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Judge Stephen Hjelt*

INTRODUCTION

The amount written about the doctrine of informed consent in the last forty years truly threatens more than one old growth forest. If one searches any of the legal, medical or psychology databases (Westlaw, Medline, Psych-Info), one ends up with "hits" that literally number in the thousands. These writings have increased almost exponentially in the last fifteen years.[2]

The writings on informed consent are not confined to the dry professional literature of law reviews and psychology journals. They are found in case law, statutes, the ethical principles for medicine and various mental health disciplines, as well as texts, specialty and popular writings. Quite simply, at least on paper, this growth in the literature on informed consent is ubiquitous and has, one would suppose, transformed the relationship of patient and caregiver.

The reality, however, is far different. Despite its apparent ubiquity, informed consent has failed to transform the essence of the treatment encounter between doctor and patient or psychotherapist and patient.

Informed consent first developed in the context of the delivery of medical services. Informed consent purported to alter the decision-making fulcrum and place decision-making authority in the hands of the patient. The results in the medical world have been decidedly mixed, although it is incontestable that some form of informed consent is

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2. *E.g.*, JAY KATZ, THE SILENT WORLD OF DOCTOR AND PATIENT (1984); RUTH R. FADEN & TOM L. BEAUCHAMP, A HISTORY AND THEORY OF INFORMED CONSENT (1986). Despite the huge volume written about informed consent, any exploration of the doctrine must include these two extremely influential books.

practiced somewhere, somewhat, sometimes.[3]

In the mental health field, informed consent is characterized by a very weak presence despite its ostensible centrality to the delivery of ethical care and explicit expression in the ethical principles at the core of the profession.[4] In the day-to-day delivery of mental health services, informed consent often appears to be missing in action.

In the last decade, many viewed informed consent as a quality control device designed to ensure consumer protection. This is based on a misreading of the doctrine of informed consent. Informed consent exists to promote individual autonomy and self-determination, a very different concept than consumer protection.

Psychotherapy is the principle product, good, or service of the mental health profession. It is a treatment that can do great good or great harm. It is a functional analog to a drug or medical device. It can relieve symptoms and resolve conditions. It can cure. It can kill. It can also cause adverse reactions. Like any drug or medical device, psychotherapy has contraindications as well as dose-specific impacts.

There have been countless new and emerging psychotherapy techniques developed and used on patients in the last forty years. Many are questionable, lacking in any showing of efficacy. Some do actual harm.[5] They continue to multiply and proliferate despite any showing of efficacy and in the face of a well-developed doctrine of informed consent.

The consequence of this is not some isolated mismatch of psychotherapy technique and patient. The result is enormous

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3. *See generally,* STEPHEN WEAR, INFORMED CONSENT: PATIENT AUTONOMY AND CLINICAL BENEFICENCE WITHIN HEALTH CARE (2d ed., Georgetown Univ. Press 1998) (1993).

4. AM. PSYCHOLOGICAL ASS'N ETHICS CODE § 4.02 (1992). Section 4.02 clearly states:

> Psychologists obtain appropriate informed consent to therapy or related procedures, using language that is reasonably understandable to participants. The content of informed consent will vary depending on many circumstances; however, informed consent generally implies that the person (1) has the capacity to consent, (2) has been informed of significant information concerning the procedure, (3) has freely and without undue influence expressed consent, and (4) consent has been appropriately documented.

Id.

5. *See e.g.,* DANIEL T. MAYS & CYRIL M. FRANKS, NEGATIVE OUTCOMES IN PSYCHOTHERAPY AND WHAT TO DO ABOUT IT (1985); JAMES L. KELLEY, PSYCHIATRIC MALPRACTICE: STORIES OF PATIENTS, PSYCHIATRISTS AND THE LAW (Rutgers University Press 1996); MARYBETH F. AYELLA, INSANE THERAPY: PORTRAIT OF A PSYCHOTHERAPY CULT (1998); CAROL L. MITHERS, THERAPY GONE MAD (1994); MARGARET T. SINGER & JANJA LALICH, CRAZY THERAPIES (1996).

economically, socially and politically. Billions of dollars are misallocated and misspent on seemingly questionable psychotherapy techniques.[6] Human suffering from mental illness and emotional distress continues at astronomical cost. Billions of dollars are misspent on what may be contemporary patent medicines of the mind.[7]

This article explores the development of the doctrine of informed consent, first in medicine and then in the mental health field. It also explores the history of psychotherapy as the primary method of treatment for mental illness and emotional distress. It then analyzes the reasons for the proliferation of new and emerging psychotherapy techniques, even as the doctrine of informed consent became commonplace. This article will next propose a two-fold solution. The first is a newly energized conception of informed consent in the mental health field. The second is the implementation of a regulatory mechanism akin to the Food and Drug Administration ("FDA") that will allow the use of psychotherapy techniques only after demonstration that the technique is safe and effective.[8]

Legal commentary has often used the metaphor of the garden to describe the growth and development of particular areas of the law. It is a comfortable metaphor because growth, development and the fruit of the labor well describe both the products of the garden and the law.

The growth of the doctrine of informed consent can certainly be viewed through the prism of this metaphor. However, the jurisprudential garden has yielded some very curious fruit. The doctrine is well developed, yet ripe, with all the appearance of a fine apple. However, when consumed, it tastes far more like an orange.

I. INFORMED CONSENT AS THE PRODUCT OF SOCIAL FORCES

The doctrine of informed consent is a product of powerful social forces that have developed over the last century. The atrocities committed by the Nazi doctors[9] and the notorious cases of research-

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6. NANCY E. MILLER & KATHRYN M. MAGRUDER, THE COST EFFECTIVENESS OF PSYCHOTHERAPY: A GUIDE FOR PRACTIONERS, RESEARCHERS, AND POLICYMAKERS (Nancy E. Miller & Kathryn M. Magruder eds., 1999).

7. *Id.*

8. This is one of the basic positions taken by Division 12, the Division of Clinical Psychology, of the American Psychological Association. A task force within Division 12 is actively working on developing treatment protocols based on empirically supported therapies.

9. *See* FADEN & BEAUCHAMP, *supra* note 2, at 153. Faden and Beauchamp wrote:

> [T]he Nazi experiments were in many respects unprecedented in the

subject abuse in the United States, including the Tuskeege Airmen[10] and the Jewish Chronic Disease Hospital,[11] were potent factors. At the same time, and particularly in the last forty years, our social and cultural landscape has been transformed by a new consciousness of individual rights.[12]

The most dramatic change is what Lawrence Friedman calls "legal culture," which he defines as "the ideas, attitudes, values, and opinions

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> extensiveness and extremity of the harm and suffering to which they knowingly exposed their victims. Using subjects drawn from the populations of concentration camps (Jews, gypsies, Poles, and Russians), Nazi scientists explored the effects of ingesting poisons, intravenous injections of gasoline, immersion in ice water, and the like. Infection with epidemic jaundice and spotted fever virus were typical parts of "medical" experiments.

Id.

10. *Id.* at 165-66. One of the most notorious cases of prolonged and knowing violations of subjects rights emerged in the 1970s. *Id.* at 165. It began in the early 1930s, when the US Public Health Service compared the health and longevity of an untreated syphilitic population with a nonsyphilitic but otherwise similar population. Beginning in 1932, the study traced the pathological evolution of syphilis in approximately 400 black males using another 200 without syphilis as controls. *Id.* The subjects were never told the name or the nature of their disease. *Id.* They were told only that they were receiving free treatment for "bad blood," a term local blacks associated with a host of unrelated ailments. *Id.* This experiment continued until 1973. *Id.* During the entire forty-year period, untreated subjects were systematically blocked from receiving available treatments. *Id.* This continued despite the fact that by 1936 it was clear that complications beset many more infected subjects than controls and within another ten years it was apparent that the death rate of those with syphilis was twice as high as for controls. *Id.* at 166.

11. In 1963, a research study was conducted at the Jewish Chronic Disease Hospital in New York. *Id.* at 161. A prominent cancer researcher was interested in the role of the body's immune system in defense against cancer. *Id.* He received permission from the hospital medical director to inject twenty-two patients who were cancer free with a suspension of live cancer cells. *Id.* None of the twenty-two were told they were being injected with cancer cells. *Id.*

12. *See id.* at 87. The authors continued:

> Perhaps the most accurate explanation is that law and ethics, as well as medicine itself, were all affected by issues and concerns in the wider society about individual liberties and social equality, made all the more dramatic by increasingly technological, powerful, and impersonal medical care . . . it seems likely that increased legal interest in the right of self-determination and increased philosophical interest in the principle of respect for autonomy and individualism were but instances of the new rights orientation that various social movements of the last 30 years introduced into society. The issues raised by civil rights, women's rights, the consumer movement, and the rights of prisoners and of the mentally ill often included health care components: reproductive rights, abortion and contraception, the right of health care information, access to care, human experimentation, and so forth. These urgent societal concerns helped reinforce public acceptance of the notion of rights as applied to health care.

Id.

about law held by people in a society."[13] The changes in law reflected in the growth and development of informed consent are the product of social change in the past century.[14]

The immense technological, medical and scientific advances of the twentieth century created new needs and expectations. For the first time in human history, the pendulum of uncertainty surrounding human existence swung favorably for mankind; disease and plague were conquered; the atom was harnessed; the environment was somewhat tamed; the human genome was mapped; life no longer seemed precarious and uncertain in an immediate sense.[15]

We have traveled from the nineteenth to the twenty-first century and from a social and legal culture of low expectations to one of high expectations.[16] As uncertainty shrinks and all things appear possible, society expects and demands more. Before the modern era of medicine, physicians had understandably low expectations of medicine. With the discoveries that transformed medicine in the last hundred years comes increased expectation of performance and outcome. Whether completely fair or not, people now have an expectation that medicine will cure and prevent. The development of the doctrine of informed

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13. LAWRENCE M. FRIEDMAN, TOTAL JUSTICE 31 (Reprint ed., Russell Sage Foundation 1994) (1987).

14. *Id.* at 42. Friedman notes:

> [B]y the nineteenth century, at the latest, a new kind of society had developed in the West: the society of technology, industry, science, machines. Science and machines gave people tremendous control over time, distance and destiny. This period was followed by the age of modern medicine; then came the age of the computer. Each advance in science and technology seemed to increase the possibility of control-over nature, over the conditions of life. But control always required regulation, rules, implementation; control was, and had to be, vested in law, legal process, and the state.

Id.

15. *Id.* at 51. Friedman continues:

> What has happened since the nineteenth century amounts to a major revolution in legal culture as well as in the social order. Technology has made the world over, and in so doing has vastly reduced certain kinds of uncertainty; it has opened the door to a vastly greater level of demands on government. Slowly people have come to expect more out of government, out of law, out of life. The mechanisms may be obscure, but one key factor is the sense that there are ways to exert control over many of man's ancient contingencies. Technology is crucial in generating this sense of control. Science and machines can conquer disease, lift the curse of early death, protect against disaster, solve the problems of the world. And from physical control the mind moves, in time, to social, collective control.

Id.

16. *Id.* at 57-58.

consent is simply one expression of the growth of expectations in a more certain and predictable existence.

Expectations rise only when there is a possibility of fulfillment. That is certainly the story of the last hundred years. With new expectations comes demand for rights; the legal entitlement to the fulfillment of those expectations. It is not mere coincidence that the growth and development of the doctrine of informed consent in the last forty years parallels the growth and development of new social movements in this country. The rising tide of expectations, or "legal culture," found expression through seminal works that helped spawn or crystallize nascent social movements. In 1962, Rachel Carson published *Silent Spring* which is credited with the birth of the ecology/environmental movement.[17] Likewise, in 1962, Michael Harrington published *The Other America* which is credited with helping to shape the "War on Poverty" and the other programs associated with Lyndon Johnson's Great Society.[18] In 1963, Betty Friedan published *The Feminine Mystique* which gave impetus to the Feminist Movement.[19] In 1965, Ralph Nader published *Unsafe at Any Speed* which is associated with the birth of the consumer safety movement.[20]

II. PRIOR SCHOLARSHIP

In 1984, a student Note in the Georgetown Law Journal explored the application of the doctrine of informed consent to psychotherapy vis-a-vis the early 1980s and concluded:

> Psychotherapy is a commonly used method of dealing with personal problems. Patients, however, are not adequately protected from its risks. The doctrine of informed consent, which functions as a barrier against professional abuse in medical settings, generally has not been applied to the psychotherapist-patient relationship. Applying the doctrine of informed consent to psychotherapy and requiring therapists to give patients an informed consent form before they agree to enter into therapy will ensure that patients are truly aware of all of the risks inherent in treatment before they give the

17. RACHEL CARSON, SILENT SPRING (1962).

18. MICHAEL HARRINGTON, THE OTHER AMERICA: POVERTY IN THE UNITED STATES (Penguin Books 1972) (1969).

19. BETTY FRIEDAN, THE FEMININE MYSTIQUE (1963).

20. RALPH NADER, UNSAFE AT ANY SPEED (1965).

therapist their consent to begin.[21]

The solution suggested by the author was to formalize the informed consent procedure by having three different documents offered to the patient at the initial therapy session including the client's rights statement, the initial contract form and the informed consent form.[22] The clients' rights statement and the initial contract form notify the patient of his or her right to terminate therapy at any time.[23] The informed consent form would disclose risks of psychotherapy.[24] The author notes that such implementation would result in substantial benefit.[25]

Use of these documents would be beneficial in three ways. First, clinicians would adhere more strictly to the doctrine of informed consent.[26] Second, by establishing a standard of disclosure, these documents would establish a professional standard of due care against which a court could measure the performance of a therapist when a plaintiff claims he has been injured during psychotherapy.[27] Third, by demonstrating the substance of a psychotherapist's disclosure, these documents would reduce the problems of proof encountered by both patients and psychotherapists during litigation.[28]

Despite almost twenty years of active development of the doctrine of informed consent and despite the fact that it is generally acknowledged to apply to psychotherapy, it has failed to have a significant impact on the relation between psychotherapist and patient.

III. THE LAW OF INFORMED CONSENT

The doctrine of informed consent originally developed in the context of the delivery of medical care. It came to define the rights and duties of physicians and patients in their therapeutic interactions. Over time, it came to be applied without alteration to the interactions of mental health professionals with their patients or clients.

The law of informed consent is almost exclusively the creation of

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21. Steven Horowitz, Note, *The Doctrine of Informed Consent Applied to Psychotherapy*, 72 GEO. L.J. 1637, 1663 (1984).

22. *Id.* at 1662.

23. *Id.*

24. *Id.*

25. *Id.*

26. *Id.*

27. *Id.*

28. *Id.* at 1662-63.

courts and judges in the last forty years. This decisional law establishes a fairly straightforward mandate regarding the duties owed to a patient or client by a medical or mental health professional. Taken together with the ethical practice codes of the various disciplines within the medical and the mental health enterprise, they set forth a practice standard by which a physician or psychotherapist's professional behavior is judged.

Like all areas of the law, the informed consent doctrine is evolving. It is not static, nor is it identical from state to state.[29] Nevertheless, it has a readily ascertainable general content which practitioners ignore at their peril.

What courts and judges have done, first in medicine and then in the mental health field, is completely shift the decision-making fulcrum. For almost the entire history of the healing arts, there was no notion of informed consent. The Hippocratic Oath contained nothing about it.[30] Only in the last forty years has the doctrine emerged and taken its uneasy place as a determinant of professional behavior. On paper at least, the decisions of the last forty years appear to have completely shifted control over treatment decisions from caregiver to patient.

In *Canterbury v. Spence*,[31] a 1972 federal appeals court discussed the limits of a doctor's obligation to advise his clients of risks.[32] The factual background that led to the appeal was quite straightforward. A young man troubled with back pain submitted to surgery without being told of the risk of paralysis.[33] The surgery cured the pain, but left him

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29. Richard A. Heineman, *Pushing the Limits of Informed Consent: Johnson v. Kokemoor and Physician-Specific Disclosure*, 1997 WIS. L. REV. 1079, 1082-83 (1997). The standard by which the adequacy of a caregiver's disclosure is determined is one such example:

> In its most basic form, the doctrine of informed consent states that physicians have a duty to make adequate disclosures to patients regarding proposed medical treatment so that patients can make knowledgeable choices. The standard for determining the adequacy of such disclosure varies among jurisdictions. Slightly more than half the states still look to the original formulation, what a "reasonable medical practitioner" would provide in the same or similar circumstances. A growing number of states, including Wisconsin, have adopted a more patient-oriented approach. This approach seeks to restrain medical paternalism by looking to the informational needs of the "reasonable patient," rather than relying solely on prevailing medical practice to determine what constitutes material disclosure.

Id.

30. STEDMAN'S MEDICAL DICTIONARY 822 (27th ed. 2000).

31. 464 F.2d 772 (D.C. Cir. 1972).

32. *Id.* at 776.

33. *Id.*

paralyzed.[34] The appellate court wrote:

> True consent to what happens to one's self is the informed exercise of a choice, and that entails an opportunity to evaluate knowledgeably the options available and the risks attendant upon each. The average patient has little or no understanding of the medical arts, and ordinarily has only his physician to whom he can look for enlightenment with which to reach an intelligent decision. From these almost axiomatic considerations springs the need, and in turn the requirements, of a reasonable divulgence by physician to patient to make such a decision possible.[35]

The court's recognition of the shift in decision-making authority was crystal clear:

> The context in which the duty of risk-disclosure arises is invariably the occasion for decision as to whether a particular treatment procedure is to be undertaken. To the physician, whose training enables a self-satisfying evaluation, the answer may seem clear, but it is the prerogative of the patient, not the physician, to determine for himself the direction in which his interests seem to lie. To enable the patient to chart his course understandably, some familiarity with the therapeutic alternatives and their hazards become essential.[36]

How is the scope of this duty to be determined? In other words, by what standard do you decide how much and what kind of information is enough to comply with the standard of care? The doctor argued that he should be held to the standard of what other doctors in the community would disclose.[37] The court ruled that the custom in the medical community is not the yardstick.[38] The court explained:

> In our view, the patient's right of self-decision shapes the boundaries of the duty to reveal. That right can be effectively exercised only if the patient possesses enough information to enable an intelligent choice. The scope of the physician's communications to the patient, then, must be measured by the patient's need, and that need is the

34. *Id.*
35. *Id.* at 780.
36. *Id.* at 781.
37. *Id.* at 779.
38. *Id.* at 796.

> information material to the decision. Thus the test for determining whether a particular peril must be divulged is its materiality to the patient's decision: all risks potentially affecting the decision must be unmasked. And to safeguard the patient's interest in achieving his own determination on treatment, the law must itself set the standard for adequate disclosure.[39]

A thorny question naturally follows: By what method does a doctor identify the type of information that a given patient needs? The court here noted that it is reasonable to expect a doctor to determine what a patient would consider important to his decision.[40] A doctor must use his medical training and experience to sense how an "average, reasonable patient" would react.[41] This court concluded:

> From these considerations we derive the breadth of the disclosure of risks legally to be required. The scope of the standard is not subjective as to either the physician or the patient; it remains objective with due regard for the patient's informational needs and with suitable leeway for the physician's situation. In broad outline, we agree that "[a] risk is thus material when a reasonable person, in what the physician knows or should know to be the patient's position, would be likely to attach significance to the risk or cluster of risks in deciding whether or not to forego the proposed therapy."
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> . . . .
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> The topics importantly demanding a communication of information are the inherent and potential hazards of the proposed treatment, the alternatives to that treatment, if any, and the results likely if the patient remains untreated.[42]

The health care professional's obligation to provide for informed consent includes specifically the obligation to disclose the risk of non-treatment.[43] In *Truman* the California Supreme Court extended liability to include disclosure of the risk of forgoing a diagnostic procedure.[44]

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39. *Id.* at 786-87.
40. *Id.* at 787.
41. *Id.*
42. *Id.* at 787-88.
43. Truman v. Thomas, 611 P.2d 902, 906 (Cal. 1980).
44. *Id.* at 904.

Rena Truman died of cervical cancer in 1970.[45] She was a patient of Dr. Thomas from ages sixty-three to sixty-nine.[46] He never performed a pap smear, which, in all likelihood, would have detected the cancer in time to allow successful treatment.[47] The California Supreme Court framed the issue in terms of whether Dr. Thomas breached his duty of care to Mrs. Truman when he failed to inform her of the potentially fatal consequences of allowing cervical cancer to develop undetected by a pap smear.[48]

The court held the doctor accountable.[49] This case has far-reaching implications for the mental health profession because their mission involves more than just talk. It involves the diagnosis and treatment of things that may well be biological. This could well impose obligations of disclosure regarding the need for psychological, genetic or neurological testing and the expected risks of a failure to have diagnostic tests done.

