Chapter 11

Laws and Regulations Governing Practitioners Who Offer Unconventional Cancer Treatments

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Chapter 11

Laws and Regulations Governing Practitioners Who Offer Unconventional Cancer Treatments

INTRODUCTION

The activities of practitioners who offer unconventional cancer treatments are regulated and monitored through several mechanisms. The most basic are licensing of physicians and other health professionals by each State and criminal prosecution of individuals who practice medicine without a license. This chapter discusses the laws and regulations governing licensed and unlicensed practitioners who offer unconventional treatments. It also describes the disciplinary actions taken against violators.

The authority to license and discipline health care practitioners is based on each State's legal responsibility to protect the public health, safety, and welfare (654,878,930). All State legal codes include acts that define the practice of medicine; stipulate the requirements for licensing health care practitioners; describe the conditions that can lead to disciplinary action against a licensed health professional; and specify the organization, membership, and function of licensing and disciplinary boards (448,872,878,930). In most States, the same body that grants medical licenses has the authority to order investigations of medical practices and to discipline doctors, but some States mandate separate licensure and disciplinary boards, the latter generally referred to as "medical boards" (295,448).

In addition to the States' involvement, professional peer groups also exert significant influence over the practice of medicine. Peer groups may publicly criticize practitioners, exclude them from referral networks, or discourage patients from consulting with practitioners whose standards differ from the norm, including practitioners of unconventional medicine (82,354). Professional associations may develop official positions on medical practice that influence their members. For instance, until recently, the professional code of the American Medical Association prohibited physicians from maintaining contact with "non-scientific" health care practitioners (e.g., chiropractors) (879). Though they are without legal standing, these professional peer activities may have the effect, similar to the ***State's laws and regulations, of restricting* a *practi*tioner's professional activities.

Two other influences on the practice of medicine are the rules that govern hospital admitting privileges and the criteria for reimbursement from third-party payers. Hospital admitting privileges are generally given by the governing body of an institution, based on the recommendation of its medical staff (712), and can be revoked. For example, Max Gerson, M. D., who prescribed unconventional cancer treatments in the 1940s and 1950s, reportedly lost his hospital admitting privileges because of the treatments he offered. (See ch. 3 for more details.) In addition, reimbursement from third-party payers for unconventional cancer treatments may be limited or unavailable. Some practitioners cite these reimbursement policies as impediments to practice, since patients may have to discontinue nonreimbursed medical treatments (216). (See ch. 9 for a discussion of insurance and unconventional cancer treatments.)

Besides directly affecting physicians who offer unconventional cancer treatments, these limits on practice may also have an inhibiting effect on physicians who see some value in certain unconventional treatments, particularly in conjunction with conventional treatments, but fear being the target of sanctions. The prospect of being censured (formally or informally), prosecuted, or just identified negatively because of unconventional practices, might make it difficult for some practitioners to comfortably offer patients care they believe is beneficial to them if they believe their ability to practice medicine might be jeopardized (82).

THE PRACTICE OF MEDICINE

Though there is some variation among States, in general they agree on a broad definition of what constitutes the practice of medicine. (See box 1 l-A.)

Almost all States allow the "practice of medicine" by non-physicians in special circumstances, such as emergencies or in administering domestic (or prescribed) remedies to family members (50). Unlicensed practitioners may also be permitted to

Box n-A-States' Definition of the Practice of Medicine

The Federation of State Medical Boards of the United States defines the practice of medicine to include the following:

