Of Law and Medicine

Psychological Assessment in Drug and Medical Device Litigation

BY PAUL R. LEES-HALEY AND RICHARD S. BROWN

Paul R. Lees-Haley and Richard S. Brown are a psychologist and a professional researcher, respectively, with offices in Encino (Los Angeles).

MORE THAN 11 million Americans have at least one medical device implant, and in 1989 more than 1.7 billion prescriptions were filled in the United States. As is the case with other human inventions, drugs and medical devices do not always work flawlessly. In recent years, this fact has led to a remarkable amount of litigation against manufacturers, distributors, hospitals and physicians.

The advancements in medicine in the latter half of this century are evolving at such a pace that "miracle cures" are now common occurrences. We have become so successful at curing so many things that many people have come to expect physicians, medicines and medical devices to work and to work without fail. They have forgotten the essential fragility of life and have laid claim to good health as a right. Sometimes it goes further: not only are they entitled to good health but they also should be free from worry about the continuance of good health. From this point of view, when medical devices or drugs fail, doctors, hospitals and drug companies are seen as being "at fault."

This shifting attitude is, in part, an explanation for the growing number of lawsuits involving the use of drugs and medical devices. More and more of this litigation also includes charges of psychological as well as physical damages. In some cases, psychological damages are the only basis for the suit—for example, cases claiming cancerphobia or fear of future illness.

When claims for psychological damages make up a substantial part of the case, counsel increasingly are calling on psychologists to present evidence of injury. Psychologists rely heavily on two sources of information as a basis for diagnosis of psychological problems allegedly associated with drugs and medical devices: psychological test data and patient self-report. Each has shortcomings that must be considered when reliance is placed on them in making evaluations.

Psychological Tests

Most psychological tests are highly vulnerable to voluntary manipulation by the patient, but many psychologists and psychiatrists treat these instruments as if they were objective measurements. As one California judge observed, it never seems to occur to many psychotherapists that the patient may not be telling the truth. Research clearly suggests that children, adolescents and adults can manipulate psychological tests, including neuropsychological and emotional distress test batteries.

Tests that are widely applied in mass tort litigation are among those that are vulnerable to plaintiffs' voluntary manipulation. Tests such as the Minnesota Multiphasic Personality Inventory (MMPI), the Impact of Event Scale (IES), the Symptom Checklist 90-R (SCL-90-R), the Beck Depression Inventory (BDI), the MMPI subscale designed to assess post-trau-

matic stress disorder (PTSD), and the tests in the Luria-Nebraska and Halstead Reitan neuropsychological test batteries, as well as other widely known tests, are susceptible. Success rates by untrained novices faking psychopathology range from 50 to 100 percent on tests used to assess drug and medical device claims.

Psychological tests are vulnerable not only to plaintiffs' conscious manipulation but also to suggestion, mass hysteria and influences of third parties. Suggestible people are influenced by discussions with their attorneys, their psychotherapists and with other plaintiffs. An honest plaintiff who is convinced of the reality of non-existent symptoms will respond to test questions in a manner consistent with these specious beliefs.

The effect of suggestion is a major concern in the assessment of the impact of drugs and medical devices. Research indicates that community and political leaders, activists, the media, friends and family can have a dramatic effect on how people perceive their surroundings. Religious leaders influence how people perceive certain medical devices, drugs and their effects.

Many psychological researchers believe that how people perceive their environment depends primarily on what information, knowledge or expectations they bring to that perception. When that information is incorrect or those expectations are unreasonable, inappropriate perceptions can become unfounded beliefs.

Some psychological tests contain validity scales or internal measures for evaluating the subjects' straightforwardness in answering the questions. The MMPI is the most widely known example. Thoughtful claims evaluators need to be aware that many psychologists use the same validity scale scores for all examinees, regardless of the context of the evaluation. Not all examinees have the same motivations, however, nor do they use identical strategies of deception. A person feigning mental illness to avoid the death penalty has a profoundly different profile of incentives from one feigning psychological injury to win a personal injury lawsuit. Fear of future illness and latent injury assessments, for example, require specific consideration of the context in order to make a thoughtful analysis of psychological test data.

Psychological tests frequently are hardly more than a written continuation of the self-reports provided by patients during the interview. Tests often ask leading questions that suggest ideas to plaintiffs that they would not otherwise imagine.

Sophisticated examiners take into account their more important findings and juxtapose them in context when making their interpretations, but numerous irrelevant factors influence the results of psychological assessment. The patient's self report during an interview will have an indirect influence on the interpretation many examiners place on the psychological test data. Fear of future illness owing to the use of a drug or medical device is caused more commonly by expert speculation than by actual human experience.

Inappropriate Interpretation

Appropriate interpretation of psychological test data is a fundamental component of effective mental health treatment and must be a primary objective of psychological test administrators for patients involved in litigation. Establishing causation is notoriously difficult and usually beyond the scope of the test being given. Nevertheless, some clinicians jump to simplistic conclusions that a litigated event caused almost all of the plaintiff's life stresses. In many cases, four or five non-compensable stressors are minimized, while a single compensable stressor is highlighted as the cause of the plaintiff's psychopathology. Often the plaintiff never mentions important stressors, and all too often the plaintiff's expert examiner fails to ask. Medical devices and drugs are discussed as if they were the only substantial negative experiences in the plaintiff entire life. Realistically, this is not likely to be the case.