In *Arato v. Avedon*,[50] the California Supreme Court was asked to extend the reach of the informed consent doctrine to include a requirement that a physician disclose information to a patient that would be material to a patient's non-medical interests.[51] The underlying malpractice action was brought by the wife and children of a deceased pancreatic cancer patient.[52] Plaintiffs claimed that the defendant doctor failed to notify the decedent fully about his illness prior to treatment by failing to disclose the decedent's low statistical life expectancy.[53] The decedent was forty-two when cancer was discovered.[54] Surgery was performed and cancerous tissue was removed, but because of concern that it could recur or spread, he was referred to an oncologist.[55] The oncologist discussed with the decedent the advisability of a course of chemotherapy which, in conjunction with radiation, had shown promise in dealing with this type of cancer.[56] Although at trial there was a dispute about the extent of the informed consent given, the defendant

45. *Id.*
46. *Id.*
47. *Id.*
48. *Id.* at 903.
49. *Id.* at 912.
50. 858 P.2d 598 (Cal. 1993).
51. *Id.* at 599.
52. *Id.* at 600.
53. *Id.*
54. *Id.*
55. *Id.*
56. *Id.* at 600-01.

admitted that neither the operating surgeon nor the oncologist specifically disclosed to the patient or his wife the high statistical mortality rate associated with pancreatic cancer.[57] The defendants testified that Mr. and Mrs. Arato were told at the outset of treatment that most victims of pancreatic cancer die of the disease and that he was at serious or great risk of a recurrence. Further, the doctor warned that should the cancer return, his condition would be judged incurable.[58] Although he had positive results from the chemotherapy, the cancer returned and he died one year and four days after his surgery.[59]

The plaintiffs argued that specific mortality information, in this case that only five to ten percent of those afflicted live as long as five years, was required to constitute a proper informed consent.[60] Plaintiffs claimed that if Mr. Arato had known the statistical probability of his early death, he would have rejected chemotherapy and spent his remaining days in peace with his family while arranging his business and financial affairs.[61] Because he lived with a false hope of cure, plaintiffs claimed, he failed to order his affairs in contemplation of his death.[62] Plaintiffs claimed that this caused the failure of his contracting business and substantial real estate and tax losses.[63]

The court began its legal analysis with homage to *Cobbs v. Grant,*[64] referring to it and its companions from other jurisdictions as "one of the epochal opinions in the legal recognition of the medical patient's protectible interest in autonomous decision-making."[65] The court then reiterated the importance placed on setting or context that *Cobbs* references.[66] The court stated:

> This sensitivity to context seems all the more appropriate in the case of life expectancy projections for cancer patients based on statistical samples. Without exception, the testimony of every physician-witness at trial confirmed what is evident even to a nonprofessional: statistical morbidity values derived from the experience of

57. *Id.* at 601.
58. *Id.*
59. *Id.*
60. *Id.* at 602.
61. *Id.*
62. *Id.*
63. *Id.*
64. 502 P.2d 1 (Cal. 1972).
65. *Arato,* 858 P.2d at 605.
66. *Id.* at 604.

> population groups are inherently unreliable and offer little assurance regarding the fate of the individual patient; indeed, to assume that such data are conclusive in themselves smacks of a refusal to explore treatment alternatives and the medical abdication of the patient's well-being.[67]

In addition to ruling that the extent of the information given was for the jury to decide, the court also held that the statistical data on life expectancy should have been disclosed because it was material to decedent's non-medical interests, his business and investment affairs and the potential adverse impact of his death on them:

> The short answer to plaintiffs' claim is our statement in *Moore* that a "physician is not the patient's financial adviser." From its inception, the rationale behind the disclosure requirement implementing the doctrine of informed consent has been to protect the patient's freedom to "exercise ... control over [one's] own body" by directing the course of *medical treatment.* We recently noted that "the principle of self-determination ... embraces all aspects of medical decisionmaking by the competent adult . . . ." Although an aspect of personal autonomy, the conditions for the exercise of the patient's right of self-decision presuppose a therapeutic focus, a supposition reflected in the text of BAJI No. 6.11 itself. The fact that a physician has "fiducial" obligations which, as the result in *Bowman* illustrates, prohibit misrepresenting the nature of the patient's medical condition, does not mean that he or she is under a duty, the scope of which is undefined, to disclose every contingency that might affect the patient's *nonmedical* "rights and interests."[68]

Although its basic legal contours are well known, the doctrine of informed consent continues to develop. In *Johnson v. Kokemoor*,[69] the Wisconsin Supreme Court significantly extended the doctrine of informed consent to require doctors to disclose to patients comparative risk data, as well as the availability of more experienced physicians.[70]

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67. *Id.* at 607.
68. *Id.* at 608-09 (citations omitted) (emphasis in original).
69. 545 N.W. 2d 495 (1996).
70. *Id.* at 510.

In doing so, the Wisconsin Supreme Court extended the principle of patient autonomy much further than previous informed consent decisions in Wisconsin and other jurisdictions.[71]

Dr. Kokemoor was a neurosurgeon who treated Ms. Johnson for an enlarging aneurysm he diagnosed at the rear of her brain.[72] He recommended and performed surgery in October 1990.[73] The surgery, while a technical success, left Ms. Johnson an incomplete quadriplegic unable to walk or control her bladder. In addition, Ms. Johnson thereafter suffered from speech and vision impairment.[74] At trial she alleged that he had overstated the need for surgery and exaggerated his level of experience in performing this type of surgery.[75]

The court concluded that disclosure requirements must be set by the patients' needs and that such needs included information that a reasonable person would deem necessary for an intelligent decision.[76] The court found that Dr. Kokemoor failed to communicate the substance of his actual experience in performing this type of procedure as required.[77] The court next found that he had a duty to disclose comparative risk data that would show the morbidity and mortality rates of physicians performing a given procedure with varying degrees of experience.[78] The court also concluded that Dr. Kokemoor had a duty to refer her to more experienced physicians.[79] This follows logically from the conclusion that a duty existed to disclose physician experience and comparative risk data.[80] It also represents a large extension of the informed consent doctrine.[81]

The law of informed consent in the mental health context, as applied to psychotherapy, is not in the least bit complicated, at least in the abstract. It has, for all practical purposes, simply been borrowed from the law of informed consent that developed and has been applied to the

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71. Richard A. Heinemann, Note, *Pushing The Limits Of Informed Consent: Johnson V. Kokemoor And Physician-Specific Disclosure*, 1997 Wis. L. Rev. 1079, 1099 (1997) (providing an extensive discussion of the development of the doctrine of informed consent and the extension of the doctrine by the Wisconsin Supreme Court).

72. *Johnson*, 545 N.W. 2d at 498.

73. *Id.*

74. *Id.* at 499.

75. *Id.*

76. *Id.* at 504.

77. *Id.* at 505.

78. *Id.* at 507.

79. *Id.* at 509.

80. Heinemann, *supra* note 71, at 1108.

81. *Id.*

practice of medicine.[82]

IV. MENTAL ILLNESS AND ITS COSTS

The dawn of a new millennium characteristically provokes a variety of social and cultural phenomena. Doomsday cults gathered and waited for the end of the world. Those with means sought a memorable way to usher in this new and different world. Some chose a jet plane flying to catch the dawn on January 1, 2000. Others, perhaps less adventurous but traditionally romantic, chose Paris. For the less sedate with the urge to really party there was Rio de Janeiro or, if the budget was limited, perhaps Times Square, New Orleans or Las Vegas. Even the "stay at homes" felt compelled to observe the passing of the twentieth century into the twenty-first.

But, despite the heady and celebratory atmosphere, few things changed in the real world as the calendar rolled from one year to the next. Human suffering took no vacation. Cancer and AIDS continued to wreak havoc on the lives of countless millions throughout the world. Indeed, sub-Saharan Africa faces the grim prospect of an AIDS epidemic that will decimate the population of countless nations.[83]

Against this contradictory tableau of celebration and misery, we wake almost daily to new announcements of medical breakthroughs. We are soon to see the complete mapping of the human genome and with it the heightened promise of cure for many of humanity's greatest scourges. No disease or problem seems beyond the ultimate reach of medical or scientific discovery. Researchers are coming closer to understanding the riddle of aging and with that understanding comes the prospect, literally, of a fountain of youth.

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82. O. BRANDT CAUDILL & KENNETH S. POPE, LAW AND MENTAL HEALTH PROFESSIONALS: CALIFORNIA 551 (American Psychological Association 1995) ("The doctrine of informed consent was articulated first in court cases involving physicians; however, the requirement that a patient give informed consent to treatment is equally applied to licensed or certified MHPs [mental health professionals]"). *See also* Rains v. Superior Court, 198 Cal. Rptr. 249 (Ct. App. 1984), Barclay v. Campbell, 704 S.W.2d 8 (Tex. 1986), Aiken v. Clary, 396 S.W. 668 (Mo. 1965).

83. John Christensen, *Aids in Africa: Dying by the numbers, at* http://www.cnn.com/SPECIALS/2000/aids/stories/overview/ (last visited Aug. 13, 2002). Estimates from UNAIDS, an umbrella group for five United Nations groups, the World Bank and the World Health Organization, are that 34.5 million people in the world have AIDS and 24.5 of them live in sub-Saharan Africa. Of the 5.4 million new AIDS infections in 1999, 4 million are in Africa. In 1999, 2.8 million people died worldwide of AIDS, 85 % of them in Africa; In 1999, 13.2 million children were orphaned by AIDS worldwide, 12.1 million of them in sub-Saharan Africa. *Id.*

Despite these stunning advances, mental illness continues to resist the efforts of researchers to solve its mysteries. It is commonplace in medical practice that diagnosis and treatment remain a challenge because the human body does not reveal its secrets easily. The nervous system, principally the brain, remains still mysterious and complex and, in some ways, beyond imagination. This is not to say that advances in the understanding of mental illness, such as schizophrenia, bipolar disorder, major depression or obsessive-compulsive disorder have been non-existent. Researchers all over the world continue to seek answers to these riddles of the brain and advances have been made. However, one of the fundamental goals of all medical research is to understand the cause or etiology of a disorder. Successful treatment of a disease or disorder ultimately depends on this.[84]

To date, unfortunately, the etiology or cause of most of these disorders remains "unknown" and thus in a very basic sense we remain in the dark about the cause or causes of major mental illness.[85]

What is mental illness? What is this "thing" that seems to possess some human beings that makes them different from the rest. Over the centuries, the names for these people have changed. People with mental illnesses have been known as, hysterics, lunatics, demented, idiots, and insane. What has not changed is their suffering and the suffering and loss experienced by family, friends and the community at large.

Terms such as mental illness and mental health are difficult to define. Both terms are defined by reference to different points on the same continuum of mental functioning. Both terms are descriptive of a condition or state of being, not a tangible thing.[86]

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84. PAUL R. MCHUGH, M.D. & PHILLIP R. SLAVNEY, M.D., THE PERSPECTIVES OF PSYCHIATRY 50 (Johns Hopkins 2d ed. 1998) ("Truly rational treatments, that is, treatments that do more than ameliorate symptoms, can emerge only with the complete understanding of the cause (etiology) of the pathological process.").

85. 2 KAPLAN & SADOCK'S COMPREHENSIVE TEXTBOOK OF PSYCHIATRY 2783 (Lippincott Williams et al. eds., 7th ed. 2000) (describing schizophrenia as "a heterogeneous disorder of unknown cause").

86. U.S. SURGEON GENERAL, MENTAL HEALTH: A REPORT OF THE SURGEON GENERAL 4-5 (1999) *available at* http://www.surgeongeneral.gov/library/mentalhealth/pdfs/C1.pdf. The Surgeon General describes these terms as follows:

> "[M]ental health" and "mental illness" are not polar opposites but may be thought of as points on a continuum. *Mental health* is a state of successful performance of mental function, resulting in productive activities, fulfilling relationships with other people, and the ability to adapt to change and to cope with adversity. Mental health is indispensable to personal wellbeing, family and interpersonal relationships, and contribution to community or society. It is easy to overlook the value of mental health until problems surface. Yet from early childhood until death, mental health is the springboard of thinking

These terms are quite general in their definition. It is almost impossible to define these terms with any more specificity. Nevertheless, these terms accurately capture the qualities that distinguish humans on that continuum that describes our mental and emotional state.

We are only now beginning to acknowledge the huge personal and social costs associated with mental illness.[87] Recognition has come as a result of large-scale epidemiology studies and sophisticated economic analysis. Epidemiology studies the pattern of disease in a given population. It is a specialty that provides crucial assistance in mapping disease. It has its own nomenclature to describe important facts. "Incidence" refers to new cases of a given condition occurring within a specific period of time. "Prevalence" refers to cases (existing and new) that exist at a given point in time or during a specific period of time. Although estimates have varied over the years, current estimates are that at least one in five people have a diagnosable mental disorder during the course of a year.[88]

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and communication skills, learning, emotional growth, resilience, and self-esteem. These are the ingredients of each individual's successful contribution to community and society. . . .

. . . .

Mental illness is the term that refers collectively to all diagnosable mental disorders. Mental disorders are health conditions that are characterized by alterations in thinking, mood, or behavior (or some combination thereof) associated with distress and/or impaired functioning. Alzheimer's disease exemplifies a mental disorder largely marked by alterations in thinking (especially forgetting). Depression exemplifies a mental disorder largely marked by alterations in behavior (overactivity) and/or thinking (inability to concentrate). Alterations in thinking, mood, or behavior contribute to a host of problems-patient distress, impaired functioning, or heightened risk of death, pain, disability, or loss of freedom.

Id.

87. *Id.* at 3. The Surgeon General's Report begins with this sobering statement:

The report was prepared against a backdrop of growing awareness in the United States and throughout the world of the immense burden of disability associated with mental illnesses. In the United States, mental disorders collectively account for more than 15 percent of the overall burden of disease from all causes and slightly more than the burden associated with all forms of cancer. These data underscore the importance and urgency of treating and preventing mental disorders and of promoting mental health in our society.

Id.

88. U.S. SURGEON GENERAL, MENTAL HEALTH: A REPORT OF THE SURGEON GENERAL 46 (1999) *available at* http://www.surgeongeneral.gov/library/mentalhealth/pdfs/C2.pdf. The Report continues:

This estimate comes from two different epidemiological surveys: the Epidemiologic Catchment area (EAC) study of the early 1980s and the National Comorbidity Survey (NCS) of the early 1990s. Those surveys

The cost of mental illness in terms of human misery and suffering is extremely difficult to quantify but not terribly difficult to appreciate. However, economists have devoted great energy and effort to quantifying the costs of mental illness, dividing costs into direct and indirect costs.[89] When viewed in the aggregate, these costs are staggering.[90]

Dollars are the most obvious and direct measure of cost. However, economists have developed sophisticated alternative methods to identify and evaluate costs. Recently, a World Bank World Health Organization publication conducted a study of the indirect costs of mental disorders in relation to years lived with a disability, with and without years of life lost due to premature death.[91] The study uses the term Disability Adjusted Life Years ("DALYs") to describe the burden of disability and premature death resulting from mental and physical disorders throughout the world.[92] This study found that mental disorders account for more than fifteen percent of the burden of disease in established

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defined mental illness according to the prevailing editions of the *Diagnostic and Statistical Manual of Mental Disorders* (i.e., DSM-III and DSM-III-R). The surveys estimate that during a one year period, 22 to 23 percent of the U.S. adult population- or 44 million people-have diagnosable mental disorders, according to reliable, established criteria. In general, 19 percent of the adult U.S. population have a mental disorder alone (in one year); 3 percent have both mental and addictive disorders; and 6 percent have addictive disorders alone. Consequently, about 28 to 30 percent of the population have either a mental *or* addictive disorder.

Id. (citations omitted).

89. *Id.* at 49. The Report further comments:

> Direct costs correspond to spending for treatment and rehabilitation nationwide.
>
> When economists calculate the costs of an illness, they also strive to identify indirect costs. Indirect costs can be defined in different ways, but here they refer to lost productivity at the workplace, school, and home due to premature death or disability. The indirect costs of mental illness were estimated in 1990 at $78.6 billion (Rice & Miller, 1996). More than 80 percent of those costs stemmed from disability rather than death because mortality from mental disorders is relatively low.

Id.

90. *Id.* The Surgeon General's Report does not mince words:

> The costs of mental illness are exceedingly high . . . . The direct costs of mental health services in the United States in 1996 totaled $69.0 Billion. This figure represents 7.3 percent of total health spending. An additional 17.7 billion was spent on Alzheimer's disease and $12.6 billion on substance abuse treatment.

Id.

91. THE GLOBAL BURDEN OF DISEASE (C.J.L. Murray & A.D. Lopez eds., Harvard School of Public Health 1996).

92. *Id.*

market economies; unipolar major depression, bipolar disorder, schizophrenia, and obsessive-compulsive disorder are found to be among the top ten leading causes of disability worldwide.[93]

Another way to view the cost of mental illness is to consider cost from the standpoint of the utilization of mental health services for the past several decades. For example, between 1970 and 1988, the number of private psychiatric hospitals grew nearly 200%, from 150 to 444.[94] "Between 1965 and 1990, the number of inpatient episodes in mental health organizations in the United States increased steadily from 1,565,525 to 2,262,474; whereas the number of psychiatry outpatient episodes nearly quintupled from 1,071,000 to 5,810,405, and the number of partial care admissions increased almost ten-fold from 55,486 to 544,201."[95] When the dollars spent on mental health care services and research are combined we see:

- The National Institute of Mental Health (NIMH) budget increased from $1,119,000 in 1945 to $178,067,000 in 1979, to over an estimated $661,290,000 in 1996, and this current estimate does not include Substance Abuse and Mental Health Services Administration (SAMHSA), which represents about $2 billion in federal funding (National Institutes of Health, 1996).
- Total Expenditures by mental health organizations in the United States, as measured in current dollars, increased more than eightfold between 1969 and 1990, from $3.3 to $28.4 billion (*Redick et al*, 1994b).[96]

The costs of mental illness are both personal and subjective as well as collective and objective. The personal and subjective involve the narratives of individuals and families that live with mental illness. The collective and objective involve the cost to the nation in reduced or lost productivity (indirect costs) and in the medical resources used for care, treatment and rehabilitation (direct costs).

A central argument of this article is that when scarce resources are devoted to treatments that do not work or cause harm, something more than a misallocation of resources is happening. Such actions call into

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93. *Id.*

94. John P. Docherty, *Market-Based Health Care Reform and the Cost-Effectiveness of Psychotherapy, in* COST–EFFECTIVENESS OF PSYCHOTHERAPY: A GUIDE FOR PRACTITIONERS, RESEARCHERS AND POLICYMAKERS 1, 3 (Nancy E. Miller & Kathryn M. Magruder eds., 1999) (citation omitted).

95. *Id.* (citation omitted).

96. *Id.*

question the methods and motives of the profession engaged in this activity. Regarding unproved psychotherapy techniques, those involved include psychiatrists, psychologists, social workers, family therapists and counselors.

V. PSYCHOTHERAPY AND ITS COSTS

Psychotherapy has many meanings and one must understand these various meanings in order to understand and appreciate its historical and contemporary impact. It is both a thing and a symbol, a treatment modality and a metaphor. Its meaning and its utility depend on whether one is a believer or a skeptic, but its social and cultural impact is undeniable. Psychotherapy is the principal product, service or good of the mental health profession. For reasons already alluded to, the mental health profession has a pervasive and ever increasing impact on American society.[97]

In reflecting on the profound and far-reaching impact of the mental health enterprise today, a social historian described psychotherapy as "The Romance of American Psychology."[98] We have come to think

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97. TANA DINEEN, MANUFACTURING VICTIMS: WHAT THE PSYCHOLOGY INDUSTRY IS DOING TO PEOPLE 17 (1996). Dineen wrote:

> No matter where one turns, one finds the effects of the psychology industry. Its influence extends across all aspects of life, telling us how to work, how to live, how to love and even, how to play. We are confronted by psychologists expounding their theories on the endless list of TV talk-shows like Oprah and Geraldo, on the TV news journals and in the supermarket tabloids, on subjects as wide ranging as the re-caps of the O.J. Simpson trial or the epidemic of post traumatic stress disorder in Bosnia.

Id.

98. ELLEN HERMAN, THE ROMANCE OF AMERICAN PSYCHOLOGY 1 (1995). Herman wrote:

> Psychological insight is the creed of our time. In the name of enlightenment, experts promise help and faith, knowledge and comfort. They devise confident formulas for happy living and ambitious plans for dissolving the knots of conflict. Psychology, according to its boosters, possesses worthwhile answers to our most difficult personal questions and practical solutions for our most intractable social problems.
>
> In the late twentieth-century United States, we are likely to believe what psychological experts tell us. They speak with authority to a vast audience and have become familiar figures in most communities, in the media, and in virtually every corner of popular culture. Their advice is big business. It is taken for granted that they have a right to a central place in debates about the current state and future direction of American society. From families to governments, from abuse and recovery to war and urban violence, from the mysteries of individual subjectivity to the manifest problems of our collective social life, few institutions, issues, or spheres of existence remain untouched by the progress of psychology in American society.

about life in psychological terms and our everyday conversation is full of the jargon of the profession.[99] It so much a part of popular culture that it is even in our music.[100]

Precise terms to describe the tasks mental health professionals do are quite elusive. Equally elusive is a precise definition of whom it is that provides psychological services. There was a time when mental health services were provided by psychologists or psychiatrists. Some called themselves psychoanalysts, claiming to strictly follow the tenets of their master, Sigmund Freud. This is clearly no longer the case. Today we have psychologists, psychiatrists, clinical social workers, marriage and family counselors, as well as advisors and helpers of all different backgrounds. Some are licensed, some are not; some have special education and training, others do not.[101]

Similarly, the term psychotherapy has a very ambiguous meaning. It is used in so many different ways to describe so many different things that it is hard to know what a user really means when he or she says "psychotherapy." This definitional ambiguity is acknowledged when one reads the texts and treatises on psychotherapy.[102]

Id.