1. advertising, holding out to the public, or representing in any manner that one is authorized to practice medicine in the jurisdiction;
2. offering or undertaking to prescribe, give, or administer any drug or medicine for the use of any other person;
3. offering or undertaking to prevent or to diagnose, correct, and/or treat in any manner or by any means, methods, devices, or instrumentalities any disease, illness, pain, wound, fracture, infirmity, deformity, defect, or abnormal physical or mental condition of any person, including the management of pregnancy and parturition;
4. offering or undertaking to perform any surgical operation upon any person; and
5. using the designation Doctor, Doctor of Medicine, Doctor of Osteopathy, Physician and Surgeon, Dr., M.D., D. O., or any combination thereof in the conduct of any occupation or profession pertaining to the prevention, diagnosis, or treatment of human disease or condition (unless such a designation is in addition to the designation of another healing art (e.g., dentistry), for which one holds a valid license in the jurisdiction). (284)

practice medicine in the context of defined religious ministries. In some States, faith healers, Christian Science healers, and other clergy are specifically exempted from regulations that apply to health care providers. California, for example, exempts faith healers from licensure, as practitioners who "treat exclusively by prayer in accordance with the teachings of a bona fide religious sect or organization. ' If, however, faith healers combine prayer with other methods, such as diet, drugs, or massage, they would not be protected by the exemption and could be prosecuted for practicing medicine without a license (791). In one case, a minister in Arizona, Kenneth Lee Anderson, was prosecuted for practicing medicine without a license after he and a doctor of osteopathy treated patients with a substance called "Tumorex," the composition of which was undisclosed (51).

Licensure

Physicians must be licensed before they may legally practice medicine in the United States. State licensing laws identify the basic qualifications an individual must have in order to practice as a health professional, define the permitted scope of practice, and provide general standards of expected professional competence and conduct. Although requirements vary among States, in general, a person must be a graduate of an accredited medical school,[1] have completed 1 year of residency training in a program approved by the Accreditation Council for Graduate Medical Education,[2] and have passed the Federation Licensing Examination sponsored by the Federation of State Medical Boards. Osteopaths and allopaths are included in the definition of physicians; currently, about 500,000 allopathic physicians (M.D.s) and 25,000 osteopathic physicians (D. O. S), are licensed in the United States (711).

All States require periodic licensure reregistration. When reregistering, physicians may be required to inform the board of any administrative sanctions, adverse liability awards, or felony charges that occurred since their last contact with the licensing board. Physicians may also be required to report substance abuse, physical illness, or mental illness that may affect the competent and professional practice of medicine. The completeness of such reporting and its effects on reregistration are not documented. Approximately 25 States mandate continuing medical education as a prerequisite to reregistration (284a), and a few may soon require a periodic competency reexamination (703).

For physicians who offer unconventional cancer treatments, continuing licensure may present more difficulties than initial licensure. If these physicians receive administrative sanctions or an adverse ruling in a liability case, State law may mandate reporting

[1] The Liaison Committee on Medical Education is the accrediting body for educational programs leading to the medical doctor degree.

[2] In most States, physicians can become licensed after 1 year of clinical training following medical school, but six States require more postgraduate training and four require none (699).

of that information, possibly making license renewal more difficult.

The statutory scope of practice for licensed, non-physician health care providers (e.g., nurses, chiropractors, acupuncturists, naturopaths) is also defined within State laws, but there is variation among States in how these health care providers are regulated and whether licensing is required. Depending on the State, these health care professionals may legally provide psychological, spiritual, or other non-drug unconventional treatments (791). Homeopaths and naturopaths are licensed separately in the States where they are allowed to practice (791). However, the majority of licensed homeopaths are M.D.s or D.O.s who use homeopathic medicine as part of the medical care they provide (909).

The Practice of Medicine Without a License

Several practitioners of unconventional cancer treatments have been prosecuted for the criminal charge of practicing medicine without a license. In California, Milan Brych claimed to have received a medical degree outside of the United States, but was treating patients without having a State license. Brych was convicted on a number of charges, including practicing medicine without a license, grand theft, and grand theft by false pretenses (714). In another case, two health food store owners in Indiana, Harry Graham, a "nutritional therapist" and Ellen Graham, a registered nurse, treated a breast cancer patient with laetrile and colonic irrigations. The patient eventually died and the Grahams were tried and convicted of practicing medicine without a license, criminal recklessness, and involuntary manslaughter (438). In another California case, an unlicensed healer was prosecuted for treating a leukemia patient with lemonade, salt water, herb tea, special light therapy, and deep abdominal massage. The patient died as a result of massive internal bleeding, possibly as a result of the abdominal massage. The practitioner was convicted of practicing medicine without a license and the illegal sale of certain drugs. The initial conviction also included the charge of second degree murder but was later reversed because causation could not be established (715).