Many psychologists interpret their tests too literally and thereby precipitate excessive interpretations of their findings in the minds of surrounding personnel, such as psychiatrists, treating physicians, media representatives, claims examiners and attorneys. A devastatingly effective rebuttal against unreasonable interpretations of psychological tests is to have your own psychologist explain to you exactly what is done in each procedure and how these findings are interpreted. After obtaining testimony from a psychologist and a psychiatrist that psychological tests are indisputable and that it is difficult to fool the expert, a fair-minded attorney can show

the jury the reality of those test procedures and deflate silly or pompous testimony.

In general, psychological tests do not identify the cause of the psychological symptoms; they measure the nature and severity of psychopathology as of the time of test administration. A person disturbed as a result of several stressors usually appears the same on psychological tests as someone equally disturbed over a single event. Components of the psychopathology that are hereditary, chronic, pre-existing or otherwise unrelated to the claim are indistinguishable on most tests from traumatic complaints.

Psychologists and psychiatrists use tests designed for other purposes, imputing false levels of validity to problems associated with drugs and medical devices. It is important to question constantly the underlying basis for opinions about psychological injury associated with drugs and medical devices.

There are many behaviors that patients are reluctant to admit but that cause them to appear disturbed on psychological tests. For example, abuse of alcohol, amphetamines or cocaine may lead to pathological results on psychological testing. Another classic example is the emotional stresses associated with an extramarital affair.

Another complication in the interpretation of psychological tests is plaintiffs' tendency to underreport pre-injury symptomatology and overreport post-injury impairment. Some clinicians simply recite the subjective history into their report and treat it as objective fact. Then, based on the clean bill of health suggested by the history, they overinterpret the psychological test findings as constituting new psychopathology.

Self-reports

Research has demonstrated that as personal historians, human beings often tend to be revisionists, changing their recollections of past events to be consistent with current beliefs and motivations. Therefore, caution must be taken before accepting self-reported accounts of past behaviors or symptom frequency as valid. Many people also are very susceptible to suggestion. If led to believe that certain symptoms or traits are more expected or are greatly valued, individuals will endorse those symptoms or traits more frequently. Attorneys, clinicians and advocates encourage this behavior. They discuss the symptoms of a diagnosis with the plaintiff prior to administration of the tests designed to find out whether the plaintiff has these complaints.

One does not need to be a psychologist to see a problem with evaluating a plaintiff's subjective complaints by saying, "Victims of your alleged injury often report complaints such as x, y and z. Now we would like you to take some tests to find out whether you have any of these problems."

Further confounding self-report data, clinicians and attorneys advise patients which symptoms are compensable and which are not. For example, because of insurance policy definitions or legal precedents, clinicians provide compensability guidelines during the initial phase of the intake procedure prior to gathering clinical evaluation data, and attorneys begin providing this information in initial interviews with prospective clients.

Base Rates

Research has shown that the clear majority of healthy individuals who have no identifiable illness and are not using medications nonetheless report symptoms that often are listed as side effects by people taking medication. Medical device complaints are common for reasons unrelated to the alleged cause of action. Attributing these normative symptoms to a medication or medical device is an erroneous causal explanation for a spurious relationship, and the numerous opportunities for anxiety and uncertainty about the future can be attributed simplistically and falsely to a single medical device or medication.

The problem of base rate influences cannot be overemphasized. Regardless of whether an individual is ever diagnosed as suffering from a clinical mental disorder, all of us have experiences such as anxiety and depression at various times in our lives. For example, the normal and expected response to serious losses in life—bereavement—is indistinguishable from a clinical depression. The diagnostic label is applied when the response appears maladaptive or excessive.

Base rates are an especially important issue for users of pharmaceutical agents and medical devices because they have a higher base rate of pre-existing problems than a random sample

of the population. For example, the National Center for Health Statistics in 1991 reported: "The likelihood of being assessed in fair or poor health was almost three times greater for persons with a medical device implant as it was for the U.S. population. An estimated 10 percent of all persons in the United States were in fair or poor health, compared with about 27 percent of the implant population."

A related base rate problem is that with increasing age, there is a greater probability of individuals using a medical device, and older persons report a much higher rate of health problems regardless of medical device usage. Thus, age is a salient confounding variable in determining the relationship between the use of a medical device and increased symptomatology—that is, older people both use medical devices more frequently and have more health problems. Any alleged relationship between medical device usage and health problems must take the age factor into consideration. Failure to do so leads to dubious conclusions.

Alternative Causation

Numerous influences in everyday life have psychological impacts that influence plaintiffs' performances on psychological tests and in psychological interviews. Common complaints associated with drug and medical device litigation—fear, fatigue, memory complaints, irritability, rapid heart beat, nausea, headaches—may be the product of hysteria, suggestion, anxiety from other life stressors, interactions with employers, medical exposure, reactions of families and neighbors to the litigation, treatment by government officials or interactions with other plaintiffs. Many individuals react with anxiety, depression and numerous other symptoms from the sheer process of litigation.