99. For example, we speak of repression, denial, Freudian slips, defense mechanisms, and our inner child.

100. *See e.g.*, Eagles, *Get Over It, on* HELL FREEZES OVER (Black Cypress Music 1994). The Eagles sing:

> I turn on the tube and what do I see
> A whole lotta of people cryin' "Don't blame me"
> They point their crooked little fingers at everybody else
> Spend all their time feelin' sorry for themselves
> Victims of this, victims of that
> Your momma's too thin; your daddy's too fat
> . . . .
> You drag it around like a ball and chain
> You wallow in the guilt; you wallow in the pain
> You wave it like a flag, you wear it like a crown
> Got your mind in the gutter, bringin' everybody down
> Complain about the present and blame it on the past
> I'd like to find your inner child and kick its little ass.

Id.

101. Ronald Fox, *Training Professional Psychologists for the Twenty—First Century*, 3 AMERICAN PSYCHOLOGIST 49 (1994) ("The general public often has difficulty in understanding the differences between professional psychologists and other types of psychologists, between professional psychologists and psychiatrists, between psychologists and counselors, or between psychologists and a variety of other professionals who deal with emotional, health, and behavioral problems.").

102. LEWIS R. WOLBERG, THE TECHNIQUE OF PSYCHOTHERAPY 3 (Grune & Stratton 4th ed. 1988). Wolberg acknowledges the elusive meaning of "psychotherapy":

One common way of defining the term is through legislation. California's definition of the term "psychotherapy" is typical of this approach. The statutory definition, like those definitions previously mentioned, is broad and inherently ambiguous.[103]

The Surgeon General's Report defines psychotherapy in a slightly different fashion as a type of learning in which a mental health

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> Few words in the lexicon of the mental health field are as ambiguous as the term "psychotherapy." It is loosely employed to connote, among other meanings, helping, treating, advising, guiding, educating, and even influencing. Definitions of psychotherapy are often bridled to fields of disciplinary operation, e.g., psychiatry, psychology, casework etc., sanctuaries for such characterizations being sought in specialized societies. This diffuseness has converted the arena of psychotherapy into a swamp of murky ideas, fostering many divergent theories and techniques. Yet a brief and precise description of therapy is important if no more than to circumscribe boundaries of operation and for purposes of hypothetical construction and empirical study.

Id. After noting the definitional challenge, Wolberg offers this definition:

> Psychotherapy is the treatment, by psychological means, of problems of an emotional nature in which a trained person deliberately establishes a professional relationship with the patient with the object of (1) removing, modifying, or retarding existing symptoms, (2) mediating disturbed patterns of behavior, and (3) promoting positive personality growth and development.

Id. See also, JEROME FRANK, PH.D. & JULIA B. FRANK, M.D., PERSUASION AND HEALING 2 (The Johns Hopkins University Press 3d ed. 1991). Dr. Frank, one of the giants of the field, described psychotherapy as a particular kind of influence:

> Since practically all forms of personal influence may affect a person's sense of well-being, the definition of psychotherapy is of necessity somewhat arbitrary. We shall consider as psychotherapy only those types of influence characterized by: 1) a healing agent, typically a person trained in a socially sanctioned method of healing believed to be effective by the sufferer and by at least some members of his or her social group. The healing agent need not be a professional. Other types include a fellow sufferer, a group of fellow sufferers with or without a trained leader, or even a book or audiotape invested by the sufferer with healing powers. Except where specifically indicated, the healing agents we shall consider are persons, 2) a sufferer who seeks relief from the healer, 3) a healing relationship-that is, a circumscribed, more or less structured series of contacts between the healer and the sufferer in which the healer, often with the aid of a group, tries to bring about relief of symptoms. This relief is typically accompanied by changes in emotional state, attitudes, and behavior. Except in cases of involuntary treatment, all concerned believe the changes to be beneficial. Although physical and chemical adjuncts may be used, the healing influence is exercised primarily by words, acts, and rituals in which sufferer, healer, and sometimes a group participate jointly.

Id.

103. CAL. BUS. & PROF. CODE § 2903 (West 1990) ("Psychotherapy within the meaning of this chapter means the use of psychological methods in a professional relationship to assist a person or persons to acquire greater human effectiveness or to modify feelings, conditions, attitudes and behavior which is emotionally, intellectually, or socially ineffectual or maladjustive.").

professional seeks to help those with mental disorders or mental health problems through a process accomplished largely by the exchange of verbal communication.[104]

The term psychotherapy is ubiquitous in its application and covers so much territory that it is difficult to exclude from its definition anything involving a listener for a fee with the goal of improvement in one's life. Trying to get accurate figures to describe the mental health enterprise is most difficult because of the vagueness and ambiguity of the bread and butter terms that define the basic activities of the mental health profession.

Beyond the vagueness of the terms is another set of questions tied to the issue of cost. Does psychotherapy do any good and can it do any harm? Until recently the first question was simply and always assumed to be "yes", at least by most of the public and most practitioners. As to its potential harm, the historical record echoes with the sounds of victims.[105] In truth, psychotherapy is a very potent tool both in terms of helping to alleviate human distress and also in terms of causing great human suffering.

Although managed care is no panacea (and in many cases has created its own set of problems),[106] it has resulted in some positive change. It has forced a spotlight on the practices of medicine and the mental health enterprise. Those who have been impacted by managed care sneeringly refer to its bottom line mentality and its sole focus on profit and loss. Yet, its insistence on an economic analysis of cost and benefit has laid bare the most glaring truth about the mental health enterprise. It has, even more than medicine, remained nearly immune to the traditional requirements of economic reality, of cost/benefit and the bottom line.[107]

Before the growth of managed care, no one seriously required a demonstration that treatment of mental health was actually effective. Nor had there ever been scrutiny of its costs and whether its costs reflected the best allocation of resources to deal with emotional problems. Now these questions are unavoidable and the mental health

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104. U.S. SURGEON GENERAL, MENTAL HEALTH: A REPORT OF THE SURGEON GENERAL 65 (1999) *available at* http://www.surgeongeneral.gov/library/mentalhealth/pdfs/C2.pdf.

105. *See generally,* ELLIOTT S. VALENSTEIN, GREAT AND DESPERATE CURES (1986); DINEEN, *supra* note 97; SINGER & LALICH, *supra* note 5; AYELLA, *supra* note 5.

106. *HMO HELL*, NEWSWEEK, Nov. 8, 1999, at 58; Christine Gorman, *Playing the HMO Game*, TIME, July 13, 1998, at 22.

107. MILLER & MAGRUDER, *supra* note 6, at xvi ("Until recently, psychotherapy, like much of medicine, remained relatively unconstrained by limits of time, data on outcomes, financial expenditures, or by growing evidence of significant regional variation in practice patterns unrelated to outcome.").

profession is scrambling to come up with justifications for its practices.[108]

It is unfair to stereotype the response of the mental health profession to this new reality. However, there has been far more energy and effort devoted to attacking managed care than to coming to terms with the glaring inadequacies in the mental health profession brought to light by managed care. One article likened managed care and psychotherapy to life under the Nazi regime,[109] another likened it to rape.[110] Long on rhetoric and regret for the loss of power and autonomy, this type of response is indicative of a profession suffering from one of its favorite conditions—denial.

Denial may be understandable. The shift from a position of unquestioned social eminence and power to one where that authority is increasingly questioned and doubted has been a very rapid one. It is not surprising that there has been a great deal of resistance to the new demands for accountability and a displaced anger directed at the messenger. But, the messenger can be demonized for only so long and eventually, the same questions remain. What do you do? What does it cost? Does it work? How does it compare cost wise with other modes of treatment?[111]

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108. *Id.* at xv. Miller and Magruder wrote:

> Psychotherapy is one of the predominant modes of mental health treatment today, yet relatively little is known about how psychotherapy is used, its cost, or its outcome, in "real world" settings. The absence of such information, since the advent of health care reform efforts, has public health officials, practitioners, researchers, and policymakers facing serious questions regarding accountability-how well do these therapies achieve their intended goals, and at what cost.

Id.

109. Karen Shore: *Managed Care The Subjugation of a Profession,* 14 PSYCHOTHERAPY IN PRIVATE PRACTICE 2 (1995).

110. Ronald E. Fox, *The Rape of Psychotherapy,* 26 PROFESSIONAL PSYCHOLOGY: RESEARCH & PRACTICE 2 (1995).

111. *See* Bob Dylan, *The Times They Are a Changin', on* THE TIMES THEY ARE A CHANGIN' (Warner Bros., Inc. 1963). Dylan sang:

> Come gather 'round people
> Wherever you roam
> And admit that the waters
> Around you have grown
> And accept it that soon.
> You'll be drenched to the bone.
> If your time to you
> Is worth savin'
> Then you better start swimmin'
> Or you'll sink like a stone

Although sometimes lost in the hue and cry over managed care, the concerns about the delivery of health care and mental health services in general are profoundly important. If this article were written a decade ago, the economic and social landscape would be very different. Ten years ago the social mood involved budget deficits, unemployment, a stagnating economy and a huge and expanding national debt.[112] Today, we have had a run of record prosperity with, at least for the foreseeable future, record surpluses in state and federal hands. However, despite the fact that the United States spends more on health care than any other nation, our health care system ranks only thirty-seventh in the world according to a report on the quality of health systems released June 21, 2000 by the World Health Organization.[113] Despite being awash in MRIs, CT scanners and pricey drugs, the United States ranks in the lowest twenty-five percent of industrialized countries when it comes to infant mortality and life expectancy.[114] Despite the current budget surplus, decisions about the allocation of resources are made from the basis of scarcity. There are a finite amount of resources that can be allocated to social problems. These problems compete for attention and dollars. Managed care is simply one manifestation of a new and powerful social and political force that is concerned with reducing costs, increasing quality of service and broadening access to care. This new focus has important and unavoidable implications for the practice of psychotherapy.

Psychotherapy is not simply earnest discussions between a therapist and a patient (or in the case of group therapy, between a therapist and a selected group of patients). Nor is psychotherapy viewed as an end in itself, a private and confidential discussion between a trusting and needy patient and a wise and compassionate therapist. The grist of the psychotherapy mill has ceased being private and confidential. It is now only the preliminary part of a secular liturgy whose end point is in court or the media. Psychotherapy not only focuses on the internal psychic life of the patient. It now confers social status. Although harsh social stigma still attaches to the label mental illness, it does not attach to those who receive psychotherapy. Psychotherapy and in particular psychoanalysis, always provided some cachet. It was the darling of the

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For the times they are a-changin'.

Id.

112. Rosie Mestel, *Despite Big Spending, U.S. Ranks 37th in Study of Global Health Care*, L.A. TIMES, June 21, 2000 at A20.

113. *Id.*

114. *Id.*

intelligencia who believed that one could not be truly wise unless one had been psychoanalyzed.

Today, psychotherapy confers status. It confers victim status on some and perpetrator or abuser status on others. Conferring victim status absolves some of responsibility for the patients' actions. Conferring abuser status on others brands them evil and malevolent.

Today, psychotherapy creates collective narratives that have great social impact. Psychotherapy now has an avowedly public aspect, most typically confessional in nature. The fifty minute hour now involves the requisite fifteen minutes of fame as psychotherapy patients confess publicly to being perpetrators or victims of abuse.

This new facet of psychotherapy helps to define the public consciousness about life in general. It helps create a shared social consciousness by virtue of the values and beliefs held by the therapists and the values, beliefs and actions of the patients. The products of psychotherapy become part of larger social movements. They are important, for example, in their impact on and interrelationship with fundamentalist Christianity, the anti cult movement, the child protection movement, and the survivor or recovery movement. As an example, there remains a widespread "popular belief in the existence [and operation] of an international conspiratorial satanic blood cult . . . promoted primarily by public declarations of alleged cult survivors, whose" public statements grew from psychotherapy and are then legitimated by the psychotherapist.[115]

To the extent that such social movements are the products of irrationality and error, they have a great cost.[116] The societal costs are the ripple effect from their use. One such example involves the use of Satanic Ritual Abuse Therapy in the criminal courts.

Satanic Ritual Abuse Therapy ("SRA Therapy") is a type of psychotherapy built upon numerous questionable assumptions. It assumes that there is a newly discovered type of crime ("Satanic Ritual Abuse" or "SRA") heretofore cloaked in secrecy. It further assumes that thousands of adults are the unknowing victims of SRA, troubled by a variety of psychological problems but unaware of the root cause of the problem due to severe physical, emotional or sexual abuse during

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115. Sherrill Mulhern, *Satanism And Psychotherapy: A Rumor In Search Of An Inquisition, in The Satanism Scare* 145-74 (James T. Richardson et al. eds., Aldine De Gruyer 1991).

116. See Samuel Knapp & Leon VandeCreek, *Risk Management For Psychologists: Treating Patients Who Recover Memories Of Childhood Abuse,* 27 PROFESSIONAL PSYCHOLOGY: RESEARCH AND PRACTICE 452-59 (Oct. 1996).

childhood.

SRA Therapy is based on the assumption that extreme traumatic childhood events of abuse were repressed. Although there is no clear definition of repression, the basic premise is that particularly shocking events can trigger the mind to hide the memory away from conscious awareness.[117] The theory then is that the presence of repressed memories in the unconscious yields unpleasant psychological symptoms.[118]

Unpleasant psychological symptoms can only be relieved if the individual can recover the traumatic memories and deal with them consciously. By definition, survivors of SRA have repressed these memories of the traumatic events and therefore are unaware. Thus, psychotherapy is devoted to helping the individual recover the memories through a variety of memory recovery techniques such as age regression, guided imagery, sodium amytal, and hypnosis.

Common recollections from SRA Therapy include blood drinking, ritual sexual acts involving children and human sacrifice both by others and the individual "survivor."[119]

Criminal prosecutors' use of SRA Therapy is well documented in California. The most well known use has been by the Kern County District Attorney's Office in Bakersfield, California.[120] In the 1980s and early 1990s, a notorious series of criminal prosecutions took place all involving a claim of an active satanic ring.[121] Hundreds of people were prosecuted and convicted of crimes using now discredited techniques surrounding SRA theories.[122]

The principal culprits in this exercise were the prosecutors' use of

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117. Elizabeth F. Loftus, *The Reality of Repressed Memories*, 48 AM. PSYCHOLOGIST 518, 535 (May 1993).

118. *Id.*

119. *See generally*, THE SATANISM SCARE (James T. Richardson et al. eds., 1991).

120. EDWARD HUMES, MEAN JUSTICE: A TOWNS TERROR, A PROSECUTOR'S POWER, A BETRAYAL OF INNOCENCE 373-74 (1999) (documenting this unfortunate history).

121. *Id.*

122. *Id.* Humes summarized the product of this sad chapter in Bakersfield's history as follows:

> With the release of the Kniffens and McCuans and Harold Weimer [in 1996 by an appellate court], the number of people freed from erroneous or wrongful prosecutions in recent years in Bakersfield reached at least ninety one . . . . The number is particularly extraordinary because the American justice system is designed to make such reversals extremely difficult, with laws that favor prosecutors over defendants at virtually every juncture once a person is pronounced guilty.

Id.

mental health professionals' testimony about the "evidence" derived from the discredited techniques surrounding SRA Therapy.[123]

How do you compute the cost of years of freedom stolen from several hundred innocent men and women, who languished in prison for over a decade, convicted with the help of mental health professionals relying on a discredited psychotherapy technique? What is the social cost of years of lives wasted and never to be reclaimed, relationships damaged or destroyed, families torn asunder? Finally, what is the cost to the integrity of a legal system that presides over such activities and allows this type of testimony?

VI. THE GROWTH OF PSYCHOTHERAPY

The history of psychotherapy, particularly in the last forty years, reflects the development of a multitude of new and emerging psychotherapy techniques. Many of these techniques appear to lack efficacy, and some do actual harm.

The mental health profession has a long history of exposing the unsuspecting to the untested with disastrous results. From lobotomies and insulin comas, to alien abduction therapy, satanic ritual abuse therapy, facilitated communications, the sandtray and reparenting, the profession continues to promote and use a variety of unproved and potentially harmful psychotherapeutic techniques. It continues to allow patients to be exposed to new and emerging therapeutic techniques without validation of their efficacy or safety and without warning labels, which are required as an ordinary component of the informed consent process.

There are numerous examples of newly emerging therapeutic techniques that have been introduced and used despite any showing of efficacy.[124]

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123. *Id.* *See generally*, DEBBIE NATHAN & MICHAEL SNEDEKER, SATAN'S SILENCE (1995).

124. SINGER & LALICH, *supra* note 5, at 3-4 (In 1995, Singer and Lalich inventoried many, but not all, of the therapeutic techniques available today). They wrote:

> The general public today is confronted with a panorama of theories and practices said to address a variety of symptoms and disorders, ranging from the supposedly scientific to the ludicrous and unchallenged. An array of therapists, counselors, and healers promote the following techniques, among others:
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> | Flower essence therapy | Hypnotherapy |
> | Chakra and aura readings | Angel therapy |
> | Sexual touching | Color therapy |
> | Soul work | Yoga |

Although many critics attribute much of this to New Age beliefs, the recent expressions of unproved psychotherapy techniques are simply part of a long tradition in the mental health field.[125]

Humor therapy	Past-life regression
Guided visualization	Alchemy hypnotherapy
Karmic astrology	Channeling
Alien-abduction therapy	Herbal brews
White goddess healings	Drumming
Crystal healings	Intuitive readings
Dreamwork	Breathwork
Mythmaking	Vibrational bodywork
Trance treks	Video work
Guided meditation	Rapid eye technology
Tarot readings	Overleaf charts
Aromatherapy	Ritual ceremonies
Chemical inductions (use of LSD, sodium amytal, and other drugs)	Shamanic counseling
Rebirthing	Facilitated communications
Intuition Development	Hot tubbing
Fighting	Floating
Tours to sacred sites	Depossession

These techniques-for which a consumer can pay anywhere from less than one hundred to several thousand dollars-are purported to bring about results such as the following:

Inner-child healing	Spirit releasement
Clear frequencies	Disharmonious energies release
Revelatory past-life journeys	Inner-child bonding
Smooth life transitions	Spiritual healing
Parents' programming release	Inner purpose revealed
Alignment of fluid	Becoming a galactic
Intelligence systems	Human being
Reclaiming your missing self	Deep, transformative healing
The body's energies rebalanced	Sexual karma revealed
Insightful shamanic journeys	Lifelong happiness
Personal empowerment	Transforming dragons
Pain control	Soul retrieval
Planetary healing	Past-life integration
Soul integration	Knowing essence twins.

Id. at 4-5.

125. VALENSTEIN, *supra* note 105, at 291-92. Valenstein reflects on the history of the mental health profession (and medicine in general) as follows:

> Although it may be comforting to believe that the forces responsible for the wide acceptance of prefrontal lobotomy and the other somatic therapies described in this book are all behind us, they are, in truth, part of the very bone and marrow of the practice not only of psychiatry but of all medicine. There are today no fewer desperate patients and desperate families; premature reports of spectacular cures with minimal risks are still accepted uncritically; the popular media promote innovative therapies even more

To understand the limits of informed consent one need look no further than the special defining characteristics of the population served by medicine and psychotherapy.[126] That is the desperation, demoralization and hopelessness of those afflicted with mental or physical illness. The hopeless and the desperate, in particular, are prey to the promoters of any new therapeutic enthusiasm. Informed consent shrivels into a withered vine in the face of a therapist who confidently says, "I have seen excellent results using this technique" or "I have a great deal of clinical experience using this method." Personal testimonials from self-interested therapists have the capacity to engage and seduce the desperate and reduce informed consent to nothing more than "fine print."

There are literally hundreds of different psychotherapeutic techniques that are marketed and practiced today. These are not simply some abstraction that appears in books and articles written for a self interested few. These therapy techniques have immense impact on society and individual lives both in terms of public and personal costs. Singer and Lalich's list is far from exhaustive.[127] Many of these techniques have arrived on the social landscape as public concern over the welfare of children has grown. Facilitated communications, Satanic ritual abuse therapy, and Sandtray therapy are a few of the many techniques.