Some States are developing legislation that ***would*** restrict ***anyone except registered*** dietitians or physicians from counseling *patients* ***about*** nutrition, making it illegal for many nutritional advocates and non-physician practitioners to give nutritional advice (855). Some nutritional advocates have already been found guilty of practicing medicine without a license. Geraldine Matson, an unlicensed nutritional consultant, was sentenced to 40 hours of community service at the American Cancer Society after pleading guilty to practicing medicine without a license in Washington State. The Washington State Department of Licensing began an investigation of Matson after a physician reported that the employees of a local wig salon had given a cancer patient information on nutritional treatments. Two undercover agents posing as a cancer patient and her husband went to the salon, and were then referred to Matson. Matson was charged with practicing medicine without a license after advising the 'cancer patient" that she had scurvy and that she should ''discontinue chemotherapy because it would prevent nutritional therapy from working" (707,730).

PHYSICIAN DISCIPLINE

Because their practices fall outside of what is generally considered standard medical practice, physicians who offer unconventional cancer treatments may be particularly vulnerable to investigations for alleged violations of State or Federal laws, medical incompetence, or unprofessional behavior. A finding of guilt in these cases may result in frees, a jail sentence, or an injunction prohibiting whatever action is under investigation. Physicians may also be subject to administrative sanctions that directly affect their ability to practice medicine. Sanctions, ranging from license revocation to a private reprimand, are typically imposed by the State medical board.

This section describes the types of disciplinary action that can be taken against physicians. A discussion of all potential restrictions is beyond the scope of this section. Licensed physicians are emphasized, because, among the 50 States, requirements for licensure and grounds for disciplinary action are more uniform for physicians than for other health care professionals. Examples of sanctions against physicians who have offered various unconventional cancer treatments are highlighted.

[3]In this chapter, the term "physician" refers to both M.D.s and D.O.s.

Administrative Sanctions

States delegate to one or more boards, generally referred to as "medical boards,' the authority to discipline physicians through administrative sanctions. Depending on State laws and the offense committed, possible disciplinary actions include revocation, suspension, limitation, or restriction of a physician's license; fries; private or public reprimand; letters of censure or concern; collection of the proceedings costs; mandatory competency testing; and additional training or education (284a). At times, informal disciplinary actions are used because of insufficient resources for full investigations, a backlog of current cases, or simply as an educational measure. Unlike formal sanctions, informal actions are often confidential matters between the medical board and the disciplined physician (872,878).

Other factors, such as the amount and type of evidence available in a case and the propensity of the medical board to pursue disciplinary actions, play a role in determining the kinds of sanctions administered (872,878). In addition, the magnitude of sanctions varies. For example, the maximum length of a suspension may be 75 days, 2 years, 5 years, or indefinite, depending on the State (284a).

Typically, physicians are disciplined for "unprofessional conduct' or 'professional incompetence. These terms cover violations of a physician's ethical and legal responsibilities, such as cheating on a licensure exam, conviction for a felony, fraudulent licensure application, sexual exploitation of patients, abuse of drugs or alcohol, or "making untruthful or exaggerated claims relating to professional excellence or abilities" (872). Other actions, such as fee-splitting,[4] overcharging, or reimbursement fraud can also lead to disciplinary actions (872).

Often, physicians who believe they have been unfairly disciplined may appeal to another State committee or to a court of law. All States provide physicians with some recourse to have administrative sanctions that have been imposed on them reviewed by another body (70 Corpus Juris Sec. 51). Some unconventional cancer practitioners who have received administrative sanctions have had their sanctions lessened after administrative review (see discussion of Revici case below).

