution, and I feel it merits further discussion within the profession.

My opinion is that the responsibility for generating evidence for efficacy rests with the individual, group, or organization that makes the claim for the safety and efficacy of a particular treatment. In the case of drugs, this responsibility is established by statute. If a pharmaceutical firm makes a claim for the efficacy of one of its products, it must generate enough evidence to satisfy the Food and Drug Administration before it can market the drug for prescription use.

No such mandate of responsibility exists for psychotherapy. Anyone can make a claim for the value of a form of psychotherapy—psychoanalysis, Gestalt, est, primal scream, etc.—with no evidence as to its efficacy.

What should be our position toward the claims of the efficacy in certain conditions of multiple treatments for which the evidence varies in quality and quantity? In my view, those treatments which make claims but have not generated evidence are in a weak position.

The efficacy of psychoanalysis and psychoanalytic treatments is in question for conditions for which there is evidence of efficacy with other treatments. For example, how many psychiatrists would justify long-term psychoanalytic treatment of panic disorder and/or agoraphobia when there is no evidence that this treatment works for these disorders but reasonably good evidence for the efficacy of certain drugs and/or forms of behavioral psychotherapy?

Who is to evaluate the evidence? A major problem arises as to the process by which the evidence regarding psychiatric treatments is to be evaluated. I believe there are serious deficiencies in our current professional and governmental arrangements for evaluating psychiatric treatments. In the case of drugs, we have the Food and Drug Administration, which makes such judgments according to established legal statutes and regulatory processes. There is no comparable statutory mandate for assessing the efficacy and safety of nonpharmacological treatments such as radiation, surgery, and psychotherapy.

In this situation, I believe the public has the right to expect that the medical profession will provide appropriate judgments as to the state of the evidence for treatments and establish criteria for standards of care. I maintain that the psychiatric profession has been lax in this responsibility and that the absence of professional consensus statements in our field leaves it open for the courts to be used by individuals, such as Dr. Osheroff, who feel they have been poorly treated and who believe they are entitled to redress of their grievances.

The fact that evidence changes is to my mind irrelevant to any policy or clinical discussion. The judgment on treatment of individual patients should be made according to the state of knowledge and professional practice at the time the individual patient is treated. In the case of *Osheroff*, this was 1979.

My strong preference would be for the profession to be more vigorous and more responsible in accepting this responsibility. I have stated these views on a number of occasions.

RECOMMENDATIONS FOR THE PRACTICING CLINICIAN

What lessons can be learned from the case of *Osheroff v. Chestnut Lodge* that can be used by the practicing clinician, whether in institutional or community settings? As Dr. Stone pointed out in a paper given at the 1988 meeting of the American College of Psychiatrists, this case has no formal legal status because it was settled out of court. However, it has been widely discussed and will likely provide the basis for possible further legal actions in similar cases. In my opinion, this case goes a long way toward establishing the patient's right to effective treatment. The following recommendations are not intended to be legal standards for negligence or malpractice but, rather, to clarify professional responsibility.

1. The psychiatrist has a responsibility to make a comprehensive assessment, including determination of the proper diagnosis. The patient should be evaluated as to social and personal background, symptoms, and medical history, including personality, need for hospitalization, and possible suicidal risk. As part of this assessment, a diagnostic formulation should be made and, wherever possible, the formulation should be in accord with *DSM-III-R*. Of course, investigators and clinicians can and do depart from *DSM-III-R* categories and criteria whenever they have good scientific or professional reasons to do so (unpublished 1988 paper of Alan Stone). However, in my opinion, when this departure is done for an individual patient, in teaching, or in research, the psychiatrist should make explicit the departure from *DSM-III-R* and name the alternative diagnostic system used.

2. The psychiatrist has a responsibility to communicate to the patient the conclusions of the assessment, including a proper diagnosis. The patient has a right to be informed as to his or her diagnosis. Wherever possible, this should be communicated in a manner consistent with *DSM-III-R* terminology and criteria. I recognize that there is a legal as well as a professional dispute as to the nature of informed consent that is expected in different jurisdictions, but the fullest possible transmission of information will facilitate trust and integrity in the doctor-patient relationship (unpublished 1988 paper of Alan Stone).

3. The psychiatrist has a responsibility to provide information as to alternative treatments. The patient has the right to be informed as to the alternative trea-

ments available, their relative efficacy and safety, and the likely outcomes of these treatments. This is a special requirement on the respectable minority of physicians, since they should inform the patient that their treatment is not the one most widely held within the profession. In communicating these alternatives to the patient, the clinician should not make pejorative statements about former types of treatment. Statements such as "Drug treatment is only a crutch," "I don't believe in drug treatment," "ECT will cause brain damage," and "I don't believe in psychotherapy" are ill-advised and may be used by the patient against the clinician in subsequent complaints, including legal action.

4. The psychiatrist has a responsibility to use effective treatment. The patient has the right to the proper treatment. Proper treatment involves those treatments for which there is substantial evidence.

5. The psychiatrist has a responsibility to modify treatment plans or seek consultation if the patient does not improve. To quote K. Livingston (unpublished 1985 manuscript):

> While psychiatry is not obliged to guarantee a cure, the courts may consider sympathetically arguments based upon the disparity between lengthy and costly treatment and the patient's failure to improve. Commentators note that when a patient fails to improve or deteriorates during treatment, there may be a duty upon the psychiatrist to abandon the treatment or to seek consultation.

Applied to the treatment of depression, the available evidence indicates that patients should begin to show improvement with medication within 4–8 weeks or with psychotherapy within 12–16 weeks. Failure of the patient to improve on a given treatment program within 3–4 months should prompt a reevaluation of the treatment plan, including consultation and consideration of alternative treatment.

CONCLUSIONS

Dr. Stone (3) stated, "When it deals with psychiatry, the law must deal with a world of complexity, dubiety, and increasing conflict about efficacy." The availability of scientific evidence will increasingly be considered by the courts as relevant to such decisions. In large part this is because of the major advances in psychiatric therapeutic research. The availability of this growing body of evidence prompts new criteria for judging standards of care and treatment. In the presence of such evidence, practitioners and institutions who continue to rely on forms of treatment with limited efficacy will be on the defensive and at possible jeopardy for legal action.

Resolution of professional issues through the courts is far from ideal and has substantial social costs. Ideally, the profession is the best judge of the available evidence. The courts are a poor tribunal in which to resolve scientific and professional issues. However, in the case of *Osheroff v. Chestnut Lodge,* there had been some professional agreement, as reflected in the APA peer review manual (44). The courts may be an appropriate arena for litigation when a small minority of the profession persist in practices that scientific evidence and professional judgment have deemed obsolete.

The problem of differences of opinion within a professional group has its analogy in issues of civil liberties—when should the majority insist that the minority accept its views? In the case of professional issues in psychiatry and medicine, however, the persistence of a minority dissent has implications beyond those of the profession because certain professional practices may involve harm to individual patients.

In the current situation in psychiatric practice, where there are large areas of ignorance, it behooves individual practitioners and institutions to avoid relying on single treatment approaches or theoretical paradigms. Thus, in modern psychiatry, treatment programs based only on psychotherapy or only on drugs are subject to criticism. Professionalism requires balancing available knowledge against clinical experience and promoting the advancement of scientific knowledge. In the case of treatment practices, such knowledge best comes from controlled trials.

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