There is a great deal written regarding each. However, there is virtually no good research literature involving any of these techniques. Regrettably, this is not unusual. It reflects one of the characteristics unique to the mental health profession: Proof that something actually works is not required. When research is done, it is like cotton candy, tasty but without substance. The three techniques referenced above are very representative of the development and use by the mental health profession of a steady stream of supposedly innovative therapy

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enthusiastically; economics is no less an influence on the selection of treatment; conflicts persists within and between specialties; and ambitious physicians still strive for "fame and name."

Id.

126. Frank, *supra* note 102, at 14. Frank wrote:

> Patients . . . typically seek or are brought to psychotherapy because they have failed to fulfill others' expectations or their own. All experience various degrees of helplessness, hopelessness, confusion, and subjective incompetence. We propose to consider these and related feelings as manifestations of *demoralization,* a term that denotes the psychological state that responds to the elements shared by all psychotherapies.

Id. (alteration in original).

127. SINGER & LALICH, *supra* note 5, at 4-5.

approaches.

The Sandtray (or Sandplay) is simply a sandbox in a therapist's office with various figures that a client is free to play with.[128] The types of play engaged in by a client are treated as symbolic stories and psychological realities that the client uses to communicate with themselves and with the therapist.[129] It grew from work done by a British pediatrician, Margaret Lowenfeld, in the 1920s.[130] The original theories were developed with reference to the thought and feeling world of the emotionally developing child. It came to be known as Worldplay or the Lowenfeld World Technique.[131]

A Swiss Jungian analyst, Dora Kalff, began using this medium in her work with children and adults.[132] "She called her work Sandplay Therapy."[133]

The Sandtray is a projective technique.[134] It was nothing more than a curious outgrowth of Jungian theory until it was embraced by the child protection movement. Ultimately, the therapist places an interpretation on this play which is an extremely powerful form of persuasion. The only problem is, there is no sound empirical support for the scientific

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128. BARBARA LABOVITZ BOIK & E. ANNA GOODWIN, SANDPLAY THERAPY 3 (2000).

129. *Id.*

130. *Id.* at 6.

131. *Id.*

132. Gisela Schubach De Domenico, Ph.D., *Sandtray World Play: A Psychotherapeutic Technique For Individuals, Couples And Families*, THE CAL. THERAPIST, Jan.-Feb. 1993, at 56, 56.

133. *Id.* De Dominico, a current practitioner, describes Kalff's work as follows:

> For Kalff, sandtray therapy taps into the autonomous, (to the Ego unconscious) healing force of the psyche (the Self), and promotes a regression to the preverbal matrices of consciousness where the wounds of inadequate mothering that resulted in the birth of a crippled and fragile ego may be healed. Sandtray therapy was found to accelerate the verbal and nonverbal workings of the Jungian analyses-the analysis and the sandtray work were often kept separate.

Id.

134. GARY B. MELTON ET AL., PSYCHOLOGICAL EVALUATIONS FOR THE COURTS 45-46 (2d ed., The Guilford Press 1997). "Mental health professionals have a [wide] array of assessment [tests] and laboratory procedures" they use in diagnosing and treating patients. *Id.* at 45. Projective tests are subjective and interpretational. "These tests do not rely on self-reports of symptoms or experiences" of the patient. *Id.* "[T]hey require the [patient] to view, interpret, and describe complex and ambiguous stimuli." *Id.* The Rorschach is the most well known of the projective tests. The patient observes the stimuli (inkblots in the case of the Rorschach) and projects his or her own perceptions onto the ambiguous stimuli. *Id.* at 45-46. The theory behind the projective test is that a patient's interpretations reveal something important about the way in which the patient views and understands the environment. *Id.* at 46. A mental health professional then interprets the patient's responses to aid in diagnosis and treatment. *Id.*

validity of the interpretation other than the therapist's "clinical experience" and the folklore surrounding the theoretical orientation of Jungian Therapy.

SRA Therapy is a form of survivor therapy.[135] It is characterized by a type of zeal fueled by very strange bedfellows.[136] It is part Christian fundamentalism, part feminism, and part "save the children." It assumes the existence of a vast conspiracy.[137]

One problem with this picture is that, based on the available evidence, it is illusory. Another problem is that there are people still in prison who have been convicted of serious crimes on the basis of these theories. The chief FBI investigator of this type of matter, Kenneth Lanning, published a monograph for child abuse investigators in 1992.[138] The monograph concluded, after more than 100 different investigations by law enforcement into cases of alleged satanic cult abuse, that no corroborative evidence was found.[139] In 1994, an exhaustive study by the Federal government lasting five years and costing $750,000 determined that the rumor of satanic conspiracies was unfounded and that there was no evidence of any organized incursions into public day care.[140]

Facilitated communications ("FC") is a technique used to help non-verbal people with severe developmental disabilities to communicate.[141]

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135. Survivor therapy assumes that most everyone has "survived" some terrible scarring from early childhood and that coming to terms with the trauma through therapy is necessary for successful adjustment.

136. NATHAN & SNEDEKER, *supra* note 123, at 1.

137. *Id.* Nathan and Snedeker describe the movement as follows:

> According to a claim that has been promoted for more than a decade by preachers, police, prosecutors, psychotherapists, child protection workers, and anti-pornography activists, there exists in this country-and indeed, around the world-a massive conspiracy of secret Satanist cults that have infiltrated everywhere into society, from the CIA to police stations to judges' chambers and churches. The devil worshipers have even secreted themselves in day-care centers and preschools, the story goes, where they pose as teachers. This prospect has been particularly frightening, for it is said that Satanists consider youngsters attractive prey for rape and torture and easy recruits for their faith.

Id.

138. *See generally,* KENNETH V. LANNING, NATIONAL CENTER FOR THE ANALYSIS OF VIOLENT CRIME, US DEP'T OF JUSTICE, INVESTIGATORS GUIDE TO ALLEGATIONS OF "RITUAL" CHILD ABUSE (Jan. 1992).

139. *Id.*

140. GAIL S. GOODMAN ET AL., CHARACTERISTICS AND SOURCES OF ALLEGATIONS OF RITUALISTIC CHILD ABUSE (1994) (The final report to the National Center on Child Abuse and Neglect).

141. SINGER & LALICH, *supra* note 5, at 176-78.

It involves "a 'facilitator' sitting beside a [subject] with the facilitator's hand over the [subject's] hand."[142] "The [subject's] hand is then facilitated to point to pictures, or words or to spell words, phrases, or sentences, as the hand moves over [the keyboard]."[143] "In this [fashion], the facilitator 'assists' the nonverbal person to communicate."[144] The belief is that the presence and touch of the facilitator unlocks the subject's ability to communicate and the selection of the keys or words "is not influenced by the facilitator."[145]

FC swept like wildfire throughout the United States beginning in 1989.[146] It was embraced uncritically, not only in the developmental disability community but also in the larger academic and treatment community.[147] It was miraculous in its apparent ability to allow words to flow, expressing thoughts and feelings that had been locked up inside the non-verbal developmentally disabled.[148] It was also a mirage.[149] Long after it had been promoted and accepted as a mainstream therapeutic tool, the cruel harsh world of proof intruded.[150] Skeptics asked for proof instead of testimonials.[151] There was no proof, only the wishing and hoping of the desperate.[152] Double blind studies determined that this technique did not work, but rather the facilitator was communicating, often without conscious awareness, rather than the subject.[153]

A hoax perpetrated on the needy and vulnerable is shameful. But that is only part of the picture. Parents were prosecuted and children were removed from their homes as a result of messages facilitated that claimed horrendous acts of sexual abuse had been perpetrated by mom or dad or some other loved one. [154]

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142. *Id.* at 176.
143. *Id.* at 177.
144. *Id.*
145. *Id.*
146. *Id.* at 178-79.
147. *Id.* at 177-78.
148. *Id.* at 177.
149. *Id.* at 178-82.
150. *Id.*
151. *Id.*
152. *Id.*
153. *Id.* at 179-80.
154. Farai Chideya, *The Language of Suspicion*, L.A. TIMES MAG., Feb. 28, 1993, at 34.

VII. INFORMED CONSENT AS A CONSUMER PROTECTION DEVICE

The doctrine of informed consent is increasingly being seen and used as a consumer protection device. This is particularly so in the mental health field where civil malpractice lawsuits, legislation, and regulatory board actions seek to protect consumers from harmful psychotherapy techniques.

The reach of such actions, even today, remains limited.[155] One of the basic challenges is defining a standard of care with respect to psychotherapy in general. Is there a standard of care with respect to psychotherapy? Well, of course there is, but it is elusive.

The question has been addressed before. In a 1984 law review note, the author identified the confusion and uncertainty behind the oft-stated general rule.[156]

The author identified the competing policy considerations that impacted the standard of care as "the need to encourage innovative psychotherapeutic techniques without denying patients their right to receive responsible mental health care."[157] The need to encourage and foster innovation has been a staple of the defense or justification for

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155. Telephone Interview with Tom O'Connor, Executive Officer of the California Board of Psychology (Sept. 25, 1998 and June 22, 2000). In California, long recognized as one of the most active and consumer oriented psychology boards, there has never been a complaint received in which the charge against the psychologist was a failure to give informed consent. Tom O'Connor confirmed this and observed that the Board complaint tracking system does not even have a separate category for violations of informed consent. O'Connor hasn't seen one, despite personally reviewing thousands of consumer complaints over the last 11 years. *Id.* The odds of facing disciplinary charges for any reason are quite small. Using California as an example, the number of charges filed against psychologists remains very small compared to the approximately 16,000 psychologists in the state. In the fiscal year 1998/1999 there were 520 complaints against psychologists received [by the California Board of Psychology], 122 investigations opened, 40 formal accusations filed and 5 revocations of a psychologist's license. *Id.*

156. Lawrence P. Hampton, Note, *Malpractice in Psychotherapy: Is There a Relevant Standard of Care 35* Case W. Res. L. Rev. 251, 253 (1984). Hampton writes:

> Courts have been hard-pressed . . . to formulate a definitive standard of care against which to measure the conduct of mental health professionals. What passes as a legitimate form of therapy in one jurisdiction may be found unacceptable in the next. Certainly one reason for the irresolution surrounding the standard of care issue is the large number of different and conflicting schools of therapy within the mental health profession itself. A profusion of new forms of treatment merely exacerbates the problem. Moreover, the very fact of change as a characteristic of psychotherapy would appear to defy the notion of a definitive standard of care.

Id.

157. *Id.*

allowing mental health professionals to try new psychotherapeutic approaches.[158] This is so despite the fact that many of these approaches can be described as nothing more than experimental.[159] In medicine, a new drug or device could not be marketed and used on patients unless a rigorous process of controlled studies were conducted that established that the drug or device was safe and effective.[160] The reasons are obvious: Experience has established that drugs and medical devices can and do harm and kill. The Hippocratic proscription "Primum non nocere" (First, do no harm) compels a practitioner to treat using methods that do not cause harm, but rather cure or relieve.[161]

There is no question that demanding proof of safety and efficacy before the public is exposed to a new drug or device has saved countless lives while fostering the development of many life saving medications and devices. It has not prevented innovation or experimentation, although the pace of discovery has been impacted by regulation.[162]

VIII. THE CONCEPTUAL LIMITS OF INFORMED CONSENT

The expectation that informed consent should act as a quality control device to insure consumer protection is based on a misreading of the basic purpose of the doctrine. The doctrine exists to further profoundly important social interests in autonomy and self determination.[163] The protection of consumers against exposure to unproved psychotherapy techniques cannot be assured simply by the implementation of informed consent.

The potential import of informed consent on individual lives and its potential impact on the law and medicine is almost immeasurable.[164]

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158. *Id.*

159. *See generally,* JAMES HARVEY YOUNG, THE TOADSTOOL MILLIONAIRES: A SOCIAL HISTORY OF PATENT MEDICINES IN AMERICA BEFORE FEDERAL REGULATION (1961) [hereinafter YOUNG, TOADSTOOL MILLIONAIRES]; JAMES HARVEY YOUNG, PURE FOOD: SECURING THE FEDERAL FOOD AND DRUGS ACT OF 1906 (1989) [hereinafter YOUNG, PURE FOOD].

160. *See generally,* LAWRENCE M. FRIEDMAN ET AL., FUNDAMENTALS OF CLINICAL TRIALS 1 (3d ed., Springer-Verlag 1998) (1942).

161. *Id.*

162. No one can seriously dispute that the process of drug approval by the FDA is lengthy and expensive.

163. CHARLES W. LIDZ et al., INFORMED CONSENT: A STUDY OF DECISION-MAKING IN PSYCHIATRY 10 (1984).

164. *Id.* at 10-11. The authors write:

> Informed consent reflects one of our highest social values, individual autonomy. It reflects a strong emotional need for a sense of control over our own lives and an admission of our dependence upon others, and it deals with

But, in the vast literature on informed consent, there is nothing in it that locates its source or its goal in what we have come to understand by the term consumer protection. It is true that tort law recognizes the value of the social good known as informed consent, but this is the only sense in which the doctrine has an obvious linkage with consumer protection. In fact, consumer protection is the by-product of the increasing expectations from the "legal culture" Friedman described, brought to bear on the delivery of medical care. Expectations rose on the tide of the delivery of safe and effective medications, devices and treatments. Modern medicine, through insistence on safety and efficacy, created a systematic body of knowledge that was the cornerstone of consumer protection. Consumer protection became a realistic and important requirement only when the tools and methods existed within medicine that could deliver on the promise.

IX. THE GOALS OF MEDICAL OR PSYCHOLOGICAL INTERVENTION

Quality control and the delivery of safe and effective treatment are core principles in medicine. These are assured by adherence to rigorous testing under controlled conditions before a technique, procedure or medication is recognized as safe and effective for use on the general patient population.

Perhaps the most powerful and important advance in medicine in the last century was the development and use of drugs to treat disease. This development did not come without human victims, particularly before creation of the Food and Drug Administration ("FDA").[165] However, by the century's end, the model used to develop new drugs came to provide two crucial things, quality control and the delivery of treatments that are safe and effective.

> a subject of fundamental importance, our health . . . .
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> Informed consent is comprised of two legal duties imposed on physicians: to inform patients about treatment, and to obtain their consent to treatment. These duties are imposed in order to assure that a person's right of self-determination may be maintained in one particular sphere of human activity, the acquisition of medical care. In addition to safeguarding the right to determine one's own destiny, the informed consent doctrine encourages, but does not require, patients to make informed or intelligent decisions about medical care.

Id. at 10 (citation omitted).

165. *See generally*, YOUNG, TOADSTOOL MILLIONAIRES, *supra* note 159; YOUNG, PURE FOOD, *supra* note 159.

The rigorous process by which drugs, devices or treatments are evaluated in medicine is not of ancient vintage. In fact, even as late as the mid-1940s, "most new medical treatments were introduced informally[, generally by] a senior physician who had tried a new treatment on a series of patients and obtained encouraging results."[166]

Today, the clinical trial is recognized as the definitive tool for the evaluation of a drug, treatment, or device. "Only in the past few decades [has] the clinical trial emerged as the preferred method for the evaluation [of drug] or medical interventions."[167] "A properly planned and executed clinical trial is a powerful experimental technique for assessing the effectiveness of an intervention . . . . A clinical trial is defined as a prospective study comparing the effect and value of intervention(s) against a control in human beings."[168]

Before the advent of the clinical trial therapeutic, effectiveness was judged on the basis of observation.[169] However, clinical observation was a poor method by which to determine the utility of an intervention.[170]

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166. EDWARD DOLNICK, MADNESS ON THE COUCH: BLAMING THE VICTIM IN THE HEYDAY OF PSYCHOANALYSIS 288 (1998). Dolnick notes:

> The more reliable, more cumbersome modern-day approach, which relies instead on so-called randomized double blind controlled trials, is remarkably recent. (The "double blinding" is an acknowledgment of the power of positive thinking; in order to insure that no one's expectations somehow muddle an experiment's results, neither patients nor physicians are allowed to know which pills are real and which are placebos.) The first such trial in the history of medicine did not take place until 1948, in Britain, when the Medical Research Council tested the effect of streptomycin on tuberculosis.

Id. (citation omitted).

167. FRIEDMAN ET AL., *supra* note 160, at 1.

168. *Id.* at 2.

169. *Id.* at 6.

170. *Id.* The authors continue:

> A clinical trial is the clearest method of determining whether an intervention has the postulated effect. Only seldom is a disease or condition so completely characterized that people fully understand its natural history and can say, from a knowledge of pertinent variables, what the subsequent course of a group of patients will be. Even more rarely can a clinician predict with certainty the outcome in individual patients. By outcome is meant not simply that an individual will die, but when, and under what circumstances; not simply that he will recover from a disease, but what complications of that disease he will suffer; not simply that some biologic variable has changed, but to what extent the change has occurred. Given the uncertain knowledge about disease course and the usual large variations in biologic measures, it is often difficult to say on the basis of uncontrolled clinical observation whether a new treatment has made a difference to outcome, and if it has, what the magnitude is. A clinical trial offers the possibility of such judgment because there exists a control group-which ideally, is comparable to the intervention

A clinical study, by definition, involves the use of intervention techniques.[171] Central to the conduct of a modern clinical trial is the notion of the control group. The control group is a group against which the intervention group is compared.[172] At the outset of the trial it is essential that the control group be sufficiently similar in relevant respects to the intervention groups so that differences in outcome may reasonably be attributed to the action of the intervention.[173]

The ideal clinical trial is one that is randomized and double blinded.[174] Randomization refers to the process by which participants are chosen to be part of the clinical trial.[175] Randomization is the selection process in which each participant has the identical chance of being assigned to either the intervention or the control group.[176] "Randomization tends to produce study groups [that are] comparable with respect to known and unknown risk factors, removes bias in the allocation of participants and guarantees that statistical tests will have valid significance levels".[177]

In the conduct of any clinical trial, bias is a primary concern; it is the enemy of validity, it distorts and misleads, it can be caused by conscious or unconscious factors or both, and it can occur at any point along the path of the trial from initial design to data collection, analysis and

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group in every way except for the intervention being studied.

Id.

171. *Id.*

172. *Id.*

173. *Id.* at 30.

174. *Id.* at 61, 82.

175. *Id.* at 61.

176. *Id.*

177. *Id.* The authors further noted:

> [R]andomization removes the potential of bias in the allocation of participants to the intervention group or control group. Such allocation bias could easily occur, and cannot be necessarily prevented, in the nonrandomized concurrent or historical control study because the investigator or the participant may influence the choice of intervention. This influence can be conscious or subconscious and can be because of numerous factors, including the prognosis of the participant. The direction of the allocation bias may go either way and can easily invalidate the comparison.
>
> The second advantage, somewhat related to the first, is that randomization tends to produce comparable groups; that is, the measured and unknown prognostic factors and other characteristics of the participants at the time of randomization will be, on the average, evenly balanced between the intervention and control group . . .
>
> The third advantage of randomization is that the validity of statistical tests of significance is guaranteed.

Id. at 43.

interpretation.[178] The recognized solution is to keep the participant and the investigator blinded as to the identity of the assigned intervention.[179]

"In an unblinded or open trial, both the participant and the investigator know which intervention the participant has been assigned."[180] Unblinded studies are easy to execute and therefore inexpensive to conduct.[181] However, unblinded studies face the real possibility of contamination by bias.[182] "In a single-blind study, only the investigators are aware of which intervention each participant is receiving."[183] It has most of the same advantages and disadvantages of the unblinded trial.[184]

"In a double-blind study, neither participants nor the investigators [who follow] the participants knows the identity of the intervention assignment."[185] Along with randomization, double blinding provides the best method by which to eliminate the extraneous from the study equation.[186]

X. PSYCHOTHERAPY AND DRUGS AS FUNCTIONAL ANALOGS

Psychotherapy, as a treatment for an emotional condition, is analogous to a drug or medication prescribed to treat a medical condition. Quality control and the protection of consumers from exposure to harmful psychotherapeutic treatments can only be assured by requiring that the mental health profession comply with the same strict requirements that pharmaceutical companies must meet before a drug can be marketed and used on patients.

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178. *Id.* at 82.
179. *Id.*
180. *Id.*
181. *Id.*
182. *Id.* at 83.
183. *Id.*
184. *Id.*
185. *Id.* at 85.
186. *Id.* The authors continued:

> The main advantage of a truly double-blind study is that the risk of bias is reduced. Preconceived ideas of the investigators will be less important, because they will not know which intervention a particular participant is receiving. Any effects of their actions, therefore, would theoretically occur equally in the intervention and control groups. As discussed later, the possibility of bias may never be completely eliminated. However, a well-designed and properly run double-blind study can minimize bias.

Id.

The problem occasioned by the absence of an FDA-like entity for the testing of psychotherapy techniques has been recognized for many decades.[187] Compounding the problem is the historical track record of the mental health profession in scrupulously investigating its own practices.[188]

The term "drug" is defined in the Food, Drug and Cosmetic Act ("FD&C Act") as "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man" and "articles (other than food) intended to affect the structure or any function of the body of man."[189]

This is a broad and inclusive definition. One would be hard pressed to argue that psychotherapy is not identical in its operation. In order for a drug to be recognized as such and marketed for use on patients, one must demonstrate many things. First, one must show that the substance or compound is biologically active. A substance that is biologically active has a therapeutic effect that is greater than a placebo. Otherwise it remains in the realm of sugar pills and saline injections.