Though the total number of physicians disciplined has increased since 1982 (the number rose from 953 in 1982 to 1,381 in 1984), it is still not high (878). Factors contributing to the relative rarity of disciplinary actions include inadequate economic, administrative, and investigative resources; insufficient personnel; and the high standard of evidence required. In addition, the opportunity for disciplined physicians to sue peer review organizations, medical boards, and their members for antitrust violations and defamation of character or discrimination discourages physicians from reporting instances of possible misconduct by other physicians (242,878). States and the Federal Government have enacted laws which, under certain conditions, protect physicians from these lawsuits (448). Whether these laws have contributed to the recent increase in the number of disciplinary actions is not known.

Administrative Sanctions Against Physicians Using Unconventional Cancer Treatments

It is possible that disciplinary boards find it easier to initiate or act on charges of alleged incompetence against a physician who offers unconventional cancer treatments than against a mainstream practitioner, because many unconventional treatments are considered to fall clearly outside of standard medical practice. In addition, the circumstances under which an unconventional cancer treatment is administered are often important in determining the grounds for disciplinary action. For instance, several physicians have been cited for administering experimental treatment without a protocol or for failing to obtain proper informed consent from patients (103,195,437).

Members of the unconventional cancer treatment community have claimed that medical boards are more persistent in the discipline of unconventional than conventional physicians (216). According to Cassileth, 3 percent of the 83 physicians (M.D.s) she surveyed who offered unconventional treatments had had their licenses suspended for "reasons related to their unorthodox practices' (177). However, the Federation of State Medical Boards does not make available to the public detailed information such as the number, type, and causes of disciplinary action taken against physicians who offer unconventional cancer treatments. Thus, it is not possible to estimate accurately the number of physicians using

[4] Fee-splitting involves one physician receiving a percentage of another practitioner's fee in payment for having referred the patient to the second practitioner.

unconventional cancer treatments who have been involved in some type of disciplinary proceeding.

Charges against physicians who prescribe unconventional cancer treatments have included gross negligence, gross incompetence, negligence and incompetence on more than one occasion, unprofessional conduct (e.g., willful violations of laws, or inadequate recordkeeping), and practicing fraudulent medicine (this can include misrepresenting their ability to cure a patient of an illness). Grounds for these charges include: use of unapproved drugs (e.g., laetrile) (103,195,437); use of unapproved substances for the treatment of cancer (e.g., Hoxsey herbs, wheatgrass juice, and pangymic acid) (832); and maintaining inadequate patient records (214,923).

Examples of efforts to discipline physicians for such violations follow. These cases reveal the complexity of disciplinary hearings.

Stanislaw Burzynski, M.D.—Besides being involved in court battles described in earlier chapters, Stanislaw Burzynski is the subject of an investigation by the Texas Board of Medical Examiners for possible violations of the Texas Food, Drug, and Cosmetic Act, which prohibits the prescribing of drugs not approved by FDA or, alternately, by the State Department of Health. The board argues that this, in turn, is a violation of the Texas Medical Practice Act. A date for a hearing, the next formal step, has not been set (as of May 1990); motions to dismiss submitted by Burzynski's attorney have been rejected. If the board finds Burzynski in violation of these laws there is a broad array of sanctions it may impose on him (458,790).

Michael Gerber, M.D.—This case was initiated by an independent oncologist who treated a former Gerber patient in her terminal phase, when her uterine cancer had metastasized widely. The central issue in this case was Gerber's unconventional treatment of the patient when she was first diagnosed. The oncologist believed that Gerber, while practicing as a self-described "orthomolecular practitioner," inappropriately treated a potentially curable patient for 27 months with Hoxsey herbs, megavitamins, chelation therapy, Wobe Mugos enzymes, Chaparral tea, pangymic acid, benzaldehyde, wheatgrass juice, coffee or enzyme enemas, apricot pits, red clover, and slippery elm (832).