The context within which sensory information is acknowledged can have dramatic effects on the way in which that information is interpreted. For example, states of high self-awareness have been associated with increased symptomatology and physical discomfort. Furthermore, attention to potentially threatening interpretations biases the processing of sensory information toward the subjective experience of fear and distress.

On May 19, 1992, two widely circulated daily newspapers reported the same event regarding a popular pharmaceutical on their front pages. The *Houston Post* front page headline read, "FDA Panel Says Halcion Safe, Effective," while *USA Today* stated, "Tough Halcion Warnings Urged." While the one headline introduced the FDA decision in a reassuring manner, the other generated concern for potential harm. The objective event that inspired both was the same, and for the most part the content of the two articles was similar. But the headlines, which are the most influential and most frequently read portions of an article, provide differing contexts in which to interpret that content and induce readers to interpret their subjective experiences in opposite ways.

Psychological problems are often iatrogenic; the complaints are caused by the treatment, not by injury, and on tests they resemble signs of mental disorders. Numerous medications used to treat depression, anxiety or pain, for example, have a sedating effect that leads to self-reports of fatigue, difficulties with concentrating or paying attention, sleepiness, feeling tired all the time, etc. In other words, as a result of medication, the patient reports (temporary) problems that are similar to those we see alleged as damages in which there is no verifiable medical problem.

The patient who takes more than one psychotropic medication or who uses alcohol while taking the medication is even more likely to report these problems. It is not unusual to discover that the patient is receiving medications from three or four physicians without fully informing all of them about the medications the others are providing.

Confounding these irrelevant causes of complaints with litigated issues leads to erroneous referrals for psychological testing, inaccurate conclusions based on the ensuing test data and inappropriate further treatment. These problems also lead to an incorrect assessment of damages.

A patient who is suffering genuine psychological problems or pseudo-symptomatology may behave in a manner that creates illusory diagnoses in other areas. Numerous subjective complaints are shared by a variety of disorders. For example, irritability, nausea, headaches, sleep difficulties, concentration deficits and memory problems—common indicators of toxic exposure, depression and mild brain injury—also are reactions to temporary stress, and they are even side effects in placebo stud-

ies—that is, some patients given an inert substance report that it makes them sick.

Conclusion

Although drugs and medical devices have been around since the dawn of mankind, the rapid and often awesome development of medical science in recent times has led to a feeling that these new treatments should be infallible. When they are not, litigation abounds, including charges of psychological damages. As psychologists become more involved in the litigation process, it is important for counsel to be aware of the methods they use for assessing psychological damages and, more especially, what are the strengths, weaknesses and limitations of those methods.

Psychological tests, which are extremely useful in an ordinary doctor-patient relationship, must be applied with more caution in drug and medical device litigation. In these high incentive situations, tests should be interpreted from a more skeptical, judicious and scientific point of view than is required with a routine psychotherapy patient for whom there are no external pressures of this nature. Factors such as patient motivation, stresses of litigation and the influence of others must be taken into account, along with the limitations of the testing methods and shortcomings of self-reports.

Selective attention to somatic sensations can distort self-reports. By directing the attention of the consumer to potential concerns, one can lead normal individuals to make erroneous attributions of their base rate or normal levels of symptomatology to the pharmaceutical or medical device in question. In contested cases, the most powerful communication of psychological test data is the one that emphasizes a common sense, clear language presentation of good scientific conclusions. Less thoughtful approaches are not better than speculation.

A Look at Medical Devices

Medical devices and drugs have an extraordinarily long history.

Since the Stone Age, beads and feathers have been used to supplement the immune system in an attempt to ward off diseases caused by evil spirits. The early Hindus replaced ears and noses with artificial materials, and the ancient Greeks, Romans and Egyptians developed dental devices such as gold bridges. French scientist Pierre Fauchard published a text in 1798, *The Surgeon Dentist*, in which he described complicated medical devices for use in dentistry.

More than 2,500 years ago, ancient Indian physicians replaced body parts removed through amputation and reconstructive surgery. Long before the birth of Hippocrates, the Egyptian physician, Imhotep, who lived approximately 2650 B.C. was administering drugs and experimenting with medical devices.

Prehistoric people discovered that they could alleviate pain by eating certain plants. For example, salicin, a substance similar to the component used to make aspirin, is present in willow bark and appears to have been used for pain relief for thousands of years. A clay tablet created approximately 2000 B.C. from the Middle Eastern Sumerian civilization identifies roughly a dozen drug prescriptions. A 3,500-year-old Egyptian scroll cites several hundred drugs.

The ancient Romans, Greeks and Chinese used many pharmaceuticals. The first drug store was opened by the Romans, and during the Middle Ages pharmacies spread throughout Europe and the Arab world. In the New World, the drug industry originated essentially around the time of the Revolutionary War, when the chief pharmacist of the Revolutionary forces supplied drugs to the military and, at the close of the war, opened a wholesale drug business.