Today, one may easily argue, based on rigorous empirically validated studies, that some forms of psychotherapy are "psychologically active." They do produce desirable effects that are quantifiable and are greater than placebo.[190]

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187. SINGER AND LALICH, *supra* note 5, at 21. "[T]here is no equivalent of a Food and Drug Administration to monitor therapies' or therapists' effectiveness. There is no psychological FDA to root out unproved claims or dangerous practices." *Id.*

188. *Id.* Singer and Lalich state:

> To society's loss, there is an alarming laxity within the mental health professions when it comes to monitoring, commenting on, and educating the public about what is good therapy, what is negligent behavior by trained professionals, and what is or borders on quackery. Not enough attention is paid to the conduct (whether illegal, damaging, or just plain crazy) of the impaired therapist, the quirky therapist, the insufficiently trained therapist.
>
> We open the daily paper and see advice about which movies are good, which books are helpful, which food products are healthful, but we find no objective guides for evaluating the efficacy of a particular treatment.

Id.

189. 21 U.S.C. § 321(g)(1)(B)-(C) (1994).

190. *See* KENNETH I. HOWARD et al., *The Cost-Effectiveness of Psychotherapy: Dose-Response and Phase Models, in* COST-EFFECTIVENESS OF PSYCHOTHERAPY: A GUIDE FOR PRACTITIONERS, RESEARCHERS AND POLICYMAKERS 143, 143 (Nancy E. Miller & Kathryn M. Magruder eds., 1999) (The efficacies of specific psychotherapies have been established in numerous controlled studies). Howard et al. wrote:

> Psychotherapy works. The evidence supporting this conclusion has accumulated from many sources and research designs. Whether one examines the retrospective survey responses of psychotherapy consumers, or the results of many clinical trials, the verdict is that psychotherapy is

Drug therapy and psychotherapy are both interventions designed for similar purposes: to reduce symptoms of physical or emotional distress and, where possible, resolve or cure disease.[191] There are various ways to measure therapeutic outcomes; however, in both drug and psychotherapy research, the most basic method is to observe and document the change in the number and severity of specific symptoms of a disease or disorder.[192] Interestingly, rigorous research of psychotherapy is now attempting to evaluate a particular therapeutic technique, not only on the basis of short-term reduction of symptoms, but also on longer-term functional and economic measures of general health, work, consumer preference, and subjective quality of life decisions.[193]

Drugs and psychotherapy are functional analogs on all relevant domains. It has long been a central focus of investigational drug studies to develop data regarding dose response. Dose response is the "[c]orrespondence between the amount of an administered drug and the magnitude of the evoked reaction."[194] Psychotherapy researchers have now developed sophisticated measures to assess the dose response of specific psychotherapeutic interventions.[195] Having solid information on the dose response rate is crucial to any health care provider, whether medical or mental.[196]

Drugs and psychotherapy share a common domain involving toxicity and adverse reactions. The evaluation of drug toxicity and adverse reactions is central to the process by which the FDA approves the use of a new drug. It involves two questions: (1) does the drug make the condition worse, or (2) does it have damaging effect on other body systems? One may obtain this type of data through psychotherapy outcome research. Equally applicable to drugs and psychotherapy is the

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generally efficacious.

Id. (citations omitted).

191. *Id.* at 144-46.

192. *Id.* at 143-44.

193. *Id.* at 146-47.

194. THE MERCK MANUAL OF DIAGNOSIS AND THERAPY 2573 (Mark H. Beers, M.D. et al. eds., 17th ed. 1999). Dose response is the correspondence between the amount of an administered drug and the magnitude of the reaction evoked. *Id.*

195. *See* MILLER & MAGRUDER, *supra* note 6, at xxii. ("Although 'dosing' is typically thought of in relationship to pharmacotherapy, the concept is equally valid for psychotherapy.").

196. *Id.* at xxi. ("Such monitoring of interim responsiveness is essential in the real world so that clinicians know when to take correctional action such as modifying the dose, augmenting with adjunct treatment, changing the treatment entirely, or reassessing the diagnosis.")

domain of benefit-to-risk ratio.[197]

There is no question that certain types of psychotherapy used on certain types of patients create harm. Suicides and extreme dependence are two of the most obvious harms, but the history of psychotherapy in the last century is filled with other examples.[198] In fact, just as certain drugs have the potential for addiction and dependence, so does psychotherapy. One of the classic indicators of some forms of psychotherapy is the tremendous dependence created intentionally by the therapist.[199]

Despite the fact that drugs and psychotherapy are functional analogs, there are some dissimilarities which are important to recognize. One of the fundamental differences is that for most medical interventions, informed consent relates to a discrete event, whether a surgery or a diagnostic test like an angiogram or an EKG. Psychotherapy is far more a process than an event, and it can last weeks, months or even years. Also, the course of psychotherapy can lead to changes in focus or approach, as some problems are addressed and others appear. In that sense, informed consent must be revisited during the process of psychotherapy.[200]

Another basic difference involves the less focused goals of psychotherapy intervention. In medicine, a drug targets a specific disease entity. The goal of the drug intervention can be judged by fairly

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197. MERCK MANUAL, *supra* note 194, at 2592. The Manual notes:

> For each clinical situation and patient, risks must be weighed against benefits by considering the qualitative and quantitative effects of using a drug and the likely outcome if the drug is withheld. Drug therapy is justified only if the possible benefits outweigh risks. The decision depends on adequate knowledge of the patient, of the disease and its natural history, and of the drug and its potential adverse effects.

Id.

198. *See generally* DOLNICK, *supra* note 166 (describing the historical approach of psychoanalysis treatment of schizophrenia, autism, and obsessive-compulsive disorders).

199. KENNETH S. POPE & MELBA J.T. VASQUEZ, ETHICS IN PSYCHOTHERAPY AND COUNSELING: A PRACTICAL GUIDE FOR PSYCHOLOGISTS 35-41 (Jossey-Bass Inc. 1991).

200. *Id.* at 75. The authors note:

> [I]nformed consent tends to be a recurrent process. The patient may consent to an initial psychological, neuropsychological, and medical assessment as well as to a course of individual psychotherapy based upon an initial, very provisional treatment plan. Several months into treatment, the treatment plan may be significantly altered on the basis of the results of the assessments, the patient's diverse reactions to various components of the treatment plan, and the patient's changing needs. As the treatment plan undergoes significant evolution, the patient must adequately understand these changes and voluntarily agree to them.

Id.

objective criteria. For example, the efficacy of an antibiotic used to treat a particular type of bacterial infection can be judged by reference to changes in a blood chemistry panel or a patient's temperature.

The field of psychotherapy, by contrast, has been characterized by a lack of focus or agreement on what the goal of psychotherapy intervention is. There has been a tremendous expansion of the purposes or goals of psychotherapy. Although many of the great names in the history of psychotherapy have referred, for example, to individual self-fulfillment or autonomy and creativity as goals of psychotherapy, there has not been much agreement about what range of problems pertaining to individual self-fulfillment should be included within the boundaries of mental health care.

The historically unfocused goals of psychotherapy intervention have changed recently primarily due to the pressures from managed care. Thus, treatment aims have become much more clearly defined due to the development of targeted, time limited interventions, many of which are empirically based.[201]

Although there are some differences in drugs and psychotherapy, they both are amenable to research and study using the same tools. The problem isn't that it is impossible to conduct randomized controlled clinical trials of specific psychotherapy interventions that would lead to empirically validated treatments. This has already been done with respect to some modes of psychotherapy intervention on certain psychiatric disorders. The problem is that the clinicians in the real world of psychotherapy practice have tended to ignore the research literature.[202]

Efficacy and safety of various psychotherapy interventions have already been demonstrated in controlled clinical trials.[203] Unfortunately,

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201. Docherty, *supra* note 94, at 6.

202. Steven D. Hollon, *Psychotherapy and Pharmacotherapy: Efficacy, Generalizability, and Cost-Effectiveness, in* COST–EFFECTIVENESS OF PSYCHOTHERAPY: A GUIDE FOR PRACTITIONERS, RESEARCHERS AND POLICYMAKERS 14, 17 (Nancy E. Miller & Kathryn M. Magruder eds., 1999). Hollon continues:

> Surveys find that practicing clinicians pay little heed to the controlled empirical literature and rely more on an informal network of case reports, workshops, and collegial interactions to inform their clinical practice. One of the most widely voiced complaints of practicing clinicians over the years has been that psychotherapy research is of minimal relevance to them.

Id. (citations omitted).

203. *Id.* at 15. Hollon further notes:

> The newly developed cognitive behavioral therapies (CBTs) and interpersonal psychotherapies (IPTs) appear to be at least as effective as medications in the reduction of acute distress in mildly to moderately

there have been very few efforts to determine efficacy of most traditional talk-based psychotherapies. These are the ones that are most widely practiced in applied treatment settings. The fact that there is such an absence of empirical support does not mean that these traditional modes of talk therapy are ineffective. Absence of empirical support does not necessarily equate to absence of efficacy. It does, however, equate to an absence of knowledge about important matters involving public safety as well as cost.

Although most practitioners are unaware of the research literature on efficacy, there are strong pressures to evaluate all methods of psychotherapy. Furthermore, because there is such a heightened emphasis on cost effectiveness, there is a growing interest in assessing the differential benefits of drugs and psychotherapy relative to their costs. The logic of this effort is compelling. If two treatments produce comparable outcomes, the less expensive alternative (either in terms of dollar costs or freedom from undesirable complications) is likely to be preferred.[204]

The challenge to establish efficacy and safety of discrete psychotherapy interventions targeted to specific psychosocial problems is not one of feasibility. The problem involves making a commitment to develop empirically based knowledge and following that knowledge in the direction it leads. Interestingly, much of the good research already done on various psychotherapy interventions has been done by or with the assistance of the National Institute of Mental Health (NIMH).[205]

Quality control and consumer protection are not the natural by-products of informed consent in medicine or in the mental health field. They are the natural by-products, in medicine, of a system of evaluation that is rigorous and empirically driven, that forces the proponent of a new drug or device to establish that the drug or device is safe and effective for use on patients. The FDA model is an imperfect one, but even a cursory history of the last century shows that the promotion of rational drug design overseen by the FDA has led to astonishing

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depressed outpatients and may enhance the breadth and stability of response relative to pharmacotherapy alone among even more severely depressed patients. Exposure-based therapies have been shown to be quite helpful in reducing compulsive rituals in obsessive-compulsive disorder and behavioral avoidance in severe agoraphobia and are often combined with medications. CBT appears to be at least as effective and possibly longer-lasting than pharmacotherapy in the treatment of panic disorder and social phobia.

Id. (citations omitted).

204. *Id.* at 19-20.

205. *Id.*

pharmacotherapy breakthroughs with a minimum of harm to the public. Today, the pharmaceutical industry is developing drugs through its design methods that are more effective than ever with fewer side effects.

Quality control and consumer protection can be, however, the natural by-products of such a system of evaluation and testing of psychotherapy techniques using the model of the FDA. Consumers are entitled to nothing less. They go to a psychotherapist expecting that they will receive a treatment that has a sound basis for use on them. If it does not, then it is an experiment and a patient is entitled to be informed of that fact. The sound basis, for most patients, is a basis created by reference to the available science. Otherwise, they would choose the company of astrologers or mystics.

XI. THE PRACTICAL LIMITS OF INFORMED CONSENT

Even when its conceptual limits are acknowledged, informed consent has had limited impact on the mental health profession. Despite decades of commentary on its important role, it is reflected more in its breach than its observance. In this regard, it shares much in common with the inadequacies of the doctrine in medicine. Furthermore, despite decades of intense debate and emphasis on informed consent in medicine and in the mental health profession, its promise remains unrealized.

Although its relative influence continues to be debated, there is no question that informed consent today occupies a central place in the relationship between physician and patient.

The doctrine of informed consent is a paradox. Despite decades of talk, writing, case law and legislation, informed consent remains long on words and short on results.[206]

Informed consent has been problematic for health care professionals on multiple levels for as long as it has been debated by clinicians and scholars. In 1980, one of the early studies was done questioning

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206. WEAR, *supra* note 3. Wear captures this paradox perfectly in his 1998 book. Wear is a professor in the Departments of Medicine and Philosophy and Co-Director of the Center for Clinical Ethics and Humanities in Health Care at the State University of New York at Buffalo. His assessment of informed consent as it is currently operant in medicine is:

> [T]hat the doctrine of informed consent, as currently articulated in the law and the bioethics literature, suffers from a substantial ritualistic and rhetorical character that both lessens its effectiveness and makes it presume to provide benefits that it often fails to accomplish. In large part, this is so because this doctrine remains uncalibrated to the realities and variables within clinical medicine.

Id. at 5.

whether cancer patients could recall receiving informed consent information. "Within one day of signing consent forms for chemotherapy, radiation therapy or surgery, 200 patients completed a test of their recall of the material in the consent explanation and filled out a questionnaire regarding their opinions of its purpose, content, and implications."[207] The conclusions the authors drew about the ineffectiveness of informed consent are sobering, but not inconsistent with the overwhelming weight of other scholarship, both before and after.[208]

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207. Barrie Cassileth et al., *Informed Consent: Why are its Goals Imperfectly Realized?*, 302 NEW ENG. J. MED. 896, 896 (1980). Cassileth et al. explained:

> Informed consent has remained a focus of intense interest since the Nuremberg Code was adopted in 1947. Attention has centered on two general aspects of informed consent: its legal and ethical ramifications, and its practical effectiveness in the clinical setting. This study is concerned with the latter.
>
> The goal of the consent process is to provide a mechanism for patients to participate in treatment decisions with full understanding of the factors relevant to their proposed care. However, previous studies have shown that patients remain inadequately informed, even when extraordinary efforts are made to provide complete information and to ensure their understanding. This appears to be true regardless of the amount of information delivered, the manner in which it is presented, or the type of medical procedure involved.

Id. (citations omitted).

208. *Id.* at 899. Cassileth et al. concluded:

> The results of this study corroborate previous work indicating that many patients fail to recall major portions of information on consent. The relation between educational background and patient's ability to describe the information, together with the similar correlation between education and the care with which patients read consent forms, suggests that such communications are too complex and difficult for many patients to grasp, despite the fact that most patients reported understanding all or most of the information.
>
> Bedridden patients were less able to recall this information than were patients in better physical condition. As patients become increasingly ill, their sense of personal control over their own destinies may give way to intensified dependence on their physicians, and this dependence may result in poorer attention to, interest in, and recall of information about consent. Intellectual as well as physical deterioration may have had a role in poorer recall, although the patients studied were competent enough to sign consent documents and participate in this research.
>
> . . . The consent form's legalistic, perhaps even adversarial, overtones may appear inconsistent to the patient who has a fundamental orientation to and preference for a doctor-patient relation based on 'trust.'
>
> The purpose of the consent procedure, to facilitate and ensure informed decisions on the part of the patient, is poorly accomplished and may actually be thwarted by the present procedure. Barriers are imposed by the difficulty of the material and by the legalistic and other negative connotations of the consent documents. These barriers need to be removed if consent forms are to achieve their intended objectives and if patients are to function as the

In a companion article, five surgical consent forms were evaluated and analyzed with two standard readability tests.[209] The study found that "[t]he readability of all five surgical forms was approximately equivalent to that of material intended for upper-division undergraduates or graduate students. Four of the five forms were written at the level of a scientific journal, and the fifth at the level of a specialized academic magazine.[210]

Not much has changed, apparently, in the ensuing twenty years. In a study reported in the Journal of The American Medical Association (JAMA) in December 1999, researches analyzed doctor-patient interactions in routine office visit situations to determine if patients were given enough information to make a truly informed consent. The researchers analyzed 1,057 audiotaped encounters between primary care doctors and surgeons and their patients. The cases involved decisions such as whether to have a lab test to check thyroid hormone level and whether to have laboratory prostate-cancer screening. Most troubling of all the findings is this: something important was missing from discussions ninety-one percent of the time.[211]

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informed consumers that many of them wish to become.

Id. at 899-900 (citations omitted).

209. T.M. Grundner, Ed.D., *On The Readability Of Surgical Consent Forms*, 302 NEW ENG. J. MED. 900, 900 (1980).

210. *Id.* Grunder explained:

> These forms are by no means to be considered anomalies. They were selected from a wide variety of hospitals serving a wide variety of people. It is likely that if every surgical consent form in the country were subjected to similar analysis, few would pass.
>
> . . . Yet we might well speculate that this situation is exactly what occurs in hundreds of hospitals around the country every day. Literally tens of thousands of people may be undergoing surgery on the basis of an ethically inadequate consent.

Id. at 901-02.

211. Clarence H. Braddock, et al. *Informed Decisionmaking In Outpatient Practice: Time to Get Back to Basics,* 282 JAMA 2313, 2313 (1999). The researchers concluded:

> In this study, we set out to determine the completeness with which physicians involved patients in routine, but important, clinical decisions in office practice. We analyzed these discussions with criteria that sought to balance an ethical ideal with practical reality by taking into account important differences in decision complexity. We found that surgeons and primary care physicians in office practice infrequently had complete discussions of clinical decisions with their patients.
>
> These findings suggest that the ethical model of informed decision making is not routinely applied in office practice. The low level of informed decision making suggests that physicians' typical practice is out of step with ethical ideals. There are practical implications of this missing practice. Inadequate efforts to foster patient involvement in decision making may

The studies cited above are representative of a vast literature that consistently shows the absence of informed consent in doctor-patient encounters.[212]

The literature about informed consent in the mental health professions is not as robust during the same period but has been and continues to be extensive. Mental health professionals have been told about their ethical and professional obligations to provide informed consent repeatedly in a variety of contexts.

An article in the September 1989 issue of The California Psychologist by Muriel Golub, Ph.D. is typical of the professional writing, although it is a more sophisticated and nuanced explication than some. Entitled *Informed Consent and the Establishment of Therapeutic Sanctuary*, it provides a well-delineated roadmap for a psychotherapy practitioner along with a well-reasoned analysis of the intrinsic value of the informed consent process.[213]

Golub identifies the often mistaken and unrealistic expectations of a

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> impair the patient-physician relationship. Furthermore, there are quality-of-care concerns, since there is mounting evidence that inadequate patient involvement may interfere with patient acceptance of treatment and adherence with medical regimens.
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> . . . .
>
> For too long, informed consent in clinical practice has been influenced by an interpretation of informed decision making as a legal obligation in which the emphasis is full disclosure, rather than an ethical obligation toward mutual decision making by fostering understanding. Furthermore, most emphasis has been on informed consent for invasive procedures or participation as a research subject. Turning attention to decision making in office practice reveals that this emphasis has not created a positive model of informed decision making that is relevant and achievable in clinical practice in which the majority of decisions are less than complex. Promotion of the patient's understanding, thereby fostering informed participation, is the essence of informed decision making.

Id. at 2318-20 (citation omitted).

212. WEAR, *supra* note 3, at 35. ("[T]he empirical data and common clinical experience strongly suggest that many patients take little or no interest in informed consent and do not readily embrace the authority and responsibility it seeks to provide.").

213. Muriel Golub, Ph.D., *Informed Consent and the Establishment of Therapeutic Sanctuary*, 23 THE CALIFORNIA PSYCHOLOGIST 19 (1989). Golub notes:

> It is the job of the psychotherapist to aid in the establishment of a therapeutic sanctuary, a place of safety and trust within which the work of psychotherapy can be done by the patient. The foundation for this sanctuary is laid in the first few sessions. A comprehensive process of informed consent leads to the development of the therapeutic alliance, aiding in the patient's acquisition of knowledge of the structure and process of psychotherapy as well as an awareness of the possible risks to be encountered.

Id.

new patient as a necessary subject for discussion. Informed consent must dispel these erroneous expectations.[214]

Golub also identifies the need for disclosure of information about the therapist himself, including the need "to know about the boundaries of the therapist's competence, as well as the therapists' training and professional orientation."[215]

While discussing the nuts and bolts of what informed consent is, Golub also suggests that informed consent is far more than an ancillary intake exercise largely unrelated to the goals of psychotherapy. It can and should be a way of establishing the framework within which the work of psychotherapy takes place.[216]

Practitioners are reminded of their duty to provide an informed consent by their own state regulatory boards[217] as well as in publications of a quasi-official nature such as the Register Report[218] of the National Register of Health Service Providers in Psychology.[219] Mental health professionals encounter a consistent message about informed consent

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214. *Id.* "It is the therapist's responsibility to advise the patient about the process itself (what it is like, what to expect, what not to expect), as well as to advise about the positive and negative consequences that may come about through participation in psychotherapy." *Id.*

215. *Id.*

216. *Id.* Golub continues:

> This process is made possible by the development of trust and safety, and a feeling of confidence in the therapist and in the process itself. Informed consent helps construct the foundation of trust and safety, and represents one very positive example of combining ethical integrity with basic good therapeutic practice.