Gerber contended that he was not attempting to treat the patient's cancer, but rather to nutritionally and metabolically support a patient who had refused conventional treatment. The Board dismissed that assertion because the witnesses for Gerber testified that the above substances typically were used because they were believed to be "cancer inhibitors. The Board did not find convincing the testimony about the nutritional and metabolic value of any of these treatments for a patient with endometrial cancer (832).

The Board agreed with the State's expert witnesses that with immediate conventional treatment, the patient would have had a 90 percent chance of long-term survival. The Board found that Gerber:

> . . . should have known and recognized that surgery and/or radiation treatment were the recognized, effective, and sole medically acceptable means of treatment of adenocarcinoma of the endometrium, according to the standard of medical practice in California. (832)

Further note was made that the patient apparently canceled a scheduled surgery several days after first consulting Gerber, and although he documented in her chart that she was being treated by several other unconventional practitioners, he did not record that he suggested she seek conventional care. The Board wrote:

> The accepted standard of medical practice for a patient [presenting] with a well-differentiated adenocarcinoma of the endometrium, and who adamantly refuses conventional accepted treatment therefore, is: 1) continuously and emphatically to encourage the patient to seek conventional treatment; 2) strongly discourage any patient attempts to seek out unproven modalities . . ., and 3) not to undertake courses of unproven treatment and/or substance use, because these have the effect of lulling patient fears or misleading her to conclude that effective cancer therapy is in progress. It was established and it is found that such activity falsely reassures cancer patients concerning their prognosis and discourages them from seeking effective and timely treatment. (832)

With no previous offenses noted, Gerber's license to practice in California was revoked in June 1984. The Board of Medical Quality Assurance found him guilty of gross negligence and incompetence, repeated similar negligent acts, and other similar charges. The finding of guilt was due, in part, to his use of substances unapproved by either State or

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Federal authorities for the treatment of cancer, and excessively prescribing and administering diagnostic tests and ineffective drugs and treatments (832).

Emanuel Revici, M.D.—Emanuel Revici has been the subject of prolonged controversy because of his unconventional treatment for cancer. Professional societies and health authorities in New York State, where Revici practices, began questioning his treatments more than 20 years ago; however, an official investigation was completed only recently. Revici's medical license was officially suspended in 1984 (for a short time) in response to New York State Department of Health charges of medical misconduct including practicing medicine fraudulently, practicing with gross incompetence, practicing with gross negligence, and substandard practices of these types on more than one occasion.

A committee of the New York State Board for Professional Medical Conduct, referred to as the hearing committee, initially held hearings on Revici's medical practice for a total of 19 days between January 1984 and May 1985 (923). While investigation into the charges proceeded, Revici continued his unconventional cancer treatment practice under specified conditions. During the investigation, Revici agreed to:

1. only treat patients for cancer if they had an established "outside" diagnosis (including a pathology report);
2. provide fully informed consent (including the recommendation that patients consult a trained oncologist); and
3. manufacture or administer any "experimental drugs or substances" in accordance-with State and Federal laws. (666)

In September 1985, the hearing committee completed its initial investigation and found Revici guilty of gross incompetence, gross negligence, negligence and incompetence on more than one occasion, violating a particular Rule of the Board of Regents, and unprofessional conduct. In particular, the committee cited Revici's attempts to dissuade at least two patients from seeking conventional cancer treatment, treatment of at least three patients with agents unapproved for the treatment of cancer, maintaining inadequate patient records, "willful violation of laws regarding unapproved agents," and "fail[ure] to realize that his method was not effective' in the treatment of cancer. The committee found that Revici produced 'no persuasive evidence that [his] method for treating cancer is effective or that it benefited [patients]. " However, they specifically reported that Revici did *not* promise patients that his treatments would cure cancer (grounds for "misrepresentation,' another basis for license revocation) (923). In November 1985, the New York State Commissioner of Health joined the committee in recommending to the New York State Board of Regents that Revici's medical license be revoked (923).