Id.

217. The California Board of Psychology, for example, publishes and distributes the BOP Update, a free periodical sent to all licensees. A January, 1997 issue featured an article by the Chairperson of the board on Informed Consent. *See* Bruce Ebert, PhD, JD, *Informed Consent*, BOP UPDATE, Jan. 1997, *available at* http://www.psychboard.ca.gov/ (last visited Aug. 20, 2002). Ebert's article detailed the history of the development of the doctrine and specifically identified ten items that a client should be informed of and concluded: "The BOP finds psychologists have a legal, ethical and clinical obligation to obtain proper informed consent from clients. Procedures to establish informed consent should be implemented immediately in your practice." *Id.*

218. Jeffrey N. Younggren, Ph.D., *Informed Consent: Simply a Reminder*, 21 REG. REP. 6 (1995).

219. The National Register of Health Service Providers in Psychology, established in 1974, is the largest credentialing organization for psychologists in health care service delivery. Its primary goal is to contribute to the improvement of health services to the public through developing standards for evaluation of the credentials of psychologists, reviewing such credentials, disseminating information on credentials, evaluating educational programs, preparing publications, conducting ethics programs. It publishes the Register Report, the Newsletter of the organization, and distributes it to members and others who subscribe to it. *See* http://www.nationalregister.com/.

from the texts and practice guides on ethical practice in the mental health field.[220]

XII. THE FAILURE OF SELF-REGULATION

The history of the mental health profession in the century just passed demonstrates that it is a profession incapable of regulating itself in any meaningful way. Innovation and creativity have become ends in themselves. Questionable psychotherapeutic techniques continue to flourish in the face of mounting evidence that they are ineffective and often harmful. Rather than cleaning its own house, the mental health profession has responded by using its time worn arguments that only it can know and understand the intricacies of the human mind and regulation and external oversight will hamper the innovation necessary to conquer the ills of the human mind.

More than anything, what has characterized the mental health enterprise in the last half century has been a focus on innovation and expanding the sphere of influence of the profession.[221] New techniques and grand theories were embraced and breakthroughs were confidently reported typically long before there was any demonstration of efficacy. The end product has time and again been social mischief and patient harm.

The cultural history of autism is today a little remembered and, for the mental health profession, a conveniently ignored dark secret. An in depth history is beyond the scope of this work,[222] but a condensed version does give clear insight into the deference that has been traditionally accorded to the "doctors of the mind" despite the lack of any compelling evidence that would demonstrate that their pronouncements were anything more than speculation on a grandiose scale.

Autism is recognized today as a disorder neurological in origin, although a definitive etiology remains elusive and to be determined. It was first recognized as a discrete clinical and diagnostic entity in 1943 when an Austrian born psychiatrist, Leo Kanner, identified a condition in children so peculiar that he felt it deserved further study. He labeled the condition "autism," Greek for "self," because of the children's

220. *See, e.g.*, GERALD P. KOOCHER & PATRICIA KEITH-SPIEGEL, ETHICS IN PSYCHOLOGY: PROFESSIONAL STANDARDS AND CASES (2d ed., Oxford University Press 1998).

221. Docherty, *supra* note 94, at 5.

222. DOLNICK, *supra* note 166.

seeming lack of any interest in other people.[223] Bettelheim noted these same qualities in some of the disturbed children he was treating, and soon this condition became the focus of blame for parents of these distressed children, as they were dubbed schizophrenogenic mothers.[224]

What Bettelheim and others managed to do is stigmatize and traumatize generations of parents, mostly mothers, blaming their poor parenting as the cause of this horrific disease that afflicted their children.[225] The enthusiasm with which the theory of the schizophrenogenic mother was embraced and promoted is today nothing more than an embarrassing footnote to history, but it is not unique, nor have its lessons been learned by the profession.[226] What stands out today, looking back, is the utter lack of science, the total disregard of the scientific method and abandonment of the healthy skepticism that is the sine qua non of good scientific investigation. That this bogus and wrong collection of theories had such powerful social currency and power tracks an eerie parallel with the history of lobotomy,[227] and today with the wildly unsupported theories surrounding recovered memory therapy. Dolnick asks the question, why didn't the psychoanalysts know any better in the 40's, 50's and 60's when they were confidently blaming mothers and parents in general for the autism of their children? The answer is that psychoanalysts were unconcerned with the rigorous demands of statistics or control groups and far more comfortable relying on anecdote and case study.[228]

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223. *Id.* at 171.

224. *Id.* at 187-88, 190-92, 193.

225 *See generally* THE SOCIAL PSYCHOLOGY OF STIGMA (Todd F. Heatherton et al. eds., 2000) (discussing various topics of importance to the social psychological understanding of stigma).

226. DOLNICK, *supra* note 166, at 294. As Dolnick concludes his book:

> There is a tendency in the human heart, or brain, to find meaning where there is only happenstance. Worse, there is a tendency to assign blame where there is only bad fortune. The psychoanalysts gave in to this perennial temptation. In doing so, they caused long-lasting, needless harm to those already bowed low by fate. Unable to acknowledge the wisdom of Robert Frost's definition of a tragedy-"something terrible happens and nobody is to blame"-they blamed the victim of illness for the misfortune that had befallen them.

Id.

227. VALENSTEIN, *supra* note 105.

228. DOLNICK, *supra* note 166, at 286-87. "Beyond hubris, beyond ideological zealotry, beyond the shutting out of outside voices, two factors played key roles. The first had to do with medicine, the second with science." *Id.* at 286. Dolnick noted:

> The reliance on anecdotes was the most important example of this non-rigorous approach. Psychoanalysts seldom bothered with controls and steered away from statistics, partly out of distaste, partly in recognition of

As we view the last century of the development of the mental health profession, it is an unavoidable conclusion that the era of *laissez faire*, of deference to self-entitled expertise and the need to promote innovation, have led not only to important insights and advances, but also to grand and catastrophic mistakes that caused great and lasting harm to patients and society as well.[229] The mistakes and errors apply to both psychology and psychiatry.[230]

The mental health enterprise faces an uncertain future as it embarks on the stormy seas of the twenty-first century. It faces serious challenges and critique both from inside and outside the profession. No evolving and dynamic academic or scientific discipline is free of controversy or immune from criticism. However, the challenges and

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genuine difficulties, and partly out of a humane impulse to focus on patients rather than on abstractions. Instead, they placed enormous weight on anecdotes and case histories. On the basis of six or ten or twenty cases, they laid down sweeping generalizations about diseases that affected thousands or millions.

Id. at 287.

229. RICHARD OFSHE & ETHAN WATTERS, MAKING MONSTERS: FALSE MEMORIES, PSYCHOTHERAPY AND SEXUAL HYSTERIA 8-9 (1994). In the following quote, Ofshe and Waters are writing about recovered memory therapists but the comment has universal applicability to the mental health profession:

> The fact that recovered memory therapists could so damage their patients and yet, until recently, largely escape criticism illustrates how incapable the mental health profession is of evaluating and curbing fad treatments that grow within its ranks. While mental health professionals look with horror at the seemingly barbaric mistakes of their predecessors, each generation appears unable to stop the birth of new damaging practices.

Id.

230. Paul R. McHugh, *Witches, Multiple Personalities, and Other Psychiatric Artifacts,* 1 NATURE MED., Feb. 1995, at 110. McHugh wrote:

> Psychiatry is a medical discipline long on disorders and short on explanations . . . .
>
> However, this shortage of agreed-upon explanations brings good news and bad news. The good news is there is plenty of room for useful scientific research in psychiatry and a great deal of this is going on at this moment. The bad news is, because practitioners in this discipline are hungry for explanations today, at least once each decade, psychiatry is swept by an enthusiasm for a fundamentally incoherent practice, and then must spend at least ten years subsequently digging out of the troubles that this practice produced. These misdirections of psychiatry rest squarely on standard medical mistakes such as oversimplification, misplaced emphasis or pure invention. The enthusiasms for these misdirections, however, usually derive from an uncritical acceptance of transient cultural attitudes and fashionable ideas. The repeated combination of these elements proves how all too often the discipline of psychiatry has been the captive of culture, to the detriment of everyone.

Id.

assaults on the mental health enterprise are unprecedented in their scope and force.

It is easier to dismiss the challenges from the outside. Perhaps outsiders don't understand. Maybe outsiders fail to see the big picture, or outsiders just have an axe to grind. The critiques from inside are another matter. These are hard to explain away and increasingly difficult to answer.

Collectively, these voices are calling into question the core practices of the mental health profession in practicing psychotherapy and in the expression of professional opinion.[231] The questions they ask are simple. What is the justification (evidence of efficacy and safety) for what you do with your patients/clients? What is the empirical support for the things that you do and the opinions you express? The truth is that there is scant empirical scientific support for much of what the mental health profession does. Heretofore, no one has really demanded it. One is forced to ask the question how can this be if a psychotherapist is required by law and the practice codes of the profession to give a patient/client an informed consent before instituting treatment?

Now, the mental health profession is being asked to justify its actions. The new economics of the marketplace (managed care) and the new legal landscape[232] are unfriendly, unwelcome visitors in the waiting rooms of today's therapists.

The response from the profession is reminiscent of a multiple personality. A segment of the profession responds by acknowledging the real limits of the profession and seeks empirical data to support or refute their practices. Another very large segment is in denial. That is, a refusal or inability to recognize the facts of one's situation and prospects.

Questionable psychotherapy techniques continue to flourish even though they rely almost solely on the same promotional techniques used to sell worthless patent medicines.[233]

A recent newspaper headline reported "Girl Dies After 'Therapy':

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231. E.g., ROBYN M. DAWES, HOUSE OF CARDS: PSYCHOLOGY AND PSYCHOTHERAPY BUILT ON MYTH (1994); MARGARET A. HAGEN, PH.D., WHORES OF THE COURT (1997); DINEEN, *supra* note 97; E. FULLER TORREY, M.D., FREUDIAN FRAUD (1992).

232. *See e.g.*, Daubert v. Merrell Dow Pharmaceuticals, Inc. 509 U.S. 579 (1993); General Elec. Co. v. Joiner, 522 U.S. 136 (1997); Kumho Tire Co, Ltd v. Carmichael, 526 U.S. 137 (1999).

233. YOUNG, TOADSTOOL MILLIONAIRES, *supra* note 159; YOUNG, PURE FOOD, *supra* note 159.

Five Charged with Abuse."[234] The article detailed the story of the death of a ten year old girl at the hands of therapists practicing a form of therapy known as rebirthing. The lead paragraph capsulizes this tragedy.

"Wrapped in a flannel blanket meant to represent the womb, 10 year old Candace Newmaker cried again and again that she couldn't breathe as therapists pushed against her with pillows, urging her to fight her way out and become 'reborn' . . . ."[235]

When the therapists finally unwrapped her she was not breathing and lying in her own vomit.[236] She died of asphyxiation a day later.[237]

Rebirthing is a technique that was started in the early 1970s. It has been on the fringe of mainstream psychology ever since. Its originator, Leonard Orr, developed his theories while spending time in his hot tub having revelations. He began to suspend his friends in the hot tub with snorkels and nose plugs. Many of them reported they began to get in touch with some of their own destructive behavior patterns. Some reported "they experienced their own birth during the process."[238]

A review of the history of rebirthing reveals its pattern similarity with other questionable psychotherapy practices. Today, there are numerous people, including Orr and others who actively promote and teach this technique. Now called the Association of Rebirth International, they give weekend training sessions to teach participants the rebirthing experience as well as sessions to certify trainers in this technique. They have lists of "certified" trainers throughout the United States.

One of the very powerful tools used by today's purveyors of the unproved is the Internet. Indeed, the Internet is simultaneously the best and the worst source of reliable information about medical or psychological techniques or treatments. Any search engine will lead

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234. *Girl Dies After "Therapy" Five Charged with Abuse*, SAN DIEGO UNION TRIB., July 9, 2000, at A11.

235. *Id.*

236. *Id.*

237. *Id.*

238. SINGER & LALICH, *supra* note 5, at 42-43. Singer and Lalich describe rebirthing as follows:

> [D]amage is done to the breathing mechanism at birth because the child is cut off from its supply of oxygen through the premature cutting of the umbilical cord. This initial panic ("breathe or die") remains in the person's subconscious as a nameless fear. The goal of the rebirthing process is to get the person to release this long-held tension and learn to take advantage of the fully functioning breathing mechanism. Once accomplished, the person can lead a full, happy breathy life.

Id.

you to numerous websites that have very professional sounding titles and credentials and memberships. What today's websites represent is a repackaging of the same basic techniques used to promote and sell the quack patent medicines of the nineteenth and early twentieth century. Filled with powerfully personal testimonials and anecdotal evidence, they very skillfully promote their nostrums as a powerfully effective agent for change.[239]

Thought Field Therapy ("TFT") is another newly emerging and classically unproved psychotherapy technique.[240] One of the products of the managed care revolution is the pressure on practitioners to produce results in shorter time frames.[241] One of the cost-cutting measures was to limit the number of visits to a psychotherapist that would be reimbursed or covered by insurance.[242] In the wake of this pressure came an emphasis on brief and short-term therapies.[243] Rather than having unlimited time and funding to plumb the depths of every client's past, the focus turned to dealing solely with a patient's presenting problem.[244] One of these short-term therapy approaches was crisis intervention.[245] "Crisis intervention involves having brief but intense contact with victims of crisis or trauma for the purpose of calming them, reducing risk, and returning them to their pre-crisis level of functioning."[246]

TFT is described as a "power" therapy due "to their claimed remarkable facility in resolving severe or persistent emotional disorders

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239. *Id.* at 45. Singer and Lalich continue:

> An additional factor that tends to make a risky situation worse is that some forms of therapy-which initially might gain support as "a breakthrough," "creative," or "innovative"-are not inspected critically by the professional community. Instead, theses therapies are allowed to harm a number of patients until the courts are asked to evaluate the conduct of the therapists, the rationality of the therapy, and the extent of the damage done. Sometimes public inspection or legal redress never occurs, and the therapies continue to be promoted for decades ... with the on-going potential for outlandish or disastrous consequences.

Id.

240. ROGER J. CALLAHAN, PH.D., THE FIVE MINUTE PHOBIA CURE: DR. CALLAHAN'S TREATMENT FOR FEARS, PHOBIAS, AND SELF-SABOTAGE (1985).

241. *Id.*

242. *Id.*

243. *Id.*

244. *Id.*

245. *Id.*

246. David X. Swenson, *Thought Field Therapy: Still Searching for the Quick Fix*, 7 SKEPTIC 60 (1999).

and trauma."[247] TFT uses sequences of finger tapping on acupressure points, and combinations of sensory activities such as repeating statements, counting, rolling the eyes, or humming a tune, while thinking of the distressing situation.[248] The promoters of TFT make extraordinary claims of healing of many physical and psychological conditions.[249]

TFT was invented by a psychologist, Roger Callahan.[250] He accidentally discovered it while treating a patient named Mary who had a severe fear of water.[251] Inspired by an acupuncture class he was taking at the time, he instructed Mary to firmly tap under her eye with her fingers, which lead to a miraculous and immediate resolution of her phobia.[252] From this he developed a comprehensive set of techniques and theories.[253] TFT is based on the idea that:

> . . . invisible energy fields called "thought fields" exist within the body. Environmental traumas and inherited predispositions are theorized to cause blockages, or what Callahan terms "perturbations" in the flow of energy in these thought fields. Callahan theorizes that the commonly observed neurochemical, behavioral, and cognitive indicators of disorders such as depression are the result of these perturbations. In other words, the root cause of all psychological problems are blockages in energy fields.[254]

Not surprisingly, TFT is marketed primarily through the Internet. It has numerous websites and markets a variety of courses for both patients and therapists.[255]

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247. *Id.* at 61.

248. *Id.*

249. *Id.* Swenson notes:

> Thought Field Therapy claims to heal the following disorders: trauma (effects of rape, abuse, crime, war), phobias, anxiety, addictions, grief, physical pain, panic, obsessive-compulsive disorders, eating disorders, depression, chronic anger, guilt, self sabotage, food addictions, rejection, sexual problems, fibromyalgia, migraine headaches, and love pain. There is even a suggestion that it might cure cancer.

Id. (citations omitted).

250. Brandon A. Gaudiano & James D. Herbert, *Can We Really Tap Our Problems Away? A Critical Analysis of Thought Field Therapy*, SKEPTICAL INQUIRER 29, 30 (2000).

251. *Id.*

252. *Id.*

253. *Id.*

254. *Id.* (citations omitted).

255. *Id.* at 30-31. The authors stated:

> To attract potential therapists to take TFT courses and to persuade

Like rebirthing, facilitated communications, and other faddish psychotherapy techniques, TFT is fueled by uncritical acceptance and entrepreneurial zeal.[256]

XIII. INFORMED CONSENT AND ACCOUNTABILITY

A fully implemented doctrine of informed consent stands ready to operate internally within the mental health profession as a self regulatory stimulus to more enlightened practice. Informed consent has profound implications for the improved practice of mental health care. A profession that actually practices informed consent is a profession that is accountable. This is so because, at its core, informed consent requires a practitioner to have an adequate knowledge base about his or her own profession. To give informed consent, one must know the risks and benefits of mental health interventions as well as know the risks and benefits of not engaging in therapy.

The mental health professions have resisted informed consent for one central reason. It would limit and restrict a large amount of psychotherapy practice. Practitioners would be required to explicitly state facts demonstrating their own lack of knowledge and the lack of sound evidence to support what they are proposing. Informed consent is so problematic for the mental health profession because psychotherapists don't know what to inform their patients. It is a profession ill informed about its own intellectual and scientific background and very self-conscious about it.[257]

Informed consent threatens their self-view and the exalted status they

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prospective clients to pay for this therapeutic approach, amazing claims are presented on several TFT –related Web sites. For example, Callahan's primary Web site claims that TFT allows individuals "to eliminate most negative emotions within minutes." Callahan asserts that TFT's effectiveness increases with higher levels of training. For example, another Web site publicizes that therapists can achieve an 80 precedent effectiveness rate learning to use specific algorithms, a 90-95 percent effectiveness rate from using "Causal Diagnostic" techniques, and an over 97 percent effectiveness rate suing a technique mysteriously termed "Voice Technology." Yet another web site, this one based in the United Kingdom, states that TFT is the only psychotherapy that can "genuinely claim to offer a cure.

Id.

256. *Id.* at 31. "Despite these miraculous assertions, no controlled studies have been published in peer-reviewed scientific journals to provide evidence for TFT's claims. Instead, testimonials and uncontrolled case studies are offered to support these astonishing declarations of success." *Id.* (citations omitted).

257. *See* Stephen E. Hjelt, *Professional Psychology: A View from the Bench,* 26 REG. REP. 8, (2000).

have come to occupy. For many mental health practitioners, it is an unwelcome reminder of their own lack of knowledge.

For a profession that relies on human memory for its basic currency, the mental health profession has demonstrated a profound lack of understanding of the basic science of memory. In the wake of what has been described as an epidemic of recovered memories of childhood sexual abuse, Michael Yapko, a respected authority on suggestibility, memory and the clinical use of hypnosis, in the early 1990s gathered data from therapists throughout the United States concerning their ideas and practices regarding the roles of suggestion and memory in therapy. He was most interested in determining whether therapists were thinking critically and in an informed manner about these subjects.[258]

Yapko devised two questionnaires. The first, called a Memory Attitude Questionnaire ("MAQ") was designed to assess the range and depth of therapists' understanding of the workings of human memory, particularly in relation to clinical issues and treatment. The second, called the Hypnosis Attitude Questionnaire ("HAQ") was created to assess how therapists view hypnosis as a method of retrieving memories and the role of suggestibility in the therapy process.

The responses were so disturbing because they revealed widespread ignorance of basis foundational facts. Unfortunately, the consuming public is not aware of this.[259]

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258. MICHAEL YAPKO, SUGGESTIONS OF ABUSE 20-21 (Simon & Schuster 1994). Yapko's blunt conclusion was:

> I was dismayed, to say the least, by what I found. It is not an exaggeration to say that many therapists appear to practice their profession on the basis of sheer myth . . .The survey data I have gathered make it abundantly clear that too many therapists treat their clients on the basis of personal beliefs and philosophy, rather than according to an objective consideration of the facts. Too many therapists seem ignorant about the suggestibility inherent in the therapy process, and ignorant about the workings of human memory, even though memory is central to the enterprise of identifying and treating survivors.

Id.

259. *Id.* at 43. Yapko continued:

> The general public seems to believe that mental health professionals serve their clients on the basis of objective diagnosis and well-established, reliable methods of treatment. Unfortunately, this is not the case. Psychotherapy involves a unique blend of art and science, but it is mostly art. Consequently, skill levels vary quite dramatically, as do perspectives about treatment. During the time I have been in practice, I have seen many diagnostic and treatment fads come and go. At any given time, there is an "in" diagnosis and a "revolutionary new approach" to therapy, which are often greeted enthusiastically by the profession but with little of the objectivity necessary to evaluate accuracy and effectiveness.