In March 1986, however, a separate Regents Review Committee recommended that the case be remanded to the hearing committee because Revici's original attorney was suffering from the strains of terminal disease during his defense, and Revici's right to council (guaranteed by the Sixth Amendment) may have been compromised. The hearing committee met again in August 1987 but Revici and his new lawyer chose not to attend because they felt the hearings were a sham and that 'no valid purpose would be served by continuing or participating in hearings before OPMC [Office of Professional Medical Conduct]" (923). By refusing to attend, Revici lost his opportunity to introduce new evidence and witnesses, and present further defenses to the OPMC's charges. The hearing committee noted this, and then reaffirmed their original recommendation of September 1985 (923).

In March 1988, Revici and his lawyer submitted additional information and testimony directly to the Regents Review Committee. Although the review committee ruled that Revici "may not obtain a *de novo* hearing before us and thereby bypass the statutory hearing process, " they did review the record from the hearing committee's proceedings. On June 27, 1988, the Regents Review Committee issued a report in which they accepted many, but not all, of the original findings of the hearing committee. Some modifications were made to the original findings, but overall, the committee felt that Revici's practices endangered his patients and found them "far below the legal standards required of a licensed physician.' The Regents Review Committee emphasized that the charges against Revici were "based on specific acts and violations' and were not brought against him for "engaging in research or writing about new, non-traditional methods for treating cancer" (923). This committee found Revici guilty of the charges and unanimously recommended in June 1988 that his license be revoked for at least 1 year beginning October 1, 1988 (923).

On July 29,1988, the New York Board of Regents accepted the Review Committee's modified findings of guilt, but decided in a 4 to 3 vote (with 2 abstaining) to mitigate the committee's recommended measure of discipline. Revici's medical license revocation was stayed and he was placed on probation for 5 years (921). During his probation, Revici is allowed to continue practicing medicine under specific terms, similar to those agreed to while his license was under investigation (922).

Medicare Sanctions Against Providers of Unconventional Cancer Treatments

Another avenue for regulating physician's activities is through the Medicare program. Under the Social Security Act, the Department of Health and Human Services (DHHS) is authorized to impose administrative sanctions on providers who defraud or abuse the Medicare program (414). DHHS delegates this authority to the office of the Inspector General. Some providers of unconventional cancer treatments have been among those excluded from the system because their services have not met the program's requirements. Medicare sanctions may include temporary or permanent exclusion from Medicare payment, or the imposition of monetary penalties if it is demonstrated that the provider:

1. overcharged Medicare for services;
2. deliberately misrepresented on Medicare claims the services that were rendered; or
3. deliberately provided services that were either in excess of patients' needs or of poor quality (substandard), as judged by local professional standards.

When monetary penalties are imposed, practitioners wishing to remain eligible for future Medicare payments must reimburse the Medicare program for the previous overcharging or inappropriate payments (414,876).

heal insurance carriers and Utilization and Quality Control Peer Review Organizations (PROs),[5] under contract to DHHS, monitor medical care provided to Medicare beneficiaries, identify possible violations, and recommend disciplinary action to the Inspector General's Office (878). Unless a practitioner's actions immediately threaten patient well-being, PROS initially impose remedial actions, such as a requirement of further education or warnings, before recommending that the Office of the Inspector General exclude or suspend the practitioner (221,872). PROS may consider a variety of factors when determining the severity or duration of the disciplinary sanction they propose, such as other related offenses, any adverse impact a sanction may have upon Medicare beneficiaries or the community, potential savings to the program, and the amount of financial damage incurred by the Medicare program (221). Professional sanctions are reported to the public through local newspapers and are also reported to State licensing boards.

Of the almost 500 practitioners excluded participating in Medicare between 1982 and 1988 (547), at least 6 were excluded for practices related to their prescribing of unconventional cancer treatments.[6] Two examples of such actions are summarized below.