One of the specific areas of focus of the MAQ was therapist attitudes regarding memory, specifically its degree of accuracy and reliability.[260]

One of the specific areas assessed by the HAQ dealt with the relative value of hypnosis as a therapeutic tool and its utility as a tool of memory enhancement. Yapko, a leading authority on hypnosis, was very pleased that an overwhelming majority (ninety-seven percent) viewed hypnosis in a very positive light. He was not as impressed by other findings.[261]

Much of what HAQ respondents believed about hypnosis were myths.[262]

In summarizing the findings regarding therapist attitudes toward hypnosis, Yapko found the overall response pattern indicative of grave cause for concern.[263]

Informed consent in medicine and the mental health context has been called many things: myth, charade, fairytale or fiction. While its uneasy existence is occasionally observed in the delivery of medical care, its

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Id.

260. *Id.* at 51-52. Yapko further stated:

> About one in ten therapists surveyed believed that "memory is not significantly influenced by suggestion," in direct contradiction to one of the most basic and well-known facts about memory. The statement "One's level of certainty about a memory is strongly positively correlated with that memory's accuracy" was designed to get at beliefs about the relationship between feeling right and being right. Feeling certain you are correct has nomore to do with actually being right . . . than shouting louder in an argument does, but nearly one in four respondents believed that feeling certain about a memory means the memory is more likely to be correct. And 41 percent believed that ". . .early memories, even from the first year of life, are accurately stored and retrievable".

Id.

261. *Id.* at 54. "Nearly half the respondents (47 percent) agreed with the statement 'Therapists can have greater faith in details of a traumatic event when obtained hypnotically than otherwise.' Attributing greater accuracy to a memory recovered hypnotically is a distortion of fact with potentially hazardous consequences for the client." *Id.*

262. *Id.* at 58-59. Yapko noted that "[a] commonly held misconception is that 'people cannot lie when in hypnosis.'" *Id.* Nothing could be further from the truth. Hypnosis is not a lie detector, nor does it prevent either intentional or unintentional deception on the part of the hypnotized person. *Id.* Yet, nearly one in five respondents (18 percent) actually believed this myth. *Id.* Even if they do not conduct the hypnosis sessions themselves, they will likely believe those clients who tell them, "during a hypnosis session, I discovered I was sexually abused." A similar percentage (19 percent) subscribed to the myth that "someone could be hypnotically age regressed and get 'stuck' at a prior age." *Id.* "It is a virtual impossibility to get 'stuck' in age regression in particular, or in any hypnotic experience in general." *Id.*

263. *Id.* at 60 ("While the great majority of therapists are well intentioned people who genuinely want to help their clients, the survey data make it abundantly clear that too many therapists hold beliefs that are sometimes arbitrary, sometimes sheer myth, and sometimes outright dangerous to their clients' well-being.").

presence in the mental health context is fleeting at best. There is a tremendous irony in this. Psychotherapy is the perfect setting for the implementation of an effective informed consent. By its very nature, it supplies fertile soil for planting the seeds of informed consent. It is far more congenial for this purpose than contemporary medicine.

Psychotherapy is a uniquely intimate enterprise where façade and pretense are discouraged and a trusting relationship built on disclosure and safety is promoted. Psychotherapy is an intense type of relationship where the treatment is, in essence, a dialogue that extends over weeks, months, and sometimes years.

Modern medicine is increasingly anonymous and impersonal, and is not fertile ground for the discussions and decisions facilitated by trust.[264] In the era of managed care and corporate medicine, the idealized close and trusting relationship between patient and physician has all but disappeared. Often patients do not even know the physician who treats them. The image of the "family physician," of Marcus Welby, M.D., is obsolete.

The vast divide separating doctors and patients is not solely a function of differing values and beliefs or the impersonality of modern medicine. It reflects a suspicion on the part of patients of the motives of the medical profession.[265] This pervasive distrust is coupled with the first hand experience, for most consumers of medical care, of "the assembly line character of modern medicine".[266]

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264. WEAR, *supra* note 3, at 36-37. Wear describes this as "Patients and Physicians as Moral Strangers":

> In the past, the predominant image was of the wise and beneficent physician, trusted and at times adored by his patients. The new ethos, however, offers us a quite different and rather jaundiced vision. In a nutshell, this view runs as follows. Medicine is an enterprise pursued within a secular, pluralistic society in which physicians and patients meet as *moral strangers* in various senses.

Id.

265. *Id.* at 35-36. Wear continued:

> Somehow or other, a deep core of distrust has developed regarding the intentions and capabilities of the medical profession.
>
> . . . this vision dovetails well with widespread postwar distrust of societal institutions and expertise. Allied to such distrust is the perception that the sciences, biological and otherwise, have been unable to generate sufficient moral sensitivity and insight to match their rapidly expanding knowledge and technical capacity, and that the interests and freedom of the citizenry have been placed in jeopardy as a result.

Id. at 36.

266. *Id.* at 37. Wear further stated:

> Care and treatment in hospitals are fragmented across loosely coordinated

It is very difficult to dispute this view of modern medicine. It is an enterprise conducted mainly by strangers who don't know each other and don't share the same values and beliefs. It is hard to think of soil more hostile and inhospitable to the growth and nurturance of informed consent. Why not consider psychotherapy, the erstwhile estranged distant relation to informed consent.

XIV. HUMAN MISERY

Even if fully operational, no amount of informed consent will, on its own, protect consumers from exposure to harmful therapy techniques. Human distress and lack of expertise are a potent combination that will always place a mental health professional in a position to persuade the unsuspecting and the needy of the benefits of an exciting and "promising" new technique.

Psychotherapy is the paradigmatic psychic contract of adhesion.[267] For the vast majority of those who seek help through psychotherapy there is no equal bargaining power. There is someone who is needy, distressed, demoralized or discouraged who is turning to a specialist because, most often, such person has been incapable of solving the problem themselves. The psychotherapist-patient relationship creates a synthetic form of intimacy through which a needy patient discloses all her secrets, fears, fantasies, shame and failures.

Psychotherapy is truly an "invasive procedure."[268] It courses through

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> team members and shifts. Often there is either no one clear person directly in charge of the individual patient's care, or even if there is, it is an overworked resident rotating across services, or a tightly scheduled community physician who stops by to check on his patient within a grueling daily marathon from hospital to clinic to private office. Often, in fact, hospitalized patients are essentially doctorless. They are picked up by residents who know nothing of their background and have little or no connection with the patient's private physician (if the patient has one, which he often does not). Further, such residents tend to be quite hesitant even to initiate a personal relationship, or investigate the patient's fears, needs, and desires, as they will probably not have the opportunity to pursue such matters in more than a quite cursory manner. So the personal interaction remains at best pro forma and minimal.

Id.

267. *See* Neal v. State Farm Ins. Co., 10 Cal. Rptr. 781, 784 (Cal. Dist. Ct. App. 1961). Contracts of adhesion are agreements that are imposed and drafted by the party of superior bargaining strength thus relegating to the subscribing party only the opportunity to adhere to the contract or reject it. *Id.* "Such an agreement does not issue from that freedom in bargaining and equality of bargaining which are the theoretical parents of the American law of contracts." *Id.*

268. *See* POPE & VASQUEZ, *supra* note 199, at 37 ("Metaphorically, psychotherapy, like surgery, is an 'invasive procedure', although in both cases the client or patient consents to

one's blood and brain in the same way that an antibiotic or an antidepressant does. Psychotherapy exposes the secrets of one's heart and mind in the same way a CT scan or MRI exposes tissues, bones and organs. When you couple the special expertise of the therapist, his exalted social status, and the often mythic and magical views promoted or held by many, you have a prescription for potential disaster.

All mental health disciplines have as part of the foundational body of knowledge the notion of transference and counter-transference. These notions trace their development to Sigmund Freud, who posited that a patient would transfer onto the therapist feelings from authority figures in early life and attempt to act out with the therapist the same role.[269]

Transference and counter-transference are, more than anything, examples of the social influence process that is at the heart of psychotherapy. A therapist and a patient influence each other by virtue of their interactions in therapy, although the influence is certainly not symmetrical. The social influence process of psychotherapy is decidedly asymmetrical as a result of a transference. However, this has nothing to do with psychodynamic conceptions of the term. Rather, it concerns the transfer of power from the patient to the therapist by virtue of the patient's neediness and demoralization, and the patient's revelations of secrets, which create a profound moment of vulnerability and exposure.

This transfer of power and subsequent vulnerability and exposure is precisely why no amount of informed consent can fully protect those who are desperate from taking a chance with someone offering hope of a cure or relief from distress. This is why fake claims of cures for cancer and AIDS continue to be promoted both here and abroad. Fortunately, the FDA drug approval process makes it impossible for these nostrums to be marketed by legitimate health care professionals. The process provides substantial protection for the most vulnerable of us who might be prepared to take a chance on a cure because alternative prospects are so bleak.

In situations of vastly unequal bargaining power, informed consent is easily ignored or manipulated. The psychotherapist patient relationship is a psychic contract of adhesion from its inception. The typical ingredients of patient neediness and distress, and the exalted special

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the invasion.").

269. Jim Hagart & John Albutt, *Freudian Psychology: The Basis of Psychotherapeutic Interventions* (Nov. 1, 2002), http://sss-student.tees.oc.uk/psychology/modules/year3/abnormal/lec9.htm.

place accorded to the healer create, *ab initio*, a relationship where the bargaining power is inherently uneven.

A new psychotherapy technique, is of course, never promoted as experimental, untested, untried, potentially harmful or lacking proof that it works as it is advertised. It is always referred to as new and exciting; exciting because of the positive results seen by the therapist. When a therapist has great success using a technique on patients with your particular problem, or there are reports of success or promising results in the professional literature, it is a potent form of persuasion. It is unrealistic to expect a patient under these circumstances to ask whether there is persuasive empirical research data to support the safety and efficacy of the therapeutic intervention you are proposing.

XV. THE NEED FOR REGULATORY OVERSIGHT

What is necessary, in addition to informed consent, is an external mechanism that is concerned with efficacy and safety. The principal product of the mental health enterprise, psychotherapy, is a commodity that has the essential hallmarks of a drug or medical device. There are many different types. Considering the long history of exposure of a vulnerable and unsuspecting public to the questionable and sometimes harmful, psychotherapeutic interventions should not be allowed unless proven safe and effective. The burden should be on the promoters of a particular mode of therapy to demonstrate through well-designed clinical studies that what is promoted works.

The history of exposure of the vulnerable and unsuspecting to the questionable and the harmful is well-documented in medicine. Indeed, FDA history is best described by two struggles; first, against the nostrums and patent medicines of a more primitive era; and then, against drugs such as thalidomide in the early 1960s, where the risks of harm caused by the drug far outweighed then potential benefits. The FDA represents an organized societal response to the grave risks threatening public health from exposure to worthless and/or harmful medicines and therapies. Because of the potential for grave harm, the FDA developed, through Congressional action, a unique regulatory scheme that declares protecting the public as its primary motivating strategy. This regulatory scheme evolved over the last 100 years in a manner dictated more by public health tragedies than anything else. As such, it has been a creature of the political process, as consumers, their advocates and

pharmaceutical companies have lobbied over the years.[270]

A brief review of historical milestones is helpful in understanding the regulatory scheme that exists today. In 1906, Congress passed the Federal Food, Drug, and Cosmetic Act.[271] The twenty years prior to the passage of the act was the heyday of the patent medicine.[272]

Although the 1906 Act was viewed as a watershed event, it only required that drugs meet standards of strength and purity.[273] The burden of proof was on the FDA to show that a drug's labeling was false and fraudulent before it could be taken off the market.[274]

By the early 1930s, the 1906 Act was essentially obsolete.[275] A bill was introduced in the United States Senate in 1933 to completely revise the 1906 drug law.[276] Drug companies resisted change and Congressional action stalled until 1938, when 107 people died from a poisonous ingredient in "Elixir Sulfanilamide."[277] Congress passed a compromise bill which, for the first time, required manufacturers to prove the safety of a drug before marketing it.[278]

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270. Elizabeth Rutherford, *The FDA and "Privatization"--The Drug Approval Process,* 50 FOOD & DRUG L.J. 203, 215 (1995) ("The FDA's regulatory framework necessarily reflects these political realities, because Congress created the regulatory scheme that was primarily a result of public health tragedies. Congress has made the FDA a powerful bureaucratic gatekeeper, by giving it absolute control over new drug approvals, as well as post-market enforcement.").

271. Wallace F. Janssen, *Outline of the History of U.S. Drug Regulation and Labeling,* 36 FOOD DRUG COSM. L.J. 420, 421-422 (1981). Wallace F. Janssen, described the event in these terms:

> On June 30, 1906, President Theodore Roosevelt signed the original Pure Food and Drugs Act . . . [n]o single event has had greater significance in the history of consumer protection laws or the industries they regulate. It signaled the beginning of an era of progress in these areas which had no precedent.

Id.

272. *Id.* at 422. Janssen further noted:

> [T]his was the heyday of "patent medicines" such as Kick-A-Poo Indian Sagwa and Warner's Safe Cure for Diabetes. The existence of thousands of these products reflected both the limited medical knowledge of the period and public acceptance of the doctrine that buyers should look out for themselves. Nostrums were so common that they were largely taken for granted-a part of the normal American scene. Anyone, no matter how ignorant or unqualified, could go into the drug manufacturing business.

Id.

273. *Id.* at 427-28.

274. *Id.*

275. *Id.*

276. *Id.* at 429.

277. *Id.*

278. *Id.*

In 1951, Congress passed the Durham-Humphrey Amendment, which mandated the labeling of certain drugs for sale by prescription only.[279] Until the passage of this amendment, there was no requirement that any drug be labeled for sale by prescription only.[280] The amendment defined prescription drugs as those unsafe for self-medication and those appropriate for use only under a doctor's supervision.[281]

In 1962, Congress passed the Kefauver-Harris Drug Amendments.[282] As was typical with proposed legislation, there was strong opposition to it.[283] Thalidomide changed all that.[284]

The Drug Amendments of 1962 passed unanimously, containing a number of new and powerful provisions:[285]

> 1) Drug companies were required to register their establishments with the FDA and to be inspected at least every two years; 2) pertinent records were required to be kept and made available for inspection; 3) reports of adverse drug effects were required to be promptly transmitted to the FDA; 4) regulation of advertising of prescription drugs was transferred from the Federal Trade Commission to the FDA and the copy required to include full information on adverse effects and contraindications so

279. *Id.* at 434-35.
280. *Id.*
281. *Id.* at 435.
282. *Id.* at 437.
283. *Id.*
284. *Id.* Janssen reports on the enactment in these terms:

> But in the early summer of 1962, complacency vanished abruptly as a horrifying story unfolded of the narrow escape of American families from the tragedy of grotesque deformities in babies caused in European countries by a supposedly safe new sleeping pill. Thalidomide was not marketed commercially in the United States because the new drug safety clearance requirements of 1938 had been applied by an FDA medical officer, Dr. Frances O. Kelsey, who refused to release the drug on what she believed was inadequate evidence . . . .
>
> Thalidomide had been distributed to over 1,000 doctors in the U.S. as an investigational drug. Seventeen cases of birth defects were connected to its use, ten traced to purchase of the drug in other countries. As the extent of this distribution was learned, it became apparent that a tightening of controls over investigational drugs was also needed. Proposed new regulations were issued; Congress quickened its pace on the pending drug legislation. As statutory gaps in consumer protection came to be interpreted in terms of deformed babies, public clamor arose for strengthening the law in every respect to close those gaps.

Id.
285. *Id.* at 438.

> as to provide a balanced picture; 5) new investigational drug provisions required informed patient consent before trials on human subjects, and, 6) effectiveness as well as safety of new drugs was required to be shown by substantial evidence from controlled studies to obtain FDA approval for marketing.[286]

The last provision was a powerful new regulatory tool. Before marketing a drug, a pharmaceutical company now had to prove not only safety, but also effectiveness for the drug's intended use.[287]

There have been further changes to the Federal Food, Drug, and Cosmetic Act, particularly in the last ten years. The changes resulted from intense pressure by the pharmaceutical industry and conservatives in Congress to reduce what they claimed is the heavy handed and onerous burdens imposed by a regulatory body that takes forever to approve a new drug and unnecessarily cost the industry billions of dollars in cost. They also complained that the Act ultimately denied the public the benefit of new and promising medications. Accordingly, there were strong pressures to privatize the regulation of drugs.

In 1992, Congress enacted the Prescription Drug User Fee Act,[288] which required that manufacturers pay user fees for certain new drug applications and supplements along with annual establishment fees and annual product fees.[289] In exchange, the FDA hired hundreds of new staff to expedite the approval process.[290] Also in 1992, the FDA created the Abbreviated New Drug Application ("ANDA").[291] This created a simplified submission process for products with the same or very closely related active ingredients, dosage form, strength of administration, use and labeling as a product that has already been shown to be safe and effective.[292] Also, the FDA implemented an accelerated approval procedure.[293]

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286. *Id.*

287. *Id.*

288. Prescription Drug User Fee Act of 1992, 21 U.S.C. §§ 301-379 (West 2000).

289. 21 U.S.C.A. § 379(h)(a)(1)(A) (West 2002) (amended 2002).

290. 21 U.S.C.A. § 379(f)-(h) (West 2002).

291. 21 U.S.C.A. § 355(j) (West Supp. 1999).

292. *Id.*

293. CENTER FOR DRUG EVALUATION AND RESEARCH, U.S. FOOD AND DRUG ADMINISTRATION, BENEFIT VS. RISK: HOW CDER APPROVES NEW DRUGS, *available at* http://www.fda.gov/cder/about/whatwedo/testtube-5.pdf (Sept. 1999). "A highly specialized mechanism intended to speed approval of drugs promising significant benefit over existing therapy for serious or life-threatening illnesses." *Id.* at *6. It incorporates elements aimed at making sure that rapid review and approval is balanced by safeguards to protect both the

What the FDA does, in its regulatory role, is balance benefits and risks. Due to various pressures, this role continues to change in emphasis. Its regulatory role, however, remains firmly in place despite efforts to gut its authority during the mid-90s. It sped up the review process, and on balance, this is good for consumers and the industry it regulates. However, the recent experience with the diabetes drug Rezulin is a case study of how the risk-benefit analysis can be improperly distorted by pressure from the self-interested parties the FDA is supposed to regulate.

The FDA granted "fast track" approval to the drug Rezulin on January 29, 1997.[294] Even before the grant of the final application, the manufacturer Warner-Lambert was heavily marketing the drug for potential use in treating Type II, or adult onset, diabetes.[295]

Warner-Lambert submitted its new drug application for Rezulin in July 1996 and, for the first time in its history, the FDA granted a six month fast-track review to a diabetes pill.[296] The FDA assigned Dr. John Gueriguian to determine the safety and efficacy of the drug.[297]

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public health and the integrity of the regulatory process. *Id.* at *6.

294. David Willman, *Rezulin's Effect on Heart Was Also Seen as Concern,* L.A. TIMES, March 23, 2000 at A1.

295. David Willman, *The Rise and Fall of the Killer Drug Rezulin,* L.A. TIMES, June 4, 2000 at A1. Willman Reported:

> By May 15, 1995 . . . Warner-Lambert was moving to position Rezulin for heavy sales. The company . . . launched a multi-tiered strategy for transforming Rezulin into a "billion dollar blockbuster." Early slide-show pitches were made to Wall Street analysts, emphasizing the market of America's 15 million adult-onset diabetics and touting Rezulin's "new mechanism of action."
>
> Warner-Lambert and its affiliates paid speaking or other fees to more than 300 doctors, from endocrinologists to family practitioners. The company flew diabetes specialists to the 1996 Olympic Games in Atlanta and provided accommodations at the Chateau Elan Winery and Resort.
>
> Warner-Lambert also put on its payroll the government's top diabetes researcher, Dr. Richard C. Eastman, who at the same time oversaw the selection of Rezulin for use in a National Institutes of Health clinical trial.

Id.

296. *Id.*

297. Willman, *supra* note 294. Willman reports:

> By the fall of 1996, Gueriguian concluded that Rezulin was unfit for approval and warned of its potential to harm both the liver and the heart. But Gueriguian came under fire from Warner-Lambert executives, who contacted the FDA's Lumpkin to complain about Gueriguian's use of intemperate language.
>
> Effective November 4, 1996, Lumpkin ordered Gueriguian removed from the evaluation of Rezulin and any further dealings with Warner-Lambert, according to physicians familiar with the matter. Gueriguian's medical

From the time of approval, evidence began to surface that suggested that there may be serious health problems associated with Rezulin.[298] Despite mounting evidence of serious, often fatal, consequences linked to Rezulin, the FDA refused to remove the drug from the market.[299] Only after investigative reporting by the Los Angeles Times and the courageous actions of a few health officers within the FDA did the agency finally conclude on March 21, 2000 to withdraw Rezulin from the U.S. market.[300]

What is frightening about the Rezulin incident is the amount of access and power that the FDA ceded to the manufacturer it was supposed to regulate. Senior officers in the agency repeatedly ignored the advice of those in the agency best positioned to speak intelligently about the obvious health risks that had been uncovered.[301]

The experience with Rezulin highlights, in clear relief, the necessity for regulation and the need for insulation from the lobbying power of those being regulated. The one tragic difference with Rezulin, compared with the patent medicines of the past, is that Warner-Lambert knew of the deaths from liver failure clearly associated with its drug, and yet continued to actively lobby the FDA with carrot and stick to keep the drug marketed.[302] No clearer example for the need for vigilance in regulation can be offered.