The late Virginia Livingston, M.D., a physician who developed and prescribed an immunologic unconventional cancer treatment (discussed in ch. 5), was originally excluded from Medicare beginning on March 29, 1986, for providing care that was considered by the Office of the Inspector General to be both substandard and substantially in excess of patient needs. Livingston argued that her treatment was experimental and therefore not substandard; however, the judge found insufficient compliance with a study protocol and informed consent procedures to allow that interpretation. On appeal, however, the judge found that while the evidence showed Livingston's treatment was not recognized as standard practice by the medical community, it was of a unique nature and should be regarded as "nonstandard" rather than "substandard." He determined that too little was known about the treatment to find that the services she provided were either substandard or substantially in excess of her patients' needs, and he overturned the exclusion. He found also that the Inspector General's Office was remiss in both apprising Livingston of the seriousness of the charges and nature of the perceived offenses and in making educational visits before imposing sanctions. Livingston became eligible to

[5]PROs are used by DHHS to monitor the care hospitals and their physicians provide to Medicare patients in order to ensure that services are medically necessary, provided in the appropriate setting, and meet professionally recognized standards of care (872).

[6]Virginia C. Livingston, M.D., William Goldwag, M.D., John Potts, M.D., James Privitera, M.D., Donald Cole, M.D., Victor Bagnall, M.D. (791).

reapply for reimbursement status under Medicare in 1987 (444).

Another practitioner of unconventional cancer treatment, Donald Cole, M.D. was excluded from Medicare reimbursement for 5 years beginning in 1983. Medicare's carrier in New York State originally identified Cole's cancer treatments as "nonstandard" and referred the case to the Inspector General's Regional Office. A local PRO convened a review panel of three practicing oncologists. After reviewing Cole's patient records, the panel reported that his medical care did not meet the professionally recognized standards of cancer treatment in that community. They specifically noted that Cole was administering standard chemotherapeutic agents in an inappropriate regimen (low-dose, high-frequency), along with laetrile, dimethyl sulfoxide (DMSO), vitamin B12, and mixed respiratory vaccines. The panel of oncologists found that the services furnished in every case reviewed were substandard and clear threats to the health of the patients (791).

Of the four other practitioners, three were excluded from Medicare for periods of time ranging from 3 to 10 years for providing services in excess of the needs of patients and providing care that does not meet professionally recognized standards. The fourth was excluded from Medicare because he was convicted of illegally manufacturing, distributing, prescribing, or dispensing a controlled substance (706).

COMMON AND STATUTORY LAWS AFFECTING PRACTITIONERS

The activities of physicians and others who provide unconventional cancer treatments may also be regulated through the application of common law or general State laws. Common law is law made by courts and judges, as opposed to statutory law which is passed by a legislative body. Usually, when one private citizen sues another, the basis for the lawsuit arises from common law. Only a State or the Federal Government may criminally prosecute an individual for violating statutory laws, and only a criminal prosecution can result in a jail sentence (791).

Criminal Charges

A typical criminal charge against practitioners of unconventional cancer treatments is the practice of medicine without a license. As described earlier, at least one unlicensed physician and several nonphysicians have been convicted on this charge in the context of unconventional cancer treatments. Other criminal charges may include murder, fraud, grand theft, involuntary manslaughter, or criminal recklessness, also in the context of unconventional cancer treatments.

Bruce Halstead, a practitioner of unconventional cancer treatments, has been convicted of multiple criminal charges. In 1986, after 3 years of investigation by the California Board of Medical Quality Assurance and the resolution of several complex international and interstate legal issues, Halstead's medical license was permanently revoked and he was convicted of several criminal charges. Halstead used an unconventional treatment called Agua del Sol (ADS) to treat patients with cancer and other chronic diseases. ADS has been described as a homeopathic herbal treatment[7] consisting of mulberry, hydrangea, and poppy, that is reportedly incubated in outdoor tanks containing water and bacteria. The ADS administered to Halstead's cancer patients had been manufactured in Costa Rica, shipped through Japan, and then purchased through a distributor in the United States (371).