The history of the mental health profession in the last 100 years reveals its own set of skeletons. The harm from questionable and unproved techniques is substantial and continuing. There is no good reason to allow this to continue. The exposure of the unsuspecting public to ineffective or harmful psychotherapeutic techniques creates a clear and present danger to the health and safety of millions of people. Allowing the mental health profession to operate as it does now cannot be justified on any sound public policy basis.

Although FDA-type regulatory oversight has never existed for psychotherapy, there is a glaring need. More importantly, there are regulatory and quasi-regulatory structures already in place that could

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review also was purged from agency files. These actions sent an early and enduring message within the FDA: [c]hallenging [r]ezulin was not without risk to one's career.

Id.

298. *Id.*

299. *Id.*

300. *Id.*

301. *Id.*

302. *Id.*

perform this function.

XVI. TWO REGULATORY MODELS

There are two models of regulatory oversight that should be considered: 1) the model of the Food and Drug Administration (FDA); and 2) the model of the National Institute of Mental Health (NIMH). Both have strengths and weaknesses that must be assessed. However, both can provide an external review that can insure efficacy and safety.

The FDA has been, to some, the poster child for a bloated and non-responsive bureaucracy. The pharmaceutical industry has often complained about the immense expense and the lengthy approval process.[303]

However, the last decade has seen improvements in the speed and efficiency with which the FDA acts. It has also seen, with Rezulin, what happens when the primary goal of public protection is diluted by industry meddling.

The FDA performs many functions, but its main function is to see that drugs marketed to consumers are safe and effective.[304] It has three basic roles: first, it acts as a regulator in promulgating rules and carrying out its legislative mandate;[305] second, it acts as a scientist, analyzing the scientific data and doing research into the risks and benefits of these products;[306] and third, it acts as an educator, by instructing consumers and the regulated industry about matters of public health.[307]

The Food, Drug & Cosmetic Act defines "drug" and "new drug," thus identifying the products which are subject to the drug approval process. [308] The Act also identifies the criteria by which all new drugs are to be evaluated in order to gain marketing approval.[309] The Act gives the

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303. *See* Rutherford, *supra* note 270, at 214. Rutherford writes:

> It takes pharmaceutical companies approximately twelve years and an average of $359,000,000 to discover and develop a new medicine. Approximately two years of this development time is devoted to FDA review of the firm's new drug application (NDA). For all this time and effort and expense, the FDA only approved twenty two new drugs in 1994.

Id.

304. AN FDA OVERVIEW: PROTECTING CONSUMERS, PROTECTING PUBLIC HEALTH, U.S. FOOD & DRUG ADMINISTRATION OFFICE OF PUBLIC AFFAIRS 1 (April 2000), *available at* http://www.fda.gov/oc/opacom/fda101/text.html.

305. *Id.*

306. *Id.*

307. *Id.*

308. 21 U.S.C. § 321 (g), (p) (West Supp. 1999).

309. 21 U.S.C. §§ 351-360 (West Supp. 1999).

FDA the broad power to interpret, implement and enforce the statute.[310] The statute provides that the manufacturer must supply "substantial evidence" of effectiveness prior to a drug's approval, but it is the FDA in its interpretive role, that decides what constitutes substantial evidence.[311] In accomplishing this, it also determines what quality of scientific testing and data accumulations are satisfactory to obtain market approval.[312]

The FDA, as interpreter of the Act, must communicate its policies and standards to the industry. It does so by developing and publishing regulations in the United States Code of Federal Regulations (CFR). The FDA also supplements the CFRs by publishing agency guidelines which are meant to give drug sponsors more detailed guidance on specific methods that would satisfy regulatory requirements.

There are three core activities in the development and approval process for a new drug: 1) scientific testing designed to provide data on a product's safety or effectiveness; 2) the preparation and submission of these data and other information in regulatory applications; and 3) review of regulatory submissions.[313]

The ultimate pre-marketing proving ground for a new drug is the clinical trial.[314] However, even before clinical trials are begun, a sponsor will seek some evidence that a compound is biologically active and develop some preliminary data showing that the drug is reasonably safe for use on humans.[315] In this pre-clinical stage, the FDA will generally ask the sponsor to evaluate the drug's toxic and pharmacologic effects through animal testing.[316] This pre-clinical drug development does not involve human exposure.[317]

When a sponsor feels that it has adequate data to show that a new drug is safe for initial small scale clinical studies, it collects the data and submits an Investigational New Drug application (IND).[318] This application permits beginning testing a drug on human subjects.[319] The

310. *Id.*
311. *Id.*
312. *Id.*
313. 21 U.S.C. § 355 (West Supp. 1999).
314. *Id.*
315. *Id.*
316. *Id.*
317. *Id.*
318. *See* FDA INVESTIGATIONAL NEW DRUG (IND) APPLICATION PROCESS, *available at* http://www.northwestern.edu/research/OPRS/irb/handbook/ind1.doc (last visited Aug. 24, 2002).
319. *Id.*

IND review process determines whether enough information is submitted to allow the clinical administration of the drug.[320] This review process involving chemistry and pharmacology ends with a clinical review which evaluates the clinical protocols to insure that: 1) the subjects will not be exposed to unreasonable and significant risks during clinical trials; and 2) that Phase 2 and Phase 3 trials are adequate in design to provide scientifically valid data.[321] If a sponsor satisfies this requirement, it is ready to conduct clinical trials; by far the most critical stage in the drug approval process.[322] The FDA has a very strict set of requirements that must be adhered to in the conduct of the clinical investigation.[323] This is to protect the health of the human subjects and to insure the integrity of the clinical data. Generally, clinical studies begin and proceed cautiously. If the results are favorable, the investigational drug is tested in progressively larger populations and in some cases over longer periods and in higher doses.[324]

A typical clinical trial has the following structure:

1) Phase 1: Cautious use of a drug in a few patients or normal human volunteers, to gain basic safety and pharmacology information (20-80 patients).[325]

2) Phase 2: Use of the drug in a small number of patients who suffer from the condition that the drug is intended to treat or diagnose (100-200 patients).[326] This provides additional safety data and provides the first indication of a drug's clinical effectiveness in its proposed use.

3) Phase 3: Use of the drug in a significantly larger group of subjects who suffer from the target condition.[327] Phase 3 trials are designed to assess a drug's safety and effectiveness and to help determine the best dosage in a larger and more varied population (several hundred-several thousand patients).[328]

The NDA, or New Drug Application, is the vehicle through which drug sponsors obtain FDA approval to market a new drug

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320. *Id.*

321. *Id.*

322. CLINICAL TRIALS, *available at* http://health.yahoo.com/health/clinical_trials/intro/p04.html (last visited Aug. 24, 2002).

323. *Id.*

324. *Id.*

325. *Id.*

326. *Id.*

327. *Id.*

328. *Id.*

commercially.[329] In the application, the sponsor proposes that the drug be approved and uses all the data collected to show that the drug is safe and effective for its proposed indication.[330] Multiple reviewers within the FDA including a clinical reviewer, pharmacology/toxicology reviewer, chemistry reviewer, statistical reviewer and biopharmaceutical reviewer, process the application.[331] During this review process, the FDA may seek advice from one of its in-house advisory committees.[332] If these strict criteria are met, a decision is made about approval.[333]

The National Institute of Mental Health (NIMH) is a very different governmental agency than the FDA. The FDA is not a research organization, although it is composed of countless research oriented scientists. Instead, the FDA reviews the research of others and evaluates the quality of that research as part of its overall regulatory oversight duties. Created in 1946, the NIMH is a part of the federal National Institutes of Health, which is the principal biomedical and behavioral research agency of the United States Government and part of the U.S. Department of Health and Human Services.[334]

The NIMH is certainly not immune to politics, but it is at heart a research institution devoted to the betterment of public health.[335]

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329. NEW DRUG APPLICATION (NDA) PROCESS (March 8, 2001), *available* at http://www.fda.gov/cder/regulatory/applications/NDA.htm.

330. *Id.*

331. *Id.*

332. *Id.*

333. CENTER FOR DRUG EVALUATION AND RESEARCH, *supra* note 293. The CDER states:

> In the final analysis, CDER's decision whether to approve a new drug for marketing boils down to two questions: Do the results of well-controlled studies provide substantial evidence of effectiveness. Do the results show the product is safe under the conditions of use in the proposed labeling? Safe, in this context, means that the benefits of the drug appear to outweigh its risks. When the review is complete, CDER writes to the applicant to say the drug is either approved for marketing, is approvable, provided minor changes are made; or is not approvable because of major problems. Once CDER approves the NDA, a drug is on the market as soon as the firm gets its production and distribution systems going.

Id.

334. OFFICE OF COMMUNICATIONS AND PUBLIC LIAISON, NATIONAL INSTITUTE OF MENTAL HEALTH, FACTS ABOUT NIMH (April 2000) at *1, *available at* http://www.nimh.nih.gov/about/factsabout.cfm.

335. *Id.* This publication describes its mission:

> The mission of the National Institute of Mental Health (NIMH) is to reduce the burden of mental illness through research on mind, brain, and behavior. This public health mandate demands that NIMH harness powerful scientific tools to achieve better understanding, treatment, and eventually prevention and cure of mental illness.
>
> Through research, NIMH and the scientists it supports seek to gain an

The total budget for NIMH for fiscal year 1999 was $859 million.[336] Of this, 13 percent was spent on intramural research (on site at NIMH), 83 percent on extramural research at facilities across the country, and 4 percent was spent on research management support.[337]

NIMH is involved in five separate activities in carrying out its mission: 1) supporting research on mental disorders and the underlying basic science of brain and behavior; 2) supporting research on these topics at universities and hospitals around the U.S.; 3) collecting, analyzing, and disseminating information on the causes, occurrence, and treatment of mental disorders; 4) supporting the training of more than 1,000 scientists to carry out basic and clinical research; and 5) communicating information to scientists, the public, the news media, and primary care and mental health professionals about mental illness, the brain, mental health, and research in these areas.[338]

NIMH sponsors and conducts research in many important research areas. One of the major research areas is Basic Behavioral and Neuroscience Research which seeks:

> . . . to learn how such basic processes as cognition (perception, attention, thought, memory, and learning) emotion, and interpersonal interactions occur and play a role in mental disorders. Research includes studies of:
>
> -Interaction of genes and the environment in shaping the brain
>
> -Molecular and cellular level events involved in brain function
>
> -Brain circuits and their function
>
> -Advanced technologies such as brain imaging, molecular genetics, and computer modeling
>
> -Basic cognitive processes such as conditioning
>
> -Mechanisms underlying emotion
>
> -Role of emotion in cognition

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understanding of the fundamental mechanisms underlying thought, emotion, and behavior-and an understanding of what goes wrong in the brain in mental illness. The Institute strives, at the same time, to hasten the translation of this basic knowledge into clinical research that will lead to better treatments and ultimately be effective in our complex world with its diverse populations and evolving health care systems.

Id. at *1.

336. *Id.*

337. *Id.*

338. *Id.*

-Complex social processes[339]

Other major research areas are depression, schizophrenia, anxiety disorders, Attention Deficit Hyperactivity Disorder (ADHD), autism, AIDS research, rural mental health, child and adolescent violence.[340] In addition, NIMH funds studies in the areas of eating disorders, conducts disorder, learning disorders, personality disorders, Alzheimer's disease and related dementias, sleep disorders, and the prevalence of and risk factors for mental disorders and mental health problems of special populations, including racial and ethnic minorities and women.[341]

NIMH also funds research studies at various universities and hospitals through the awarding of grant funding.[342] It also conducts clinical trials.[343]

The clinical trials test methods for the diagnosis, treatment, risk assessment or prediction and prevention of mental disorders.[344] NIMH is currently conducting extramural clinical trials in the following areas:

-Systematic treatment enhancement program for Bipolar disorder

-Treatment of adolescent depression study

-Sequenced treatment alternatives to relieve depression

-Clinical antipsychotic trials of intervention effectiveness

-Hypericum clinical trials

-Is panic disorder inherited?[345]

NIMH research is not limited to studies of medications for serious psychiatric conditions such as schizophrenia.[346] In fact, the NIMH has conducted or sponsored rigorous clinical research studies on psychosocial interventions such as psychotherapy.[347]

XVII. CONCLUSION AND RECOMMENDATIONS

The suggestion that the delivery of psychotherapy services be regulated in the same fashion as drugs or medical devices will no doubt be met with rage and disdain within some segments of the mental health profession. There is no question that governmental regulation comes

339. *Id.* at *2.
340. *Id.* at *2-4.
341. *Id.* at *4-5.
342. *Id.* at *5.
343. *Id.*
344. *Id.*
345. *Id.*
346. *Id.*
347. *See* MILLER & MAGRUDER, *supra* note 6.

with its own baggage of bureaucracy and inefficiency. The assault on the FDA in the last fifteen years, however, has not resulted in the dismantling of the agency and the privatization of public protection. However, it has resulted in greater flexibility and efficiency in the drug approval process.

Despite the acknowledged costs associated with a regulatory bureaucracy, there will be, without question, many advantages. One of them will be increased credibility for the mental health profession. At a time when the profession is the subject of intense criticism both from within and without, well-earned credibility as a science devoted to treating emotional ills with empirically validated treatments carries with it inestimable value.

The choice of the regulatory model (FDA or NIMH) is certainly not without consequence. The models are quite different in how they conduct business. Neither could perform this function of regulating psychotherapy without new legislation and a broadening of their current scope of operation. The FDA operates strictly as a regulatory agency, whereas the NIMH is a research and funding agency.

The FDA certainly could regulate psychotherapy as it does drugs or medical devices, but the FDA draws its statutory authority from its power to regulate drugs and devices sold in interstate commerce. Psychotherapy is not a commodity sold in interstate commerce.

The NIMH would need to have additional and very specific regulatory powers granted to it by Congress. Empowering the NIMH, as part of a new regulatory scheme, to determine what is required by way of research to satisfy a "substantial evidence" of efficacy standard, would be required. Alternatively, the NIMH could fund additional studies to evaluate specific psychotherapies, and if proven to be ineffective, common law negligence could be utilized to restrict such practices, since they would no longer meet the standard of care. Such an approach would rely on the content of the standard of care as it relates to the mental health profession. In the past, there has been great ambiguity as to what such a standard of care requires.

The NIMH has certain qualities that make it a more advantageous choice. The paramount one is that it is already heavily involved in supporting, conducting and evaluating rigorous empirically based research on both psychopharmaceutical and psychotherapeutic interventions. It has a track record of evaluating good science. It has been evaluating the types of interventions that are the subject of this article. It knows what to look for; it knows the questions to ask. It

already has a large base of institutional knowledge on safety and efficacy of some currently used psychotherapy techniques. Additionally, it has sound, empirically supported research showing that some psychotherapy interventions are safe and effective.[348] This is crucial. By requiring proof of safety and efficacy before using a psychotherapy technique, patients needing mental health services will not, all of a sudden, be unable to engage in psychotherapy. They will, however, be protected from exposure to bogus and harmful treatment.

The issue at its most basic level is quality control in health care. Governmental control, through administrative regulation, is only one source of this. The tort system and the market are others. In addition, there are professional ethics and licensure. All of these potentially play a role in the assurance of quality control in health care. However, it is one of the central arguments of this article that the tort system (and the doctrine of informed consent in particular), the market and professional ethics and licensure have failed to prevent exposure of the needy and the vulnerable to ineffective and potentially harmful psychotherapy techniques.

The suggestion that psychotherapy should be regulated is not a casual one and is not made without awareness of the challenges to the creation of an effective regulatory body. The proliferation of unproved and potentially harmful psychotherapy techniques is a public health issue so important that it should not be left to the vagaries of the market. The harm done by bogus psychotherapy is no different in its public consequences than that caused by phony cancer or AIDS cures. They each pose an imminent risk of harm to the needy and vulnerable.

The regulation of psychotherapy, as this article proposes, is justified on the basis of the public health consequences of untreated and improperly treated mental health conditions. Most health care matters are not viewed as concerns of the federal government. These fall within the exercise of the police power which is generally reserved to the states. For example, health care matters regarding the standard of practice and licensure are left to the states. However, there are some matters deemed so important to public health and so national in character that they demand federal attention. The Clean Air Act[349] that created the Environmental Protection Agency ("EPA") is one such example. Under the Clean Air Act, the EPA is charged with setting national standards for certain air pollutants to protect both public health

348. *Id.*

349. The Clean Air Act Amendments of 1990, 42 U.S.C. § 7408 (1994).

and the environment.

The provision of long-term care in nursing homes is another example of federal regulation in what historically was a state regulated exercise of the police power. Long-term care is a very important and growing portion of the nation's health care sector. As a result of competitive market pressures, the distinction between nursing homes and hospitals and the services they provide is blurring. In addition to their traditional custodial or supportive role, nursing homes are treating increasingly sicker patients with increasing medical needs. The federal government largely deferred quality control regulation of nursing homes to the state licensure systems until the late 1980s. However, in 1987, the federal government undertook a very significant new role in the enforcement of quality of care standards in the nursing home industry.[350]

The NIMH is the preferred choice for another reason specifically addressing another difference between psychotherapy research and pharmaceutical research. As previously noted, the FDA is structured around a model in which the agency primarily reviews the research work of others. This works well when the marketplace provides the necessary incentives for pharmaceutical companies to spend the large amount of money needed to research and test a new drug. In the case of the pharmaceutical industry, the economic incentive is very basic. The industry cannot sell a new drug in interstate commerce without prior approval of the FDA.

Psychotherapy research does not enjoy the same place in terms of market incentives. Historically, funding for psychotherapy research has been almost entirely government supported, almost exclusively within the NIMH. The mental health field itself has been very deficient in supplying funds to support research, due in large part to its roots as a "cottage industry." Furthermore, professional societies such as the American Psychiatric Association and the American Psychological Association have failed to take an active role in developing independent funding sources for such a central activity of their professions. In addition, there has not been an industrial base in psychotherapy to support research and development like there is in the pharmaceutical industry.[351]

Government support of psychotherapy research is not adequate to fully fund all the research necessary to determine safety and efficacy of

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350. FURROW ET AL., HEALTH LAW: CASES, MATERIALS AND PROBLEMS 110-142 (3d ed., West Publishing Co. 1997).

351. Docherty, *supra* note 94, at 11.

discrete psychotherapy interventions. However, despite the history of lack of financial incentives and inability to raise funds, the picture is changing due to new developments in the marketplace. The first is the ability of some larger managed care organizations to provide support for research on cost effective patient outcomes.[352]

The pharmaceutical industry is also a possible partner in this research endeavor due to a growing recognition that it could be in its economic self interest. There is a growing awareness in the pharmaceutical industry that the effectiveness of various medications can be enhanced by psychotherapy, especially those forms of talk therapy that help facilitate compliance.[353]

Because the burden of proof will be on the promoters of psychotherapeutic techniques, there will be tremendous incentive to do good research. Despite the doomsayers, placing the burden of proof of efficacy and safety on promoters will not throw the world into darkness. As a result of the huge changes in the health care enterprise brought about by managed care, there have been efforts to demonstrate the effectiveness of different modalities of treatment. There are movements[354] within the profession to require empirically validated treatments. There have been books written that advertise "Treatments That Work."[355] Additionally, for the first time, the mental health profession has seen the emergence of practice guidelines for the treatments of various emotional ailments.

Requiring proof of efficacy and safety will not arrest the course of human progress in the understanding and treatment of emotional distress and mental illness. In fact, it will hasten it. In the last century, the mental health profession has been responsible for tremendous advances in the understanding and treatment of mental illness and human distress. A small minority of the profession appears unconcerned with the need to practice using only the best methods and techniques supported by good research. This small minority should not be allowed to detract from the

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352. *Id.* ("As demands to demonstrate quality improvement as well as cost control increase, research on the utility of psychosocial interventions will be of inherent value for the economic well-being of health care plans.")

353.. *Id.*

354. A Guide to Beneficial Psychotherapy, *available* at http://www.apa.org/divisions/div12/rev-est/index.shtml/(last visited Aug. 24, 2002). A task force within Division 12 of the American Psychological Association has, since 1995, studied the research literature on empirically validated psychotherapies for the purpose of training the profession and producing treatment protocols.

355. A GUIDE TO TREATMENTS THAT WORK 3 (Peter E. Nathan & Jack M. Gorman eds., Oxford University Press 1998).

tremendous accomplishments of the profession.