The charges brought against Halstead under California's Penal Code and Health and Safety Code originally included:

- conspiracy to cheat and defraud by false pretenses;
- false advertising of a drug;
- falsely advertising a drug to have an effect upon cancer;
- selling and offering for sale an adulterated drug;
- selling and offering for sale a misbranded drug;
- grand theft by false pretenses;
- unlawfully selling drugs or compounds for the alleviation of cancer; and
- fraudulently providing treatment as being effective in treating cancer. (371)

Unassisted by an attorney for much of the litigation, Halstead relied on the testimony of his patients, family, friends, ministers, and colleagues.

[7]However, ADS and two of its components are not listed in the *Homeopathic Pharmacopeia*, making this description inaccurate (909).

A special "Hearing Report," submitted on his behalf by the National Center for Institutions and Alternatives, urged that only a probationary sanction be issued. Halstead, who denied wrongdoing, asked to be allowed to continue practicing medicine under terms of probation, or community service, or both. He maintained that in prescribing ADS, he "followed [his] own deep scientific, conscientious convictions [and]. . . did everything in [his] power to attempt to save the lives of [his] patients" (371).

However, at the sentencing hearing, the probation officer assigned to the case testified that the current charges against Halstead were not isolated incidents. Halstead had been called before the Board of Medical Quality Assurance in the past, his license had been suspended at least once, and he had previously been placed on probation. This history, combined with the probation officer's finding that Halstead "shows little or no remorse for his . . . crimes,' led to the conclusion that unless his license was revoked, Halstead would continue to prescribe unconventional treatments. In addition, the probation officer noted that Halstead 'used his position of trust, as a physician" to sell unconventional treatments to terminally and chronically ill patients. He recommended that Halstead "be removed from the community for as long a period of time as is legally possible" (371). The court found Halstead guilty of 20 felonies and several misdemeanors. In addition to the permanent revocation of his medical license, he was sentenced to 4 years in prison and fined $10,000 (372).

Civil Charges

Because their practices fall outside of standard medical practice, physicians who offer unconventional cancer treatments are vulnerable to the civil charge of malpractice. Suits can be brought by former patients and their relatives. The basis for malpractice is the physician's negligence in fulfilling professional duties, such as selecting the best treatment for the patient; informing patients about the treatment effects; determining the correct dosage for the treatment; storing, preparing, or using the treatment; warning the patient about possible adverse reactions; monitoring the patient's needs and changing dosages or treatments as the condition warrants; and providing appropriate informed consent (791). Emanuel Revici recently lost a medical malpractice case brought against him in Federal District Court involving a patient with a rectal tumor, who was under his care for 2 years before dying. This case, *Boyle v. Revici,* was brought by the nephew of the deceased patient. The jury found in favor of Boyle and awarded him $1.5 million. Revici is appealing the verdict on evidentiary grounds.[8]

Surviving family members also may sue a practitioner for loss of support caused by death under a "wrongful death' theory. Oftentimes, the allegation of wrongful death is combined with a "survival action, where the surviving family member sues on the deceased's behalf for pain and suffering sustained before death. In civil suits, plaintiffs may request financial compensation for economic losses or for emotional damages. In some cases, punitive damages also may be awarded (791). Organizations, such as third-party payers, may also bring civil charges. When Medicare and other third-party payers act as plaintiffs in civil litigation, they often sue practitioners for fraudulent insurance claims (631). (See ch. 9 for a discussion of insurance coverage for unconventional treatments.)

Some physicians have defended their use of unconventional treatments by arguing that patients, when fully informed about the treatment, its alternatives, and attendant risks, may legally assume some of the risk inherent in receiving the treatment. In at least one case, *Schneider v. Revici,* a Federal Appeals Court found this argument valid and suggested that it may alleviate or diminish the physician's liability for negligence. The Federal court has remanded the case to the original trial court for consideration of whether the consent agreement signed by the patient constitutes an assumption of risk. It was set to be retried starting in November 1989 (631), but was postponed (70). (See ch. 10 for discussion of the case.)

[8] Under what is called the "dead man's statute" in New York State, a recounting of conversations between the decedent and the defendant is inadmissible as evidence. Revici is appealing the judge's application of that statute to this case (150).